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; ROBERT F. KENNEDY, JR., in his official capacity as 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' COMBINED RESPONSE TO DEFENDANTS' MOTION TO DISMISS AND REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND PRELIMINARY RELIEF

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INTRODUCTION

HHS does not defend the Final Rule on the merits. Instead, it claims Plaintiff States have not demonstrated standing and, in any event, that universal vacatur is inappropriate. Both arguments fail.

It is basic APA law that parties subject to a challenged regulation generally have an "easy" case for standing because the imposition of a regulatory burden itself causes injury. *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). The Final Rule directly regulates Plaintiff States: Each is a sovereign that operates HIPAA-covered entities (with a new duty to validate attestations) as well as law-enforcement agencies that investigate public-health violations (with a new duty to make attestations). So Plaintiff States plainly have standing to challenge the new rule-made obligations they must follow. On top of Plaintiff States' regulatory harms, their new compliance obligations require time, resources, and personnel and further slow investigations meant to promote their sovereign interest in "safeguard[ing] '[their] domain' and [their citizens'] 'health, comfort and welfare.'" *Kentucky v. Biden*, 23 F.4th 585, 596 (6th Cir. 2022) (citations omitted). HHS's claim (at 12) that Plaintiff States offer "no evidence" of these compliance- and sovereignty-based harms ignores fifteen declarations detailing Plaintiff States' efforts to navigate the Final Rule's new regime, and the States have secured more.

HHS's silence on the Final Rule's substance is fitting. As Plaintiff States explained, HHS lacks statutory power to impose the Final Rule's bespoke reproductive healthcare-privacy regime. States' Br. 12-20. Nor does the Final Rule's scheme clear the APA's bar for reasoned decision-making: It requires non-lawyers to resolve difficult, abstract legal questions before disclosing information under threat of criminal penalty while granting investigative targets near-veto power over providing records of their potential wrongdoing. *Id.* at 20-22. HHS contests neither merits claim, forfeiting both. *Adkins v. Marathon Petrol. Co., LP*, 105 F.4th 841, 854 (6th Cir. 2024). Plaintiff States are thus "likely to succeed." *See Tennessee v. U.S. Dep't of Educ.*, 104 F.4th 577, 607 (6th Cir. 2024). Though that unlocks a right to preliminary relief, States' Br. 23-25, the final legal issues here do not turn on anything further.

To promote clarity in state programs and investigations, this Court should proceed to final judgment, hold that the Final Rule is "unlawful," and set it aside. 5 U.S.C. § 706(2)(A), (C).

That means vacatur of the Final Rule. Vacatur is "the default" remedy when agencies act unlawfully. *Kentucky v. EPA*, 123 F.4th 447, 473 (6th Cir. 2024); *accord Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 831 (2024) (Kavanaugh, J., concurring) (collecting cases). This is not one of the "rare" instances when an alternative remedy suffices. *Kentucky v. EPA*, 123 F.4th at 473. If anything, the way the Final Rule compels third parties to gum up state investigations counsels a clean remedy like vacatur rather than a party-specific injunction with complex implementation concerns. Nor can severance salvage some kernel of the Final Rule given HHS's pervasive lack of statutory authority. *See Tennessee v. Cardona*, No. 24-5588, 2024 WL 3453880, at *4 (6th Cir. July 17, 2024).

In sum, Plaintiff States have standing, the Final Rule is unlawful, and entry of relief is warranted to stop the States' ongoing harms. The Court should therefore enter summary judgment for Plaintiff States, or at a minimum grant preliminary relief that protects Plaintiff States from the Final Rule's unlawful mandates.

ARGUMENT

I. Plaintiff States have standing.

Because they are directly regulated by the Final Rule—in their capacities as HIPAA-covered entities and investigators requesting HIPAA-protected information—Plaintiff States' standing is "self-evident." *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d 501, 508 (W.D. Ky. 2024) (quoting *Tennessee Republican Party v. SEC*, 863 F.3d 507, 517 (6th Cir. 2017)). Plaintiff States' complaint demonstrates why, alleging standing to a degree that amply satisfies Rule 12's requirements (which HHS agrees govern its motion to dismiss, *see* HHS Br. 7). The States' accompanying declarations, which detail the Final Rule's disruptive and costly impacts, crystallize that the Final Rule causes concrete harms with evidence sufficient to support entry of judgment or preliminary relief.[1] And the States provide more proof now.[2] Further, a remedy against the Final Rule would redress the States' injuries, which flow directly from the rule. HHS's counters on standing are misplaced in this APA context.

A. Plaintiff States adequately allege their standing as directly regulated entities.

1. Typically, under the APA, standing is "easy to establish" when a party seeks to challenge a rule that directly regulates it. *All. for Hippocratic Med.*, 602 U.S. at 382. That axiom governs here, where

[1] Groover Decl., Dkt. #26-1; Zeigler Decl., Dkt. #26-2; Kreutz Decl., Dkt. #26-3; Johnson Decl., Dkt. #26-5; Spahr Decl., Dkt. #26-6; Traxler Decl., Dkt. #26-7; Targia Decl., Dkt. #26-8; Klenski Decl., Dkt. #26-9; Joiner Decl., Dkt. #26-10; Dietz Decl., Dkt. #26-11; Menefee Decl., Dkt. #26-12; Azar Decl., Dkt. #26-13; Stover Decl., Dkt. #26-14; Osborne Decl., Dkt. #26-15; Karrasch Decl., Dkt. #27.

[2] Decl. of Charles Hardin (Exhibit Q); Decl. of Tammera Harrelson (Exhibit R); Decl. of Lisa Davies (Exhibit S); Decl. of Andrew Pack (Exhibit T); Supp. Decl. of Katherine Zeigler (Exhibit U); Decl. of Kelsey McKnight (Exhibit V). Plaintiffs regularly file, and courts routinely approve, supplemental declarations in response to particular opposition points or in support of preliminary relief. *See, e.g.*, *Tennessee v. Cardona*, No. 2:24-cv-72, Dkt. #94 (E.D. Ky. June 7, 2024) (allowing leave to file supplemental declaration rebutting lack-of-harm argument); *Bingham v. Root*, No. 6:22-cv-00094, Dkt. #15-1 (E.D. Ky. July 11, 2022) (supplemental declaration rebutting claim that plaintiff had not established a preliminary-injunction factor); *MxPx Global Enters. v. Tooth & Nail Record*, No. 3:01-cv-00377, Dkt. # 31 (M.D. Tenn. May 30, 2001) (granting plaintiffs leave to file reply and additional declarations in support of their preliminary injunction motion); *cf.* LR7.1(a). Though Plaintiff States have explained why relief is warranted even absent these declarations, they alternatively seek leave to file the supplemental declarations appended here.

the Plaintiff States have adequately alleged that the Final Rule directly regulates and harms them.

To start, "[t]he imposition of a regulatory burden itself causes injury." *Tennessee v. EEOC*, 129 F.4th 452, 458 (8th Cir. 2025); *see also Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 773 (5th Cir. 2024). So, "regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements." *All. for Hippocratic Med.*, 602 U.S. at 382. For example, the Supreme Court held in *West Virginia v. EPA* that the "plaintiff States were injured by an EPA regulation" because they were "'the object of' its requirement that they more stringently regulate power plant emissions within their borders." *Tennessee v. EEOC*, 129 F.4th at 458 (quoting 597 U.S. 697, 719 (2022)). The Court "deemed it unnecessary" to further "consider whether the requirement caused any specific economic harms." *Id.* Indeed, setting aside "myriad other" potential injuries, "including compliance costs and economic harms," allegations that a State is the object of an agency action that compels or prohibits some activity establish standing. *See Carmen v. Yellen*, 112 F.4th 386, 407-08 (6th Cir. 2014). "No additional proof is necessary when a rule purports to impose legal obligations directly on a state plaintiff." *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 507.

The multiple bases for this well-worn principle are broadly accepted. *First*, "[i]n our federal system, the National Government possesses only limited powers; the States and the people retain the remainder." *Bond v. United States*, 572 U.S. 844, 854 (2014). States thus have "their *own* interests" as sovereigns in self-government to "safeguard '[their] domain' and [their citizens'] 'health, comfort and welfare.'" *Kentucky v. Biden*, 23 F.4th at 596 (citations omitted). So they have a "concrete interest" in "avoiding regulatory obligations above and beyond those that can be statutorily imposed upon them." *Iowa League of Cities v. EPA*, 711 F.3d 844, 871 (8th Cir. 2013). *Second*, "complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs" given the federal government's sovereign immunity. *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220-21 (1994) (Scalia, J., concurring in part); *see Kentucky v. Biden*, 57 F.4th 545, 555-56 (6th Cir. 2023). The

Final Rule acknowledges it comes with costs. 89 Fed. Reg. at 33,054-56. Those compliance costs "are a recognized harm" for Article III purposes. *Kentucky v. Yellen*, 54 F.4th 325, 342 (6th Cir. 2022).

Thus, the Supreme Court, the Sixth Circuit, and other courts of appeals have recognized that standing generally is "self-evident" for the object of a regulation.[3] States' standing to challenge direct federal regulation is so well established that courts have been unable to cite "a single precedent holding that 'states lack standing to challenge a rule that operates on States qua States.'" *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 507. A case cutting the other way—a district-court decision in *Tennessee v. EEOC*—was unanimously reversed in straightforward fashion. 129 F.4th at 458.

2. HHS does not dispute the obvious: the Final Rule directly regulates Plaintiff States. As health-plan administrators and healthcare providers, States must disclose HIPAA-protected information consistent with the Final Rule. As law enforcement entities, States must jump through new Final-Rule-created hoops to obtain HIPAA-protected information for public health investigations.

Plaintiff States plausibly alleged the bases for those conclusions. Each plaintiff is a "sovereign," Compl. ¶¶ 3-17, that operates HIPAA-covered entities, *id.* ¶¶ 113-15, and conducts investigations promoting health and welfare that often rely on medical records obtained from HIPAA-covered entities, *id.* ¶¶ 91-112. Plaintiff States also allege that the Final Rule imposes new burdens on both HIPAA-covered entities and investigators. For example, HIPAA-covered entities now must undertake a complex legal assessment to evaluate whether requested records will be used "[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." *Id.* ¶¶ 67-71. For investigators, the Final Rule

[3] *See, e.g.*, *West Virginia*, 597 U.S. at 719; *Tennessee v. EEOC*, 129 F.4th at 458; *Tex. Med. Ass'n*, 110 F.4th at 773; *Carmen*, 112 F.4th at 407-08; *New Mexico v. U.S. Dep't of Interior*, 854 F.3d 1207, 1218 (10th Cir. 2017); *L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 655 (9th Cir. 2011); *Sierra Club v. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002); *Cotovsky-Kaplan Physical Therapy Assocs., Ltd. v. United States*, 507 F.2d 1363, 1366 (7th Cir. 1975).

imposes a new attestation requirement. *See id.* ¶¶ 91-112. And any use or disclosure of information that is inconsistent with the Final Rule's new regulatory standards carries the risk of criminal penalties. *See id.* ¶ 89; 42 U.S.C. § 1320d-6(b). These new "regulatory burden[s] … cause[] injury." *Tennessee v. EEOC*, 129 F.4th at 458. Having alleged that they are the "direct object" of the Final Rule and would "be spared" from the rule's mandates if it were declared unlawful, Plaintiff States have pleaded a redressable "injury in fact" establishing standing. *Carmen*, 112 F.4th at 407 (cleaned up).

3. HHS's counterarguments flounder on law and fact alike.

Targeting the complaint, HHS dismisses Plaintiff States' allegation that the Final Rule impedes state investigations as "conclusory, speculative, and vague" because the complaint does not "explain[] how the Rule is *actually* impeding any investigation." HHS Br. 10 (emphasis added). Yet HHS then concedes that the complaint details multiple investigations the attestation requirement has hampered—including one in which a healthcare provider refused to comply with a request for information from a state agency that provided an attestation. *Id.* at 10 & n.1 (citing Compl. ¶ 110). In short, the States provide details aplenty—even on HHS's selective accounting.

Contra HHS (at 10), these allegations do not require "guesswork" about the Final Rule's impacts. Consider paragraph 107. Tennessee is litigating a consumer protection case against a physician and his fertility clinic. Compl. ¶ 107. But during discovery the State could not "obtain relevant patient data subject to HIPAA's protections, without the attestation required by the Final Rule, which a state employee must sign under pain of criminal liability." *Id.* Without the Final Rule, no attestation would be necessary, meaning one less barrier to investigators' obtaining the discovery they have requested. So it is beside the point whether, for example, state officials could obtain the information "by some other means" or whether they received the information upon providing an attestation, HHS Br. 11, because Congress prohibited any "*limit*" on States' investigative authorities, *see Purl v. HHS*, No. 2:24-

cv-228, 2024 WL 5202497, at *6-10 (N.D. Tex. Dec. 22, 2024).[4] And, as Plaintiff States explained, the Final Rule's vague, broad "terms appear to sweep in any records request relating to the provision of care in a range of areas," Compl. ¶ 65, making it "foreseeable" this same unlawful limitation will arise in nearly every case, *id.* ¶ 103.[5]

Beyond explaining how the Final Rule imposes barriers to investigations promoting States' sovereign interest in "safeguard[ing]" their "domain" and their citizens' "'health, comfort and welfare,'" *Kentucky v. Biden*, 23 F.4th at 596, the complaint plausibly alleges that overcoming those barriers costs time and money. Plaintiff States' complaint lays out the complex, high-stakes legal analysis an investigator must undertake each time his signs an attestation. Compl. ¶¶ 79-89, 91-112. It also explains that Plaintiff States' HIPAA-covered entities must undertake a similar analysis each time they receive a request for information or an attestation. *Id.* ¶¶ 66-78, 113-15. Neither investigators nor HIPAA-covered entities would have to navigate this morass but for the Final Rule, *see id.* ¶¶ 59-66, and Plaintiff States explained that to avoid the Final Rule's criminally punishable pitfalls, it has been necessary to develop "processing systems" or "overhaul" those systems already in place, *see id.* ¶¶ 99, 111, 115. The time, personnel, and resources required to conduct these compliance measures "produce[] administrative costs." *Id.* ¶¶ 99, 115. Indeed, these are exactly the administrative costs that HHS itself predicted. *See* 89 Fed. Reg. at 33,054-56 (anticipating costs for, among other things, implementing the new attestation requirement, altering disclosure policies, and training staff). Thus, accepting the complaints' allegations as true and drawing all reasonable inferences in Plaintiff States' favor, *Block v. Canepa*, 74 F.4th 400, 408 (6th Cir. 2023), they have adequately alleged compliance costs.

[4] For "standing purposes," courts accept the merits of a plaintiff's claims "as valid." *Kentucky v. Yellen*, 54 F.4th at 349 n.16 (citation omitted).

[5] Those allegations have been borne out. In the months since the Final Rule has taken hold, state investigators have consistently received requests for attestations, even in matters lacking a "reproductive health care" hook. *See, e.g.*, Zeigler Decl. ¶¶ 8-11; Zeigler Supp. Decl. ¶¶ 8-10.

Plaintiff States need not provide a "precise dollar figure" for those costs. *Rest. L. Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 600 (5th Cir. 2023). Nor must they allege that the costs are "material[]" or particularly "extra." HHS Br. 11. After all, "a loss of even a small amount of money" is a concrete injury for purposes of Article III. *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017).

The cases HHS cites (at 11) do not say otherwise. Unlike Ohio, Plaintiff States' *complaint* explains that the Final Rule triggers analyses and procedures that impose "financial, logistical, and personnel burdens," *see* Compl. ¶ 115, and Plaintiff States have backed those allegations with "affidavit[s]" and "other evidence." *Compare Ohio v. Yellen*, 53 F.4th 983, 994 (6th Cir. 2022). The D.C. Circuit reasonably chose not to over read a single sentence in a party's reply brief in *Interstate Nat. Gas Association of America v. FERC*, 285 F.3d 18, 46 (D.C. Cir. 2002), but Plaintiff States' complaint lays out fully the burdens imposed by the Final Rule, *supra* 5-7. And HHS's reliance on *Kentucky v. EPA*, No. 2:23-cv-7-GFVT, 2023 WL 3326102, at *3 (E.D. Ky. May 9, 2023), is particularly misplaced given that the Sixth Circuit administratively stayed the district court's decision in that case sua sponte because its standing analysis so missed the mark. Order, ECF No. 9, *Kentucky v. EPA*, Nos. 23-5343/5345 (6th Cir. Apr. 20, 2023); *see* Order, ECF No. 24, *Kentucky v. EPA*, Nos. 23-5343/5345, at 6-7 (6th Cir. May 10, 2023) (finding challengers' "costs to ensure their compliance" as well as risk of punishment sufficient to show irreparable injury). In so doing, the Sixth Circuit rejected HHS's suggestion that pleading compliance costs requires exacting detail about steps taken and specific costs incurred. *See* Order, ECF No. 24, *Kentucky v. EPA*, Nos. 23-5343/5345, at 5-6.

Most fundamentally, HHS seeks (at 10-11) to require pleading at a level of granular detail that is simply not required when the plaintiff is "the direct object" of an agency action. *Carmen*, 112 F.4th at 407. Plaintiff States cannot distinguish between prohibited and permissible disclosure of a record without analyzing the underlying HIPAA-protected information or the potential ends of an investigation. *See, e.g.*, 89 Fed. Reg. at 33,004 (disclosure permitted "where there is suspicion of sexual abuse

that could be the basis of permitted reporting," but not if suspicion "[is] based solely on the fact that a parent seeks reproductive health care…for a child"). And Plaintiff States have plausibly alleged that providing attestations, screening for "reproductive health care," and questioning a requestor's motives and purpose "increase[] regulatory burden[s]," which "satisfies the injury-in-fact-requirement." *Texas v. Becerra*, 577 F. Supp. 3d 527, 555 (N.D. Tex. 2021); *see also Tennessee v. EEOC*, 129 F.4th at 458. It is "unnecessary" to further "consider whether the requirement caused any specific economic harms." *Tennessee v. EEOC*, 129 F.4th at 458 (describing the Court's standing decision in *West Virginia v. EPA*). Rather, it is sufficient that Plaintiff States have alleged that the Final Rule mandates "some action[s]," those mandates are unlawful, and this Court can "spare[]" Plaintiff States by setting the rule aside. *Carmen*, 112 F.4th at 407-08 (citations omitted). HHS's motion to dismiss thus should be denied.

B. Plaintiff States' evidence adequately supports standing for entry of relief.

Since Plaintiff States have put forward evidence that the Final Rule's new burdens are an on-going problem, they've likewise cleared the standing requirement for entry of summary judgment and injunctive relief. Again, HHS's attempt to sidestep the States' evidence-backed showing fails.

1. Plaintiff States attached to their motion for summary judgment and preliminary relief fifteen declarations from various state officials detailing the burdens the Final Rule has imposed. They explain that States regularly conduct public-health investigations that require seeking HIPAA-protected information. *See, e.g.*, Groover Decl. ¶¶ 3, 9-11; Zeigler Decl. ¶¶ 3-4; Traxler Decl. ¶¶ 3-6. Before the Final Rule, investigators could propound requests for information on HIPAA-covered entities without considering whether "reproductive health care" was at issue or providing an attestation, and HIPAA-covered entities typically complied with those requests. *See, e.g.*, Zeigler Decl. ¶ 5; Jonhson Decl. ¶¶ 5-9; *see also* Pack Decl. ¶¶ 8-10. Now that HIPAA-covered entities must comply with the Final Rule, they are either denying investigators' requests for information or demanding the attestation required by the Final Rule, even in cases well outside the heartland of "reproductive health

care." *See, e.g.*, Groover Decl. ¶¶ 7-8; Targia Decl. ¶ 18 & Attachment A; Joiner Decl. ¶¶ 8-9; Zeigler Decl. ¶¶ 8-11; *see also* Harrelson Decl. ¶¶ 14-16.

HHS (at 12-14) does not deny these new burdens; it just thinks they aren't that burdensome. But having to clear *any* new hurdle is an Article III injury since "[t]he imposition of a regulatory burden itself causes injury." *Tennessee v. EEOC*, 129 F.4th at 458. That's particularly so here, where Congress prohibited any "*limit*" on States' investigative authorities, *see Purl*, 2024 WL 5202497, at *6-10.

Regardless, navigating the attestation requirement is not the small task HHS claims. Investigators must sign attestations and use HIPAA-protected information under threat of potential criminal liability. 42 U.S.C. § 1320d-6(b); *see also* 89 Fed. Reg. at 33,030 ("adding another new required element[:] a statement that the attestation is signed with the understanding that a person who knowingly and in violation of HIPAA obtains or discloses [information] relating to another individual … may be subject to criminal liability"). Thus, investigative agencies have had to consider their processes for requesting information and providing attestations. *See, e.g.*, Azar Decl. ¶¶ 12-15; Stover Decl. ¶¶ 7-11; Karrasch Decl. ¶¶ 10-12; *see also* Davies Decl. ¶¶ 7-10. For specific cases, an attestation demand requires investigators to consult internally to confirm whether the information sought could touch on "reproductive health care" data. *See, e.g.*, Menefee Decl. ¶¶ 7-14; Kreutz Decl. ¶¶ 16-17; *see also* Harrelson Decl. ¶¶ 14-17; Zeigler Supp. Decl. ¶¶ 11-13. This can include seeking legal counsel and carefully re-evaluating the information sought, particularly because these requests often come early in an investigation, before the full extent of potential wrongdoing is known. *See, e.g.*, Menefee Decl. ¶¶ 8-9; Dietz Decl. ¶ 18; Zeigler Decl. ¶ 12; Kreutz Decl. ¶¶ 16-21; *see also* McKnight Decl. ¶¶ 14-18.

Conducting these evaluations takes time, resources, and personnel, particularly because the Final Rule's vague, broad standards create uncertainty around its application and the risks of criminal liability that come with that. *See, e.g.*, Traxler Decl. ¶¶ 18-21; *see also* Davies Decl. ¶¶ 8-9. Sometimes the process may end in a decision not to provide an attestation. *See, e.g.*, Zeigler Decl. ¶¶ 8-12. At

other times investigators may provide an attestation but the HIPAA-covered nonetheless denies the request for information, which the Final Rule allows. Even when things go smoothly—*i.e.*, when investigators provide an attestation and the covered entity provides the requested information—investigators were subjected to additional, front-end work unlawfully required by the Final Rule. In each instance, the Final Rule's new regulatory burdens—which have slowed or stymied many public health investigations promoting Plaintiff States' sovereign interests, *see, e.g.*, Groover Decl. ¶¶ 7-9; Zeigler Decl. ¶¶ 8-11; Johnson Decl. ¶¶ 9-15; Dietz Decl. ¶¶ 18-22; *see also* Davies Decl. ¶¶ 8-10; Hardin Decl. ¶¶ 9-11—"cause[] injury" for standing purposes. *Tennessee v. EEOC*, 129 F.4th at 458.

2. None of HHS's remaining standing counters is convincing. HHS's curious claim that "the record is *devoid* of any" evidence, HHS Br. 12 (emphasis added), misses the fifteen-declaration elephant in the room. Upon later confronting the declarations, HHS claims they are insufficient because they demonstrate only self-inflicted harm rather than harm traceable to the Final Rule. HHS Br. 12-13 (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 416 (2013)). Not so. Plaintiff States' declarations lay out repeatedly how the Final Rule is adding new, unlawful barriers to investigators' obtaining vital information. Whether investigators might successfully overcome the Final Rule's burdens in any one case does not disprove standing; Plaintiff States' point is that *no* burdens the Final Rule imposes are lawful, and that satisfying any such burden requires time, energy, and resources that's typically the stuff of APA standing. *See Tennessee v. EEOC*, 129 F.4th at 458. Anyway, the declarations' detailing of investigative efforts *does* provide the concrete evidence of "compliance costs" that HHS claims (at 14) is lacking. For example, investigators have been denied information without an attestation, *see, e.g.*, Zeigler Decl. ¶ 11, which has required internal consultation and discussions with legal counsel, *see, e.g.*, Johnson Decl. ¶ 11; Kreutz Decl. ¶ 17; *see also* McKnight ¶¶ 11-14, as well as dialogue with hospitals and other covered entities, *see, e.g.*, Traxler Decl. ¶ 19; *see also* Zeigler Supp. Decl. ¶¶ 11-13, and investigators have had to consider whether and how to seek recourse against covered entities that

deny requests, *see, e.g.*, Spahr Decl. ¶¶ 16, 18; Davies Decl. ¶ 10. Plus, covered entities incur parallel costs when navigating similar factors before disclosing information. *See, e.g.*, Hardin Decl. ¶¶ 8-10.

Nor should these costs catch HHS off-guard. They are akin to the costs HHS's Final Rule predicted for *all* covered entities. *See* 89 Fed. Reg. at 33,054-56. Having spotted *all* regulated entities increased costs in the Final Rule, HHS cannot now credibly suggest (at 14) that the Final Rule lacks a "*particularized*" effect *on Plaintiff States*. *Cf. SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943).

Finally, HHS notes (at 12) that some Plaintiff States did not attach declarations to the motion for relief. For a few reasons, that is no problem here. First, as explained, *supra* 3-6, States' standing as directly regulated parties is both "self-evident," *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 508, and posited in the body of the Final Rule, *see* 89 Fed. Reg. at 33,054-56. Second, at least one Plaintiff State has demonstrated standing for the reasons above, and "only one plaintiff needs to have standing in order for the suit to move forward." *Parsons v. U.S. Dep't of Just.*, 801 F.3d 701, 710 (6th Cir. 2015). Plaintiff States seek the APA's "default" vacatur remedy, *Kentucky v. EPA*, 123 F.4th at 472-73, "which is not party-restricted," *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024); *cf. Griffin v. HM Florida-ORL*, 144 S. Ct. 1, 1, n.1 (2023) (Kavanaugh, J., concurring in stay denial) (explaining APA remedies). Third, to the extent equitable relief hinges on party-specific evidence, Plaintiff States submit additional declarations in support of their requested relief. *Supra* 3 n.2.

II. The Final Rule is unlawful.

As Plaintiff States previously explained, the Final Rule's mandates exceed HHS's statutory authority under HIPAA. States' Br. 12-20. And the Final Rule's regulatory regime is not the product of reasoned decision-making. *Id.* at 20-22. HHS has forfeited those arguments by declining to

respond to them. *See Adkins*, 105 F.4th at 854.[6] Thus, the Court should hold the Final Rule "unlawful" and "set [it] aside." *See* 5 U.S.C. § 706(2)(A), (C).[7]

III. This Court can and should vacate the Final Rule.

The APA's instruction that reviewing courts "shall … hold unlawful and set aside" any agency action that is "arbitrary, capricious," or "in excess of statutory jurisdiction[or] authority," 5 U.S.C. § 706(a)(A), (C), authorizes vacatur of the unlawful agency action. *Kentucky v. EPA*, 123 F.4th at 472-73; *see also Corner Post*, 603 U.S. at 829 (Kavanaugh, J., concurring) ("[T]he APA authorizes vacatur of unlawful agency actions, including agency rules."). In fact, vacatur is "the default" remedy, and narrower alternative remedies are "rare." *Kentucky v. EPA*, 123 F.4th at 473. As Plaintiff States explained previously, States' Br. 23, because this straightforward APA challenge is not one of those "rare" cases, the APA's "normal" vacatur remedy is warranted. *See Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 51-52 (D.D.C. 2020) (K.B. Jackson, J.). HHS's arguments to the contrary are unavailing. So is its attempt to salvage scraps of a rule promulgated explicitly to guard "reproductive health care" information, 89 Fed. Reg. at 32,978, after the provisions achieving that purpose are stripped out.

First, HHS responds (at 15-16) by slaying a strawman. Plaintiff States never suggested that vacatur is "*required*." Rather, they explained that vacatur is "the default" APA remedy in this circuit, *Kentucky v. EPA*, 123 F.4th at 472-73, and the Final Rule's many "legal flaws warrant" that normal

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[6] Two localities and a nonprofit group moved to intervene to defend the Final Rule. *See* Mot. to Intervene, Dkt. #31 (Feb. 10, 2025). Their intervention motion remains pending. Under this Court's scheduling order, *see* Dkt. #71, Plaintiff States will submit a supplemental brief replying to the Proposed Intervenors' opposition to summary judgment no later than 14 days after an order granting intervention, if any.

[7] Courts regularly decide APA cases without the administrative record when, as here, it "is not necessary for [the court's] decision." *See Connecticut v. U.S. Dep't of Interior*, 344 F. Supp. 3d 279, 294 (D.D.C. 2018). In any event, HHS already filed the administrative record related to the Final Rule in *Purl v. HHS*, No. 2:24-cv-228 (N.D. Tex.). This "Court may take judicial notice of public records and government documents available from reliable sources on the internet." *Roane Cnty. v. Jacobs Eng'g Grp., Inc.*, No. 3:19-CV-206-TAV-HBG, 2020 WL 2025613, at *3 (E.D. Tenn. Apr. 27, 2020) (citations omitted). Or HHS could be ordered to re-file that same record here in short order. But a current lack of administrative record is no reason to delay resolving this case.

remedy here. States' Br. 23. Indeed, vacatur is "the *ordinary result*" when a reviewing court determines that agency regulations are unlawful. *Corner Post*, 603 U.S. at 831 (Kavanaugh, J., concurring) (emphasis added) (citation omitted). The D.C. Circuit—"where much litigation concerning federal agencies takes place," *see Sierra Club v. EPA*, 60 F.4th 1008, 1022 (6th Cir. 2023)—applies this same default. *See, e.g.*, *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) ("[V]acatur is the normal remedy[.]"). As do the First, Third, Fifth, Ninth, Tenth, and Eleventh Circuits.[8]

HHS must explain why this Court should deviate from this well-established norm; it is not enough to say (at 16) that courts *can* do so. *Kentucky v. EPA*, 123 F.4th at 472-73; *see also Allina Health Servs.*, 746 F.3d at 1110. But HHS fails to justify its request for narrower relief. Maybe courts have declined to order universal vacatur when a plaintiff does not seek it or in light of certain equitable considerations. *See* HHS Br. 16 (citing, *e.g.*, *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 521-27 & *Ohio Env't Council v. U.S. Forest Serv.*, 2023 WL 6370383, at *2-5 (S.D. Ohio Aug. 3, 2023)). But that says nothing about whether this Court should deny Plaintiff States "the default" relief that they do seek when HHS "has failed to establish that the equities justify" something else. *Kentucky v. EPA*, 123 F.4th at 472-73; *see also Allina Health Servs.*, 746 F.3d at 1110. That's especially true given that the cases HHS cites to support its request for alternative relief treat vacatur as the "[n]ormal" APA remedy. *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 521; *see also GBX Assocs., LLC v. United States*, 2022

[8] *See, e.g.*, *Martinez v. Bondi*, No. 24-1057, 2025 WL 855018, at *9 (1st Cir. Mar. 19, 2025) ("Under the so-called 'ordinary remand rule,' an error of this kind would thus typically result in vacatur of the agency's decision[.]") (citation omitted); *Comite' De Apoyo A Los Trabajadores Agricoloas v. Perez*, 774 F.3d 173, 191 (3rd Cir. 2014) ("Ordinarily, reviewing courts have applied [APA § 706(2)] by vacating invalid agency action and remanding the matter to the agency for further review."); *Rest. L. Ctr. v. U.S. Dep't of Labor*, 120 F.4th 163, 177 (5th Cir. 2024) ("[O]ur court's 'default rule is that vacatur is the appropriate remedy.'") (citation omitted); *E. Bay Sanctuary Covenant v. Garland*, 994 F.3d 962, 987 (9th Cir. 2020) ("Because the Rule is 'not in accordance' with [statutory authority], our obligation as a reviewing court is to vacate the unlawful agency action."); *High Country Conservation Advocs. v. U.S. Forest Serv.*, 951 F.3d 1217, 1228 (10th Cir. 2020) ("The typical remedy for an [unlawful agency action] is remand to the district court with instructions to vacate the agency action."); *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*, 781 F.3d 1271, 1290 (11th Cir. 2015) ("[V]acatur ... is the ordinary APA remedy[.]") (citation omitted).

WL 16923886, at *15-18 (N.D. Ohio Nov. 14, 2022) (assuming "that federal courts have the authority to order universal vacatur" and justifying its decision to enter less-than-full vacatur); *Ohio Env't Council*, 2023 WL 6370383, at *2 (calling vacatur "[t]he standard remedy for violations of the APA").

Second, HHS suggests (at 16 & n.5) that vacatur is *not allowed* because it "contradict[s] constitutional and equitable limitations on this Court's remedial authority." But that stance "disregards a lot of history and a lot of law." *Corner Post*, 603 U.S. at 827 (Kavanaugh, J., concurring) (quoting M. Sohoni, *The Past and Future of Universal Vacatur*, 133 Yale L. J. 2304, 2310-11 (2024)); *cf. supra* 14 n.8 (collecting cases). "Over the decades, [the Supreme] Court has affirmed countless decisions that vacated agency actions, including agency rules." *Corner Post*, 603 U.S. at 830 (Kavanaugh, J., concurring) (collecting cases). That includes cases in which a court may have been able to craft party-specific remedies. *See, e.g.*, *Bd. of Governors of Fed. Rsrv. Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 364-65 (1986); *see also, e.g.*, *Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1143-48 (6th Cir. 2022). None of the cases HHS cites (at 16-17) requires the contrary. Indeed, "[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—*not* that their application to the individual petitioners is proscribed." *Harmon v. Thornburgh*, 878 F.2d 484, 495 n. 21 (D.C. Cir. 1989) (emphasis added).

Third, HHS misdirects to other pending actions. Contra HHS (at 17), though, an order from this Court vacating the Final Rule need not preempt review of other parallel challenges that are pending in other courts. As the Department of Justice recently explained to a district court in Texas, a case challenging a rule "remains a live controversy" even if another district court "enter[s] judgment vacating" that same rule until that "judgment is affirmed on appeal and no further appellate review is available" or "the deadline to appeal passes without" a party filing a notice of appeal. Joint Status Report, Dkt. #85, *Carroll Indep. Sch. Dist. v. U.S. Dep't of Educ.*, No. 4:24-cv-461-O (N.D. Tex. Feb. 17, 2025). Therefore, other plaintiffs' pending challenges can continue even after a vacatur order from this Court,

meaning the "best ideas" about whether HHS's Final Rule is lawful can "percolate to the top." *Cf. Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring).

Fourth, this is not a case in which equity favors narrower relief, like remand without vacatur. *Kentucky v. EPA*, 123 F.4th at 473. When considering whether to stray from the APA's "default" remedy, courts consider "how serious of an error the agency made" and "how disruptive … vacatur would be." *Id.* at 472-73; *see also Allina Health Servs.*, 746 F.3d at 1110. It is "rare" that these factors militate against the default vacatur remedy, *Kentucky v. EPA*, 123 F.4th at 472-73, and it is not even clear whether such relief is available in the Sixth Circuit if an agency action is unlawful, *see id.* at 478-79 (Murphy, J., concurring). In the "rare" case the Sixth Circuit "has remanded to an agency without vacating its action" the court "did not find the action unlawful and instead remanded for additional proceedings at the agency's request." *Id.* at 472 (citing *Sierra Club*, 60 F.4th at 1021-23).

That is not this case. HHS's "exceeding [its] statutory authority is a serious defect." *Ins. Mktg. Coal. Ltd. v. FCC*, 127 F.4th 303, 317 (11th Cir. 2025). Indeed, because federal agencies' "power to act … is authoritatively prescribed by Congress," *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013), the Final Rule is "a substantively illegal action," and narrowed relief is not appropriate to address such "'fundamental' error[s]." *Kentucky v. EPA*, 123 F.4th at 472. On that basis alone, this Court should not "let the action stand." *Id.* And because HHS erected a scheme "so implausible that it could not be … the product of agency expertise," *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983), it would be illogical to preserve the Final Rule while the agency takes a futile second go at justifying it. *See Louisville Gas & Elec. Co. v. FERC*, 988 F.3d 841, 843, 848-49, 851 (6th Cir. 2021) (vacating agency action upon finding agency acted arbitrarily and capriciously).

Nor has HHS demonstrated that vacatur would be particularly disruptive. Vacatur would not "upend years" of "reliance on the agency's action." *Kentucky v. EPA*, 123 F.4th at 473. So "[t]his is not a case in which the 'egg has been scrambled,' and it is too late to reverse course." *Allina Health*

Servs., 746 F.3d at 1110 (citation omitted). If anything, narrower, party-specific relief could cause more disruption or confusion than vacatur, as regulated parties would be forced into navigating dueling regulatory regimes depending on the identity of the entity seeking or disclosing information. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165-66 (2010) (finding "no recourse to … an injunction" is "warranted" if vacatur is viable). This could "add to the confusion" among affected parties and potentially put regulated officials in a "position of trying to communicate" multiple, conflicting instructions over the span of the case. *Ohio State Conf. of NAACP v. Husted*, 769 F.3d 385, 389-90 (6th Cir. 2014). On the other hand, vacatur would assure regulated parties that the familiar, long-standing Privacy Rule again governs. While Plaintiff States are sympathetic to the costs that covered entities have sunk into modifying their "policies or practices" to comply with the rule, *see supra* 7, 9-11 (explaining Plaintiff States bear those same costs), HHS is wrong to suggest (at 18) that any covered entity has a legitimate interest in "continu[ing]" to "operat[e] under" a rule that unlawfully impedes States' sovereign authority. As the Sixth Circuit has noted in similar contexts, "the public's true interest lies in the correct application of the law." *Tennessee v. U.S. Dep't of Educ.*, 104 F.4th at 614 (cleaned up).

Fifth, the Final Rule's severability provision does not salvage the scraps left over after excising the unlawful provisions regarding "reproductive health care" information. HHS was explicit about its motivation for promulgating the Final Rule: "In order to continue to protect privacy in a manner that promotes trust between individuals and health care providers and advances access to, and improves the quality of, health care," after *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), HHS "determined that the Privacy Rule must be modified to limit the circumstances in which provisions of the Privacy Rule permit the use or disclosure of an individual's [information] about reproductive health care[.]" 89 Fed. Reg. at 32,978. So along those lines, each regulatory change made in the Final Rule either creates the new "reproductive health care" regime or conforms the Privacy Rule to its new standard. *See, e.g.*, 45 C.F.R. § 164.520(b)(ii)(F)-(H) (amended requirement to provide "[n]otice of

privacy practices" to ensure coverage of "reproductive health care" information).

HHS does not explain how any of the Final Rule's amendments to the Privacy Rule concern something else or could be partially implemented. Nor has HHS "identified any evidence that it contemplated" "enforcement of the Rule without *any* of the core provisions" Plaintiff States have challenged. *Tennessee v. Cardona*, 2024 WL 3453880, at *4. To the contrary, given the Final Rule's post-*Dobbs* justification, there is "substantial doubt" HHS would have promulgated the Final Rule absent the challenged limitations. *Mayor of Baltimore v. Azar*, 973 F.3d 258, 292-93 (4th Cir. 2020) (citation omitted). The severability clause thus has "little impact on the Court's analysis because the" illegal portions of the Final Rule "permeate[]" its remaining bits. *Tennessee v. Cardona*, 737 F. Supp. 3d 510, 570 (E.D. Ky. 2024). On top of that, the justification for the Final Rule rests on arbitrary-and-capricious reasoning, "resulting in a rule that is invalid in its entirety." *Id.* at 570. In short, given the Final Rule's widespread legal defects, the Final Rule's severability clause is not the get-out-of-jail-free card HHS claims. *See Ohio v. EPA*, 603 U.S. 279, 294-97 (2024). The Court should apply the default remedy and vacate the Final Rule in its entirety. *Kentucky v. EPA*, 123 F.4th at 472-73.

IV. At a minimum, preliminary relief is warranted.

Even if this Court declines entry of final judgment, Plaintiff States have demonstrated entitlement to the requested preliminary relief. Contra HHS (at 14-15), the same harms detailed in Plaintiff States' complaint and declarations establish that the Final Rule inflicts irreparable harm. The new barriers for investigators to obtain HIPAA-protected information are slowing or halting public health investigations, damaging Plaintiff States' sovereign interest in "safeguard[ing] '[their] domain' and [their citizens'] 'health, comfort and welfare.'" *Kentucky v. Biden*, 23 F.4th at 596 (citations omitted). Such sovereign harms are irreparable injuries. *See Tennessee v. U.S. Dep't of Educ.*, 104 F.4th at 591-95. As are the compliance costs Plaintiff States must expend under the Final Rule. *See Kentucky v. Biden*, 57 F.4th at 555-56. Because the federal government enjoys sovereign immunity, Plaintiff States cannot

recover the sunk costs of complying with the rule. *Id.*

Nor can HHS (at 15) lean on Plaintiff States' alleged "seven-month delay." Though the Final Rule became effective in June 2024, compliance was not required until late December 2024. 89 Fed. Reg. at 32,976. Plaintiff States sued within weeks of the costs and impacts of compliance materializing—enabling an evidentiary showing that details their ongoing harms. Elsewhere, the federal government has knocked States' pre-effective-date suits as too *early* to support preliminary relief.[9] Having sued now when directly subject to Final-Rule compliance, Plaintiff States' case for injunctive relief should not suffer under HHS's heads-I-win, tails-you-lose approach to relief.

The requested preliminary relief is appropriately tailored. The APA allows the court to "postpone the effective date of an agency action." 5 U.S.C. § 705; *see* Compl. at 32 (requesting "a stay … that preserves the States' rights against the Final Rule pending review"). Such relief need not be "party-restricted." *Career Colls. & Sch. of Tex.*, 98 F.4th at 255. This result tracks the difference between the APA context—where vacatur of a rule "for everyone" is the normal remedy, *Kiakombua*, 498 F. Supp. 3d at 52 (citation omitted)—and non-APA cases involving requests for equitable relief that flow to particular parties, *cf., e.g.*, *Labrador v. Poe ex rel. Poe*, 144 S. Ct. 921, 928-34 (2024) (Kavanaugh, J., concurring). And courts "routinely stay already-effective agency action under Section 705." *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022); *see also, e.g.*, *Airlines for Am. v. U.S. Dep't of Trans.*, 110 F.4th 672, 677 (5th Cir. 2024) (stay granted July 29, 2024; 89 Fed. Reg. 34,620 effective July 1, 2024); *Kansas v. United States*, No. 1:24-cv-150-DMT, 2024 WL 5220178, at *9 (D.N.D. Dec. 9, 2024) (89 Fed. Reg. 39,392 effective Nov. 1, 2024); *Int'l Fresh Produce Ass'n v. U.S. Dep't of Labor*, No. 1:24-cv-309-

[9] *See, e.g.*, Def.'s Mem. in Opp'n to Pltfs.' Mot. for a § 705 Stay & Prelim Inj. 21, Dkt. #34, *Tennessee v. EEOC*, No. 2:24-cv-84 (E.D. Ark. May 17, 2024) (arguing pre-enforcement challenge was unripe and court should await "concrete setting" of challenged rule's application); Defs.' Opp'n to Pltfs.' Mot. for a § 705 Stay & Prelim Inj. 22, *Tennessee v. Cardona*, No. 2:24-cv-72, Dkt. #73 (E.D. Ky. May 24, 2024) (arguing States lack "imminent" injury and suggesting they wait to challenge enforcement "once the Rule goes into effect").

HSO, 2024 WL 4886058, at *12 (S.D. Miss. Nov. 25, 2024) (89 Fed. Reg. 33,898 effective June 28, 2024); *Gomez v. Trump*, 485 F. Supp. 3d 145, 205 (D.D.C. 2020) (stay granted Sep. 4, 2020; 85 Fed. Reg. 23,441 effective Apr. 23, 2020; 85 Fed. Reg. 38,263 effective June 24, 2020)

Even if this Court favors the more traditional preliminary injunction route, every State plaintiff is entitled to that relief. HHS repeats (at 20) that a few States did not initially provide harm declarations. But as already explained, it is "self-evident" and conceded by the Final Rule itself that it irreparably harms those States. *See Tennessee v. U.S. Dep't of Educ.*, 615 F. Supp. 3d 807, 842 (E.D. Tenn. 2022) (granting injunctive relief to all plaintiff States, including States that did not provide a harm declaration), *aff'd by* 104 F.4th at 613. And in any event, more States have now submitted declarations. *Supra* 3 n.2. Nor would it be sufficient to enjoin only the attestation requirement, as HHS suggests (at 20-21). The Final Rule's hindering state investigators demonstrates the significant harms that flow from the Final Rule's regime, but the costs and burdens placed on Plaintiff States' covered entities are equally harmful and unlawful, *see* Compl. ¶¶ 113-15; *Purl*, 2024 WL 5202497, at *4-10. Any time a State, as a HIPAA-covered entity, receives a request for information it must devote "resources to comply with the Final Rule's byzantine procedural burdens." States' Br. 24; *see also* Hardin Decl. ¶¶ 8-10. There is no "application of the Rule['s]" limitations on the use or disclosure of "reproductive health care" information Plaintiff States has not alleged is "unlawful." HHS Br. 21.

CONCLUSION

This Court should grant summary judgment to Plaintiff States and set aside the Final Rule as unlawful. At a minimum, preliminary relief against the Final Rule pending the case's resolution is warranted.

Date: April 3, 2025

Respectfully submitted,

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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 3rd day of April, 2025 to all counsel of record.

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EXHIBIT Q

Declaration of Charles Hardin, Privacy Officer for the Arkansas Department of 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-00025

DECLARATION OF CHARLES HARDIN

Pursuant to 28 U.S.C. § 1746, I, CHARLES HARDIN, 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 Privacy Officer for the Arkansas Department of Health. As the Privacy Officer, I ensure agency compliance with the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"), develop, implement, and update privacy policies in accordance with current laws, investigate privacy complaints, address patient privacy inquiries, and provide staff training on the HIPAA Privacy

Rule. Because the Department of Health is also a public health authority, I work with our public health officials on privacy requirements affecting their ability to perform public health activities.

3. As part of my responsibilities, I help coordinate the Department of Health's release of protected health information in compliance with HIPAA. For example, if the Department of Health receives a civil investigatory demand from an agency investigating public health matters, I help ensure that information is disclosed only as permitted by HIPAA and its accompanying regulations.

4. 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.

5. The Final Rule has created compliance costs for the Department of Health that are on-going.

6. 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.

7. When the Department of Health requests reproductive health care records as part of their health care function, other healthcare providers have been reluctant to provide records, and some have refused, despite the request being for treatment purposes and the Department of Health, as a covered entity, referring the patients to the provider. The Department of Health has an increased financial burden because staff now navigate these unnecessary administrative hurdles to

patient care put in place due to the Final Rule. These hurdles also create delays which prevent patients from receiving timely care.

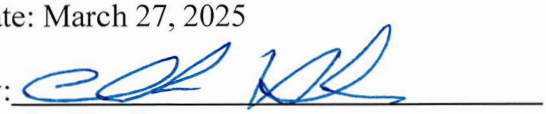
8. Under the Final Rule, when the Department of Health receives a request for information, it now must consider whether that information is sought for a prohibited purpose, like "[t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care." *Id.* § 164.502(a)(5)(iii)(A)(1). Making this evaluation involves resolving many difficult legal questions, like whether certain health care is "authorized by Federal law … regardless of the state in which it is provided." *Id.* § 164.502(a)(5)(iii)(B). And if requested information is *potentially related* to "reproductive health care" information, the Department of Health must request an attestation from the investigator required by the Final Rule. *Id.* § 164.509. The Department of Health then must determine whether that attestation is valid.

9. The Department of Health has worked with the state's child protective services to provide health care to children who are in the state's custody. The Final Rule has created greater confusion over when a child protective service worker is an investigator, triggering the greater protections, or when they are acting as the child's personal representative in a *in loco parentis* role and therefore allowed access to the child's protected health information. This is complicated further because HIPAA requires covered entities to "treat a personal representative as the individual." *Id.* § 164.502(g)(1). HIPAA also requires a covered entity to disclose protected health information to the individual. *Id.* 164.502(a)(2)(i). This conflict with the Final Rule has led to delays in treatment and significant compliance burdens as the fact-based analysis must accompany every request, even one as simple as making an appointment.

10. Despite assurances made by the Department of Health and Human Services in the publication of the Final Rule, the Department of Health's public health activity has also suffered significant compliance burdens. Public health requests have been routinely denied by other covered entities. Public health officials have been denied records for reportable diseases such as Alpha-Gal and Lyme disease, neither of which are related to reproductive care. To receive the records, public health officials have been required to complete an attestation. Because each covered entity has interpreted the information required by the attestation differently, the public health officials have an increased burden to determine what information is required for each request they make, despite the Department of Health being a covered entity with its own requirements.

11. Thus, the Final Rule prompted the Department of Health to re-evaluate its processes for disclosing information and train its staff on new disclosure procedures. Now each request for information triggers a series of evaluations—*e.g.*, is reproductive health care information potentially implicated? If so, has the investigator provided an attestation? If so, is that attestation valid, meaning that the Department of Health can reasonably determine that the information is not sought for a prohibited purpose? Each step of this pre-disclosure process takes time, resources, and personnel. Thus, the Final Rule imposes significant compliance costs on the Department of Health and other state agencies that respond to public health investigators' requests for information.

Date: March 27, 2025

By: 

Charles Hardin
HIPAA Privacy Officer
Arkansas Department of Health

EXHIBIT R

Declaration of Tammera Harrelson, Deputy Attorney General and Director for the Medicaid Fraud Control Unit in the Office of the Arkansas 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 TAMMERA HARRELSON

Pursuant to 28 U.S.C. § 1746, I, Tammera Harrelson, 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 Deputy Attorney General and Director for the Medicaid Fraud Control Unit (MFCU) in the Office of the Arkansas Attorney General. The MFCU is responsible for investigating and prosecuting, both criminally and civilly, Medicaid fraud, False Claims, and the abuse, neglect, and exploitation of residents in long term care facilities or board and care facilities with a Medicaid nexus.

3) As part of my responsibilities, I regularly review criminal subpoenas and civil investigative demands ("CIDs") 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, False Claims, abuse, neglect, and exploitation. The MFCU is authorized to issue CIDs and criminal subpoenas pursuant to Ark. Code Ann. § 20-77-904 and Ark. Code Ann. § 25-16-705.

4) The MFCU routinely requests medical records during an investigation for civil or criminal fraud, as well as records involved in the abuse, neglect, or exploitation of vulnerable patients. At the beginning of an investigation, the investigators and agents may not have any idea of the breadth and depth of misconduct. We often receive a general complaint of wrongdoing and will not know the specifics until we review the medical records.

5) Obtaining medical records is a first step in any investigation the MFCU initiates. For Medicaid Fraud or False Claims, the medical records must be reviewed against the data to determine whether the billing was correct. For abuse and neglect claims, records reveal any injuries and the extent of those injuries. Even with financial exploitation claims, the MFCU investigators and agents must use medical records to help determine whether the victim was physically or mentally compromised.

6) 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 generally was not required until December 23, 2024, *id.* at 32,976.

7) The Final Rule has created compliance costs and barriers to investigation, impeding our investigation of Medicaid Fraud, False Claims, and abuse, neglect, and exploitation in Arkansas.

8) Before the Final Rule, the MFCU could issue CIDs and subpoenas without considering whether the information sought "potentially related" to "reproductive health care." Since the Final Rule, however, the MFCU investigators and agents are trapped between the vague requirements of the Final Rule and the ability to perform their missions.

9) The Final Rule now 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 any purpose described in paragraphs (a)(5)(iii)(A)(1) or (2) of this section.

45 C.F.R. § 164.502(a)(5)(iii)(A)(1)-(3).

10) If the PHI will be used for the above activities, the covered entity cannot disclose the requested information if the entity "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)(1)-(2).

11) 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).

12) Covered entities that receive a request for PHI are making these determinations, including assessments of state and federal laws, for themselves. 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.

13) Under the Final Rule, covered entities must also 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.* § 164.512(f)(1)-(6). Investigators and agents now must thoroughly consider the bases and potential ends of their investigation before requesting HIPAA-protected information from a covered entity with a particular focus on "reproductive health care." If there is any risk that "reproductive health care" information will be subsumed in the requested data, investigators are to consult internally to consider, among other things, whether their request can be narrowed and whether the information is sought for a prohibited purpose. Because of the Final Rule's broad, vague standards, sometimes these internal discussions require

consultation with legal counsel. And even once an investigator is satisfied that he can provide an attestation, he must complete the form and provide it to the covered entity.

14) The Final Rule places the power to assess the validity of an 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. This means that in some cases the entity under investigation will have a veto on the MFCU's ability to obtain records necessary for investigations.

15) Rather than making individualized determinations, some covered entities are demanding an attestation in response to all subpoenas or CIDs sent by the MFCU, regardless of the circumstances. As of the end of January 2025, the MFCU had already received five denials for criminal subpoenas. The entity in each instance insisted that it would not release the medical documents without an attestation.

16) Hence, the investigators and agents are left with poor options by the Final Rule, especially in cases where they do not know whether the investigation will involve something that will run afoul of the Final Rule. For example, they could refuse to send an attestation and try to get a court of competent jurisdiction to enforce the subpoena, but that process takes time, resources, and personnel. Further, considering that the Arkansas Statute of Limitations in certain cases runs within one year, the MFCU could easily lose cases due to the delay.

17) Ultimately, the Final Rule has already complicated my team's duty and ability to investigate Medicaid Fraud, False Claims, and abuse, neglect, and exploitation of vulnerable citizens. For those reasons, the Final Rule is impacting the public health and safety of the State of Arkansas due to the fact that it is delaying, impeding, and deterring investigations.

By: Tammera Harrelson Dated: 4-2-25

Tammera Harrelson, Deputy Attorney General
Director, Medicaid Fraud Control Unit
Office of the Arkansas Attorney General

EXHIBIT S

Declaration of Lisa Davies, Executive Director of the Healthcare Facility Regulation Division of the Georgia Department of Community 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-00025

DECLARATION OF LISA DAVIES

Pursuant to 28 U.S.C. § 1746, I, **LISA DAVIES**, 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 Executive Director of the Healthcare Facility Regulation Division (HFRD) of the Georgia Department of Community Health. HFRD is the State Survey Agency for Georgia under agreement with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") pursuant to Section 1864 of the Social Security Act. As such, HFRD is responsible for inspecting health care facilities, including but not limited to hospitals, nursing homes, dialysis centers, home health agencies, hospices and ambulatory surgery

centers, to ensure compliance with the minimum health and safety standards applicable to providers and suppliers participating in the Medicare and Medicaid programs pursuant to Titles 18 and 19 of the Social Security Act and accompanying federal regulations. HFRD also licenses and regulates over 30,000 healthcare facilities pursuant to state laws and regulations (*see* O.C.G.A. §§ 26-5-1 et seq.; 31-7-1 et seq.; 37-3-200 et seq. and 49-6-80 et seq.).

3. As part of my responsibilities, I oversee survey activities for over 100 field surveyors who conduct on-site inspections ("surveys") of healthcare facilities in Georgia every week; prepare survey reports, including but not limited to Statement of Deficiencies (CMS Form 2567); receive and review corrective action plans filed by healthcare facilities; and transfer cases to CMS with recommendation for federal enforcement actions and/or issue adverse action letters to impose state sanctions on non-compliant facilities that pose potential risk to patients and residents. These surveys include investigations of complaint allegations received from patients and their family members, as well as comprehensive licensure, certification or recertification surveys, and are conducted at entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA").

4. The survey process requires a review of relevant medical records, including protected health information ("PHI"), to substantiate allegations of noncompliance or conduct routine reviews of critical safety protocols (e.g., maintaining timely documentation of patient vital signs and medication administration, obtaining patient consent for surgery, conducting appropriate triage and stabilization of emergency room patients, etc.). Evidence compiled by the state surveyor relating to violations of federal conditions of participation, such as patient or resident abuse or neglect, or violations of the Emergency Medical Treatment and Labor Act (EMTALA), must be submitted to CMS along with the Statement of Deficiencies. In EMTALA cases, the state agency

has only ten working days from the survey exit date to transmit all documentation to the CMS Regional Office for review (*see* Chapter 5, Section 5450, Medicare State Operations Manual "SOM", Complaint Procedures).

5. In cases involving serious physical harm, abuse or death, known as "immediate jeopardy" situations, the state agency must initiate the onsite inspection within two to three business days. Once onsite, if the state agency identifies an immediate jeopardy situation in a long-term care facility, for example, the facility's enrollment in Medicare and Medicaid is automatically terminated within twenty-three days of the survey exit date (*see* Chapter 7, Section 7301.1, SOM). This requires immediate exchange of all relevant documentation between the state agency and CMS. If the facility cannot abate the immediate jeopardy findings within this short time period, CMS terminates payments to the facility and all residents supported by those payments, most of whom are elderly and medically unstable, must be relocated. There is no mechanism under federal law for any extension of this enforcement remedy. Due to these short timeframes and the potentially catastrophic consequences of the investigation findings, it is imperative for the state agency to receive relevant medical records as expeditiously as possible.

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 has created barriers to the survey process, impeding the ability of our agency to complete thorough and timely investigations at healthcare facilities.

8. Under the Final Rule, healthcare facilities, including hospitals and nursing homes, are requiring that state surveyors sign an attestation that the information contained in the requested

medical records, if "potentially related" to "reproductive health care", is not sought for a purpose prohibited by the Final Rule. *See* 45 C.F.R. § 164.509(a).

9. These attestations reference potential criminal penalties, and must be signed by the field surveyor, who does not have a legal background, but instead is a nurse or other healthcare worker trained to conduct health and safety inspections. The interruption of the investigatory process to assess the ends and bases of an early-stage investigation, review legal documents, and, if needed, consult with an agency attorney, results in unnecessary delay in the completion of the survey and, thus, in the healthcare facility's response with the corrective action that may be needed to safeguard patients and residents in care. In cases where the allegation is rape or sexual abuse, or other forms of immediate jeopardy, delays in the investigation that may substantiate serious allegations could have far reaching consequences as the state agency also may need to refer matters to local law enforcement, professional licensing boards or other appropriate agencies for immediate action.

10. The Final Rule places the power to assess the validity of an 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. This means that in some cases the entity under investigation will have a veto on the investigators' ability to obtain records necessary for their investigation. As a result, HFRD has had to expend time and resources considering whether and how it will respond in cases when a covered entity refuses to provide requested information. Additionally, CMS has put state agencies on notice that failure to conduct complete surveys and investigations may impact the federal funding that the state agency receives for such purpose. (*see* QSO-22-12-ALL).

11. Thus, the Final Rule is impacting the public health and safety of patients and residents in Georgia healthcare facilities by delaying, impeding, and deterring critical, time-sensitive surveys and investigations.

Lisa Davies Digitally signed by Lisa Davies Date: 2025.03.31 14:42:05 -04'00'

Lisa Davies
Executive Director
Healthcare Facility Regulation Division
Georgia Department of Community Health

Date: March 31, 2025

EXHIBIT T

Declaration of Andrew Pack, Director of the West Virginia Bureau of Medical Services' Office of Program Integrity

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 ANDREW PACK

Pursuant to 28 U.S.C. § 1746, I, Andrew Pack, 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 Director of the West Virginia Bureau for Medical Services' Office of Program Integrity (OPI). OPI conducts post-payment reviews and is responsible for identifying fraud, waste, and abuse cases in West Virginia's Medicaid reimbursement system. OPI achieves this by completing the activities required under 42 C.F.R. § 456.

3. As part of my responsibilities, I regularly oversee audits of 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, waste, and abuse.

4. Any credible allegations of fraud uncovered are referred to West Virginia's Medicaid Fraud Control Unit (MFCU). In turn, MFCU is authorized to continue investigating and issue subpoenas pursuant to West Virginia Code § 9-7-3(a) and 45 C.F.R. § 164.512, as MFCU performs both law enforcement and health oversight duties. Thus, in substantiated cases, OPI's investigations may lead to criminal charges brought by MFCU.

5. OPI routinely requests information from providers of services reimbursed by the West Virginia Medicaid program and health plan payers to investigate suspected Medicaid fraud. Given the nature of its investigations, OPI must request this information with imperfect knowledge of the possible misconduct being investigated because it is impossible to know the particulars of the investigation until OPI receives the information. Indeed, obtaining medical records and PHI is crucial to the investigation, reporting, and litigation of Medicaid fraud, waste, and abuse.

6. 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), 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 creates compliance costs and barriers to investigation, impeding OPI's investigation of Medicaid fraud, waste, and abuse in West Virginia.

8. Before the Final Rule, OPI could request information without considering whether the information sought "potentially related" to "reproductive health care."

9. But under the Final Rule, if a covered entity receives a request for information from OPI and concludes that information even "*potentially* related" to "reproductive health care" is part

of the requested information, it may delay or withhold submission of the information requested until investigators provide an attestation that the information is not sought for a purpose prohibited by the Final Rule. *See* 45 C.F.R. § 164.509(a) (emphasis added). The Final Rule's prohibited purposes include using the information to "conduct a criminal, civil or administrative investigation" or to "impose criminal, civil, or administrative liability" on a person "seeking, obtaining, providing, or facilitating reproductive health care." *Id.* § 164.502(a)(5)(iii)(A).

10. And similarly, under the Final Rule, a covered entity that receives a request for PHI cannot disclose that information unless it "reasonably determine[s]" that the "reproductive health care" is either "lawful under the law of the state in which such health care is provided under the circumstances in which it is provided" or "protected, required, or authorized by Federal law, including the United State Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided." 45 C.F.R. § 164.502(a)(5)(iii)(B).

11. To make that assessment, the Final Rule instructs covered entities to presume that "reproductive health care" is lawful and therefore not subject to investigation by a State. 45 C.F.R. § 164.52(a)(5)(iii)(C). The only exceptions to this are if a covered entity has "[a]ctual knowledge that the reproductive health care was not lawful" or "[f]actual information supplied by the person requesting the use or disclosure of [PHI] that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.*

12. The covered entity receiving a request for PHI makes these determinations, and if it 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.

13. Because of its new requirements, the Final Rule necessitates organization-level re-evaluation of OPI's systems and processes for requesting HIPAA-protected material. The need

for this evaluation is particularly justified by the risk of criminal liability that attaches to misusing HIPAA-protected information. 42 U.S.C. § 1320d-6(b).

14. OPI will be required to thoroughly consider the bases and potential ends of its investigations when requesting HIPAA-protected information from a covered entity with a particular focus on "reproductive health care." Because of the Final Rule's broad, vague standards, if there is any risk that "reproductive health care" information will be subsumed in the requested data, OPI will be required to seek consultation with legal counsel. And even once OPI is satisfied that it can provide an attestation, it must complete the form and provide it to the covered entity.

15. Indeed, OPI is particularly concerned that its investigators cannot truthfully fulfill the attestation requirement under the Final Rule because OPI cannot predict the ways information will be used if a case is later referred to MFCU. This is especially true considering the Final Rule's expansive definition of "reproductive health care."

16. In any case, the Final Rule places the power to assess the validity of an 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. This means that in some cases the entity under investigation will have a veto on OPI's investigators' ability to obtain records necessary for their investigation.

17. This process creates significant tangible costs, including time, resources and personal, that are likely to grow. But the costs do not end there: OPI's investigations into important public health matters are necessarily slowed to undertake compliance with the Final Rule's attestation requirements. Thus, in addition to imposing additional costs on OPI, the Final Rule is impacting the public health and safety of West Virginia by delaying, impeding, and deterring viable public health investigations.

Date: 4/2/25

Andrew Pack
Director
Office of Program Integrity

EXHIBIT U

Supplemental Declaration of Katherine Zeigler, West Tennessee Regional Administrator of the Health Facilities Commission of the State of Tennessee

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 West Tennessee Regional Administrator of 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 patient complaints regarding care and conditions at healthcare facilities. 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 U.S. Department of Health and Human Services, 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 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 are required to provide records in accordance with the survey process.

6. I am aware of the U.S. 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 has required HFC to spend time and resources considering how it can comply with the rule's new attestation requirement. This includes reconsidering our processes and systems for requesting information. This review has involved internal consultation at HFC as well as discussions with the Tennessee Attorney General's office and extended discussions with healthcare facilities and the Tennessee Hospital Association. Given its authorities as the State Survey Agency for Tennessee under its agreement with CMS pursuant to Section 1864 of the Social Security Act, HFC has also sought clarification from CMS and the Association of Health Facility Survey Agencies about complying with the Final Rule, but uncertainty remains. Indeed, CMS has offered inconsistent guidance. Typically, CMS communicates any interpretation or guidance to State Survey Agencies in a Quality Safety and Oversight ("QSO") Memorandum. But no written guidance in the form of a QSO has been provided to date.

8. The Final Rule is currently hindering HFC's investigation of healthcare facilities. For example, HFC recently commenced an investigation into a healthcare facility pursuant to a complaint. As part of that investigation, HFC sought medical records related to the care and treatments of the complainant patient. Specifically, HFC requested emergency medical treatment records from a hospital involving the transport of a patient from a psychiatric hospital who had overdosed on medication. Surveyors were seeking no information regarding the patient's reproductive status, merely the condition upon arrival for emergency treatment. Surveyors were told that they were unable to be provided records, unless an attestation was signed.

9. Further, in several other instances, HFC surveyors have sought admitting diagnoses from hospitals regarding patients who are transported from nursing facilities due to falls, burns, or other injuries which occurred in certified and licensed nursing facilities. In multiple instances,

hospitals have indicated that they are unable or unwilling to release the records without a signed attestation or in some instances a subpoena.

10. Finally, in another instance, a surveyor sought information regarding end stage renal dialysis treatment as part of a recertification and complaint for an end stage renal dialysis facility (a facility which dialyzes patients in end stage renal failure). The hospital refused to give records to the surveyor, citing the Final Rule.

11. Because non-complaint use or disclosure of HIPAA-protected information carries criminal liability, HFC's surveyors have declined to reflexively sign the requested attestations. Instead, surveyors have engaged in a dialogue with the healthcare facility, their legal counsels, and privacy officers, to determine whether the facility could provide the requested information even without an attestation. There have been instances since the Final Rule became effective in which negotiations with a healthcare facility have allowed HFC to obtain *some redacted* records without supplying an attestation. But the records HFC has received in those cases have been incomplete and were delivered only after significant discussions with the healthcare facility to ensure compliance with the Final Rule.

12. While engaging with the healthcare facility about the requested records, the HFC surveyors spend time and resources considering the propriety of the requested attestation. For example, in the case involving a psychiatric hospital, the surveyor considered whether any of the information requested was potentially related to reproductive healthcare. The patient was a seventy-two (72) year old man and the surveyor was simply seeking information about whether or not the patient had an overdose. Still, the surveyor's analysis was made more difficult because the investigation was in an early stage, making it hard to predict what unlawful activity it might encompass or uncover. To date, HFC has not received these records. As a result, the investigation

is still in "pending" status and is unable to be completed. This investigation has now been open for several weeks and is unable to be timely completed.

13. Surveyors' analyses of attestation requests have been further complicated by the Final Rule's vague, broad definition of "reproductive health care." After all, the human body's organ systems are interrelated, so care may "affect[] the health of an individual in [*some*] matters *relating to* the reproductive system and to its *functions* and *processes*" even if it would not be generally considered "reproductive health care." 89 Fed. Reg. at 32,993. Surveyors therefore have had to engage in internal discussion with colleagues and leadership at HFC about the ends and bases for their investigations. They also have engaged with legal counsel given the Final Rule's vague definition of "reproductive health care"

14. Under the Privacy Rule, which preexisted the Final Rule, HFC surveyors did not have to take such cumbersome steps to receive necessary information for investigations of health facilities.

Date: 4/2/2025 Katherine Zeigler: Katherine Zeigler Digitally signed by Katherine Zeigler Date: 2025.04.02 11:41:04 -05'00'

EXHIBIT V

Declaration of Kelsey McKnight, Assistant 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, 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 KELSEY MCKNIGHT

Pursuant to 28 U.S.C. § 1746, I, Kelsey E. McKnight, 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 Assistant 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. I currently supervise 16 investigators who are responsible for investigating consumer complaints that have been filed against medical and professional licensees, and individuals engaging in the unlicensed practice of regulated professions. At any given time, each investigator is responsible for a caseload of approximately 100–150 active investigations.

8. I also supervise 3 case screeners, who are responsible for completing a preliminary review of all consumer complaints that have been filed with Licensing Enforcement. The case screeners ensure that accurate information has been collected, and if additional information is needed, will correspond with the persons that filed a consumer complaint. At any given time, the case screeners maintain a review queue of approximately 50–100 consumer complaints.

9. 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.

10. 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.

11. The Final Rule is currently causing significant additional work for the Division and hindering its investigations.

12. Before the rule, investigators would mail and/or email an opening letter with an attached consumer complaint to the individual that was the target of an active investigation. This letter asks that the target person please provide a response to the consumer complaint within 20–30 days. While these responses are not required, they are quite often imperative in determining what next steps, if any, need to be taken in the investigation.

13. Additionally, if the investigator determined it was necessary after their initial review of the file, a *subpoena duces tecum* would be sent to the target of the investigation or a medical facility where treatment was provided requesting that certain relevant medical records be produced.

14. Now, because of the rule, certain healthcare providers require a release of information ("ROI") completed by the patient or their guardian, be included with the opening letter and consumer complaint so that the investigator may obtain a response to the consumer complaint. An ROI is not a requirement of filing a consumer complaint, so this additional step requires that an investigator work with the patient or patient's guardian to obtain the ROI, and then send, and in many cases, resend, the opening letter and consumer complaint to the investigation's target or their counsel.

15. While this change in process does not seem significant, based on the size of each investigator's caseload and when taken in the cumulative, it has not only increased the length of time an investigation may remain open, but it has caused investigators to expend time and resources on collecting paperwork rather than making substantive steps in their investigations. This is not only to the detriment of the investigators, but to the target of the investigation as an investigation may remain open longer than necessary, placing undue stress on the medical professional.

16. Similarly, it is now required that all *subpoena duces tecum* include a completed attestation. Again, this change in process has a cumulative effect in the investigative process. For example, on more than one occasion, a completed attestation and *subpoena duces tecum* had been sent, but because the medical facility/healthcare provider required the attestation to be completed on their own form, the investigator had to complete the new attestation and reissue the *subpoena duces tecum*. This again has shifted investigators' valuable time to collecting and signing paperwork.

17. In addition to the extra time and resources that have been expended because of this change in process, in at least one circumstance, an attorney of the Division was reluctant to have an investigator sign an attestation because of the attorney's interpretation of the Final Rule. In general, there is an uneasiness amongst staff about the Final Rule and what, if any, criminal or civil liability they may be exposed to whilst making proper, necessary steps during their investigations.

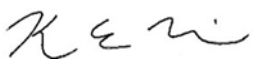
18. As stated previously herein, a ROI has become a requirement by some providers for a response to a consumer complaint be provided to an investigator. There have been consumer complaints that contain concerning allegations, but because of several reasons – the complainant's

failure to communicate, inaccurate address/email address, etc. – the investigator was unable to obtain an ROI. Often an investigator can properly complete an investigation without the response, but in other circumstances a response is often crucial in determining whether there has been a standard of care violation. Medical records paint a picture, but a response is quite often the interpretation to that picture, and without that interpretation, an investigation could be completely stalled or closed.

19. 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).

20. The Final Rule is frustrating 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 3rd day of April 2025.



Kelsey E. McKnight
Assistant Section Chief, Licensing Enforcement
Indiana Office of the Attorney General