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

STATE OF TENNESSEE, *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

No. 3:25-cv-25

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PRELIMINARY RELIEF AND CROSS-MOTION TO DISMISS

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INTRODUCTION

Last year, the Department of Health and Human Services ("HHS") issued a rule that imposed additional restrictions on the use and disclosure of reproductive health information protected under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), with a compliance date of December 23, 2024. *See HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) ("Rule"). The Rule has since been challenged in several cases, including by a coalition of fifteen states (together, the "States") who filed this Administrative Procedure Act ("APA") suit on January 17, 2025, seeking to vacate the Rule in its entirety. *See* Compl., ECF No. 1 (filed Jan. 17, 2025); *see also Texas v. HHS*, No. 5:24-cv-204 (N.D. Tex.) (filed Sept. 4, 2024); *Purl v. HHS*, No. 2:24-cv-228 (N.D. Tex.) (filed Oct. 21, 2024); *Missouri v. HHS*, No. 4:25-cv-77 (E.D. Mo.) (filed Jan. 17, 2025). Shortly thereafter, the States moved for summary judgment and preliminary relief on all their claims. *See* Mem. in Supp. of Pls.' Mot. for Summ. J. & Prelim. Relief ("Mot."), ECF No. 26.

As Defendants have indicated elsewhere, *see, e.g.*, *Texas v. HHS*, No. 5:24-cv-204 (N.D. Tex.), ECF No. 39, HHS's new leadership is currently reviewing the Rule. Defendants therefore do not address the merits at this time. But the Court need not reach the merits at all, because this case suffers from a threshold jurisdictional defect: the States have failed to plausibly allege any cognizable harm caused by the Rule. Indeed, the complaint is devoid of any concrete facts supporting the States' assertions that the Rule will impede their investigations or require them to expend extra resources to comply with its requirements. Absent such facts, the States lack Article III standing, and this case should therefore be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1). Even if the States could avoid dismissal, though, their motion for relief fails, as they submit no evidence showing that they are actually suffering the harms they allege, and thus fall short of their evidentiary burden, whether for purposes of summary judgment or preliminary relief. And certainly they offer nothing to show that any supposed harm is irreparable, a claim cast into serious doubt by their seven-month delay in

seeking any relief. But if the Court nevertheless reaches the merits and finds that the States should prevail on any of their claims, the Court should limit any relief—whether preliminary or final—to those States that have demonstrated an actual injury from the Rule, consistent with the constitutional and equitable constraints on this Court's remedial authority.

BACKGROUND

I. Statutory and Regulatory Background

Congress enacted HIPAA in 1996, recognizing the need to protect the privacy of health information "in the midst of the rapid evolution of health information systems." *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 348 (4th Cir. 2003). The Act's "Administrative Simplification" provisions sought to improve health care systems by "encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information." 42 U.S.C. § 1320d note (Purpose). These standards and requirements would apply to "covered entities"—*i.e.*, health plans, health care clearinghouses, and health care providers who transmit any health information electronically in connection with a standard transaction under HIPAA (*e.g.*, billing insurance electronically). *Id.* § 1320d-1.

To protect confidentiality and ensure trust in the health care system, Congress directed HHS to submit, within one year of HIPAA's enactment, "detailed recommendations on standards" regarding "the privacy of individually identifiable health information." *Id.* § 1320d-2 note. Congress instructed HHS to cover "at least" the following three subjects in its recommendations:

> (i) The rights that an individual who is a subject of individually identifiable health information should have.
>
> (ii) The procedures that should be established for the exercise of such rights.
>
> (iii) The uses and disclosures of such information that should be authorized or required.

Id. If Congress did not enact legislation covering these matters within three years, HIPAA directed

HHS to "promulgate final regulations containing such standards." *Id.* And acknowledging that unforeseen developments might warrant revisions to HIPAA's privacy regulations, Congress further charged HHS to "review" and "adopt modifications" to those standards, as it "determined appropriate, but not more frequently than once every 12 months." *Id.* § 1320d-3(b)(1).

HIPAA includes an express preemption provision, mandating that any "provision or requirement under" the Act, or any "standard or implementation specification adopted" pursuant to the Act, "shall supersede any contrary" state law, with limited exceptions. *Id.* § 1320d-7(a)(1). Among those exceptions is that any regulation that HHS promulgates "shall not" supersede a contrary state law that imposes "more stringent" requirements. *Id.* §§ 1320d-2 note, 1320d-7(a)(2)(B). HIPAA also includes a "public health" exception, providing that "[n]othing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." *Id.* § 1320d-7(b).

In 1997, HHS submitted detailed recommendations consistent with HIPAA's directive. *See Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82462, 82470 (Dec. 28, 2000) ("Privacy Rule"). When Congress did not enact legislation within three years of those recommendations, HHS promulgated regulations in 2000 in the form of the Privacy Rule. *Id.* The Privacy Rule sets out detailed standards for the use and disclosure of "protected health information"—*i.e.*, "individually identifiable health information" that is "[t]ransmitted" or "maintained" in "electronic media" or "any other form or medium." 45 C.F.R. § 160.103. Under that rule, protected health information is generally protected from use or disclosure without an individual's written authorization. *Id.* § 164.502(a). However, an individual's protected health information can be used and disclosed for a number of purposes (*e.g.*, treatment, payment, health care operations) without the individual's written authorization. *Id.* §§ 164.502(a)(1)(ii), 164.506.

The Privacy Rule also permits the disclosure of protected health information without the individual's written authorization to government agencies in limited, clearly defined circumstances. *Id.* § 164.512. In particular, the Privacy Rule permits the disclosure of protected health information for "law enforcement purposes," including where it is required by a "court order," a "grand jury subpoena," or an "administrative request for which [a] response is required by law," so long as (i) the information sought "is relevant and material to a legitimate law enforcement inquiry," (ii) the request is "specific and limited in scope," and (iii) "[d]e-identified information could not reasonably be used." *Id.* § 164.512(f)(1). The Privacy Rule also permits the disclosure of protected health information where necessary for "public health activities," like "the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions," as well as to make reports of "child abuse or neglect," *id.* § 164.512(b); where necessary to make reports of "abuse, neglect, or domestic violence," if such reports are "required by law," *id.* § 164.512(c); for "health oversight activities," *id.* § 164.512(d); as required by judicial and administrative proceedings, *id.* § 164.512(e); and where necessary "to prevent or lessen a serious and imminent threat to the health or safety of a person or the public," *id.* § 164.512(j).

II. The Rule

In 2023, HHS proposed to amend the Privacy Rule. *See HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 88 Fed. Reg. 23506, 23506 (Apr. 17, 2023). The Department promulgated the Rule on April 26, 2024. *See* 89 Fed. Reg. at 32978, 32991. The Rule became effective on June 25, 2024, and regulated entities generally had until December 23, 2024, to comply with its requirements. *Id.* at 32976. However, the Rule allowed covered entities until February 16, 2026, to make required amendments to their Notices of Privacy Practices. *Id.* at 32976, 32979.

The Rule prohibits regulated entities from using or disclosing protected health information regarding an individual's reproductive health care for any of the following activities:

(i) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(ii) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(iii) To identify any person for any purpose described in [(i) or (ii)]."

45 C.F.R. § 164.502(a)(5)(iii)(A). The Rule contains a "[r]ule of applicability," clarifying that the Rule's prohibitions apply only where the "reproductive health care is lawful under the law of the state in which such health care is provided" or "is protected, required, or authorized by Federal law." *Id.* § 164.502(a)(5)(iii)(B). The Rule further instructs that "[t]he reproductive health care provided by another person is presumed lawful … unless the 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 protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.* § 164.502(a)(5)(iii)(C).

"To assist in effectuating this prohibition," 89 Fed. Reg. at 32990, the 2024 Rule contains a requirement that a covered entity "obtain[] an attestation" from the relevant state or federal agency before it may "use[] or disclose protected health information potentially related to reproductive health care" for the purposes of health oversight, judicial and administrative proceedings, law enforcement, and disclosures to coroners and medical examiners. 45 C.F.R. § 164.509(a). An attestation must contain, *inter alia*, "[a] description of the information requested" and "[a] clear statement that the use or disclosure is not for a purpose" prohibited by the Rule. *Id.* § 164.509(c)(1)(i), (iv). And an attestation is "[d]efective" if the covered entity "has actual knowledge that material information in the attestation is false" or "[a] reasonable covered entity … would not believe that the attestation" is for a permitted purpose. *Id.* § 164.509(b)(2)(iv), (v) (emphasis omitted).

The Rule also explicitly preserves the Privacy Rule's existing provisions permitting the disclosure of protected health information for public health activities, including the reporting of child abuse. HHS explained that, when HIPAA was enacted, "most, if not all, states had laws that mandated reporting of child abuse or neglect to the appropriate authorities," 65 Fed. Reg. at 82527, that Congress had already addressed such reporting in other laws, and that the term "child abuse," as used in these statutes, "does not include activities related to reproductive health care, such as abortion," 89 Fed. Reg. at 33004 (citation omitted). The Rule thus clarifies that a covered entity may not disclose protected health information "as part of a report of suspected child abuse based *solely* on the fact that a parent seeks reproductive health care (*e.g.*, treatment for a sexually transmitted infection) for a child." *Id.* (emphasis added). As to the Privacy Rule's provision concerning disclosures about adult abuse victims, the Rule similarly adds a rule of construction that "[n]othing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care." 45 C.F.R. § 164.512(c)(3). Finally, the Rule defines "[p]ublic health as used in the terms 'public health surveillance,' 'public health investigation,' and 'public health intervention'" to mean "population-level activities to prevent disease in and promote the health of populations," rather than efforts to "conduct … investigation[s]" or "impose … liability" on individuals. *Id.* § 160.103 (emphasis omitted).

III. This Lawsuit

On January 17, 2025, nearly seven months after the Rule went into effect, the States filed this APA suit, claiming that the Rule unlawfully interferes with their authority to investigate violations of state law and is otherwise arbitrary and capricious. *See* Compl. ¶¶ 135–46. Three weeks later, the States moved for summary judgment and preliminary relief on all their claims, requesting that the Court vacate the Rule in its entirety or, "[a]t a minimum," preliminarily enjoin Defendants from applying it to the States. *See* Mot. 23–25.

LEGAL STANDARDS

I. Rule 12(b)(1): Lack of subject-matter jurisdiction

A motion to dismiss under Rule 12(b)(1) may challenge the Court's subject-matter jurisdiction either "facially" or "factually." *L.C. v. United States*, 83 F.4th 534, 542 (6th Cir. 2023). A "facial' attack under Rule 12(b)(1) accepts the truth of the plaintiff's well-pleaded allegations but asserts that they are insufficient on their face to invoke federal jurisdiction. *Id.* A "factual" attack, by contrast, contests the "factual existence" of subject-matter jurisdiction, typically based on evidence outside the pleadings, and the court may review extrinsic evidence without converting the motion into one for summary judgment. *Id.* In all cases, the party invoking a federal court's limited jurisdiction bears the burden of establishing that it exists. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994).

II. Rule 65(a) and 5 U.S.C. § 705: Preliminary relief

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To justify this "drastic remedy," a plaintiff must make a "*clear showing*" that (1) it has a substantial likelihood of success on the merits; (2) it will suffer irreparable harm without the requested injunction; (3) the balance of equities tips in its favor; and (4) preliminary relief serves the public interest. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). This same four-part test governs the issuance of a § 705 stay. *District of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 15 (D.D.C. 2020). Failure to demonstrate any one of these elements requires denial of preliminary relief. *Malibu Boats, LLC v. Nautique Boat Co.*, 997 F. Supp. 2d 866, 873 (E.D. Tenn. 2014).

III. Rule 56: Summary judgment

In a case challenging agency action under the APA, summary judgment "serves as the mechanism for deciding" whether the action "is supported by the administrative record and otherwise consistent with the APA standard of review." *Vaught v. FDIC*, 2018 WL 5098531, at *6 (E.D. Tenn. Apr. 4, 2018) (citation omitted). The agency resolves "factual issues to arrive at a decision that should

be supported by the administrative record," and the district court determines whether, as a matter of law, "the evidence in the administrative record permitted the agency to make the decision it did." *CIC Servs., LLC v. IRS*, 592 F. Supp. 3d 677, 682–83 (E.D. Tenn. 2022) (cleaned up). The entire case is thus a question of law, with the district court sitting as an appellate tribunal. *Chamber of Com. of U.S. v. SEC*, 670 F. Supp. 3d 537, 550–51 (M.D. Tenn. 2023) (citation omitted). And the party challenging the agency action bears the burden of demonstrating an APA violation. *Lomak Petroleum, Inc. v. FERC*, 206 F.3d 1193, 1198 (D.C. Cir. 2000).

ARGUMENT

I. The States' theories of harm establish neither standing nor irreparable injury.

In challenging the Rule, the States invoke two general theories of harm. *First*, they claim that the Rule will impede their investigations by making it difficult to obtain necessary information. *See* Compl. ¶ 99; Mot. 11. And *second*, they claim that the Rule requires them to expend time and resources to comply with its requirements. *See* Compl. ¶¶ 99, 115; Mot. 12. The problem is, the States' complaint contains no *facts* to support either theory, but instead relies on speculation and threadbare assertions that do not suffice to plausibly allege Article III standing. The Court should therefore dismiss this case for lack of subject-matter jurisdiction. Should the Court disagree, the States' motion for relief fails in any event, as the States devote only a couple of its pages to the issue of standing and irreparable injury, nowhere in which they cite any actual *evidence* showing any ongoing or certainly impending harm from the Rule—a burden they bear to obtain the relief they seek.

A. The complaint fails to plausibly allege an injury in fact attributable to the Rule.

Article III limits federal courts' jurisdiction to resolving actual "Cases" and "Controversies," not any dispute that happens to arise between two parties. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). For there to be a case or controversy, a plaintiff must have standing to sue. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024). If standing is absent, a court cannot proceed at all to the

merits of the dispute. *Coal. of Clergy, Laws., & Professors v. Bush*, 310 F.3d 1153, 1164 (9th Cir. 2002) ("[W]here litigants lack standing," any further ruling on the merits "is, by very definition, for a court to act ultra vires." (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101–02 (1998))).

To establish standing, a plaintiff must (i) have suffered or be likely to suffer an injury in fact (ii) that is fairly traceable to the defendant's challenged conduct (iii) that a favorable ruling would redress. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). An injury in fact must be both "concrete and particularized," and "actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992); *accord All. for Hippocratic Med.*, 602 U.S. at 381 (an injury in fact must be "real and not abstract," "actual or imminent, not speculative," and "personal," not "generalized"). And where, as here, the relief sought is prospective, the injury must be ongoing or "certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). The "mere *possibility*" of future injury "does not suffice." *Ass'n of Am. Phys. & Surgeons v. FDA*, 13 F.4th 531, 545 (6th Cir. 2021) (emphasis added). More still, plaintiffs must demonstrate standing "for each claim that they press and for each form of relief that they seek." *TransUnion*, 594 U.S. at 431. That means that if "a plaintiff has been injured by one part of the law, the plaintiff cannot invoke that injury to challenge other parts of the law that have done nothing to" it. *Davis v. Colerain Township*, 51 F.4th 164, 171 (6th Cir. 2022).

At the pleading stage, a plaintiff must allege a "plausible claim" of standing, *Am. Phys. & Surgeons*, 13 F.4th at 543–44 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)), by pleading "specific, concrete facts" that establish each element, *Mackinac Ctr. for Pub. Policy v. Cardona*, 102 F.4th 343, 352 (6th Cir. 2024); *accord Spokeo*, 578 U.S. at 338 (requiring a plaintiff to "clearly allege facts demonstrating each element" of standing (cleaned up)). Vague or conclusory allegations of harm will not suffice. *Am. Phys. & Surgeons*, 13 F.4th at 545. Nor will speculation. *Mackinac Ctr.*, 102 F.4th at 357.

Measured by these principles, the States' allegations in the complaint fall well short of establishing Article III standing to challenge the Rule.

To begin, the States' principal theory of harm—*i.e.*, that the Rule will "hamper" their ability to obtain information as part of their investigations into violations of state law, *see* Compl. ¶¶ 2, 99—rests solely on conclusory, speculative, and vague allegations. Indeed, the bulk of the complaint's allegations on this score merely describe how the States use certain information in their investigations, the States' understanding of how the Rule's requirements work in the abstract, and how the States *suppose* those requirements might affect their investigations. *See id.* ¶¶ 92–105. What the complaint lacks, however, are any well-pleaded "specific, concrete facts" explaining how the Rule is *actually* impeding any investigations. *See Mackinac Ctr.*, 102 F.4th at 352; *see also Lewis v. ACB Bus. Servs., Inc.*, 135 F.3d 389, 405 (6th Cir. 1998) ("Only well-pleaded facts … must be taken as true."). In fact, the most specific the complaint ever gets is to allege that, in a handful of investigations, state authorities have failed to obtain certain information that they have requested, typically without an attestation. *See* Compl. ¶¶ 107–10. But the States' vague allegations regarding each of these instances leave too much to "guesswork," *see Am. Phys. & Surgeons*, 13 F.4th at 546, including, *e.g.*, whether the Rule required an attestation in a particular instance; whether there were other reasons a state authority was unable to obtain the requested information; whether the state authority was able to obtain the records without an attestation or by some other means; or whether the state authority provided an attestation after being asked to do so, and if not, why it declined.[1] Without these facts, the Court cannot meaningfully evaluate whether, taking the complaint's well-pleaded allegations as true, the Rule *itself* is actually hampering any State's ability to obtain information or is likely to do so. And if the Rule truly posed the risks that the States allege, one would expect the States to have pleaded facts sufficient to answer that basic question, given that the Rule has been in effect since June and compliance was anticipated

[1] The complaint alleges one instance where a healthcare provider refused to comply with a request for information from a state agency that provided an attestation. *See* Compl. ¶ 110. But the complaint does not explain why the provider refused to comply or what impact, if any, the Rule had on the state agency's ability to obtain the requested information or otherwise pursue its investigation.

beginning in December. *See supra* 4.[2]

The States' claim that the Rule requires them to expend resources to comply with its requirements rests on allegations even more threadbare. For example, the complaint includes a cursory allegation that "processing" an attestation "produces administrative costs," *see* Compl. ¶ 99, but never explains what those supposed costs are, much less how they materially change whatever costs the States already incur when making requests for information that comply with other HIPAA requirements and other applicable laws. *See, e.g.*, *Ohio v. Yellen*, 53 F.4th 983 (6th Cir. 2022) (rejecting conclusory assertions of compliance costs); *Interstate Nat. Gas Ass'n of Am. v. FERC*, 285 F.3d 18, 46 (D.C. Cir. 2002) (same); *Kentucky v. EPA*, 2023 WL 3326102, at *3 (E.D. Ky. May 9, 2023) (same). And given that the requesting authority should readily know what to include in an attestation—namely, what information the authority wants and why the authority wants it—it is hard to imagine what extra costs a state would actually incur. But given the absence of any specific, concrete facts on that score in the complaint, whether there would be any extra costs is mere "guesswork." *See Am. Phys. & Surgeons*, 13 F.4th at 546. Similarly, the complaint alleges that some state agencies that are covered entities are having to "overhaul" their "processing systems" for making and responding to requests for HIPAA-protected information. *See* Compl. ¶ 115. But the States never even explain, *e.g.*, which state agencies are overhauling their systems, what an "overhaul" entails, why one is necessary, or what "financial, logistical, and personnel burdens" these efforts impose. *See id.* Absent any specific, concrete facts that answer these questions, the States' conclusory allegations of harm cannot be credited. *See*

[2] The complaint contains scattered allusions to the States' "sovereign" and "quasi-sovereign" interests, *see, e.g.*, Compl. ¶¶ 1, 3–17, 91, but never clarifies what specific interests the States believe are at stake, other than to claim a "sovereign interest in pursuing investigations that promote health and welfare" and "root out waste, fraud, and abuse," *see id.* ¶ 91. But the complaint's assertion that the Rule "harms" that that interest, *see id.*, appears to be merely derivative of the States' speculative and conclusory claim that the Rule impedes their ability to obtain information, and therefore fails for the same reasons. *See supra* 10.

Mackinac Ctr., 102 F.4th at 352.

In sum, the complaint fails to include any well-pleaded facts that, when taken as true, plausibly allege an Article III injury in fact that is directly attributable to the Rule. The Court should therefore dismiss this case pursuant to Rule 12(b)(1) for lack of subject-matter jurisdiction.

B. The States submitted no evidence establishing Article III standing for purposes of summary judgment or preliminary relief.

Even if this Court were to find that the States have plausibly alleged Article III standing to challenge the Rule, they cannot rest upon those "mere allegations" in support of their motion for summary judgment or preliminary relief. *See Lujan*, 504 U.S. at 561. Rather, to support their motion, the States needed to put forth "specific facts" by "affidavit or other evidence" that demonstrate each element of standing. *Id.*; *accord, e.g.*, *Schickel v. Dilger*, 925 F.3d 858, 866–68 (6th Cir. 2019) (rejecting plaintiffs' claims on summary judgment because the declarations they submitted lacked sufficient facts to demonstrate each element of standing). But the record is devoid of any such evidence.

Indeed, most of the States either submitted no evidence whatsoever in support of their motion (*i.e.*, Arkansas, Georgia, Montana, South Dakota, West Virginia) or failed to identify with any particularity a single investigation that the Rule allegedly implicates (*i.e.*, Alabama, Idaho, Nebraska, North Dakota, Ohio), relying instead on declarations that contain only vague, conclusory, and speculative assertions of harm. *See, e.g.*, *Davis*, 51 F.4th at 171–72 (rejecting "conclusory testimony" regarding plaintiff's standing at summary judgment); *Lujan*, 504 U.S. at 564 (similar). What the other States allege simply belies their assertion that their inability to obtain information in particular investigations is directly attributable to the Rule. According to these States, some recipients of information requests (or in one case, a court-appointed receiver) have asked that the state authority

provide an attestation before making the requested disclosure.[3] And in each case, the state authority declined based on supposed fears that signing the attestation could result in potential criminal liability. *See, e.g.*, Decl. of Kelley Groover ¶ 8, ECF No. 26-1; Decl. of Katherine Zeigler ¶¶ 11–12, ECF No. 26-2; Decl. of Larry Johnson, Jr. ¶ 11, ECF No. 26-5; Decl. of Michael Targia ¶ 18, ECF No. 26-8. But nowhere do these States explain why signing any of the requested attestations could possibly result in criminal liability, especially when they insist that the information was requested to assist with legitimate law enforcement matters (*e.g.*, fraud, consumer protection, public health oversight) and not for any prohibited purpose. *See, e.g.*, 89 Fed. Reg. at 33012 ("For example, the prohibition does not restrict a regulated entity from using or disclosing [protected health information] to a health oversight agency conducting health oversight activities, such as investigating whether reproductive health care was actually provided or appropriately billed in connection with a claim for such services, or investigating substandard medical care or patient abuse."). At any rate, these States "cannot manufacture standing merely by inflicting harm on themselves"—that is, by declining to provide an attestation—based merely "on their fears of hypothetical future harm." *See Clapper*, 568 U.S. at 416. Therefore, insofar as these States have failed to obtain information as part of any investigation, that is a self-inflicted injury that, "by definition, is not traceable to anyone but [themselves]." *Bucholz v. Meyer Njus Tanick, PA*, 946 F.3d 855, 866–67 (6th Cir. 2020); *accord Geomatrix, LLC v. NSF Int'l*, 82 F.4th 466, 476 (6th Cir. 2023); *Garland v. Orlans, PC*, 999 F.3d 432, 440–41 (6th Cir. 2021).[4]

[3] Although the State of Indiana attests that certain health care providers have declined to respond to subpoenas, leading it to file motions to enforce, it does not assert that it supplied an attestation in these cases. *See* Decl. of Amy Osborne ¶ 10, ECF No. 26-15. And while the State claims that in other cases health care providers have cited the Rule in declining to provide requested information in the absence of a "patient release," it acknowledges that "[n]either federal nor state law" imposes such a requirement, *id.* ¶ 11, so those refusals are not attributable to the Rule.

[4] While the States' motion, like their complaint, is adorned with vague invocations of "sovereign" and "quasi-sovereign" interests, it still never explains how the Rule implicates any of those asserted interests, other than to claim that the Rule impedes their ability to obtain information. *See* Mot. 12. But as explained, *see supra* 12–13, the States have submitted no evidence to support that claim.

The States' claim that the Rule has required state agencies to "assess[] their systems" for potential compliance issues, *see* Mot. 12, is similarly unsubstantiated. As the Sixth Circuit explained in *Ohio*, merely invoking "compliance costs" does not get the States through the courthouse doors. *See* 53 F.4th at 993–94 (rejecting conclusory and unsubstantiated compliance-cost theory of standing). Like in *Ohio*, the States here claim to have expended resources to comply with the Rule's requirements, *see* Mot. 12, but offer "no insight about" these "alleged resources," including the circumstances under which they were allegedly expended and whether any expenditures were necessary and directly attributable to the Rule, *see Ohio*, 53 F.4th at 994; *see also supra* 11. Without this information, there is no way for the Court to determine whether the Rule itself is actually requiring the States to incur any extra costs. *See Ohio*, 53 F.4th at 994 ("[While the state] had the burden to establish whatever such costs have ensued with *evidence*," it "put forth no specific facts by affidavit or other evidence about what, if any, particular resources it has reallocated to ensure compliance with the [challenged rule]." (cleaned up)). And that the Rule assumed that covered entities would generally need to develop new or modified policies or procedures following the Rule says nothing about whether *the States* will, in fact, suffer a "*particularized*" injury. *See All. for Hippocratic Med.*, 602 U.S. at 381 (emphasis added).

All told, the States' motion for summary judgment or preliminary relief is unsupported by any actual evidence upon which the Court could base a finding that the States have Article III standing to challenge the Rule. The motion can be denied on that ground alone.

C. The States' claim of irreparable injury is unsubstantiated by any evidence.

For much the same reasons, the States have not shown that the Rule will cause them imminent, irreparable injury during the pendency of this lawsuit—an "'indispensable' requirement for a preliminary injunction." *See Memphis A. Philip Randolph Inst. v. Hargett*, 978 F.3d 378, 391 (6th Cir. 2020) (citation omitted). To make that requisite showing, the States needed to provide evidence, *Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 154 (6th Cir. 1991), showing that they would

suffer an irreparable injury that is "both certain and immediate, not speculative or theoretical," *D.T. v. Sumner Cnty. Schs.*, 942 F.3d 324, 327 (6th Cir. 2019) (cleaned up), and that would "directly result" from the Rule, *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). But like with standing, the States rely on two theories of harm—*i.e.*, that the Rule is impeding state investigations and imposing compliance costs, *see* Mot. 24—neither of which have they substantiated with competent evidence, *see supra* 12–14. And their seven-month delay in seeking preliminary relief casts serious doubt on the notion that the States are suffering any harm that is truly irreparable. *See, e.g.*, *Cheetah Miner USA, Inc. v. 19200 Glendale, LLC*, 2023 WL 6601863, at *3 (6th Cir. Oct. 10, 2023) (finding a 60-day delay "undercut[] the sense of urgency that ordinarily accompanies a motion for preliminary relief and suggests that there is, in fact, no irreparable injury"). The States' failure to show an irreparable injury alone defeats their request for preliminary relief. *See Memphis A. Philip Randolph Inst.*, 978 F.3d at 391.

II. In all events, this Court should narrowly tailor any relief to redress only the States' actual injuries.

Even if this Court had jurisdiction and the States were successful on one or more of their claims, the sweeping remedies they request are unjustified and contrary to the constitutional and equitable constraints on this Court's remedial authority.

A. Universal vacatur of the Rule would be improper.

The States begin by asking the Court to vacate the Rule in its entirety, rather than limit any relief to the parties before the Court or the provisions the States have demonstrated to be unlawful. *See* Mot. 23. The Court should decline that invitation for several reasons.

First, the States are mistaken that universal vacatur is *required* to remedy an APA violation. *See id.* Although Sixth Circuit precedent recognizes vacatur as an available remedy for a successful APA

challenge,[5] it is an equitable one that is neither automatic nor compelled upon finding an APA violation. *See, e.g.*, *Sierra Club v. EPA*, 60 F.4th 1008, 1022 (6th Cir. 2023); *Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023); *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d 501, 521–27 (W.D. Ky. 2024) (Beaton, J.) ("[Vacatur is] not automatic."); *see also* 5 U.S.C. § 702 (clarifying that "nothing" in the APA affects "the power or duty" of a court to "deny relief on" any "equitable ground"). Indeed, rather than reflexively vacate rules that they determined violated the APA—as one would expect if vacatur were the mandatory remedy for an APA violation—multiple courts within this Circuit have found that more limited remedies than vacatur (*e.g.*, injunctive or declaratory) were proper. *See, e.g.*, *Kentucky*, 728 F. Supp. 3d at 521–27; *GBX Assocs., LLC v. United States*, 2022 WL 16923886, at *15–18 (N.D. Ohio Nov. 14, 2022); *Ohio Env't Council v. U.S. Forest Serv.*, 2023 WL 6370383, at *2–5 (S.D. Ohio Aug. 3, 2023). So contrary to the States' argument, it is entirely appropriate for a court not to vacate agency action at all where more limited remedies would fully redress a plaintiff's asserted injuries.

Second, where (as here) party-specific remedies are capable of providing plaintiffs with complete relief, any broader relief would contradict constitutional and equitable limitations on this Court's remedial authority. Because this Court's "constitutionally prescribed role is to vindicate the individual rights of the people appearing before it," any "remedy must be tailored to redress" each State's "particular injury." *Gill v. Whitford*, 585 U.S. 48, 72–73 (2018); *accord Texas*, 599 U.S. at 702 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) ("*Any remedy* … must not be more burdensome to the defendant than necessary to redress the complaining parties." (cleaned up with emphasis added)). Traditional principles of equity reinforce that constitutional limitation,

[5] Still, the APA does not mention vacatur. And there is little indication that Congress intended to create a new and radically different remedy in the form of universal vacatur by directing courts to "set aside" agency "action, findings, and conclusions," 5 U.S.C. § 706(2), as the States' argument suggests. *See United States v. Texas*, 599 U.S. 670, 693–703 (2023) (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment).

Grupo Mexicano de Desarrollo, S.A. v. All. Bond Fund, Inc., 527 U.S. 308, 318–19 (1999), instructing that a remedy "be no more burdensome" to defendants "than necessary to provide complete relief" to plaintiffs, *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted); *accord Trump v. Hawaii*, 585 U.S. 667, 717 (2018) (Thomas, J., concurring) (explaining that English and early American "courts of equity" typically "did not provide relief beyond the parties to the case"). The States' request for universal vacatur disregards these well-established principles, however, as they attempt no showing that such sweeping relief is necessary to fully redress their asserted injuries. They have thus fallen well short of establishing an entitlement to universal vacatur.

Third, universal vacatur of the Rule would trench on the review of other plaintiffs' challenges that are pending in other courts. *See Texas v. HHS*, 5:24-cv-204 (N.D. Tex.); *Purl v. HHS*, No. 2:24-cv-228 (N.D. Tex.); *Missouri v. HHS*, No. 4:25-cv-77 (E.D. Mo.). Granting such a remedy in this case would thus not only contravene traditional limitations on this Court's remedial authority, but would also undermine basic principles of comity by providing other plaintiffs not before this Court with the very relief they are seeking from sister courts, regardless of whether those courts believe those plaintiffs are entitled to any relief. *See Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021) ("[Where] [o]ther courts are considering [the] same issues" at the same time, "[p]rinciples of judicial restraint control" and counsel against universal remedies.); *accord Texas*, 599 U.S. at 702–03 (Gorsuch, J., concurring in the judgment) (recounting the well-known systemic issues created by universal remedies that courts should, at the very least, "carefully consider" "before granting such sweeping relief," including that "vacatur can stymie the orderly [judicial] review of important questions." (cleaned up)); *cf. Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring) ("[Universal remedies] short-circuit the decisionmaking benefits of having different courts weigh in on vexing questions of law and allowing the best ideas to percolate to the top."); *accord Georgia v. President of the U.S.*, 46 F.4th 1283, 1305 (11th Cir. 2022); *see also, e.g.*, *GBX Assocs.*, 2022 WL 16923886, at *17 ("Ordering universal

relief in the instant action … would inhibit the ability of other federal courts to address the validity of [the challenged action] …. The Court declines to take this path" to "promote[] respect for our fellow federal courts and the healthy development of the law."); *Kentucky*, 728 F. Supp. 3d at 526 (lamenting how the 21 plaintiff states were provided the very relief they originally sought because an out-of-circuit district court decided to universally vacate the challenged rule in a separate action).

Fourth, the State's argument ignores that some APA violations should be corrected by an equitable remedy that the Sixth Circuit describes as "remand without vacatur." *See, e.g.*, *Sierra Club*, 60 F.4th at 1022–23; *Kentucky*, 728 F. Supp. 3d at 522 ("[T]he Sixth Circuit also recognizes that remand without vacatur may be an appropriate remedy in some cases."). Such relief is generally appropriate where there is a possibility that the agency "will be able to justify its decision on remand" and where vacatur would be "disruptive." *See Sierra Club*, 60 F.4th at 1022 (cleaned up). For example, if this Court were to find that HHS did not consider an issue or adequately explain its actions, that would at most justify an instruction to the agency to cure the asserted failure without granting additional relief. *See id.* (explaining that remand without vacatur is generally appropriate where an agency could cure on remand "an incomplete record" or "a defect in its explanation of a decision" (citations omitted)); *see also, e.g.*, *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 383, 389–90 (5th Cir. 2021) (remanding without vacatur to allow consideration of an issue that the agency failed to address); *Ohio Env't Council*, 2023 WL 6370383, at *3, *5 (remanding without vacatur to allow the agency to cure its deficient analysis). That approach, moreover, would avoid unnecessarily disrupting covered entities that may wish to continue operating under the Rule or that may have modified their policies or practices to comply with the Rule and would have to unwind those changes if the Rule were vacated. *See, e.g.*, *Cent. & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (declining to vacate a rule because "it would be disruptive" to "the regulated community"); *cf. Kentucky*, 728 F. Supp. 3d at 525 ("Vacating the rule" would "sweep up nonparties who may not wish to receive the benefit of the

court's decision." (quoting *Arizona*, 40 F.4th at 396 (Sutton, C.J., concurring))).

Finally, the States' invitation for this Court to universally vacate the Rule *entirely*, *see* Mot. 23, disregards the availability of other less burdensome remedies. As an initial matter, the fact that the States' alleged injuries center on a particular context—*i.e.*, where the Rule applies to state investigations into violations of state law—suggests that injunctive relief, as opposed to vacatur, would be a more appropriate remedy in this case, given that such relief could be tailored to prevent the Rule's application only in the context that gives rise to the States' asserted injuries. *See Kentucky*, 728 F. Supp. 3d at 523 (explaining that an injunction can be "fashion[ed] … to particular parties and applications").

But even if this Court were to find vacatur appropriate, vacating the Rule in its entirety would ignore well-established severability principles. Where a provision of a rule is found to be unlawful, the remainder may stay in effect "unless there is a substantial doubt that the agency would have left the balance of the rule intact." *Finnbin, LLC v. Consumer Prod. Safety Comm'n*, 45 F.4th 127, 136 (D.C. Cir. 2022) (cleaned up); *see also* 5 U.S.C. § 551(13) (defining "agency action" to include "the whole *or a part* of an agency rule" (emphasis added)). Here, while the States do not acknowledge it, the Rule contains a severability clause communicating HHS's intent that any provisions held to be facially invalid or unenforceable "shall be severable … and shall not affect the remainder" of the Rule. *See* 45 C.F.R. § 164.535; *see also* 89 Fed. Reg. at 33048. This express severability clause "leaves no doubt" about whether HHS wanted the unchallenged provisions of the Rule to continue operating if the challenged portions were vacated. *See Barr v. Am. Ass'n of Political Consultants, Inc.*, 591 U.S. 610, 624 (2020); *cf. id.* ("[A]bsent extraordinary circumstances, the Court should adhere to the text of [a] severability … clause"). If more were needed, the States also fail to explain why the entire Rule must fall if any of their claims were successful. For example, the States identify a handful of provisions that they contend impose unlawful limits on various types of reporting, *see* Mot. 14–16, but they make no showing that the Rule's other provisions could not "function sensibly" were this Court to vacate (or enjoin) the

provisions the States challenge, *see Carlson v. Postal Regul. Comm'n*, 938 F.3d 337, 351 (D.C. Cir. 2019) (citation omitted); *cf. Lewis v. Casey*, 518 U.S. 343, 357 (1996) ("The remedy must … be limited to the inadequacy that produced the injury in fact that the plaintiff has established."); *Union Home Mortg. Corp. v. Cromer*, 31 F.4th 356, 364 (6th Cir. 2022) ("[A]n equitable remedy] is overly broad when there is a risk that it restrains legal conduct").

* * *

In sum, the States have offered no persuasive reason why this Court should universally vacate the Rule in its entirety. The Court should therefore, at a minimum, decline to enter universal vacatur.

B. The States' proposed preliminary injunction is overbroad.

In addition to universal vacatur, the States request a preliminary injunction preventing Defendants from enforcing the Rule against any of the "States, their HIPAA-covered entities, and their investigative agencies." *See* Mot. 23. But they have failed to justify such unnecessarily broad relief.

First of all, the States request that any preliminary relief apply to five states—Arkansas, Georgia, Montana, South Dakota, and West Virginia—that submitted no evidence in support of their motion. *See supra* 12. These states have thus left the record empty of any evidence whatsoever upon which the Court could find that they are entitled to preliminary relief. *See, e.g.*, *Texas v. United States*, 126 F.4th 392, 421 (5th Cir. 2025) (narrowing injunction to apply only to the state plaintiff that demonstrated an actual injury). Moreover, preliminarily enjoining enforcement of the entire Rule would be an ill-fitting remedy for the particular claims that the States assert. The propriety and form of an equitable remedy are determined by "the nature of the violation" established. *Swann v. Charlotte-Mecklenburg Bd. of Ed.*, 402 U.S. 1, 16 (1971); *accord Lewis*, 518 U.S. at 357 ("The remedy must … be limited to the inadequacy that produced the injury in fact that the plaintiff has established."). Although the States' claims focus on how the Rule's disclosure requirements allegedly constrain state investigations into violations of state law, they request an injunction that would prevent the Rule's

enforcement in completely unrelated contexts. In other words, the States' proposed injunction would preclude applications of the Rule that they do not allege are unlawful, contrary to well-established equitable principles. *See, e.g.*, *John Doe #1 v. Veneman*, 380 F.3d 807, 819 (5th Cir. 2004) ("[A]n injunction is necessarily overbroad" where "it exceeds the extent of the violation established.").

CONCLUSION

For these reasons, the Court should dismiss this case for lack of Article III standing or, alternatively, deny the States' motion for summary judgment and preliminary relief. But should the Court instead proceed to the merits and find that the States are entitled to relief, it should limit any remedy so as to redress only the States' actual injuries.

Dated: March 13, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

On March 13, 2025, I electronically submitted the foregoing document with the Clerk of Court for the U.S. District Court, Eastern District of Tennessee, using the Court's electronic case filing system. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Jody D. Lowenstein
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