**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF MISSOURI**
**EASTERN DIVISION**

STATE OF MISSOURI,

*Plaintiff*,

v.

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

*Defendants*.

Case No. 4:25-cv-77-JAR

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

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## INTRODUCTION

The State of Missouri filed this lawsuit to challenge a Department of Health and Human Services ("HHS") rule that imposes additional restrictions on certain uses and disclosures of health information that is protected under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). *See HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) ("Rule"). Missouri's complaint vaguely alleges that the Rule impedes state investigations and requires the state to expend resources to comply with the Rule's requirements. *See* Compl. ¶¶ 75–89, ECF No. 1. But absent from the complaint are any concrete facts supporting these conclusory assertions of harm, which one would expect to see if the Rule truly posed the risks that the state alleges. Without such facts, Missouri has not plausibly alleged Article III standing to challenge the Rule. This Court thus lacks jurisdiction and should dismiss this case.

## 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). HIPAA'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, provided that certain conditions are met. *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); in the course of 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 Rule contains a requirement that a covered entity or business associate "obtain[] an attestation" from a person who

requests protected health information potentially related to reproductive health care before the covered entity or business associate may use or disclose that information for the purposes of health oversight, judicial and administrative proceedings, law enforcement, or 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, Missouri filed this Administrative Procedure Act ("APA") suit, claiming that the Rule unlawfully interferes with the state's authority to investigate violations of state law and is otherwise arbitrary and capricious. *See* Compl. ¶¶ 90–115. The state requests that the Court vacate the Rule in its entirety and permanently enjoin its enforcement. *See id.* p. 24 (Prayer for Relief).

## LEGAL STANDARDS

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) may challenge the Court's subject-matter jurisdiction either "facially" or "factually." *Carlsen v. GameStop, Inc.*, 833 F.3d 903, 908 (8th Cir. 2016). 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. *Moss v. United States*, 895 F.3d 1091, 1097 (8th Cir. 2018). 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).

## ARGUMENT

In its complaint, Missouri invokes two general theories of harm. *First*, it claims that the Rule will impede the state's investigations by making it difficult to obtain necessary information. *See* Compl. ¶¶ 81–86. And *second*, the state claims that it must expend time and resources to comply with the Rule's requirements. *See id.* ¶¶ 81, 89. The problem is, Missouri's 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.

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 and (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. *In re SuperValu, Inc.*, 870 F.3d 763, 771 (8th Cir. 2017) (emphasis added). More still, plaintiffs must demonstrate standing "for each claim that they press" and "for each form of relief they seek." *Murthy v. Missouri*, 603 U.S. 43, 44 (2024) (citation omitted). 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 "plausibly allege" standing, *Missouri v. Biden*, 52 F.4th 362, 371 (8th Cir. 2022), by pleading "specific, concrete facts" that establish each element, *Warth v. Seldin*, 422 U.S. 490, 508 (1975); *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. *Ark. Right to Life State Political Action Comm. v. Butler*, 146 F.3d 558, 560 (8th Cir. 1998); *accord Hekel v. Hunter Warfield, Inc*, 118 F.4th 938, 943 (8th Cir. 2024). Nor will speculation. *Auer v. Trans Union, LLC*, 902 F.3d 873, 878–79 (8th Cir. 2018)

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

*State investigations.* To begin, Missouri's principal theory of harm—*i.e.*, that the Rule "impedes" the state's ability to obtain information as part of its investigations into violations of state law, *see* Compl. ¶ 81—rests solely on vague allegations that are "devoid of further factual enhancement," *see Hekel*, 118 F.4th at 943 (citation omitted). Indeed, the bulk of the complaint's allegations on this score merely describe how Missouri uses certain information in its investigations, its understanding of how the Rule's requirements work in the abstract, and how it *supposes* those requirements might affect its investigations. *See* Compl. ¶¶ 75–86. What the complaint lacks, however, are any well-pleaded, "specific, concrete facts" explaining how the Rule is *actually* impeding any investigations. *See Warth*, 422 U.S. at 508; *see also Guenther v. Griffin Const. Co.*, 846 F.3d 979, 981 (8th Cir. 2017) (requiring only "well-pleaded factual allegations" to be taken as true).

In fact, the most specific the complaint ever gets is to allege that healthcare providers have started requesting attestations from certain state agencies "regardless of the type of records sought," "significantly affect[ing]" those agencies' ability to conduct their operations. *See* Compl. ¶ 82. But these sorts of generalized, conclusory allegations leave too much to "guesswork," *see Murthy*, 603 U.S. at 57, including, *e.g.*, what records these agencies have requested and for what purposes; whether the Rule actually required an attestation in any particular instance; whether these agencies have been able to obtain requested records without an attestation or by some other means; whether these agencies have been unable to obtain requested records, and if so, for what reasons; or whether these agencies have

provided an attestation after being asked to do so, and if not, why they 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 of the state's investigations or is likely to do so. *See Hekel*, 118 F.4th at 943 ("[T]he complaint tells us nothing about *how* the defendant's actions … harmed [the plaintiff]" and thus "fall[s] short of plausibly establishing injury." (citation omitted)). And if the Rule truly posed the risks Missouri alleges, one would expect the state to have pleaded facts sufficient to answer that basic question, given that the Rule has been in effect since June and compliance was required beginning in December. *See supra* 4.[2]

*Compliance costs.* Missouri's claim that it must expend resources to comply with the Rule's requirements rests on allegations even more threadbare. For example, the complaint includes a cursory allegation that "processing" an attestation "produces administrative costs," *see* Compl. ¶ 81, but never explains what those supposed costs are, much less how they materially change whatever costs state agencies already incur when making requests for information that comply with other HIPAA requirements and other applicable laws. This conclusory allegation of economic harm is thus valueless,

[1] The complaint also alleges that, in one investigation, a covered entity cited the Rule "as a full bar" to disclosing information in response to a request from a state official. *See* Compl. ¶ 83. But the complaint says nothing about why the covered entity believed that the Rule prohibited the disclosure or whether the Rule actually prohibited it—which is doubtful given that the state official was allegedly investigating "fraud, deception, and unfair practices," *id.*, none of which are prohibited purposes under the Rule, *see supra* 4; *see also, 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.").

[2] The complaint is adorned with scattered allusions to Missouri's "sovereign" and "quasi-sovereign" interests, *see, e.g.*, Compl. ¶¶ 1–2, 75, 106, but never clarifies what specific interests the state believes 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.* ¶ 75. But the complaint's assertion that the Rule "harms" that interest, *see id.*, appears to be merely derivative of Missouri's speculative and conclusory claim that the Rule impedes its ability to obtain information, and therefore fails for the same reasons. *See supra* 8–9.

as it is unaccompanied by any allegations of "*specific* … expenses" that the Rule "cause[d]" Missouri "to incur." *See Hekel*, 118 F.4th at 943–44; *see also, 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). 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 the 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 Murthy*, 603 U.S. at 57; *accord Hekel*, 118 F.4th at 943–44.

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. ¶ 89. But the complaint never explains, *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 facts that answer these questions, Missouri's "boilerplate, breezy" allegations of harm "fall well short of establishing … standing." *Hekel*, 118 F.4th at 943–44. Indeed, these allegations warrant some skepticism, as they appear to have been lifted almost verbatim from a complaint that other states filed in a separate challenge to the Rule, *see Tennessee v. HHS*, No. 3:25-cv-25 (E.D. Tenn.), even retaining a reference to "the Plaintiff States."[3]

[3] *Compare* Compl. ¶ 89 ("HHS's Final Rule is currently necessitating a system-wide overhaul of state agencies' processing systems for HIPAA requests. The financial, logistical, and personnel burdens required to come into compliance with the Rule's currently effective disclosure requirements for 'reproductive health care' data are substantial. Yet on account of HHS's sovereign immunity, the Plaintiff States could not later recover these costs even should they prevail in litigation."), *with* Compl. ¶ 115, *Tennessee v. HHS*, No. 3:25-cv-25 (E.D. Tenn.), ECF No. 1 ("HHS's Final Rule is currently necessitating a systemwide overhaul of state agencies' processing systems for requests for HIPAA-covered information. That compliance has in turn imposed financial, logistical, and personnel burdens on state agencies to ensure effective disclosure requirements. Yet on account of HHS's sovereign

* * *

In sum, Missouri has failed to plead in its complaint any specific facts that, when taken as true, plausibly allege an Article III injury in fact that is directly attributable to the Rule. This Court thus lacks subject-matter jurisdiction.

## CONCLUSION

For the foregoing reasons, the Court should dismiss this case pursuant to Rule 12(b)(1).

Dated: March 31, 2025

Respectfully submitted,

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immunity, the Plaintiff States could not later recover these costs even should they prevail in litigation.").

**CERTIFICATE OF SERVICE**

On March 31, 2025, I electronically submitted the foregoing document with the Clerk of Court for the U.S. District Court, Eastern District of Missouri, 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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