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

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

As Defendants' motion to dismiss explains, this case is precisely the type that Article III is intended to "screen[] out." *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024). Although the State of Missouri undoubtedly opposes the rule it seeks to challenge, *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) ("Rule"), there is no indication in the complaint that the Rule *itself* is injuring the state in any cognizable way—a fundamental condition of Article III standing. Missouri's counterarguments cannot cure this failure. Contrary to what it contends, the state cannot establish standing based purely on the fact that the Rule regulates it. Nor can it do so based on speculative fears about preemption. And though Missouri insists that the Rule's requirements thwart the state's investigations and impose compliance costs, the state points to no specific, concrete *facts* in the complaint that support those allegations. The absence of any well-pleaded facts showing a cognizable injury attributable to the Rule is dispositive: This Court lacks jurisdiction and should dismiss this case accordingly.

ARGUMENT

In its opposition brief, *see* Missouri's Mem. in Opp. to Defs.' MTD ("Opp."), ECF No. 32, Missouri insists it has done enough to plausibly allege Article III standing to challenge the Rule. But its arguments on this score miss the mark. Although Defendants' prior briefing already rebuts most of these arguments, *see* Mem. in Supp. of Defs.' MTD ("Mot.") at 8–10, ECF No. 31, a few points warrant a response.

First, Missouri appears to suggest that it need not show an actual injury attributable to the Rule to establish Article III standing, because it is enough that the state is subject to the Rule's requirements. *See, e.g.*, Opp. at 7 ("[T]he rule regulates Missouri and its agencies. That is sufficient to reject Defendants' motion."). But the state's own cases contradict this claim. A line of authority that the state invokes—originating with *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992)—explains that

standing is typically easier to establish where a regulation requires the plaintiff, rather than someone else, to act. *See, e.g.*, *All. for Hippocratic Med.*, 602 U.S. at 382. But a plaintiff that is regulated by a challenged action, like any other, must still establish a cognizable injury resulting from that action and redressable by a favorable judgment. *Lujan*, 504 U.S. at 561–62. These cases thus do not support the proposition that a regulated plaintiff has standing *ipso facto*. And while Missouri suggests that *Tennessee v. EEOC*, 129 F.4th 452 (8th Cir. 2025), and *Iowa League of Cities v. EPA*, 711 F.3d 844 (8th Cir. 2013), support its theory, those cases cannot be read for the proposition that mere regulation confers standing upon a plaintiff absent an attendant "*burden*" that cognizably injures the plaintiff, *see Tennessee*, 129 F.4th at 458 (emphasis added), without contradicting binding Supreme Court precedent like *Lujan*, which acknowledges that a plaintiff that is "an object of" a challenged action still must show that the "action … caused" it a cognizable "injury," 504 U.S. at 561–62. Indeed, it "would fly in the face of Article III's injury-in-fact requirement" to hold, as Missouri seems to contend, that a plaintiff has standing to challenge a "regulation in the abstract," "apart from any concrete application that threatens imminent harm" to its interests. *Summers v. Earth Island Inst.*, 555 U.S. 488, 494 (2009); *see also, e.g.*, *Littman v. U.S. Dep't of Labor*, 2025 WL 763583, at *5 (M.D. Tenn. Mar. 11, 2025) ("While 'objects' of a regulation ordinarily will have an easier time satisfying the three standing requirements, that does not mean 'objects' are absolved from establishing [those requirements] altogether." (quoting *Lujan*, 504 U.S. at 560)); *Lower E. Side People's Fed. Credit Union v. Trump*, 289 F. Supp. 3d 568, 579 (S.D.N.Y. 2018) ("[T]he mere fact that Plaintiff is regulated by the CFPB does not confer standing to bring this suit. Plaintiff must instead allege a concrete and particularized injury caused by CFPB actions….").[1]

[1] *West Virginia v. EPA*, 597 U.S. 697 (2022), is not to the contrary. There, the Supreme Court explained that the Clean Power Plan ("CPP"), if it came back into legal effect as a result of a lower court's decision, would "injure" the state plaintiffs that were "'the object of' its requirement that they more stringently regulate power plan emissions within their borders." *Id.* at 718–19 (quoting *Lujan*, 504 U.S. at 561–62). The fact that the Court did not expound on what those precise injuries were is unsurprising given that the government *conceded* that the state plaintiffs would have standing under

Insofar as Missouri contends that simply disclosing protected health information as the Rule prescribes injures the state in an Article III sense, *see* Opp. at 8, that new theory of harm is nowhere featured in the state's complaint. While the complaint describes the Rule's requirements (as the state sees them), the harms the state alleges are merely twofold: that the Rule "impedes" its ability to obtain information through state-run investigations and requires administrative costs to comply. *See* Compl. ¶¶ 74–89, ECF No. 1. Missouri never explains how state-run covered entities, *see* Opp. at 8, are meaningfully burdened by having to disclose certain information consistent with the Rule. The state cannot shoehorn new allegations of harm into its complaint through briefing on Defendants' motion to dismiss. *See, e.g.*, *Calderwood v. United States*, 623 F. Supp. 3d 1260, 1278–79 (N.D. Ala. 2022) (finding that "new injuries" raised "only in briefing" and "found nowhere in the[] complaint" "cannot support standing"); *see also Null v. Entrepreneur Startup Bus. Dev.*, 2024 WL 551607, at *4 (E.D. Mo. Feb. 9, 2024) ("[A] plaintiff may not amend its pleadings through a memorandum ….").

Second, Missouri's half-baked preemption theory fares no better. The state suggests that Missouri Revised Statute § 191.910—which generally requires, as part of any investigation or hearing regarding health care fraud or abuse, that a health care provider "ma[k]e available … to the attorney general or the court" records in the provider's possession or control—"faces preemption risk" because of the Rule. *See* Opp. at 9. But preemption is not implicated in the abstract. The Supremacy Clause "provides 'a rule of decision' for determining whether federal or state law applies *in a particular situation*.'" *Kansas v. Garcia*, 589 U.S. 191, 202 (2020) (citation omitted with emphasis added). Yet Missouri cites no specific instance where applying § 191.910 has, or would have, actually conflicted with the Rule. The state's preemption concerns are therefore entirely speculative and cannot create a

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those circumstances, *see* Br. for Fed. Resp'ts at 21–22, *West Virgina v. EPA*, Nos. 20-1530, 20-1531, 20-1778, 20-1780 (U.S. Jan. 18, 2022) ("Petitioners had a concrete stake … when vacatur of the CPP Repeal Rule might have caused the CPP to take effect."), and that the principal justiciability issue before the Court was one of mootness, not standing, *West Virginia*, 597 U.S. at 719–20.

basis for standing. *See Auer v. Trans Union, LLC*, 902 F.3d 873, 878–79 (8th Cir. 2018).

Third, as Defendants explained, *see* Mot. at 8–9, Missouri failed to allege sufficient facts that would allow this Court to meaningfully assess whether the Rule *itself* is actually impeding the state's ability to investigate violations of state law. The state's response fails to seriously grapple with this pleading defect. Instead, Missouri suggests that the Court should simply "presume" from the complaint's vague, conclusory allegations that each standing element has been satisfied. *See* Opp. at 9. But that would ignore the state's burden to plead "specific, concrete *facts*" that plausibly allege each element. *See Warth v. Seldin*, 422 U.S. 490, 508 (1975) (emphasis added); *accord, e.g.*, *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (requiring a plaintiff to "clearly allege facts demonstrating each element" of standing); *Hekel v. Hutner Warfield, Inc.*, 118 F.4th 938, 943 (8th Cir. 2024) (requiring "supporting facts" that "plausibly establish[]" standing). And Missouri's repeated assertion that "general factual allegations … may suffice" at the pleading stage, *see* Opp. at 10 (citation omitted), offers no succor. As explained, *see* Mot. at 8–9, the complaint is devoid of the necessary factual allegations, whether general or specific, that would provide a basis for this Court to conclude, taking the well-pleaded facts as true, that any state investigation has actually been thwarted (*i.e.*, injury), much less that the Rule itself was the cause (*i.e.*, traceability).[2] *See, e.g.*, *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" standing. (citation omitted)). Missouri cannot shrug off these factual gaps as "inconsequential queries," *see* Opp. at 9, or escape basic pleading requirements by dressing up its harms with vague references to state sovereignty, *see id.* at 9–10.[3]

[2] Because Defendants' motion highlights several ways in which Missouri failed to alleged facts showing a causal connection between the Rule and any alleged injury, *see* Mot. at 8–10, the state's suggestion that Defendants have "argue[d] only that Missouri has not pleaded an 'injury in fact,'" *see* Opp. at 7, is mistaken.

[3] Missouri suggests that Defendants' reliance on *Murthy v. Missouri*, 603 U.S. 43 (2024), "is misplaced" because that decision resolved an appeal from an order granting a preliminary injunction.

Finally, as Defendants explained, *see* Mot. at 9–10, Missouri's threadbare allegation that complying with the Rule "produces administrative costs," *see* Compl. ¶ 81, lacks the factual support necessary to plausibly allege Article III standing. *See Warth*, 422 U.S. at 508; *see also, e.g.*, *Hekel*, 118 F.4th at 943 (rejecting a standing theory that rested on conclusory allegations of economic injury where the complaint identified no "*specific* … expenses" that the defendant's action "caused" the plaintiff "to incur"). In response, the state never tries to explain why it failed to provide even a barebones description of the costs it would supposedly incur to comply with the Rule—which should have been easy to provide when the state filed its complaint if the Rule truly imposed the resource burdens it alleges. Instead, Missouri misdirects by arguing that it need not describe its alleged compliance costs down to a "specific dollar amount." *See* Opp. at 12 (citation omitted). But that misses the point entirely: the state has provided *no* detail whatsoever, relying instead on highly generalized assertions unaccompanied by supporting facts. *See* Opp. at 13–14 (citing multiple examples from the complaint); *see also, e.g.*, Compl. ¶ 89 (alleging, without further explanation, that "compliance with the Rule[]" has required "financial, logistical, and personnel burdens"). Nothing in *Tennessee* suggests that assertions like these, which are "devoid of" any "factual enhancement," *Hekel*, 118 F.4th at 943, can suffice to plausibly allege Article III standing, contrary to what Missouri contends. And that the Rule assumed that covered entities generally would need to develop new or modified policies or procedures following the Rule's promulgation says nothing about whether *Missouri* will, in fact, suffer a "*particularized*" injury. *See All. for Hippocratic Med.*, 602 U.S. at 381 (emphasis added); *accord Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982) ("Art[icle] III requires the party who invokes the court's authority *to show* that he *personally* has suffered some actual

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See Opp. at 11. But that's irrelevant to the two standing principles for which Defendants cited *Murthy*, which apply at all stages of litigation—*i.e.*, (i) that plaintiffs must demonstrate standing "for each claim that they press" and "for each form of relief they seek," *Murthy*, 603 U.S. at 44, and (ii) that standing cannot be premised on "guesswork," *id.* at 57.

or threatened injury as a result of the putatively illegal conduct of the defendant." (cleaned up with emphasis added)).

CONCLUSION

The Court should dismiss this case for lack of jurisdiction.

Dated: April 24, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

On April 24, 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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