UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ABBVIE INC. et al., Plaintiffs, v. ANDREW BAILEY, in his official capacity as Attorney General of the State of Missouri et al., Defendants.	)	Case No. 4:24-cv-00996-SRC

Memorandum and Order

The federal government allows AbbVie Inc., a pharmaceutical manufacturer, to participate in Medicaid. In exchange, federal law requires AbbVie to offer its drugs at discounted prices to healthcare providers serving underserved communities. Not all those providers have their own pharmacies, so some of them ask AbbVie to deliver the discounted drugs to for-profit, commercial pharmacies with which the providers have contracts. AbbVie doesn't like that because, it claims, those third-party pharmacies use special accounting and inventory methods to buy drugs at a discount and resell them at a higher price, in violation of federal law. Last year, Missouri enacted a law that prevents companies like AbbVie from refusing to deliver the discounted drugs to these pharmacies. AbbVie sued various state officials to enjoin enforcement of the law. Missouri moves to dismiss for failure to state a claim and failure to join necessary parties, and two organizations of healthcare providers move to intervene. But because AbbVie only alleges injuries stemming not from the Missouri law at issue but from violations of federal law—which violations AbbVie does not ask the Court to

address—the complaint fails to adequately allege standing. Thus, the Court does not reach the merits of either motion.

I. Background

A. Section 340B

Section 340B of the Public Health Service Act (codified at 42 U.S.C. § 256b) "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). Section 340B requires the Secretary of the United States Department of Health and Human Services to "enter into an agreement with each manufacturer of covered outpatient drugs." 42 U.S.C. § 256b(a)(1). Manufacturers include entities engaged in the production of prescription drugs. 42 U.S.C. § 1396r-8(k)(5)(A). Whether a drug qualifies as a "covered outpatient drug" depends on whether the drug satisfies a complex, and, for purposes of the pending motions, irrelevant, statutory definition. *See* 42 U.S.C. § 1396r-8(k)(2). As part of the deal with HHS (which has delegated its authority to the Health Resources and Services Administration (HRSA)), *see Astra*, 563 U.S. at 113–14, manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below" a price ceiling, 42 U.S.C. § 256b(a)(1). Long story short, section 340B requires pharmaceutical manufacturers that participate in Medicaid to offer drugs at discounted prices to certain entities called "covered entities."

Section 340B defines "covered entity" to include fifteen subsets of healthcare providers. *See* 42 U.S.C. § 256b(a)(4). Federally qualified health centers, Native Hawaiian health centers, black-lung clinics, some children's hospitals, and a host of other providers qualify as covered entities. *See id.*

Through two provisions, section 340B restricts covered entities from abusing their access to discounted drugs. First, a covered entity—which is the only type of entity qualified to receive 340B discounts, *see* 42 U.S.C. § 256b(a)(1)—may not "resell or otherwise transfer" a drug for which it obtained a discount to anyone "who is not a patient of the [covered] entity," 42 U.S.C. § 256b(a)(5)(B). This operates as a no-resale provision.

Second, if the covered entity obtains a drug through section 340B, the covered entity may not request payment for medical assistance with respect to that drug if the same drug is subject to the payment of a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A)(i). "Medical assistance" includes Medicaid payments for "part or all of the cost" of prescription drugs, i.e. a subsidy. 42 U.S.C. §§ 1396d(a), 1396d(a)(12). To have its drugs covered by Medicaid, a manufacturer must agree to pay a rebate to the state Medicaid plan determined by the number of drug units that the plan covers. *See* 42 U.S.C. §§ 1396r–8(a)(1), 1396r–8(b)(1)(A), 1396r–8(c)(1)(A). To tie it all together, if a manufacturer pays a Medicaid rebate for a drug, then a covered entity cannot obtain from the manufacturer a 340B discount for the same drug. *See Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023) (noting that "covered entities cannot get the 340B discount on drugs already subject to a Medicaid rebate" (citing 42 U.S.C. § 256b(a)(5)(A)(i)). This operates as a no-double-discount provision.

Section 340B provides a number of avenues to ensure compliance and resolve disputes among HRSA, manufacturers, and covered entities. For one, a covered entity must permit HRSA and manufacturers to audit the "records of the entity that directly pertain to the entity's compliance with the requirements" of section 340B. 42 U.S.C. § 256b(a)(5)(C). And section 340B provides for an administrative-dispute-resolution process to resolve claims of

manufacturers' overcharging and of covered entities' violations of the no-resale and no-double-discount provisions. *See* 42 U.S.C. § 256b(d)(3).

To opt into the 340B program, manufacturers must enter into a "form contract" with HHS called the Pharmaceutical Pricing Agreement (PPA). *Astra*, 563 U.S. at 115; *see also* 58 Fed. Reg. 27,289, 27,289 (May 7, 1993). Neither section 340B nor the PPAs require manufacturers to transfer 340B drugs to anyone besides covered entities. *See generally* 42 U.S.C. § 256b; *see also Astra*, 563 U.S. at 113 (describing PPAs as "uniform agreements that recite the responsibilities [section] 340B imposes, respectively, on drug manufacturers and the Secretary of HHS").

B. Contract pharmacies

1. Legal framework

As described above, only covered entities may obtain discounted drugs under section 340B. But what happens when, as is often the case, a covered entity doesn't have a pharmacy of its own? In 1996, HRSA issued a notice stating its position that a covered entity that lacks an on-site pharmacy may, without violating section 340B, have an outside pharmacy receive and dispense 340B drugs on the covered entity's behalf:

> [Section 340B] is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.
>
> It has been [HHS's] position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion.

61 Fed. Reg. 43,549, 43,549–43,550 (Aug. 23, 1996). These outside pharmacies are referred to as "contract pharmacies." HRSA envisioned that "[t]he contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity." *Id.* at 43,550.

In 2010, HRSA issued new guidance. This time, HRSA stated that it would permit covered entities to use *multiple* contract pharmacies "as long as [the covered entities] comply with guidance developed to help ensure against diversion and duplicate discounts." 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). And HRSA clarified that "[t]he covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity." *Id.*

2. AbbVie's factual allegations

AbbVie alleges the following about the on-the-ground use of contract pharmacies. "Following issuance of the 2010 guidance, covered entities dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 4,228% between 2010 and 2020." Doc. 1 at ¶ 54. Contract pharmacies "are predominantly large commercial pharmacy chains" that "do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe fiduciary duties to the covered entities." *Id.* at ¶ 57. Contract pharmacies use one of two inventory models to track sales of 340B drugs: (1) pre-purchased inventory or (2) replenishment. *Id.* at ¶ 58.

Under the pre-purchased-inventory model, the contract pharmacy keeps 340B drugs in stock at the pharmacy. *Id.* at ¶ 59. When the covered entity's patient comes to the pharmacy to get a prescription filled, the pharmacy fills it with drugs from the 340B stock. *Id.* But "few

contract pharmacies use the pre-purchased inventory model," because most use the replenishment model instead. *Id.* at ¶¶ 59–60.

AbbVie alleges the following about the replenishment model. "Under the replenishment model, no 340B purchased drugs are kept in stock at the contract pharmacy." *Id.* at ¶ 60. "Instead, the contract pharmacy fills all prescriptions using its own non-340B purchased inventory (that is, full price inventory)—including those prescriptions issued by covered entities." *Id.* "After a sufficient quantity of a particular drug is dispensed, the covered entity orders additional quantities of that drug at the federal 340B price [to] be transferred to the contract pharmacy to 'replenish' the non-340B drugs dispensed by the contract pharmacy on the covered entity's behalf." *Id.* (citation omitted). Thus, the contract pharmacy, or a third-party administrator with which it contracts, determines which sales qualified for 340B prices "at the back end, well after a drug has been dispensed." *Id.* at ¶ 61. In theory, if the contract pharmacy accurately tracks which dispensations qualify for 340B treatment, then "the post-sale determination may be able to calculate how many 340B drugs AbbVie must sell." *Id.* at ¶ 63. But AbbVie alleges that in practice, contract pharmacies and their third-party administrators "use their own distorted criteria to mark otherwise 340B-ineligible sales as deserving the federally mandated low prices." *Id.* at ¶ 64. And as a result, contract pharmacies can instruct covered entities "to place orders of additional quantities of drugs at the discounted 340B price to 'replenish' their general inventories that they will use to supply non-340B eligible sales." *Id.*

AbbVie alleges that, due to the expansion in the use of contract pharmacies, abuses of the 340B program have skyrocketed. Although section 340B prohibits covered entities from transferring drugs to persons who aren't their patients, "contract pharmacies take title to the drugs" that covered entities obtain through the 340B program. *Id.* And "[a]t no point in time

does a covered entity take title to the drugs." *Id.* (citation omitted). "AbbVie is also not aware of any instance where a contract pharmacy or covered entity represents that an agency relationship exists between them such that the contract pharmacy acts at the direction of a principal covered entity." *Id.*

AbbVie alleges that when contract pharmacies and covered entities obtain extra drugs at 340B prices, they "share in the 'spread' generated by selling the drugs at higher prices to pharmacy customers." *Id.* at ¶ 65. "For-profit, commercial pharmacies thereby obtain significant profits from selling [at a higher price] the 340B covered outpatient drugs that manufacturers must offer to covered entities at deeply discounted prices." *Id.*

Disillusioned by the section 340B abuses, some manufacturers, including AbbVie, have taken matters into their own hands. *See id.* at ¶¶ 73–79. AbbVie implemented a policy that it will not tolerate covered entities' requests to transfer 340B drugs to an unlimited number of contract pharmacies. *Id.* at ¶ 74. "Specifically, if a covered entity has its own in-house pharmacy, AbbVie's policy is to only take orders for direct delivery to the in-house pharmacy." *Id.* at ¶ 75. And "if a covered entity does not have an in-house pharmacy capable of dispensing to outpatients, it is permitted to designate one contract pharmacy located within 40 miles of the HRSA[-]registered covered[-]entity parent site." *Id.*

Policies like AbbVie's have provoked litigation between manufacturers and HHS. Two federal courts of appeals have held that similar delivery restrictions comply with the manufacturers' obligations under section 340B. *See Sanofi*, 58 F.4th at 706; *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 464 (D.C. Cir. 2024).

C. S.B. 751

Missouri enacted S.B. 751 (codified at Mo. Rev. Stat. § 376.414) in response to *Sanofi* and *Novartis*. Doc. 1 at ¶ 11–12. S.B. 751 says, in relevant part:

> A pharmaceutical manufacturer, third-party logistics provider, or an agent or affiliate of such pharmaceutical manufacturer or third-party logistics provider shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

Mo. Rev. Stat. § 376.414.2. S.B. 751 defines "340B drug" as "a drug that: (a) [i]s a covered outpatient drug within the meaning of [s]ection 340B . . . (b) [h]as been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. [s]ection 256b(a)(1); and (c) [i]s purchased by a covered entity." Mo. Rev. Stat. § 376.414.1(1). S.B. 751's definition of "covered entity" matches the definition supplied by section 340B. Mo. Rev. Stat. § 376.414.1(2); *see* 42 U.S.C. § 256b(a)(4).

D. AbbVie's complaint

AbbVie and related companies sued the Missouri Attorney General and the president, vice president, and three members of the Missouri Board of Pharmacy, all in their official capacities, in July 2024. Doc. 1. AbbVie sought a declaratory judgment that S.B. 751 is invalid and an injunction to restrain Missouri from enforcing the law. Doc. 1 at 43–44 (The Court cites to page numbers as assigned by CM/ECF.). In its complaint, AbbVie argued that S.B. 751 runs afoul of four higher laws: (1) the Takings Clause of the Fifth Amendment to the United States Constitution, *see id.* at ¶¶ 110–18, (2) the Takings Clause of article I, section 28 of the Missouri Constitution, *see id.* at ¶¶ 119–21, (3) the Supremacy Clause of article VI, clause 2 of the United

States Constitution, *see id.* at ¶¶ 122–31, and (4) the so-called "dormant" Commerce Clause of the United States Constitution, *see id.* at ¶¶ 132–38.

E. Missouri's Motion to Dismiss

In September 2024, Missouri moved to dismiss AbbVie's claims. Doc. 32. Missouri moves to dismiss each of AbbVie's claims for failure to state a claim upon which relief can be granted. *Id.* at 1. And Missouri moves to dismiss the first two claims for failure to join necessary parties. *Id.*

F. Intervenors' Motion to Intervene and Motion to Dismiss

Fifteen days after Missouri moved to dismiss, the Missouri Hospital Association and the Missouri Primary Care Association (collectively "Movants") filed a Motion to Intervene and a Motion to Dismiss of their own. *See* docs. 46–47. Movants allege that their members "participate in the 340B [p]rogram and rely on contract pharmacies to meet the needs of their patients and communities." Doc. 46 at 3. Missouri did not oppose Movants' Motion to Intervene, but AbbVie did. *See* doc. 72.

G. Oral argument

After the pending motions ripened, the Court scheduled oral argument. Doc. 80. The Court ordered the parties to come prepared to discuss not only the merits of the pending motions but also "whether AbbVie's complaint adequately alleges an Article III injury in fact" and "[t]o the extent that AbbVie's complaint adequately alleges an injury in fact, whether AbbVie's complaint adequately alleges that its injury is fairly traceable to Missouri's enforcement of S.B. 751 rather than to abuses of the 340B drug-pricing program." *Id.* at 2.

In April 2025, the Court heard oral argument. Doc. 84. At the end of the argument, the Court ordered AbbVie and Missouri to submit supplemental briefs on the standing issues that the

Court raised, which the parties filed. *See* doc. 88, Oral Arg. Tr. at 78:21–79:9; docs. 89–90. Having thoroughly reviewed AbbVie's complaint, the oral-argument transcript, and the supplemental briefs, the Court rules as follows.

II. Standard

"Article III of the Constitution limits the jurisdiction of the federal courts to cases or controversies." *In re SuperValu, Inc.*, 870 F.3d 763, 767–68 (8th Cir. 2017) (citing *Spokeo, Inc. v. Robins*, 578 U.S. 330, 337 (2016)). "A plaintiff invoking the jurisdiction of the court must demonstrate standing to sue by showing that she has suffered an injury in fact that is fairly traceable to the defendant's conduct and that is likely to be redressed by the relief she seeks." *Id.* (citing *Spokeo*, 578 U.S. at 337). "To establish an injury in fact, a plaintiff must show that her injury is '"concrete and particularized" and "actual or imminent, not conjectural or hypothetical."'" *Id.* (quoting *Spokeo*, 578 U.S. at 339). "An injury is fairly traceable if the plaintiff shows 'a causal connection between the injury and the conduct complained of' that is 'not . . . th[e] result [of] the independent action of some third party not before the court.'" *Id.* (alterations in original) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

"Standing . . . is a jurisdictional requirement, and thus 'can be raised by the court sua sponte at any time during the litigation.'" *Pucket v. Hot Springs Sch. Dist. No. 23-2*, 526 F.3d 1151, 1156–57 (8th Cir. 2008) (quoting *Delorme v. United States*, 354 F.3d 810, 815 (8th Cir. 2004)). "Where, as here, a case is at the pleading stage, the plaintiff must 'clearly . . . allege facts demonstrating' each element" of standing. *Spokeo*, 578 U.S. at 338 (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). The Court "accept[s] as true the factual allegations in the complaint[] but give[s] 'no effect to conclusory allegations of law.'" *In re Polaris Mktg., Sales*

Pracs., & Prods. Liab. Litig., 9 F.4th 793, 796 (8th Cir. 2021) (quoting *Stalley ex rel. United States v. Cath. Health Initiatives*, 509 F.3d 517, 521 (8th Cir. 2007)).

III. Discussion

A. Article III standing

In its supplemental brief, AbbVie characterizes its alleged injury as economic:

> AbbVie has adequately alleged its injuries flow from the additional 340B sales that S.B. 751 compels. . . . AbbVie's injury is concrete and particularized because S.B. 751 bans AbbVie's contract-pharmacy policy and compels it to complete sales it otherwise would not. AbbVie, through terms it lawfully includes in its 340B transactions, reasonably limits covered entities to in-house pharmacies or one designated contract pharmacy for purposes of accessing the 340B price. And to be clear, AbbVie's policy does not limit the number of discounted units available for sale. Covered entities can still obtain as many 340B-priced drugs as they need. However, S.B. 751 leads to a higher number of discounted transactions not because AbbVie imposes any cap, but because the statute expands the number of contract pharmacies that can receive 340B-priced drugs. With more pharmacies comes more orders and more compelled discounted sales—transactions that would not have occurred but for the Missouri law. S.B. 751 expressly protects the expansion of the pool. And, without S.B. 751, AbbVie's policy would have remained in effect—those discounted transactions would not have occurred.

Doc. 90 at 5– 6 (citations omitted). At oral argument, though, AbbVie attempted to characterize its injury differently, as a matter of property rights rather than economic loss:

> To be clear, AbbVie alleges that it is injured by S.B. 751, not as a matter of an economic injury but because it affects [sic] a per se taking. I suppose in the end that could have an economic effect, but actually the injury that AbbVie alleges is that it is dispossessed of its chattels . . . . [I]ts physical drugs are transferred through the covered entity/contract pharmacy arrangement, back to contract pharmacies who can then sell them at full price and keep some of that profit spread.

Doc. 88, Oral Arg. Tr. at 18:25–19:8. But both theories remain essentially the same: AbbVie argues that S.B. 751 requires it to provide more discounted drugs than AbbVie would be required to provide absent S.B. 751, and thus, AbbVie concludes, S.B. 751 causes AbbVie financial loss.

Financial loss doubtless qualifies as an Article III injury in fact. *See, e.g.*, *Muff v. Wells Fargo Bank NA*, 71 F.4th 1094, 1103 (8th Cir. 2023) (holding that the estate had standing

because it "assert[ed] a classic monetary injury to Joseph's personal account at Wells Fargo"); *Biden v. Nebraska*, 600 U.S. 477, 490 (2023) (finding injury in fact based on "financial harm"). But AbbVie's mere labelling of S.B. 751 as a "per se taking" does not. *See Polaris*, 9 F.4th at 796 (holding that courts must "give 'no effect to conclusory allegations of law'" when determining whether a plaintiff has adequately alleged Article III standing (quoting *Stalley*, 509 F.3d at 521). Thus, the Court must determine whether, based on the factual allegations in the complaint, AbbVie's alleged financial loss is fairly traceable to Missouri's enforcement of S.B. 751.

The gravamen of AbbVie's complaint is that its contract-pharmacy policy "address[es] abuses of the 340B program by covered entities and contract pharmacies." Doc. 1 at ¶ 77. So framed, the Court must then address the question of what 340B "abuses" does AbbVie seek to address? AbbVie identifies only one in its complaint—the transfer of title of discounted 340B drugs from AbbVie to contract pharmacies *through the replenishment model*. *See, e.g.*, doc. 1 at ¶ 5 ("Instead of serving the covered entities' uninsured and low-income patients, the for-profit contract pharmacies acquire manufacturers' drugs at the federally discounted price, sell them to patients (including indigent patients) at full price, and pocket the difference. Contract pharmacies accomplish this arbitrage through . . . the 'replenishment model,' . . . ."); *id.* at ¶ 57 ("Contract pharmacies are not 'agents' of the covered entities; they are merely business partners."); *id.* at ¶ 64 ("Significantly, *as a result of such replenishment*, contract pharmacies take title to the drugs they purchase from manufacturers, either through covered entities or on their own behalf. At no point in time does a covered entity take title to the drugs under this model." (emphasis added)); *id.* ("AbbVie is also not aware of any instance where a contract pharmacy or covered entity represents that an agency relationship exists between them such that

the contract pharmacy acts at the direction of a principal covered entity."); *id.* at ¶ 68 ("Because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, ***allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit***." (emphasis added)); *id.* at ¶ 107 ("[S.B. 751] effects a repeated and ongoing mandatory private wealth transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies for the private benefit of that pharmacy and for no recognized public use, in violation of the United States' Constitution.").

The federal 340B statute does not require AbbVie to transfer the title of discounted drugs to contract pharmacies (which, AbbVie alleges, "do not themselves qualify as covered entities," *id.* at ¶ 57). Only covered entities can purchase 340B drugs from drug manufacturers. 42 U.S.C. § 256b(a)(1) (discount applies to drugs "purchased by a covered entity"). And section 340B *prohibits* covered entities from transferring title of discounted drugs to anyone except their own patients. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.").

The very HRSA notices that *allow* the use of contract pharmacies clarify that contract pharmacies may not themselves take title to the discounted drugs. *See* 61 Fed. Reg. at 43,549–50 ("If the [covered] entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. *However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion*." (emphasis added));

id. at 43,550 ("Under the guidelines, the contract pharmacy would dispense 340B drugs to patients of the covered entity pursuant to a prescription. *The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity*." (emphasis added)); 75 Fed. Reg. at 10,273 ("The covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity . . . ."); *id.* ("Covered entities will be permitted to use multiple pharmacy arrangements *as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition*." (emphasis added)). And even AbbVie's own complaint concedes that section 340B prohibits the transactions of which it complains. *See* doc. 1 at ¶ 42 (arguing that the complained-of 340B abuses "violate both the letter and spirit of the federal 340B statute").

S.B. 751 doesn't require AbbVie to transfer title of discounted drugs to contract pharmacies, either. Two provisions of S.B. 751 support this conclusion.

First, S.B. 751 doesn't apply to any receipt that "is prohibited by the United States Department of Health and Human Services." Mo. Rev. Stat. § 376.414.2. Transfers that violate section 340B—such as transfers to anyone not a covered entity or a patient of a covered entity—plainly fall within this exception to S.B. 751. *See Astra*, 563 U.S. at 114 (holding that "Congress placed the Secretary [of the Department of Health and Human Services] . . . in control of § 340B's drug-price prescriptions").

Second, S.B. 751 provides that manufacturers may not "deny, restrict, or prohibit . . . the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is *under contract with*, or *otherwise authorized by*, a covered entity to receive 340B drugs *on behalf of the covered*

entity." Mo. Rev. Stat. § 376.414.2 (emphasis added). In context, "otherwise" means "in a different way or manner." *Otherwise*, Merriam-Webster, https://www.merriam-webster.com/dictionary/otherwise (last visited July 11, 2025). Thus, whether a contract exists or not, a delivery or acquisition does not fall within S.B. 751 unless the pharmacy is "authorized" to receive the drugs "on behalf of the covered entity." Mo. Rev. Stat. § 376.414.2; *see State ex rel. Hillman v. Beger*, 566 S.W.3d 600, 604–05 (Mo. 2019) (holding that "[a]ny time a court is called upon to apply a statute, the primary obligation 'is to ascertain the intent of the legislature from the language used, to give effect to that intent if possible, and to consider the words in their plain and ordinary meaning.'" (quoting *S. Metro. Fire Prot. Dist. v. City of Lee's Summit*, 278 S.W.3d 659, 666 (Mo. 2009)). In other words, if no agency relationship exists between the covered entity and the contract pharmacy, the statute doesn't require AbbVie to deliver the 340B drugs to the contract pharmacy. *See Bach v. Winfield-Foley Fire Prot. Dist.*, 257 S.W.3d 605, 608 (Mo. 2008) (holding that "[a]gency is the fiduciary relationship resulting from the manifestation of consent by an agent to a principal *that the agent will act on the principal's behalf* and subject to his control" (emphasis added) (citations omitted)).

So to the extent that contract pharmacies take 340B drugs for themselves through the replenishment model, in violation of section 340B, S.B. 751 has no hand in AbbVie's injury. To the extent that AbbVie's complaint alleges financial loss from increased sales of discounted drugs, two things bear responsibility for that financial loss: (1) section 340B, and (2) illegal transfers of 340B drugs through the replenishment model. S.B. 751 neither requires nor permits illegal transfers of 340B drugs. That renders AbbVie's alleged financial injury—to the extent that AbbVie has adequately alleged such an injury—not fairly traceable to S.B. 751. *See SuperValu*, 870 F.3d at 768 ("An injury is fairly traceable if the plaintiff shows 'a causal

connection between the injury and the conduct complained of' that is 'not . . . th[e] result [of] the independent action of some third party not before the court.'" (alterations in original) (quoting *Lujan*, 504 U.S. at 560)).

AbbVie's additional arguments do not save its complaint. AbbVie, citing *Sanofi* and *Novartis*, argues that "the extent to which AbbVie will recognize a contract pharmacy's access to the 340B price on behalf of a covered entity is a decision the federal statute left with AbbVie; S.B. 751 is the law the [sic] seeks to take that decision out of AbbVie's hands." Doc. 90 at 10. The Court need not—and thus will not—decide whether the *Sanofi* and *Novartis* courts got it right with respect to the legality of manufacturers' contract-pharmacy restrictions. But even if those courts did get it right, that wouldn't supply AbbVie with standing. As explained above, S.B. 751 bears no responsibility for the transactions that give rise to AbbVie's alleged injury. Indeed, AbbVie conceded at oral argument that it would sell the same number of drugs to 340B-qualifying patients regardless of S.B. 751:

> **THE COURT:** [I]sn't it, at the end of the day, essentially that S.B. 751 is preventing you from limiting the number of pharmacies to which you sell, but it's not going to limit the number of drugs that you sell?
>
> **[Counsel for AbbVie]:** That's correct, Your Honor. I agree with that conception. I'm sorry if I didn't understand your question before. I agree with that.

Doc. 88, Oral Arg. Tr. at 22:16–22:22; *see also id.* at 46:16–46:17 (conceding that S.B. 751 "doesn't change the number of drugs that are sold at the 340B price to the covered entity").

In other words, S.B. 751 does not require AbbVie to sell any more drugs than it otherwise would. It is the replenishment model, i.e. the buyer's inventory-and-accounting model, that causes AbbVie's alleged losses. Another way to look at it is this: if the federal government banned the replenishment model, and S.B. 751 remained in effect, AbbVie would suffer no

damages. However, if S.B. 751 were repealed but the replenishment model were still allowed, AbbVie would continue to suffer the exact same damages it complains of here.

Next, AbbVie argues that "S.B. 751 will compel AbbVie to make additional *discounted* sales, irrespective of the inventory or accounting methods that contract pharmacies utilize." Doc. 90 at 10 (emphasis added) (citing doc. 1 at ¶¶ 58–62). But the well-pleaded allegations in the complaint fail to support this conclusion. AbbVie cites to paragraphs 58–62 of its complaint to support its argument. *See id.* But those paragraphs merely *describe* two different types of accounting models that contract pharmacies use: the pre-purchased-inventory model and the replenishment model. *See* doc. 1 at ¶¶ 58–62. They don't mention S.B. 751 *at all*. *See id.* Much less do they allege—with any well-pleaded facts—that S.B. 751 causes AbbVie financial loss. *See id.*

Finally, AbbVie argues that it has standing based on Missouri's threatened enforcement of S.B. 751. *See* doc. 90 at 13 ("S.B. 751 presents a classic pre-enforcement injury Hobson's choice: comply with an unconstitutional mandate or risk enforcement and severe penalties."). But again, AbbVie's mere labeling of S.B. 751 as an "unconstitutional mandate" does not supply AbbVie with standing. *Id.* As already explained, AbbVie's damages flow not from S.B. 751 but from the replenishment model. While the Supreme Court has held that "a plaintiff satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder,'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)), the *Susan B. Anthony List* Court found that the plaintiff had established injury in fact because the plaintiff "pleaded specific statements [it] intend[ed] to make" that "concern[ed] political speech," *id.* at 161–62.

Thus, the Supreme Court held, the plaintiff's intended conduct "[was] certainly 'affected with a constitutional interest[,]'" and the harms plaintiffs alleged flowed from the enforcement of the statute. *Id.* at 162 (quoting *Babbit*, 442 U.S. at 298). But here, the only interest that AbbVie claims to have in its contract-pharmacy policy is its interest in preventing transactions for which S.B. 751 bears no responsibility. Thus, AbbVie's complaint fails to establish, through well-pleaded facts, that the enforcement of S.B. 751 arguably affects a constitutional interest.

Thus, AbbVie's complaint fails to adequately allege Article III standing. The Court therefore dismisses it. The Court denies as moot Missouri's Motion to Dismiss. Doc. 32.

B. Leave to amend

In its supplemental brief, AbbVie alternatively requests leave to amend its complaint. Doc. 90 at 15–16. AbbVie argues that, in its amended complaint, it would plead, among other things, facts showing that the cost of compliance with S.B. 751 has already totaled around $35 million. *Id.* Missouri argues that "any amendment would be futile." Doc. 89 at 16.

For at least two reasons, the Court cannot construe AbbVie's request as a motion for leave to amend. First, under Federal Rule of Civil Procedure 7(b)(1)(B), a motion must "state with particularity the grounds for seeking the order" that the movant seeks. "The particularity requirement of Rule 7(b) is met by submitting a proposed amendment with the motion for leave to amend the complaint." *Wolgin v. Simon*, 722 F.2d 389, 394 (8th Cir. 1983) (citations omitted). But here, AbbVie did not attach a proposed amended complaint to its supplemental brief. *See* doc. 90.

Second, both the Local Rules and the undersigned's Judge's Requirements require a party seeking leave to amend to present a tracked-changes version of its proposed amended pleading. *See* E.D. Mo. L.R. 4.07; Judge's Requirements at 4. Without having access to a full version of

AbbVie's proposed amended complaint (with changes tracked), the Court cannot determine whether it should allow amendment.

To the extent that AbbVie still seeks leave to amend its complaint, it must file, no later than July 25, 2025, a motion for leave to amend that complies with all applicable rules, including the undersigned's Judge's Requirements. If AbbVie fails to timely file a motion for leave to amend, the Court will dismiss the case without prejudice and without further notice.

C. Intervention

Having dismissed AbbVie's complaint, the Court finds that Movants lack standing at this time. *See Mausolf v. Babbitt*, 85 F.3d 1295, 1300 (8th Cir. 1996) ("An Article III case or controversy is one where all parties have standing, and a would-be intervenor, because he seeks to participate as a party, must have standing as well."). Indeed, Movants allege that they have suffered an Article III injury in fact because AbbVie's "attack on S.B. 751 threatens the protections for delivery of 340B drugs to contract pharmacies, which are essential to the continued viability of the operations and services provided by [Movants'] members." Doc. 46 at 10. But now that the Court has dismissed AbbVie's complaint, an injunction against S.B. 751 depends on a "speculative chain of possibilities," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013), namely, (1) that AbbVie will move to amend its complaint, (2) that the Court will allow amendment, and (3) that the Court will enjoin enforcement of S.B. 751. Because Movants lack standing, the Court denies, without prejudice, Movants' Verified Motion to Intervene and Suggestions in Support. Doc. 46. Movants may file a renewed motion to intervene if, and only if, the Court allows AbbVie to amend its complaint. The Court denies as moot, without prejudice, Movants' Motion to Dismiss. Doc. 47.

IV. Conclusion

Accordingly, the Court dismisses, without prejudice, for lack of standing, AbbVie's [1] Complaint for Declaratory and Injunctive Relief. If AbbVie seeks to amend its complaint, it must file, no later than July 25, 2025, a motion for leave to amend its complaint that complies with all applicable rules, including the Eastern District of Missouri Local Rules and the undersigned's Judge's Requirements. AbbVie's failure to file a compliant motion for leave to amend by this date will result in the dismissal of this case without prejudice and without further notice. The Court denies as moot, without prejudice, Missouri's [32] Motion to Dismiss. The Court denies, without prejudice, for lack of standing, Movants' [46] Verified Motion to Intervene and Suggestions in Support. The Court denies as moot, without prejudice, Movants' [47] Motion to Dismiss.

So ordered this 11th day of July 2025.

STEPHEN R. CLARK
CHIEF UNITED STATES DISTRICT JUDGE