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United States District Court, M.D.
Tennessee, Nashville Division.

ABBVIE INC. et al., Plaintiffs,
v.
Jonathan **SKRMETTI**, in his official capacity as Attorney General of the State of Tennessee, Defendant.

Case No. 3:25-cv-00519
|
Filed 02/26/2026

Attorneys and Law Firms

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MEMORANDUM

ALETA A. TRAUGER, United States District Judge

***1** Plaintiffs **AbbVie** Inc., Allergan, Inc., Durata Therapeutics, Inc., **AbbVie** Products LLC, Pharmacyclics LLC, and Allergan Sales, LLC (collectively "**AbbVie**" or "plaintiffs") filed suit on May 6, 2025 against Jonathan **Skrmetti**, in his official capacity as the Attorney General of the State of Tennessee (referred to herein as the "State"), to enjoin the enforcement of the Tennessee Hospital Protection Act (the "Act"), Tenn. Code Ann. § 47-18-136. The Act was signed by Tennessee Governor Bill Lee on May 5, 2025; parts of it went into effect immediately, and parts took effect on July 1, 2025.

AbbVie's Complaint characterizes the Act as mandating that pharmaceutical manufacturers, including the plaintiffs, sell drugs at discounted prices to commercial pharmacies. (Doc. No. 1, Compl. ¶ 1.) **AbbVie** contends that the Act thus "impermissibly chang[es] the terms of a federal drug-pricing regime—the so-called federal "340B program"—and significantly increase[es] the cost of participation in that regime." (*Id.*) Invoking 42 U.S.C. § 1983, **AbbVie** challenges the Act as unconstitutional on the grounds that it (1) violates the Supremacy Clause; (2) effects a taking in violation of the Takings Clause; (3) "unlawfully discriminates against or unduly burdens interstate commerce in violation of the Commerce Clause, as established by Dormant Commerce Clause principles"; (4) is unconstitutionally vague in violation of the Due Process Clause; and (5) "violates the First Amendment's Free Speech and Petition Clauses." (*Id.*)

The court previously denied **AbbVie's** Motion for Preliminary Injunction, which was filed within days of its Complaint. *See* ***AbbVie*** *Inc. v.* ***Skrmetti*** ("***AbbVie*** *I*"), No. 3:25-cv-00519, 2025 WL 1805271 (M.D. Tenn. June 30, 2025). Now before the court is the State's Motion to Dismiss. (Doc. No. 47.) For largely the same reasons articulated in the court's Memorandum denying the Motion for Preliminary Injunction, the Motion to Dismiss will be granted.

I. BACKGROUND

As also described in the court's opinion denying **AbbVie's** Motion for Preliminary Injunction,[1] Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical companies that want to participate in Medicaid and Medicare Part B to offer steep discounts on certain outpatient drugs to "covered entities," a term defined to include public hospitals and community health centers and other entities typically engaged in "car[ing] for low-income and rural persons." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023); *see also* 42 U.S.C. § 256b(a)(4) (defining "covered entity"). (*See also* Compl., Doc. No. 1 ¶¶ 37–38.) This program, referred to as the "340B program," helps covered entities provide "safety-net services to the poor," *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011), because the entities "turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount," *Sanofi Aventis*, 58 F.4th at 699.

The 340B program is administered by the Secretary of Health and Human Services ("HHS") and "superintended by the Health Resources and Services Administration" ("HRSA"), which is an HHS agency. *Astra USA*, 563 U.S. at 113.

***2** "Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement (PPA) used nationwide." *Id.* PPAs are "uniform agreements," *id.*, that "require" participating manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a). "Covered entities may only prescribe 340B discounted drugs to patients who qualify and may not request or receive duplicative 340B discounts and Medicaid rebates for the same drug." *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1141–42 (8th Cir.) (citing 42 U.S.C. § 256b(a)(5)(A)–(B)), *pet. for rehearing en banc and by panel denied*, No. 22-3675, 2024 WL 1919676 (8th Cir. May 2, 2024), *cert. denied*, 145 S. Ct. 768 (2024). "Additionally, covered entities may not engage in diversion of covered outpatient drugs through 'resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity.' " *Id.* at 1142 (quoting 42 U.S.C. § 256b(a)(5)(B)).

HHS and drug manufacturers are authorized to audit covered entities to ensure compliance with the diversion and duplicate rebate prohibitions, "in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits." *Id.* (citing 42 U.S.C. § 256b(a)(5)(C)). The program contains enforcement mechanisms and penalties for manufacturers and covered entities that fail to comply with those provisions. *Id.* (citing *Sanofi Aventis*, 58 F.4th at 700). Any disputes arising under the 340B program must first be submitted to HHS's dispute resolution program. *Id.* (citing 42 U.S.C. § 256b(d)(3)).

Although the 340B program was apparently designed with the expectation that it would apply to covered entities that operated in-house pharmacies, "[s]ince the beginning, covered entities have contracted with outside pharmacies, referred to as 'contract pharmacies,' for the distribution and dispensation of 340B drugs." *Id.* at 1139. "Indeed, early in the 340B Program, HRSA observed that most covered entities relied on contract pharmacies, while only about four percent of such entities used in-house pharmacies." *Id.* at 1142 (citing Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("1996 Guidance")).

While the Secretary of HHS "lacks rulemaking authority over the section 340B program," the HRSA has, on several occasions, issued non-binding "guidance" documents, such as the 1996 Guidance, "interpreting and implementing the scheme." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). In the 1996 Guidance, the HRSA "acknowledged that section 340B 'is silent as to permissible drug distribution systems,' " and it "sought to fill 'gaps in the legislation' and thereby 'move the program forward.' " *Id.* (quoting 1996 Guidance at 43,549–50). In addition, HRSA "recognized that many covered entities use outside pharmacies to distribute drugs to their patients," and, to accommodate them, HRSA determined that any covered entity that did not have an in-house pharmacy could contract with *one* outside pharmacy to dispense drugs at a single location. *Id.* at 457 (citing1996 Guidance at 43,550, 43,555).

However, HRSA reversed course in 2010, when it issued another guidance document "opin[ing] that covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies." *Id.* (citing Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) ("2010 Guidance")). Following the issuance of the 2010 Guidance, "the use of contract pharmacies skyrocketed," increasing by "twentyfold." *Sanofi Aventis*, 58 F.4th at 700.

***3** Purportedly worried that "contract pharmacies were driving up duplicate discounting and diversion," drug makers began to respond in 2020 by adopting policies that limited or prohibited covered entities from contracting with outside pharmacies for the dispensation of 340B drugs to patients. *Id.*; *see also McClain*, 95 F.4th at 1139. In some instances, these limitations "caused covered entities dependent on contract pharmacies to become unable to serve patients in need." *McClain*, 95 F.4th at 1139.

HHS responded to these efforts, first, by "releas[ing] an Advisory Opinion declaring that Section 340B unambiguously requires drug makers to deliver 340B drugs to an unlimited number of contract pharmacies." *Sanofi Aventis*, 58 F.4th at 701 (citing HHS Off. Gen. Couns., Advisory Op. 20-06 on Cont. Pharmacies Under the 340B Program (Dec. 30, 2020), https://perma.cc/L7W2-H597). Second, it issued violation letters to several drug manufacturers, who then sued HHS. *Id.* The Third Circuit held that the Advisory Opinion and violation letters were unlawful because § 340B is silent

regarding delivery to contract pharmacies. *Id.* at 706. The court enjoined HHS's "reading of Section 340B as *requiring* delivery of discounted drugs to an unlimited number of contract pharmacies," because "[l]egal duties do not spring from silence." *Id.* at 707 (emphasis added). The D.C. Circuit reached the same conclusion. *See Johnson*, 102 F.4th at 461 ("agree[ing] entirely" with the Third Circuit's conclusion that, "because section 340B is 'silent about delivery,' HRSA erred in concluding that the statute 'requires drug makers to deliver drugs to an unlimited number of contract pharmacies' " (quoting *Sanofi Aventis*, 58 F.3d at 703)).

Following these rulings, approximately twenty states, including Tennessee, have attempted to fill the "silence" recognized by the Third and D.C. Circuits by passing laws that prohibit pharmaceutical companies from limiting the number of contract pharmacies with which covered entities can enter agreements pertaining to the delivery of 340B drugs or otherwise imposing distribution obstacles not required by the federal program. Under Tennessee's Hospital Protection Act, effective July 1, 2025, drug manufacturers and their agents and affiliates "shall not":

> (1) Impose additional requirements or limitations on a 340B entity, including requiring the submission of any health information, claims or utilization data, purchasing data, payment data, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless such data submission is explicitly required by the United States department of health and human services or applicable state law;
>
> (2) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of business and not related to the 340B program;
>
> (3) Impose any requirements relating to inventory management systems of 340B drugs, unless such requirement is required by the United States department of health and human services or applicable state law;
>
> (4) Impose any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities;
>
> (5) Impose requirements relating to accreditation, recertification, credentialing, or recredentialing that are not imposed on pharmacies or providers that are not 340B entities; or
>
> ***4** (6) Impose any requirement determined by the attorney general and reporter to interfere with the ability of a 340B entity to access discounts provided under the 340B program.

Tenn. Code Ann. § 47-18-136(a). Generally, in other words, pharmaceutical companies may not impose requirements on covered entities in addition to those requirements expressly set out in § 340B or discriminate against covered entities by imposing upon them requirements that they do not impose on providers that are not 340B entities.

In addition, the Act prohibits drug manufacturers from

> deny[ing], impos[ing] any restrictions or prohibitions on, discriminat[ing] against, or otherwise limit[ing] the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity or other location that is under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity unless such receipt is prohibited by the United States department of health and human services or applicable state law.

Id. § 47-18-136(c). Subsection (c), however, also contains a "grandfather clause," which provides that it "does not apply to any requirements, prohibitions, limitations, or restrictions in place on or before June 1, 2025." *Id.*

The Act further provides that each violation of subsection (a) or (c)[2] constitutes an "unfair or deceptive act or practice affecting trade or commerce" in violation of the Tennessee Consumer Protection Act ("TCPA") and may give rise to a civil penalty of $50,000 "per violation." *Id.* § 47-18-136(d)(1). As **AbbVie** points out, under Tennessee law, any act deemed to be an unfair or deceptive act or practice under the TCPA is also a Class B misdemeanor. *Id.* § 47-18-104(a). The Act further states that it "must not be construed or applied to be in conflict with or less restrictive than ... [a]pplicable federal law and regulations." *Id.* § 47-18-136(e)(1).

While there are minor differences between Tennessee's law and the analogous statutes passed by other states,

the laws share many features, "including prohibitions on certain manufacturer limits on covered entities and contract pharmacies, as well as alternative remedies for violations of the prohibitions." *Pharm. Rsch. & Mfrs. of Am. v. Frey*, No. 1:25-cv-00469-JCN, 2026 WL 184504, at *1 (D. Me. Jan. 23, 2026). Drug manufacturers have filed lawsuits in many of these states to enjoin the statutes' enforcement. There are at least thirteen district court opinions, including one issued by this court, denying motions for preliminary injunctions or granting defendants' motions for summary judgment in cases filed by drug manufacturers seeking to enjoin enforcement of state statutory schemes, three of which have been affirmed by two different circuit courts.[3] Only two district courts have granted injunctive relief to drug manufacturers,[4] and a handful of opinions from Utah and the Western District of Missouri have denied in part motions to dismiss filed by state defendants.[5]

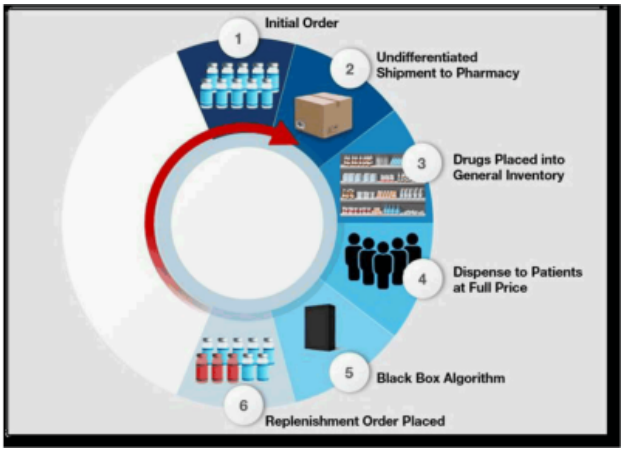
II. THE PLAINTIFFS' CLAIMS

***5** In the present lawsuit, the plaintiffs are all drug manufacturers and signatories (or successors-in-interest to signatories) to 340B Pharmaceutical Pricing Agreements with HRSA. (Doc. No. 1 ¶¶ 23–28.) They allege that the Act "impermissibly changes the terms" of the federal 340B program and "significantly increase[es] the cost of participation in that regime." (Doc. No. 1 ¶ 1.) They further allege that, following issuance of the 2010 Guidance effectively authorizing covered entities to enter into contractual arrangements with an unlimited number of commercial pharmacies, many covered entities have entered into "novel contractual arrangements" with commercial pharmacies that employ a "complicated accounting system known as the 'replenishment model.' " (*Id.* ¶ 6.)

Under the replenishment model, as described by **AbbVie**, covered entities enter into contractual relationships with commercial pharmacies ("contract pharmacies") pursuant to which the contract pharmacies "sell manufacturers' drugs at regular prices to pharmacy customers and then demand that their stocks be replenished with drugs purchased by the covered entity through the federal 340B program at discounted prices, pocketing the difference ... for their own financial benefit." (*Id.* ¶ 42.) More specifically, a contract pharmacy obtains an

> initial stock of drugs ... through ordinary commercial purchases [from the manufacturer] at the non-340B price. Initially, 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.... [T]he pharmacy [subsequently] determines which previous dispenses were 340B eligible and[,] once sufficient eligible dispenses for a particular drug accumulate, the covered entity orders additional quantities of that drug at the federal 340B price. The covered entity directs **AbbVie** to transfer those drugs to the contract pharmacy to "replenish" the non-340B-priced drugs dispensed by the contract pharmacy on the covered entity's behalf. Sometimes the contract pharmacy actually places the order on behalf of the covered entity for more drugs at the federal 340B price.

(*Id.* ¶ 63 (internal quotation marks and citations omitted). **AbbVie** supplies a model to illustrate this procedure:



(Compl. 22, Fig. 1.)

AbbVie asserts that these arrangements violate both the "letter and spirit" of the 340B statute. (*Id.* ¶ 44.) They allegedly violate the "spirit" of the 340B program because they do not further the "only valid public purpose" of the program, which, according to **AbbVie**, is to "help[ ] low-income and uninsured patients obtain access to medications at discounted prices." (*Id.*)[6] And the arrangement violates

the "letter," insofar as it violates the 340B statute's express prohibitions of "diversion," *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"), and receiving or causing duplicate discounts or rebates, *see id.* § 256b(a)(5)(A). (*See* Compl. ¶¶ 44–46.) This is because, **AbbVie** believes, the replenishment model permits the "transfer" of 340B-priced drugs to contract pharmacies "with the full knowledge that those drugs will be sold to any customer who comes in the door, whether 340B-eligible or not." (Doc. No. 52 at 9 (citing Compl. ¶¶ 63–64).) And contract pharmacies are not covered entities either, though the replenishment model permits the contract pharmacies to take title to the 340B-priced drugs, despite not being "agents" of the covered entities but, instead, mere "business partners." (*Id.* ¶ 59.)

***6** In other words, **AbbVie** objects to these arrangements on the grounds that they do not benefit indigent patients but, instead, allow contract pharmacies and covered entities to pocket "billions of dollars every year," allegedly "at the expense of both manufacturers and the needy patients" the covered entities are supposed to serve. (*Id.*) And the arrangements purportedly "unconstitutionally compel **AbbVie** to make sales under conditions it would not agree to, thereby perpetuating the very abuses federal law forbids." (*Id.* ¶ 47.)

Under its current policy, **AbbVie** continues to offer covered entities unlimited 340B-priced drugs at or below the ceiling price established by the 340B program, but it will not provide discounted drugs to unlimited, third-party contract pharmacies that are serving hospital-type covered entities. (Doc. No. 52 at 9 (citing Compl. ¶¶ 82–84).) "Specifically, if a covered entity has its own in-house pharmacy, **AbbVie's** policy now is to take orders for the in-house pharmacy." (Compl. ¶ 84.) If the covered entity does not have an in-house pharmacy, "**AbbVie** will take orders for one designated contract pharmacy, provided that the one contract pharmacy is located with 40 miles of the HRSA covered entity parent site, and the covered entity submits limited claims data on 340B utilization for that pharmacy location." (*Id.*) In addition, it will allow "Grantee Covered Entities" (a term it does not define) to use "an unlimited number of contract pharmacies" if they agree to submit claims data through a free web-based platform. (*Id.*) "If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, **AbbVie** will work with the covered entity to identify a suitable alternative." (*Id.* ¶ 85.)

AbbVie characterizes subsection (c) of § 47-18-136 as eliminating drug manufacturers' "ability to adopt policies to prevent 340B abuse or prevent the taking of their own property by entities not otherwise entitled to it." (Compl. ¶ 104.) While **AbbVie** acknowledges the grandfather clause in subsection (c), which expressly states that that subsection will not apply to restrictions in place on or before June 1, 2025, **AbbVie** maintains that, "in practice, **AbbVie's** policy likely cannot qualify for the exception," because it must "frequently amend and revise [its] policies to comply with the various prohibitions and requirements" imposed by constantly changing state laws. (*Id.* ¶ 105.) It alleges that, if it at any time updates its policy "to reflect a new state law," it will automatically fall outside the protection of the grandfather clause. (*Id.*) For example, as of the May 6, 2025 filing date of the Complaint, **AbbVie** anticipated updating its "current contract pharmacy policies in South Dakota and North Dakota, on July 1, 2025 and August 1, 2025—the two state law's effective dates"—meaning, according to **AbbVie**, that it would fall outside the protection of the grandfather clause in § 47-18-136(c) almost immediately upon subsection (c)'s taking effect on June 1, 2025.

AbbVie also takes issue with the restrictions included in subsection (a) of the Act—those that prohibit drug manufacturers from (1) "requiring the submission of any health information, claims or utilization data, purchasing data, payment data, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless such data submission is explicitly required by the United States department of health and human services or applicable state law"; (2) requiring a 340B entity to "reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of business and not related to the 340B program"; (3) imposing "requirements relating to inventory management systems of 340B drugs"; (4) imposing "any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities"; (5) imposing "requirements relating to accreditation, recertification, credentialing, or recredentialing that are not imposed on pharmacies or providers that are not 340B entities"; and (6) imposing any other requirement that, as determined by the Attorney General, "interfere[s] with the ability of a 340B entity to access discounts provided under the 340B program." Tenn. Code Ann. § 47-18-136(a)(1)–(6).

***7** According to **AbbVie**, these restrictions prevent drug manufacturers from "collecting basic claims and utilization data from covered entities"—even though the entities are already sharing that data with the contract pharmacies. (Compl. ¶ 111.) By impairing its ability to obtain this "basic claims data," **AbbVie** says, the Act effectively prevents it from accessing the federal audit and dispute resolution process.

It also contends that the Act impermissibly expands the federal definition of a covered entity by defining contract pharmacies as 340B entities, adds requirements to the conditions for participating in the 340B program, compels the transfer of **AbbVie's** property "at confiscatory prices for private use," and allows the Tennessee Attorney General to "seek remedies for alleged violations of the federal 340B requirements." (*Id.* ¶ 113.) It also contends that violations of the Act are characterized as a crime, through the Act's incorporation of the TCPA, and that individual consumers who lose money or property can also bring actions against drug manufacturers to enforce "Tennessee's expansion of the federal 340B program." (*Id.* ¶¶ 115–16.) "Put together," these provisions mean that the Tennessee Attorney General can "use the full extent of his powers to impose severe consequences" on any manufacturer that fails to comply with the Act's restrictions.

Based on these and other allegations (many of which are statements of law rather than fact), **AbbVie** seeks a judicial declaration that the Act is unconstitutional and a permanent injunction barring its enforcement on the basis that: (1) the Act is preempted by federal law, under the Supremacy Clause of the U.S. Constitution, insofar as "[e]very element of the federal 340B program ... is governed by federal law" (Compl. ¶ 140); (2) the Act "appropriates **AbbVie's** property rights in its drugs for the private benefit of for-profit, commercial pharmacies," in violation of the Constitution's Takings and Due Process Clauses (*id.* ¶ 168); (3) the Act violates **AbbVie's** Fourteenth Amendment due process rights because it is unconstitutionally vague on its face and creates the risk of arbitrary enforcement; (4) the Act violates the Dormant Commerce Clause, insofar as it purports to regulate conduct occurring outside the territorial boundaries of the State of Tennessee; and (5) the Act violates **AbbVie's** First Amendment rights to free speech and to petition the government for redress.

The State now moves to dismiss all of **AbbVie's** claims, reprising many of the arguments it raised in opposition to **AbbVie's** Motion for Preliminary Injunction, including that **AbbVie** lacks standing, along with arguments that the complaint fails to state a colorable claim for which relief may be granted. (Doc. No. 47.) **AbbVie** opposes the motion (Doc. No. 52), except in part (as noted in the context of discussing the specific claims). The American Hospital Association, 340B Health, the Tennessee Hospital Association, and the American Society of Health-System Pharmacists ("Amici"), with the court's permission, filed a Brief of Amici Curiae in Opposition to the Plaintiffs' Motion for Preliminary Injunction (Doc. No. 40). The Amici subsequently asked the court to deem their Brief "part of the record in connection with Defendant's now-pending Motion to Dismiss" (Doc. No. 49); the court granted this request as unopposed (Doc. No. 51). The State filed a Reply brief in further support of its motion. (Doc. No. 54.) The court also acknowledges **AbbVie's** Notices of Supplemental Authority (Doc. Nos. 59, 64), and the State's Responses (Doc. Nos. 60, 65).

III. DISCUSSION

A. Standing

***8** Because standing raises the question of the court's jurisdiction, the court must address it first. *See Miller v. Bruenger*, 949 F.3d 986, 990 (6th Cir. 2020) ("Before a federal court takes up a case's merits, it must assure itself of its jurisdiction over the case's subject matter.").

Article III of the Constitution limits the jurisdiction of federal courts to "Cases" and "Controversies." U.S. Const. art. III, § 2, cl. 1. A case or controversy exists only when at least one plaintiff "establish[es] that [she] ha[s] standing to sue." *Murthy v. Missouri*, 603 U.S. 43, 57 (2024) (alterations in original) (quoting *Raines v. Byrd*, 521 U.S. 811, 818 (1997)). To have standing, the plaintiff must show that "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Block v. Canepa*, 74 F.4th 400, 408 (6th Cir. 2023) (quoting *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000)). "These constitutional requirements—commonly known as (1) injury-in-fact, (2) causation, and (3) redressability—apply in every case." *Welty v. Dunaway*, 749 F. Supp. 3d 882, 901 (M.D. Tenn. 2024).

When, as here, a plaintiff challenges a state law prior to the commencement of an enforcement action against him, "whether the plaintiff has standing to sue often turns upon whether he can demonstrate an 'injury in fact.' " *McKay v. Federspiel*, 823 F.3d 862, 867 (6th Cir. 2016) (quoting *Kiser v. Reitz*, 765 F.3d 601, 607 (6th Cir. 2014)). "[A]n allegation of future injury may satisfy the injury-in-fact requirement if the alleged threatened injury is certainly impending, or there is a substantial risk that the harm will occur.' " *Id.* (internal quotation marks omitted) (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)). In this context, "a threat of enforcement is 'sufficiently imminent' to constitute an injury in fact if the plaintiff alleges (1) an intent 'to engage in a course of conduct' arguably 'affected with a constitutional interest,' (2) that this conduct is arguably 'proscribed by a statute,' and (3) that there is 'a credible threat' of the statute's enforcement against the plaintiff." *Christian Healthcare Ctrs., Inc. v. Nessel*, 117 F.4th 826, 843 (6th Cir. 2024) (quoting *Susan B. Anthony List*, 573 U.S. at 159).

The State argues, first, that **AbbVie** cannot establish a credible threat of *criminal* enforcement of the Act, because the Attorney General is not empowered to initiate criminal prosecutions. Indeed, in Tennessee, only District Attorneys—not the Tennessee Attorney General who is the only defendant in this case—can bring criminal charges. *Accord Friends of George's, Inc. v. Mulroy*, 108 F.4th 431, 439 (6th Cir. 2024) ("[A] district attorney general has the sole duty, authority, and discretion to prosecute criminal matters in the State of Tennessee." (quoting *State v. Spradlin*, 12 S.W.3d 432, 433–34 (Tenn. 2000))), *cert. denied*, 145 S. Ct. 1178 (2025). In addition, as the State points out, while criminal charges under the TCPA are technically possible, **AbbVie** does not allege any instance in which any district attorney has brought such criminal charges. **AbbVie** does not respond to this argument, likely because the court already held, in ruling on the Motion for Preliminary Injunction, that **AbbVie** has not alleged a credible fear of enforcement of, and therefore lacks standing to challenge, the criminal enforcement provisions of the TCPA that are incorporated into the Hospital Protection Act. The court reiterates that finding here: **AbbVie** lacks standing to challenge the criminal enforcement provision of the TCPA.

9** Likewise, the court already determined, in addressing the Motion for Preliminary Injunction, that **AbbVie** lacked standing to challenge subsection (c) of the Act, because **AbbVie** cannot show a credible threat of imminent enforcement of that provision against it in light of the grandfather clause, notwithstanding **AbbVie's** speculation about the potential effect of its anticipated modification of its policies to address other states' changing legal landscapes. As this court stated in ***AbbVie *I*,

> [t]he grandfather clause would not apply to new or more stringent restrictions, but simply altering the drugs included in its 340B program ... or limiting the states to which the restriction applies based on courts' enforcement of laws similar to [the Act] in those states (which would have no effect on the restriction in place in Tennessee), would not remove the policy from the protection of the grandfather clause. **AbbVie**, in other words, cannot establish a credible threat of imminent enforcement of [§ 47-18-136(c)] against it.

AbbVie *I*, 2025 WL 1805271, at *9. That holding continues to apply. In other words, **AbbVie** has not established preenforcement standing to challenge subsection (c).

The State continues to argue that **AbbVie** lacks standing to bring its claims regarding the vagueness and extraterritorial reach of the Act, asserting that **AbbVie** offers "only the most threadbare and conclusory assertions about how it might test the law's supposed gray areas" and no allegations at all suggesting that there is a credible threat of enforcement of those provisions by the Attorney General in a way that would "test the limits of his enforcement authority." (Doc. No. 47 at 17.) The State also argues very generally that **AbbVie** has not alleged that it "intends to violate any—much less *every*—provision of the Hospital Protection Act" and that it fails to identify even one Tennessee hospital to which it sells 340B drugs and from which it intends to require "submission of claims data." (Doc. No. 47 at 15.)

Without actually addressing standing or the court's previous opinion, the State appears to acknowledge that **AbbVie** has plausibly alleged that its current policy of limiting the number of contract pharmacies to which it will deliver 340B drugs is proscribed by the Act, but it argues that this policy does not put "every provision of the Hospital Protection Act at

issue"; instead, at most, it "would put the prohibition on delivery restrictions at issue." (*Id.* at 16.) The State argues that it would be more sensible for the court to address the constitutionality of that provision of the Act if and when the Attorney General actually brings an enforcement action against **AbbVie** or another manufacturer. (*Id.*) It also argues that, if **AbbVie** were "limited to litigating the validity of that restriction only, its various theories of obstacle preemption, extraterritorial reach, vagueness, and the right to petition would be irrelevant." (*Id.*) Finally, the State argues that **AbbVie** simply has not established a basis for the "sweeping" declarations and "injunction covering every attempt to ever enforce the Hospital Protection Act." (*Id.* at 17.)

It is true that the Complaint seeks declarations stating that the Act, in its entirety, is unlawful based on the plaintiffs' various theories, and the plaintiffs seek to enjoin the enforcement of the Act in its entirety. (*See* Compl. at 72–73.) The factual allegations in the Complaint, however, do not suggest that **AbbVie** intends to violate every portion of the Act. Still, regarding the Act's subsection (a), **AbbVie's** articulated policies clearly implicate the claims data restrictions set forth in Tenn. Code Ann. § 47-18-136(a)(1), and **AbbVie** clearly pleaded facts indicating that its policies conflict with that provision, as well as, potentially at least, the dispute resolution and audit limitations in subsections (a)(3) and (4). As the court has already stated, "what the Act says is undisputed; **AbbVie** has clearly articulated its policy; [and] while the State has not affirmatively admitted that **AbbVie's** 'current practices violate [the Act],' they obviously do; and it is undisputed that [the Act] was enacted for the purpose of countering policies like **AbbVie's**." ***AbbVie*** *I*, 2025 WL 1805271, at *9. The court finds that **AbbVie** has standing to bring its challenges to at least parts of subsection (a). Whether it states colorable claims is a wholly different question.

B. Substantive Claims

10** As noted above, while the State proceeds as though it were still an active issue, **AbbVie** acknowledges in its Response to the defendant's Motion to Dismiss that the court has already concluded that **AbbVie** lacks standing to challenge Tenn. Code Ann. § 47-18-136(c). (*See* Doc. No. 52 at 19 (recognizing that the court held that "**AbbVie's** contract-pharmacy limitation is exempted from the statute's reach" by the grandfather clause, and "the remainder of the statute's provisions cannot be construed to prohibit the same conduct as subsection (c)." (citing ***AbbVie *I*, 2025 WL 1805271, at *9–10 & n.7)).)

Assuming that that ruling continues to apply, **AbbVie** consents to the dismissal without prejudice of all of its claims that are premised upon the Act's prohibiting **AbbVie's** contract-pharmacy limitations—the very limitations the court found to be permitted by the grandfather clause. The claims implicated by subsection (c) include **AbbVie's** claims under the Takings Clause, field preemption related to prescription pricing and eligibility under the 340B program, and the Dormant Commerce Clause.[7] Because the court's previous determination that **AbbVie** lacks standing to challenge subsection (c) continues to apply, as already discussed above, the claims depending on that subsection will be dismissed without prejudice. This leaves for resolution (1) the Supremacy Clause/preemption claim related to subsection (a) of the Act; (2) the Due Process claim based on vagueness and "unbounded delegation"; and (3) the First Amendment claim premised on the violation of **AbbVie's** right to "petition the government for redress."

1. Preemption Under the Supremacy Clause

"Federalism, central to the constitutional design, adopts the principle that both the National and State Governments have elements of sovereignty the other is bound to respect." *Churchill Downs Tech. Initiatives Co. v. Mich. Gaming Control Bd.*, 162 F.4th 631, 637 (6th Cir. 2025) (quoting *Arizona v. United States*, 567 U.S. 387, 398 (2012)). On the other hand, the Supremacy Clause states that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof ... shall be the supreme Law of the Land ... , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Under the Supremacy Clause, when federal and state laws " 'conflict or [are] at cross-purposes,' ... the Supremacy Clause 'provides a clear rule' that federal law wins out." *Id.* (internal quotation marks omitted) (quoting *Arizona*, 567 U.S. at 399). In other words, federal laws enacted by Congress may preempt state laws. *Id.*

Although the Supremacy Clause does not "include[ ] a private right of action," *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326 (2015), a plaintiff may seek "declaratory or injunctive relief against a state or local government that is presently taking or threatening action against the plaintiff pursuant an allegedly preempted state law," *Chase Bank USA, N.A. v. City of Cleveland*, 695 F.3d 548, 554 n.4 (6th Cir. 2012). There are two types of preemption, both of which

are implicated in this case: field preemption and conflict preemption.

a) Field Preemption

Field preemption is "fundamentally ... a question of congressional intent." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990). It arises "when federal law is so 'pervasive' in one particular field that it exclusively occupies that field." *Torres v. Precision Indus., Inc.*, 995 F.3d 485, 491 (6th Cir. 2021) (quoting *In re Schafer*, 689 F.3d 601, 614 (6th Cir. 2012)). "States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Id.* (quoting *Arizona*, 567 U.S. at 399). However, "[b]ecause preemption can trammel upon state sovereignty, courts apply a 'strong presumption' against implied preemption in fields that States traditionally regulate." *Id.* (quoting *Merrick v. Diageo Ams. Supply, Inc.*, 805 F.3d 685, 694 (6th Cir. 2015)). Specifically, "state or local regulation of matters related to health and safety" are presumed not to be preempted under the Supremacy Clause." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985).

***11** In denying **AbbVie's** Motion for Preliminary Injunction, this court already concluded that **AbbVie** had failed to show that Congress intended to preempt the entire field of drug distribution. In its response to the defendant's Motion to Dismiss, **AbbVie** argues that, at a minimum, § 47-18-136(a)(1) "improperly enters an exclusive federal field by seeking to regulate (and eliminate) a liberty that the 340B statute includes: the ability of manufacturers to include claims data conditions in their 340B offers." (Doc. No. 52 at 16.) As the State points out, this is an entirely different theory of field preemption than the one **AbbVie** raised in moving for a preliminary injunction. Regardless, the court finds that Congress's *silence* on the issue of whether a manufacturer can *require* claims data as a condition of offering drugs to covered entities at the 340B price does not suggest Congress's intent to occupy that "field" exclusively, so field preemption does not apply.

b) Conflict Preemption

Conflict preemption applies if a state law "directly conflict[s]" with federal law—that is, "when compliance with both is impossible, or when ... state law 'stand[s] as an obstacle to the accomplishment' of Congress's objectives." *Churchill Downs*, 162 F.4th at 638 (first quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011); and then quoting *Kansas v. Garcia*, 589 U.S. 191, 210–11 (2020)).

AbbVie raises three distinct arguments for why conflict preemption applies. First, it contends that the Act's prohibition on requiring covered entities to provide claims data "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in the 340B program, insofar as it "prevent[s] **AbbVie** from obtaining basic claims data," and thus "hamstrings **AbbVie's** ability to avail itself of the [340B] Program's enforcement tools." (Doc. No. 52 at 14 (citing § 47-13-146(a)(1)).)

Second, it contends that the state statute directly conflicts with a recently adopted "rebate pilot program" intended to "address concerns about the compliance burdens created by the overlap between the [recently enacted] Inflation Reduction Act's Drug Price Negotiation Program and the 340B Program." (*Id.*)

Third, it argues that the Act's creation of a parallel state enforcement mechanism is an obstacle to the creation of a centralized federal enforcement scheme intended to permit the Executive Branch to "administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." (*Id.* at 16 (quoting *Astra*, 563 U.S. at 120).) **AbbVie** contends that the Act impedes that goal by "bringing questions about the federal statute into a state forum," including such questions as what entities qualify as 340B entities, what qualifies as a "340B drug," "how that price must be made available," and "what constitutes an 'additional requirement[ ] or limitation[ ]' to, or 'interfere[nce]' with, a 340B transaction." (*Id.*)

The court finds that these issues are all largely illusory problems. First, **AbbVie** expressly concedes that "no rule in the 340B Program has ever required covered entities to provide claims data to manufacturers." (Doc. No. 52 at 15.) Because federal law never expressly *required* covered entities to provide claims data, **AbbVie** cannot explain how the state law expressly conflicts with federal law. This is particularly so here, where the state law at issue stipulates that manufacturers may not "require[e] the submission of any ... claims or utilization data ... unless such data submission is explicitly required" by federal or state law. Tenn. Code Ann. § 47-18-136(a)(1).

Regarding **AbbVie's** third argument, it is clear that the 340B program does occupy the field of audits and the enforcement of the 340B program, and federal law defines what entities qualify as covered entities, which drugs are covered, and the pricing scheme that applies to covered drugs purchased by covered entities. *Accord* ***AbbVie**, Inc. v. Murrill*, No. 24-30645, 2026 WL 350685, at *5 (5th Cir. Feb. 9, 2026) (identifying the fields that the 340B program does and does not regulate). But **AbbVie's** contentions that the state law disrupts these areas are wholly speculative. More to the point, the fact that the Act may call upon state regulators (and potentially state courts) to construe terms used in federal statutes and regulations does not suggest preemption. Regardless, the state statute does not set up a parallel enforcement scheme; it provides only for the enforcement of the Tennessee law.

***12** Regarding **AbbVie's** access to the federal enforcement scheme, the Tennessee law only prohibits imposing across-the-board *requirements* relating to "frequency, duration, or scope of audits" that are not imposed on pharmacies and providers not involved in the 340B program, either as contract pharmacies or covered entities. Tenn. Code Ann. § 47-18-136(a)(4). **AbbVie** does not plausibly allege facts suggesting that this requirement in any way interferes with its ability to participate in the federal dispute resolution process or to request audits in accordance with the procedure established by the 340B regulations, as the court explained exhaustively in denying **AbbVie's** Motion for Preliminary Injunction. *See* ***AbbVie** I*, 2025 WL 1805271, at *14–17.

The Fifth Circuit (which has now had two occasions to address state laws in this arena) recently reconfirmed that the 340B regulatory scheme "is not 'so pervasive that Congress left no room for state supplementation.' " *Murrill*, 2026 WL 350685, at *5 (quoting ***AbbVie**, Inc. v. Fitch*, 152 F.4th 635, 646 (5th Cir. 2025)). It defined the areas that 340B "*does* regulate: price ceilings for covered outpatient drugs; eligibility criteria for covered entities; prohibitions on duplicate discounts and diversion; audit and enforcement mechanisms; and the terms governing manufacturers' and wholesalers' sales of discounted drugs to covered entities." *Id.* (citation omitted). And what it "conspicuously does not regulate: 'neither the distribution of drugs to patients nor the role of pharmacies in this distribution.' " *Id.* (quoting *Fitch*, 152 F.4th at 646); *see also id.* at *7 n.61 (noting that the Louisiana statute at issue "does not address the pharmaceutical companies' agreements with HHS or the pricing, diversion, or 'double dipping' restrictions addressed in the HHS[ ] enforcement scheme" (citation omitted)).

The same analysis applies here, and the court finds that **AbbVie's** Complaint fails to state a colorable claim based on either field preemption or conflict preemption under the Supremacy Clause, requiring dismissal of the Complaint's First Claim for Relief.

2. Due Process Claims

The Complaint asserts that the Act violates **AbbVie's** Fourteenth Amendment due process rights because it is unconstitutionally vague on its face and creates the risk of arbitrary enforcement. (*See* Compl. ¶¶ 176–88.) **AbbVie** points specifically to subsections (a)(3) (prohibiting requirements relating to inventory management systems), (a)(4) (prohibiting requirements relating to the "frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities"), and (a)(6) (which contains a catch-all prohibition on "[i]mpos[ing] any requirement determined by the attorney general and reporter to interfere with the ability of a 340B entity to access discounts provided under the 340B program") (*Id.* ¶¶ 179, 180, 182.)

Regarding (a)(6), **AbbVie** contends that this provision impermissibly delegates open-ended enforcement discretion to the Attorney General and leaves manufacturers to "guess what conduct [he] might consider 'interference.' " (*Id.* ¶ 179.) It objects to (a)(3) because the statute does not define "what constitutes a 'requirement' " or explain how it "must 'relate' to an inventory management system, or even what an 'inventory management system' is." (*Id.* ¶ 180.) It objects to (a)(4) because the Act does not define "providers that are not 340B entities" and further contends that, if the term "audit" does not mean the federal audit process, then it is "unconstitutionally vague." (*Id.* ¶ 182.)

"In our constitutional order, a vague law is no law at all." *United States v. Davis*, 588 U.S. 445, 447 (2019). Due process "bars enforcement of 'a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.' " *United States v. Lanier*, 520 U.S. 259, 266 (1997) (quoting *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926)). At the same time, however, the Due Process Clause does not require precision.

See United States v. Theunick, 651 F.3d 578, 585 (6th Cir. 2011) ("[T]he practical necessities of discharging the business of government inevitably limit the specificity with which legislators can spell out prohibitions." (quoting *Boyce Motor Lines v. United States*, 342 U.S. 337, 340 (1952))). Thus, "no more than a reasonable degree of certainty can be demanded. Nor is it unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line." *Boyce Motor Lines*, 342 U.S. at 340.

***13** Regarding subsections (a)(3) and (a)(6), this court already held as follows:

> [T]hese provisions, read in the context of the statute as a whole and considered from the perspective of a reasonable business person—and, more specifically, a reasonable drug manufacturer—provide adequate notice of what conduct is prohibited and do not invite arbitrary enforcement. The Act is targeted at precisely the conduct in which **AbbVie** and other drug manufacturers want to engage in order to limit the expansion of the 340B program. That is, the State seeks to ensure that drug manufacturers do not impose restrictions on covered entities' access to 340B discounted drugs that are not expressly authorized by federal law. The word "requirement" is not ambiguous in this context. It has its ordinary dictionary meaning of "something required," a "necessity," or a condition—that is, "something essential to the existence or occurrence of something else." *Requirement*, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/requirement (last visited June 27, 2025). "Inventory management system," given the context in which it appears, obviously refers to the replenishment model to which **AbbVie** strenuously objects—and to virtually any other inventory system covered entities and contract pharmacies might devise, so long as they are compliant with federal law. Thus, subsection (a)[(3)] prohibits drug manufacturers from imposing any inventory-related conditions upon the delivery of 340B discounted drugs to covered entities.
>
> Similarly, ordinarily intelligent drug manufacturers would not need to guess at the meaning of the term "interfere" as used in subsection (a)(6). As another district court observed in addressing a similar challenge to a similar statute enacted in Mississippi,
>
> > Black's Law Dictionary defines "interference" as "[t]he act or process of obstructing normal operations or intervening or meddling in the affairs of others." Interference, Black's Law Dictionary (11th ed. 2019). [The Mississippi statute] thus prohibits manufacturers from "obstructing [the] normal operations" of, "or intervening or meddling in the affairs" of a contract pharmacy receiving and dispensing 340B drugs to 340B patients.
>
> *Pharm. Rsch. & Mfrs. of Am. v. Fitch*, No. 1:24-CV-160-HSO-BWR, 2024 WL 3277365, at *14 (S.D. Miss. July 1, 2024). As that court concluded:
>
> > The statute plainly requires manufacturers to deliver 340B drugs to contract pharmacies and prohibits manufacturers from obstructing contract pharmacies in their dispensation of 340B drugs. The Court need not determine the precise contours of the statute in every hypothetical application because Plaintiff's "facial challenge may only be sustained if the enactment is impermissibly vague in all of its applications."
>
> *Id.* (quoting *McClelland v. Katy Indep. Sch. Dist.*, 63 F.4th 996, 1013 (5th Cir. 2023), cert. denied, 144 S. Ct. 348, 217 L.Ed.2d 186 (2023), *reh'g denied*, 144 S. Ct. 629 (2024)).

AbbVie I, 2025 WL 1805271, at *21–22; *see also Murrill*, 2026 WL 350685, at *11 (finding that the term "interfere" as used in the Louisiana statute at issue there is not unconstitutionally vague). The court adopts its prior holding here and finds that the Complaint fails to state a void-for-vagueness claim in connection with subsections (a)(3) and (a)(6). [8]

***14** **AbbVie** did not argue for a preliminary injunction in connection with (a)(4), the provision relating to requirements relating to the frequency, duration, or scope of audits, but that provision is not unconstitutionally vague either. The use of the term "audits" is obviously intended, by context, to mean the same thing as "audits" in the 340B regulations, and the term "pharmacies or providers that are not 340B entities," given its ordinary meaning, refers to entities that are not "covered entities." **AbbVie** does not plausibly allege that subsection (a)(4) is so vague that pharmaceutical manufacturers of ordinary sophistication will be left to guess at its meaning.

The Complaint fails to state a Due Process void-for-vagueness claim, and its Third Claim for Relief will be dismissed.

3. First Amendment Claims

The First Amendment protects "the right of the people ... to petition the Government for a redress of grievances." U.S. Const. amend. I. "This right 'extends to all departments of the Government.' " *EJS Props., LLC v. City of Toledo*, 698 F.3d 845, 863 (6th Cir. 2012) (quoting *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972)). "[T]he 'right to petition [is] one of the most precious of the liberties safeguarded by the Bill of Rights.' " *Lozman v. Riviera Beach*, 585 U.S. 87, 101 (2018) (quoting *BE & K Constr. Co. v. NLRB*, 536 U.S. 516, 524 (2002)). "[T]he right allows an ordinary citizen to 'convey[ ] the special concerns of [the petition's] author to the government,' and to 'request[ ] action by the government to address those concerns,' generally without fear of criminal or civil repercussions." *Rudd v. City of Norton Shores*, 977 F.3d 503, 513 (6th Cir. 2020) (alterations in original) (quoting *Borough of Duryea v. Guarnieri*, 564 U.S. 379, 388–89 (2011)).

AbbVie's Complaint asserts that the Act violates **AbbVie's** First Amendment rights to free speech and to petition the government for redress (Doc. No. 1 at 69), but it focuses its arguments on the latter, arguing that the First Amendment protects its right to "engage in targeted, meaningful communication necessary to petition the government for redress, which includes access to the [dispute resolution] process." (Doc. No. 52 at 18.) It asserts that the Act violates that right by effectively barring **AbbVie** from accessing the federal dispute resolution process established by the 340B regulations, which require a "good faith" inquiry prior to seeking HRSA resolution, "and part of that good faith inquiry necessarily requires **AbbVie** to seek clarity on claims from covered entities." (*Id.* at 19.) .

The plain language of the statute refutes **AbbVie's** contentions. In particular, subsection (a)(2) of the Act, from which **AbbVie's** reference to "seeking clarity" is drawn, states that drug manufacturers may not "*[r]equire* a 340B entity to ... clarify a claim after the initial adjudication unless [this] action[ ] [is] in the normal course of business and not related to the 340B program." Tenn. Code Ann. § 47-18-136(a)(2). Similar to the provision on requiring claims data, nothing in the Act prevents **AbbVie** from *requesting* information (as opposed to requiring it), and nothing prevents it from requesting clarity in the "normal course of business." *Id.* **AbbVie's** contention that it will in the future somehow be barred from seeking an audit or accessing the federal dispute resolution process as a result of covered entities' failure to provide information, whether clarity or claims data, requested by **AbbVie** in good faith amounts to nothing more than speculation.[9] **AbbVie** does not plausibly allege that the Act impedes its ability to petition the government.

***15** As the court explained further in denying preliminary injunctive relief,

> For the same reasons propelling the court to reject **AbbVie's** preemption claim rooted in the same allegations, the court finds that [§ 47-18-136(a)] does not obstruct **AbbVie's** right to petition the government by barring its access to the federal ADR system relating to 340B claims. In particular, nothing prevents **AbbVie** from simply requesting claims data or other documentation from covered entities (or pharmacies) or from requesting an audit of a covered entity based upon reasonable cause. A covered entity's failure to comply with a reasonable request—coupled with the articulable facts that gave rise to suspicions of diversion or other prohibited conduct in the first place ... —would be sufficient to establish such reasonable cause. And the plaintiffs have not [alleged concrete] facts suggesting, to the contrary, that the standards for requesting an audit require any particular type of claims data or other documentation from the covered entity.

AbbVie I, 2025 WL 1805271, at *24 (alterations added).

In short, the court finds that the Complaint fails to plausibly allege that the Act violates **AbbVie's** First Amendment right to petition the government. This claim, too, will be dismissed.

IV. CONCLUSION

For the reasons set forth herein, the State's Motion to Dismiss (Doc. No. 47) will be granted. Those claims premised

upon Tenn. Code Ann. § 47-18-136(c), which **AbbVie** lacks standing to challenge in the preenforcement context, will be dismissed without prejudice. This includes **AbbVie's** takings claims, its Supremacy Clause challenge to subsection (c), and its dormant Commerce Clause claim. Its First Amendment, Due Process, and Supremacy Clause challenge related to subsection (a) will be dismissed with prejudice.

An appropriate Order is filed herewith.

All Citations

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Footnotes

1 This background section is taken nearly verbatim from the court's Memorandum denying **AbbVie's** Motion for Preliminary Injunction, ***AbbVie*** *I*, 2025 WL 1805271, at *2–4, with minor revisions.

2 Subsection (b) does not govern the activities of drug manufacturers and is not at issue in this lawsuit.

3 *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (granting Louisiana's cross-motion for summary judgment), *aff'd in relevant part and reversed in part sub nom.* ***AbbVie****, Inc. v. Murrill*, No. 24-30645, 2026 WL 350685 (5th Cir. Feb. 9, 2026); ***AbbVie*** *Inc. v. Fitch*, No. 1:24-CV-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024), *aff'd*, 152 F.4th 635 (5th Cir. 2025) (affirming summary judgment for Louisiana); *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 645 F. Supp. 3d 890 (E.D. Ark. 2022) (denying plaintiff's motion for summary judgment on preemption), *aff'd*, 95 F.4th 1136 (8th Cir.), *pet. for rehearing en banc and by panel denied*, No. 22-3675, 2024 WL 1919676 (8th Cir. May 2, 2024), *cert. denied*, 145 S. Ct. 768 (2024); *AstraZeneca Pharms. LP v. Lopez*, No. 25-00369 MWJS-WRP, 2026 WL 497141 (D. Haw. Feb. 23, 2026) (denying motion for preliminary injunction); *Frey*, 2026 WL 184504 (same), *appeal docketed*, No. 26-1099 (1st Cir. Jan. 28, 2026); ***AbbVie****, Inc. v. Jackley*, No. 3:25-CV-03006-RAL, 2025 WL 3706066 (D.S.D. Dec. 22, 2025) (same); ***AbbVie*** *Inc. v. Hilgers*, No. 4:25-cv-3089, 2025 WL 3688051 (D. Neb. Dec. 19, 2025) (same); *AstraZeneca Pharms. LP v. Weiser*, No. 25-CV-02685-PAB-STV, 2025 WL 3653161 (D. Colo. Dec. 17, 2025) (same), *appeal docketed*, No. 25-1466 (10th Cir. Dec. 22, 2025); ***AbbVie****, Inc. v. Weiser*, No. 25-CV-1847-WJM-KAS, --- F. Supp. 3d ---, 2025 WL 3041825 (D. Colo. Oct. 31, 2025) (same), *appeal docketed*, No. 25-1438 (10th Cir. Nov. 21, 2025); *Novartis Pharms. Corp. v. Frey*, No. 1:25-CV-00407-JCN, 2025 WL 2813787 (D. Me. Sept. 23, 2025) (same), *appeal docketed*, No. 25-1914 (1st Cir. Sept. 26, 2025); ***AbbVie*** *Inc. v.* ***Skrmetti***, No. 3:25-cv-00519, 2025 WL 1805271 (M.D. Tenn. June 30, 2025) (same); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 595189 (W.D. Mo. Feb. 24, 2025) (same), *appeal docketed sub nom. Novartis Pharms. Corp. v. Hanaway*, No. 25-1619 (8th Cir. Mar. 28, 2025); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024) (same), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024).

4 *See* ***AbbVie*** *Inc. v. Drummond*, Nos. CIV-25-726-PRW, 25-727-PRW, 25-1156-PRW, --- F. Supp. 3d ---, 2025 WL 3048929 (W.D. Okla. Oct. 31, 2025) (granting in part drug manufacturers' motions for preliminary injunction in case challenging Oklahoma statute); *Pharm. Rsch. & Mfrs. of Am., Inc. v. Morrisey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024) (granting motions for preliminary injunction in consolidated lawsuits challenging West Virginia statute).

5 ***AbbVie****, Inc. v. Brown*, Nos. 2:25-CV-00271-RJS-DAO, 2:25-cv-00284-RJS-DAO, 2:25-cv-00308-RJS-DAO, --- F. Supp. 3d ---2025 WL 3228898 (D. Utah Nov. 19, 2025) (dismissing claims for violations of the Due Process and Commerce Clauses and denying motions to dismiss claims under the Supremacy Clause and Takings Clause); *Pharm. Rsch. & Manufacturers of Am. v. Bailey*, No. 2:24-cv-04144-MDH, 2025 WL 644281 (W.D. Mo. Feb. 27, 2025) (dismissing claims for violation of the Supremacy Clause based on various theories

of conflict and filed preemption and extraterritorial regulation claims under Contracts Clause, Article IV, and Due Process Clause, but denying motion to dismiss dormant Commerce Clause claim); *AstraZeneca Pharms. LP v. Bailey*, No. 2:24-CV-04143-MDH, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025) (granting motion to dismiss as to preemption and takings claims but denying it as to contract impairment claim); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-CV-04131-MDH, 2025 WL 489881 (W.D. Mo. Feb. 13, 2025) (same).

6 In fact, as explained above, this is not the purpose of the 340B program. Instead, its purpose is to benefit the hospitals serving low-income populations by allowing those entities to "turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount," *Sanofi Aventis*, 58 F.4th at 699, which in turn allows covered entities to continue to provide "safety-net services to the poor," *Astra USA*, 563 U.S. at 113.

7 **AbbVie** offers arguments in support of these claims in case the court finds that it has standing to bring its challenges to subsection (c).

8 ***AbbVie*** *I* mistakenly referred to subsection (a)(4) as containing the prohibition on imposing requirements related to "inventory management systems," when the court intended to refer to (a)(3).

9 The speculative nature of **AbbVie's** claims calls into question its standing to bring the claims in the first place.

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