IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

ABBVIE INC. *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 3:25-cv-00519**
	)	**Judge Aleta A. Trauger**
JONATHAN SKRMETTI, in his official capacity as ATTORNEY GENERAL OF THE STATE OF TENNESSEE,	)	
	)	
Defendant.	)	

MEMORANDUM

Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Pharmacyclics LLC, and Allergan Sales, LLC (collectively "AbbVie" or "plaintiffs") seek to enjoin the enforcement of a recently enacted Tennessee law (the "Act" or "S.B. 1414"), which the defendant, Jonathan Skrmetti, sued in his official capacity as the Attorney General of the State of Tennessee (referred to herein as the "State"), calls the Hospital Protection Act. The Act was signed by Tennessee Governor Bill Lee on May 5, 2025 and went into effect immediately, although some provisions of it are not slated to take effect until July 1, 2025. (*See* Doc. No. 23-1.)[1]

AbbVie characterizes the Act as mandating pharmaceutical manufacturers to sell drugs at discounted prices to commercial pharmacies. (Doc. No. 1, Compl. ¶ 1.) It contends that, in doing so, the Act "impermissibly chang[es] the terms of a federal drug-pricing regime—the federal 340B program—and significantly increase[s] the cost of participation in that regime." (*Id.*) AbbVie challenges the Act as unconstitutional on the grounds that it (1) violates the Supremacy Clause;

[1] The Act is to be codified at Tenn. Code Ann. § 47-18-13. (*See* Doc. No. 23-1, Act § 1.)

(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.*)

Now before the court is AbbVie's Motion for a Preliminary Injunction (Doc. No. 17), through which AbbVie asks the court to preliminarily enjoin the enforcement of the Act. In the Memorandum of Law filed in support of its motion, AbbVie argues, as it did in its Complaint, that the Act is preempted by the federal 340B program, which constitutes a comprehensive regulatory scheme; effects an unconstitutional taking by compelling drug manufacturers to sell drugs to private parties at discounted prices, thus benefitting the private parties at drug manufacturers' expense; is unconstitutionally vague, insofar as it lacks explicit standards and invites arbitrary enforcement; violates the Dormant Commerce Clause by regulating commerce outside the State of Tennessee; and violates the First Amendment by impeding AbbVie's ability to petition the government. (*See generally* Doc. No. 18.)

The State has filed a Response in Opposition to the Motion (Doc. No. 23), and the American Hospital Association, 340B Health, the Tennessee Hospital Association, and the American Society of Health-System Pharmacists ("Amici"), with the court's permission, have filed a Brief of Amici Curiae in Opposition to the Plaintiffs' Motion (Doc. No. 40). The court heard oral argument on the motion on June 20, 2025, during which the parties focused primarily on the issue of the plaintiffs' standing and their preemption and takings claims.[2]

[2] The oral argument did little to clarify the issues and arguments already set forth in the parties' briefs.

Having considered the arguments advanced by both parties and the governing legal standards, the court finds that the plaintiffs have failed to establish a substantial likelihood of success on any of their claims. Accordingly, the plaintiffs' Motion for Preliminary Injunction will be denied.

I. LEGAL STANDARD

A preliminary injunction is "an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). Generally, district courts must balance four factors when considering a motion for preliminary injunction:

> (1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury without the injunction; (3) whether issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of the injunction.

Union Home Mortg. Corp. v. Cromer, 31 F.4th 356, 365–66 (6th Cir. 2022) (quoting *City of Pontiac Retired Emps. Ass'n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (en banc) (per curiam)). These "are factors to be balanced, not prerequisites that must be met." *Hamad v. Woodcrest Condo. Ass'n*, 328 F.3d 224, 230 (6th Cir. 2003) (quoting *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 592 (6th Cir. 2001)). However, where the movant fails to establish either likelihood of success on the merits or irreparable harm if the motion were not granted, "an injunction is unwarranted—regardless of the showing on the other factors." *Union Home Mortg. Corp.*, 31 F.4th at 366 (collecting cases).

II. BACKGROUND

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(b) (defining "covered entity"). 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.

"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)), *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 provisions. *Id.* (citing 52 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).

In 2010, HRSA issued another guidance document, in which it "opined 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.

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, Tennessee, like many other states, has 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. Specifically, in this case, Tennessee enacted S.B. 1414, which provides that, beginning July 1, 2024, drug manufacturers may 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
>
> (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.

S.B. 1414 § 1(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. § 1(c). Subsection 1(c) took effect "immediately upon becoming a law." *Id.* § 4. However, this subsection also contains a "grandfather clause," which provides that this specific subsection "does not apply to any requirements, prohibitions, limitations, or restrictions in place on or before June 1, 2025." *Id.* Subsection 1(a)[3] does not contain a similar grandfathering provision and instead goes into effect on July 1, 2025.

The Act further provides that a violation of subsection (a) or (c) will constitute an "unfair or deceptive act or practice affecting trade or commerce" in violation of the Tennessee Consumer Protection Act and may give rise to a civil penalty of $50,000 "per violation." *Id.* §§ (1)(d)(1), (2).

III. THIS LAWSUIT

AbbVie filed this lawsuit on May 6, 2025, challenging the constitutionality of the Act on multiple fronts and seeking injunctive and declaratory relief only. It contends that the Act "impermissibly changes the terms" of the federal 340B program and "significantly increas[es] the cost of participation in that regime." (Doc. No. 1 ¶ 1.)

It explains 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 and contract pharmacies began adopting a "complicated accounting system known as the 'replenishment model.'" (*Id.* ¶ 6.) Edward Scheidler, AbbVie's Head of the 340B Center of Excellence, explains that, under the "replenishment model," contract

[3] Subsection 1(b) does not govern the activities of drug manufacturers and is not at issue in this lawsuit.

pharmacies typically "purchase AbbVie products for their general inventories at market prices." (Scheidler Decl., Doc. No. 33-2 ¶ 9.) The contract pharmacies then "dispense drugs to 340B and non-340B patients out of their general inventories. . . . In other words, in almost all instances, contract pharmacies order AbbVie-manufactured drugs and dispense them to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient." (*Id.* ¶ 8.)

Once inventory of a particular drug is low enough, having been "dispensed to pharmacy customers, the pharmacy (either itself or through a Third-Party Administrator ['TPA'] with which it contracts) determines which prior dispensing events should be linked with 340B eligibility." (*Id.* ¶ 9.) According to AbbVie, it has no idea how this determination is made or what criteria the contract pharmacies and TPAs use (sometimes working with covered entities) to decide which of the prescriptions previously filled came from covered entities. (*Id.*) Regardless, after the contract pharmacy determines how many of the prescriptions sold from a given quantum of inventory are "340B eligible," "the contract pharmacy (typically through a TPA) instructs the [relevant] covered entity . . . to place an order of additional quantities of that drug at the discounted 340B price to "replenish" the contract pharmacy's inventory of non-340B-discounted drugs." (*Id.* ¶ 10.) However, the covered entity itself typically does not directly place the replenishment order. Instead, according to AbbVie, "the order is typically generated and submitted by the contract pharmacy (either itself or through a TPA) using a third-party covered entity's purchasing account information." (*Id.*)

Further, "[w]hen a contract pharmacy places an order on behalf of a covered entity, AbbVie usually does not ship its 340B-discounted 'replenishment' drugs to the covered entity." (*Id.* ¶ 12.) Instead, although the covered entity makes the purchase, the "replenishment product is shipped

directly from the wholesaler to the contract pharmacy." (*Id.*) In other words, "the wholesaler bills the covered entity but ships to the contract pharmacy." (*Id.*) And, according to AbbVie, "[t]hese shipments of 340B-priced drugs to contract pharmacies are not based on orders needed for specific 340B-eligible patients based on actual or projected future need." (*Id.*)

AbbVie also maintains that covered entities do not actually maintain title to the 340B drugs while they are "held in a contract pharmacy's general inventory prior to being identified, post-sale, as 340B-linked drugs. Instead, as of the time of sale to a patient, a unit of drugs is owned by the contract pharmacy itself." (*Id.* ¶ 13.) But, when the "drug is 'replenished' at the 340B discounted price, that creates a difference between the full price paid by customers at the pharmacy counter and the discounted price AbbVie offers to covered entities, known as 'spread.' The contract pharmacy and covered entity split that spread pursuant to the terms of the agreements between them . . . ." (*Id.* ¶ 14.)

Scheidler provides an illustration of this model, using a hypothetical "Drug A," which he presumes for purposes of his illustration has a commercial price of $100.00 per unit and is subject to a discount rate of 99% under AbbVie's PPA, meaning that it has a 340B discount price of $1.00 and that the difference between the commercial price and the 340B price is $99.00. (*Id.* ¶ 15.) Assume that a contract pharmacy in Nashville—hypothetically, a CVS Pharmacy—orders ten units of Drug A at the commercial price. It pays $100.00 per unit and sells them at $120.00 per unit. The replenishment model then plays out as follows:

> a. Over the next month, ten customers receive prescriptions for Drug A, have them filled at the CVS Pharmacy, and pay $120 per unit either out-of-pocket (*i.e.*, a $25 copayment) or via private insurance coverage for which they pay a premium. The CVS receives, in total[,] $1,200 from the 10 customers who purchased Drug A,

recouping both the initial commercial price and $200 in profit. . . .[4]

b. Later, the TPA of CVS Pharmacy . . . calculates how many of those ten units of Drug A they believe were dispensed to a 340B patient of a specific Covered Entity under contract with that particular CVS location. . . . [T]hese determinations are often not accurate. Their criteria for determining whether a customer was a 340B patient can include factors like the identity of the prescriber or how long ago the patient last received a prescription from a 340B-eligible covered entity. . . .

c. In our example, let us assume that the CVS Pharmacy and its TPA determine five of the ten customers who purchased Drug A were 340B-eligible patients. The CVS Pharmacy and its TPA then notify the covered entity to order five units of Drug A for the CVS Pharmacy to "replenish" the five full-priced units of Drug A that the CVS Pharmacy previously purchased and dispensed to 340B patients.

d. As explained above, those five 340B patients have already paid full price (or their insurer has) for their unit of Drug A at the $120 price. . . .

e. AbbVie or its wholesaler receive[s] the covered entity's order for five units of Drug A and ships them to the CVS Pharmacy in the same package or on the same pallet as commercially-purchased units of Drug A and other drugs being sent to the CVS Pharmacy via a commercial order.

f. There is no way to discern which units of Drug A are the five units sold at the 340B price. They are not packaged differently, labeled differently, or shipped separately or in a different kind of box. . . . Once received by the contract pharmacy, they are placed into the general inventory and dispensed to any customer who walks in the door, 340B-eligible or otherwise. The only difference between a unit of Drug A shipped for "replenishment" and other units of Drug A is the price AbbVie receives for the shipment of its drugs. Placing 340B replenishment orders has no effect on how AbbVie drugs are transported or delivered.

g. The CVS receives the five units of Drug A at the 340B price and, as a matter of accounting, adjusts the previous paid price for those five units down to the cost of the 340B price, $1.00. The CVS then splits the differential, $495, between itself and the covered entity at some percentage. If we assume it is 70/30 in favor of the covered entity, then CVS keeps $148.50 and pays the covered entity $346.50. The patient who paid the full $120 (or their $25 copayment) receives no discount.

(*Id.* ¶ 15(a)–(g).)

[4] AbbVie does not explain what third party pays the remainder when a patient pays only a $25 copayment or how it reaches the $1,200 total based on this math.

According to AbbVie, the use of this type of scheme means that covered entities can contract with "numerous pharmacies—often located hundreds of miles away" and use the 340B discounted prices to "generate profits instead of using them for the benefit of the covered entities' indigent and uninsured patients." (AbbVie Corr. Memo., Doc. No. 33-1 at 11.)[5] The arrangement also allows large, for-profit pharmacies to "obtain massive amounts of manufacturers' drugs for pennies on the dollar, sell them at full price, and split the profits with covered entities." (*Id.*) It also increases the risk of diversion, "since contract pharmacies cannot verify 340B eligibility in real time and dispense from their general inventory rather than from a segregated stock of 340B-priced drugs." (*Id.* at 11–12 (citing, among other exhibits, Doc. No. 33-9 at 4–5, Hr'g Tr. at 59–60, *Pharma. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-cv-997 (W.D. La. June 6, 2024), ECF No. 78).)

In response to the rise of the replenishment model and the *Sanofi Aventis* opinion holding that § 256b is silent about delivery, AbbVie began imposing restrictions designed to prevent covered entities from contracting with numerous contract pharmacies and their use of the replenishment model. Specifically, as relevant here, AbbVie implemented a policy in April 2023 (the "340B Program Integrity Initiative") pursuant to which it would continue to offer any hospital "covered entity" the ability to purchase drugs at the price set by the 340B program but "clarified that it would no longer indiscriminately accept requests to transfer or otherwise ship 340B discounted drugs to an unlimited number of contract pharmacies serving hospital covered entities." (Scheidler Decl. ¶ 4.) Instead, under its current 340B Program Integrity Initiative, AbbVie "facilitates the shipment of orders of 340B-priced medicines to one contract pharmacy location if the hospital covered entity does not have an in-house pharmacy," so long as the hospital covered

[5] The court employs the page numbers assigned by the court's electronic filing system, which is not always consistent with the parties' original pagination.

entity also "submits limited claims data on 340B utilization for that contract pharmacy, and the contract pharmacy is located within 40 miles of the HRSA registered covered entity," or, if there is no eligible pharmacy within 40 miles of the covered entity, AbbVie will ship to a "suitable alternative." (*Id.* ¶ 5; *see also* April 17, 2023 340B Program Integrity Initiative, Doc. No. 34-1 at 27–31.)[6] According to AbbVie, its 340B Program Integrity Initiative "does not limit the ***amount*** of drugs available" and "in no way affects patient access to 340B-discounted drugs." (Doc. No. 33-1 at 13.) Rather, "AbbVie's offer condition merely limits the terms upon which non-covered entity pharmacies can access the ***discounted*** price. . . . AbbVie will not indiscriminately and unconditionally accept requests to transfer 340B-discounted drugs to an unlimited number of commercial contract pharmacies." (*Id.*)

As set forth above, Tennessee, like many other states, responded to initiatives like AbbVie's by passing a law that attempts to do something the 340B statute does not—that is, S.B. 1414 (1) requires drug manufacturers that participate in the federal 340B program to deliver drugs purchased by covered entities at the 340B reduced price to an unlimited number of contract pharmacies and (2) bars manufacturers from conditioning delivery upon the provision of claims data or other documentation, from imposing requirements "relating to inventory management systems of 340B drugs," and from imposing any requirements related to audits that are not imposed on "pharmacies or providers that are not 340B entities." S.B. 1414 § 1(a)(3) & (4). AbbVie describes the Act as "effectively forc[ing] manufacturers to sell their drugs at discounted prices to entities not enumerated in the federal 340B statute, all while prohibiting manufacturers from accessing the federal [alternative dispute resolution ("ADR")] system, their only avenue for

[6] AbbVie has updated the policy several times since April 2023, but largely only to add additional covered drugs and to update the FAQ section of the initiative. (*See* Doc. No. 34-1 at 36–61.)

redress." (Doc. No. 33-1 at 15.)

AbbVie asks the court to preliminarily enjoin enforcement of the Act, arguing that it has shown a strong likelihood of success on the merits of its constitutional challenges to the Act, that it will be irreparably harmed in the absence of an injunction, and that the public interest favors the preservation of the status quo.

IV. DISCUSSION

A. Standing

In response to the plaintiffs' arguments regarding their likelihood of success on the merits of their claims, the State asserts that the case is "plagued by threshold issues" that prevent the court from even reaching the merits of the claims in the first place. (Doc. No. 23 at 15.) The only threshold issue the defendant identifies, however, is standing. 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. The Supreme Court has repeatedly recognized that the "'case or controversy' requirement is 'fundamental to the judiciary's proper role in our system of government.'" *Murthy v. Missouri*, 603 U.S. 43, 56–57 (2024) (some internal quotation marks omitted) (quoting *Raines v. Byrd*, 521 U.S. 811, 818 (1997)). Thus, "[f]ederal courts can only review statutes and executive actions when necessary 'to redress or prevent actual or imminently threatened injury to persons caused by . . . official violation of law." *Id.* at 57 (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 492 (2009)).

A case or controversy exists only when at least one plaintiff "establish[es] that [she] ha[s] standing to sue." *Id.* (quoting *Raines*, 521 U.S. at 818) (alterations in original). "[T]o satisfy Article

III's standing requirements, a plaintiff must show (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).

In the "pre-enforcement context," that is, when a plaintiff challenges a law prior to the commencement of an enforcement 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)). The Supreme Court has recognized that "'[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.* (some internal quotation marks omitted) (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)).

"[D]etermining when the threatened enforcement of a law creates an Article III injury" is a "difficult and 'recurring issue." *Christian Healthcare Ctrs., Inc. v. Nessel*, 117 F.4th 826, 843 (6th Cir. 2024). The Supreme Court and the Sixth Circuit have explained that "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." *Id.* (quoting *Susan B. Anthony List*, 573 U.S. at 159).

In arguing that AbbVie lacks standing, the State focuses on the injury-in-fact element and argues that (1) AbbVie's fears of criminal sanctions ignore the fact that criminal sanctions under the Tennessee Consumer Protection Act ("TCPA") are entrusted to the State's individual *District* Attorneys General, not to Attorney General Skrmetti, and that corporations are unlikely to face criminal sanctions in Tennessee; (2) AbbVie has failed to show with specificity that it intends to engage in a course of conduct that will violate the Act (particularly with respect to its extraterritoriality claim); (3) AbbVie chose to bring suit "mere days" after the enactment of the Act, before Attorney General Skrmetti had the opportunity to "take any position on its scope or even threaten to wield his new enforcement authority," as a result of which AbbVie cannot establish a credible fear of enforcement and, in any event, the TCPA requires the Attorney General to give at least ten days' notice before bringing an enforcement lawsuit (Doc. No. 23 at 18); (4) AbbVie has not identified any individuals who might bring suit against it under the private enforcement provisions of the TCPA, and even if it had, the private enforcement provisions of the TCPA would not "justify this Court's use of equity power against General Skrmetti" (*id.* at 19).

AbbVie replies that it has established standing, and the court agrees, at least in part. First, as AbbVie argues, it has established an "intent to engage in conduct arguably affected with a constitutional interest," *Christian Healthcare Ctrs.*, 117 F.4th at 843—specifically, an intent to continue selling drugs in Tennessee and in interstate commerce, as a participant of the 340B program, *see Dennis v. Higgins*, 498 U.S. 439, 448 (1991) (describing the Commerce Clause as conferring a "'right' to engage in interstate commerce free from restrictive state regulation").

Second, its anticipated conduct is clearly proscribed by statute. AbbVie's written 340B Program Integrity Initiative provides that it will deliver 340B drugs only to covered entities or, if a covered entity does not have an in-house pharmacy, to *one* outside contract pharmacy, and then

only if the covered entity submits certain claims data for that pharmacy. (*See* Doc. No. 34-1 at 27.) This policy is directly at odds with the Act, which prohibits drug manufacturers that participate in the 340B program in Tennessee from placing any limitations on the number or location of the delivery of drugs to contract pharmacies and further prohibits them from imposing any conditions on delivery related to the provision of claims data or inventory management systems. S.B. 1414 § 1(a), (c). The State argues that AbbVie has failed to identify "impending, real-world circumstances in which discrete acts would invite liability." (Doc. No. 23 at 17.) There is no apparent dispute, however, that AbbVie currently sells and distributes drugs to multiple 340B covered entities in Tennessee that "purport to maintain contract pharmacy arrangements." (Compl., Doc. No. 1 ¶ 33.) AbbVie's sales to covered entities in Tennessee are currently governed by its 340B Program Integrity Initiative and will no longer be legal under S.B. 1414.

As for a credible threat of enforcement, the Sixth Circuit typically considers the so-called "*McKay* factors," from *McKay v. Federspiel*, 823 F.3d at 969, to evaluate threats of enforcement. *See Christian Healthcare Ctrs.*, 117 F.4th at 851 (describing the application of the *McKay* factors in pre-enforcement challenges as "settled circuit law" (collecting cases)). These factors include:

> (1) "a history of past enforcement against the plaintiffs or others"; (2) "enforcement warning letters sent to the plaintiffs regarding their specific conduct"; (3) "an attribute of the challenged statute that makes enforcement easier or more likely, such as a provision allowing any member of the public to initiate an enforcement action"; and (4) the "defendant's refusal to disavow enforcement of the challenged statute against a particular plaintiff."

Id. at 848 (quoting *Online Merchs. Guild v. Cameron*, 995 F.3d 540, 550 (6th Cir. 2021)). "These *McKay* factors are not exhaustive, nor must each be established." *Id.* (quoting *Online Merchs. Guild*, 995 F.3d at 550); *see also Fischer v. Thomas*, 52 F.4th 303, 307 (6th Cir. 2022) (noting that the McKay factors are not "a laundry list"). This inquiry "distills to whether 'surrounding factual circumstances' plausibly suggest a credible fear of enforcement." *Id.* (quoting *Universal Life*

Church Monastery Storehouse v. Nabors, 35 F.4th 1021, 1034 (6th Cir. 2022)).

Here, the history of past enforcement—or lack thereof—carries little, if any weight, because the challenged statute is new. *Arizona v. Yellen*, 34 F.4th 841, 850 (9th Cir. 2022) (citation omitted). Likewise, the lack of enforcement warning letters has little bearing, given that the plaintiffs filed suit the day after Governor Bill Lee signed the Act. What the court finds particularly relevant is the fact that the law was evidently passed specifically for the purpose of invalidating policies like AbbVie's 340B Program Integrity Initiative—combined with the fact that there has been ongoing litigation nationwide about the issues raised here for the past several years. The Attorney General certainly has not disavowed an intent to enforce it. While it is true that government officials cannot be required to disavow enforcement of statutes in the *abstract*, here, it does not appear that the defendant would need any "additional fact[s]" to adjudicate a claim against AbbVie under the TCPA, aside from its invoking the policy in its dealings with a covered entity. *Accord Braidwood Mgmt., Inc. v. Equal Emp. Opportunity Comm'n*, 70 F.4th 914, 929 (5th Cir. 2023). Rather, what the Act says is undisputed; AbbVie has clearly articulated its policy; while the State has not affirmatively admitted that AbbVie's "current practices violate [the Act]," they obviously do; and it is undisputed that S.B. 1414 was enacted for the purpose of countering policies like AbbVie's. *Id.* "There is remarkably little else needed to adjudicate the issue[s]." *Id.*

Two matters bear closer consideration, however. First, subsection 1(c) has a grandfather clause that specifically exempts the application of that subsection to "requirements, prohibitions, limitations, or restrictions in place on or before June 1, 2025." S.B. 1414 § 1(c). The grandfather clause does not merely provide a defense; it provides an exception, meaning that the provision effectively does not apply to restrictions already in place as of June 1, 2025. Subsection 1(c) contains the prohibition on restrictions on the delivery of "340B drug[s]" to any location

authorized by a 340B covered entity. The plaintiffs argue that this grandfather clause does not provide it any assurance that § 1(c) will not be enforced against them, because they frequently update their 340B policy. However, the record conclusively establishes that AbbVie implemented its one-pharmacy restriction on its delivery of drugs purchased by 340B covered entities in April 2023, and it has not significantly changed that restriction since. (*See* Doc. No. 34-1 at 27–61.) The grandfather clause would not apply to new or more stringent restrictions, but simply altering the drugs included in its 340B program (*e.g.*, expanding its 340B program) or limiting the states to which the restriction applies based on courts' enforcement of laws similar to S.B. 1414 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 S.B. 1414 § 1(c) against it.

The other parts of S.B. 1414 have no similar grandfather clause, however, and AbbVie's policy of requiring claims data from covered entities that request 340B drug delivery to a contract pharmacy is clearly implicated by one or more provisions of § 1(a), as discussed in greater detail below. With respect to this provision, at least, AbbVie has established its intent to engage in conduct that is proscribed by statute *and* "'a credible threat' of the statute's enforcement against[it]." *Christian Healthcare Ctrs.*, 117 F.4th at 843. The court finds that AbbVie has standing to bring its constitutional challenges to at least some of the provisions in S.B. 1414 § 1(a) (as detailed below).[7]

[7] The broad language used in the statute makes the assessment of what activity is (or is not) subject to the grandfather clause somewhat difficult. For example, subsection 1(c) can be read as prohibiting the imposition of "any restrictions" or other limits on the "acquisition of a 340B drug by . . . a 340B entity . . . unless such receipt is prohibited by" federal law. S.B. 1414 § 1(c). This language could arguably be construed to prohibit conditioning a covered entity's receipt of 340B drugs on the provision of certain claims data, as AbbVie's policy does. If subsection 1(c) is thus construed, however, then subsection 1(a)'s prohibitions on the drug manufacturers' conditioning

The other matter that warrants further discussion is AbbVie's challenge based on the possibility of criminal sanctions. While the TCPA indeed authorizes criminal sanctions, in Tennessee, only District Attorneys—not the Tennessee Attorney General named as a defendant—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). AbbVie has not named the state District Attorneys as defendants; nor has it addressed the likelihood that they ever do or would bring criminal charges under the TCPA. While, as the State points out, it is at least theoretically possible for a corporation to be criminally charged and convicted, *see Louisville & N. R. Co. v. State*, 40 Tenn. (3 Head) 523, 523 (1859), AbbVie has not cited—and this court is unaware—of any instances in which criminal charges were brought against a corporation for violation of the TCPA. AbbVie, that is, has not established a credible fear of enforcement of the criminal sanctions

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delivery of 340B drugs on the provision of claims data or other documentation by the covered entities would be redundant, and it does not appear that either the State or the plaintiffs read subsection 1(c) that broadly. (*See, e.g.*, Doc. No. 23 at 14 ("[T]he Hospital Protection Act prevents drug manufacturers from restricting who can 'receive 340B drugs on behalf of' a 340B Hospital, beyond what is already prohibited by the federal government or 'applicable state law.'" (quoting S.B. 1414 § 1(c)).) Conversely, subsection 1(a)(6) prohibits "[i]mposing 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." AbbVie argued during the hearing that this provision can be read broadly enough to cover the conduct expressly prohibited by subsection 1(c) and asked the court to conclude, as a result, that none of its intended conduct would be covered by the grandfather clause. As the State points out, however, such "catch-all" provisions should not be construed as encompassing express provisions embodied elsewhere in a statute. *Accord RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 646 (2012) ("[G]eneral language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment." (quoting *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932))). To read subsection 1(a)(6) that broadly would make subsection 1(c) redundant, thus "violat[ing] the cardinal rule that, if possible, effect shall be given to every clause and part of a statute." *Id.* (quoting *D. Ginsberg*, 285 U.S. at 208).)

provision against it—and particularly not a credible fear that the named defendant will or is authorized to pursue criminal charges against it. AbbVie therefore lacks standing to challenge the criminal sanctions provision of the TCPA, insofar as it incorporates a violation of S.B. 1414.

In any event, because AbbVie has established standing to challenge S.B. 1414 § 1(a) and the Act's civil enforcement provisions, the court will address the merits of its claims addressed to those portions of the Act.

B. Likelihood of success on the merits

The first preliminary injunction factor requires the moving party to demonstrate a "a strong likelihood of success on the merits." *Overstreet v. Lexington-Fayette Urb. Cnty. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002). This factor is often "determinative." *Wilson v. Williams*, 961 F.3d 829, 837 (6th Cir. 2020) (citation omitted). At this stage, the plaintiffs are not required to "prove [their] case in full"; rather, "[i]t is ordinarily sufficient if the plaintiff has raised questions going to the merits so serious, substantial, difficult, and doubtful as to make them a fair ground for litigation and thus for more deliberate investigation." *Ne. Ohio Coal. for Homeless v. Husted*, 696 F.3d 580, 591 (6th Cir. 2012) (internal quotation marks and citations omitted). This standard, however, is "much more stringent than the proof required to survive a summary judgment motion," which requires only that the plaintiff "create a jury issue." *Leary v. Daeschner*, 228 F.3d 729, 739 (6th Cir. 2000) (citations omitted).

As noted above, AbbVie argues that the Act violates the U.S. Constitution in five distinct ways: (1) it is preempted by federal law; (2) it effects an unconstitutional taking; (3) it is unconstitutionally vague; (4) it offends the dormant Commerce Clause; and (5) it unlawfully burdens AbbVie's First Amendment right to petition the government. It contends that it has a strong likelihood of success on each of these claims. Because AbbVie has standing only to challenge subsection 1(a) of the Act, the court's inquiry focuses on that part of the statute.

1. Preemption

"Article VI of the Constitution provides that the laws of the United States 'shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.'" *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting U.S. Const. art. VI). Under this provision, known as the Supremacy Clause, "state law that conflicts with federal law is 'without effect.'" *Id.* (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)); *see also McClain*, 95 F.4th at 1140 (quoting *Cipollone*, 505 U.S. at 516).

While the Supremacy Clause does not "include[] a private right of action," *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326 (2015), courts have long recognized that "plaintiffs can challenge an allegedly preempted state law in federal court prior to enforcement by asserting a cause of action in equity," *Farmworker Ass'n of Fla., Inc. v. Uthmeier*, No. 23-CV-22655-RAR, 2025 WL 1133682, at *3–4 (S.D. Fla. Apr. 17, 2025). *Accord, e.g.*, *Armstrong*, 575 U.S. at 326–27 (recognizing that equitable relief from the unconstitutional actions of state officers does not depend upon an implied right of action under the Supremacy Clause); *Chase Bank USA, N.A. v. City of Cleveland*, 695 F.3d 548, 554 n.4 (6th Cir. 2012) (noting that the question, at that time (pre-*Armstrong*) of whether the Supremacy Clause created an implied cause of action was a "matter of debate" but that "[e]ven the critics of an implied cause of action" recognize that plaintiffs 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").

Preemption may be either express or implied. *Torres v. Precision Indus., Inc.*, 995 F.3d 485, 491 (6th Cir. 2021). Where, as here, Congress did not "explicit[ly] state its intent to preempt state law, *In re Schafer*, 689 F.3d 601, 614 (6th Cir. 2012), it may "impliedly preempt state law either through 'field' pre-emption or 'conflict' preemption," *McClain*, 95 F.4th at 1140 (citation modified). Field preemption "applies when federal law is so 'pervasive' in one particular field that

it exclusively occupies that field." *Torres*, 995 F.3d at 491 (quoting *In re Schafer*, 689 F.3d at 614). Conflict preemption "applies when federal and state laws conflict in a way that would make compliance with both impossible, or when the state laws 'interfere[] with the operation of the federal program.'" *Id.* (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 604 (2011)). "In either situation, federal law must prevail." *McClain*, 95 F.4th at 1140.

AbbVie argues both that the Act "intrudes on a field of federal regulation—340B pricing—created and occupied by Congress" and that it "directly conflicts with Congress's objections . . . by expanding the number of entities entitled to receive 340B discounted prices, effectively barring manufacturers from accessing the 340B programs' ADR system and installing a parallel state enforcement regime." (Doc. No. 33-1 at 17.) In other words, AbbVie contends that both field preemption and conflict preemption apply.

a) Field Preemption

"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." *Torres*, 995 F.3d at 491 (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)). 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)). The Supreme Court has recognized a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985), *quoted in McClain*, 95 F.4th at 1140.

In support of field preemption, AbbVie argues that the federal 340B program "authorizes *no state regulation* of 340B pricing or entity eligibility to access manufacturers' drugs at 340B discounted prices." (Doc. No. 33-1 at 18.) It contends that, "[b]y prohibiting manufacturers from

denying contract pharmacies access to their drugs at the 340B price, Tennessee is ostensibly demanding that manufacturers provide their drugs to entities not otherwise required by federal law and at a particular price." (*Id.*)

The primary problem with the plaintiffs' position is that neither AbbVie's policy nor S.B. 1414 says anything about the *pricing* of 340B drugs; both entirely concern the *delivery* of 340B drugs. AbbVie seeks to limit the locations to which it is required to deliver 340B drugs and to impose additional requirements whenever its drugs are delivered to an outside pharmacy rather than to a covered entity. Tennessee seeks to restrict drug manufacturers' ability to impose such restrictions on delivery. The Third and D.C. Circuit Courts of Appeal have both held that the 340B statute is "silent about delivery." *Sanofi Aventi*s, 58 F.3d at 703; *Johnson*, 102 F.4th at 461. And the Eighth Circuit, presented with an Arkansas statute similar to S.B. 1414, concluded that "the 340B Program is not 'so pervasive . . . that Congress left no room for the States to supplement it.'" *McClain*, 95 F.4th at 1143 (quoting *Arizona*, 567 US. at 399). The court noted that outside pharmacies "have always been an essential part of the 340B Program" and that the program's "silence" regarding the delivery of drugs to patients "contrasts with 340B's provisions that directly address distribution by third-party wholesalers." *Id.* (citing 42 U.S.C. § 256b(a)(8)). The court held that "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." *Id.* Its conclusion was further bolstered by the fact that "the practice of pharmacy is an area traditionally left to state regulation" and that the court was required to "assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *Id.* at 1143, 1144 (quoting and then citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)).

For the same reasons, this court finds that Congress did not intend to preempt the field. *Accord Pharm. Rsch. & Mfrs. of Am. v. Bailey*, No. 2:24-CV-04144-MDH, 2025 WL 644281, at *5 (W.D. Mo. Feb. 27, 2025) (finding no field preemption based on *McClain*); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657, 665 (S.D. Miss. 2024) (same); *Pharm. Rsch. & Manufacturers of Am. v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *8 (W.D. La. Sept. 30, 2024) (same).

b) Conflict Preemption

As set forth above, conflict preemption may arise "when federal and state laws conflict in a way that would make compliance with both *impossible*, or when the state laws *interfere* with the operation of the federal program." 995 F.3d at 491 (emphasis added) (citation modified). In other words, there are two types of conflict preemption: "direct conflict" (when compliance with both federal and state law is impossible) and "obstacle preemption" (when a state law interferes with—or "stands as an obstacle" to—Congress's objectives). *See Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 452 (S.D.W. Va. 2024). Without specifically distinguishing between them, AbbVie appears to invoke both types. Specifically, it argues that

> (1) S.B. 1414 directly conflicts with the 340B program's "explicit enumeration of covered entities with access to 340B pricing by forcing manufacturers to transfer their drugs at 340B prices to third parties unenumerated in federal law," *i.e.*, to contract pharmacies (Doc. No. 33-1 at 19);
>
> (2) S.B. 1414 directly conflicts with "340B's exclusive federal enforcement scheme by prohibiting manufacturers from demanding claims data from or initiating audits of covered entities or contract pharmacies" (*id.*); and
>
> (3) S.B. 1414 interferes with ("undermines") the "enforcement scheme contemplated by Congress" by "install[ing] its own parallel enforcement regime in the Attorney General and private citizens" (*id.*).

The first conflict preemption argument is directed to S.B. 1414 § 1(c), the provision that, according to the plaintiffs "forc[es] manufacturers to transfer their drugs at 340B prices to third

parties unenumerated in federal law." The court, however, has already found that AbbVie lacks standing to bring this claim, because its policy restricting delivery to contract pharmacies falls directly within the scope of § 1(c)'s grandfather clause. The court, therefore, does not reach the merits of this argument, but will address the other two.[8]

i. S.B. 1414 § 1(a)—Claims Data Provisions

AbbVie's second argument implicates S.B. 1414 § 1(a)(1), (2), and (4). Subsection (a)(1) prohibits drug manufacturers from requiring covered entities or contract pharmacies to submit "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[9] unless such data submission is explicitly required" by federal or state law. Subsection (a)(2)

[8] Numerous other courts, however, have held that similar state laws do not directly conflict with the federal 340B program, and this court would largely agree with their reasoning, if called upon to address the merits of the plaintiffs' preemption argument. *See, e.g.*, *McClain*, 95 F.4th at 1144–45 ("Act 1103 does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B. In arguing otherwise, PhRMA presents no evidence of an obstacle. Instead, PhRMA raises the same arguments it raised with field preemption."); *Murrill*, 2024 WL 4361597, at *8 ("[I]f Section 340B does not address contract pharmacies or the relationship between covered entities and their contract pharmacies, a state statute that specifically addresses contract pharmacies cannot conflict with Section 340B. Put another way, Plaintiffs cannot credibly argue that it is impossible to comply with both Louisiana Act 358 and the federal Section 340B program in light of *Sanofi*."); *Bailey*, 2025 WL 644281, at *5 ("S.B. 751 does not require manufacturers to extend the federal 340B discount to contract pharmacies, it just restricts pharmaceutical companies from infringing on the distribution and delivery of 340B drugs bought by covered entities utilizing the 340B program. S.B. 751 does not set or enforce discount pricing but protects covered entities['] use of contract pharmacies. As such, there is no obstacle to the enforcement of the 340B program."); *AbbVie Inc. v. Fitch*, No. 1:24-CV-184-HSO-BWR, 2024 WL 3503965, at *12 (S.D. Miss. July 22, 2024) ("Plaintiffs do not persuasively show . . . how H.B. 728 creates a substantial obstacle to Section 340B's purposes, or what consideration Congress had in mind in not addressing delivery of 340B drugs.").

[9] The Act defines the term "340B entity" to include both covered entities, as defined by federal law, and "the entity's pharmacy or pharmacies." S.B. 1414 § 1(g)(2). From context, it appears that the "entity's pharmacies" would include both in-house pharmacies and contract pharmacies acting as agents for the covered entity for purposes of distributing 340B drugs. Contrary to AbbVie's arguments elsewhere, S.B. 1414 does not redefine "covered entity," and it

prohibits drug manufacturers from "requir[ing] 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." Subsection 1(a)(4) prohibits the imposition of "any requirement relating to the frequency, duration, or scope of audits that are [sic] not imposed on pharmacies or providers that are not 340B entities."

AbbVie's position regarding these clauses is that Congress specifically "delineated" the "tools and penalties available to the Secretary" for the enforcement of the 340B program's compliance mechanisms and restrictions on covered entities and placed enforcement "exclusively in HRSA's hands." (Doc. No. 33-1 at 20 (citing 42 U.S.C. § 256b(d)(l)(B)(v), (vi), (d)(3)).) Of particular concern to AbbVie is the ADR system. Under regulations adopted by HHS, drug manufacturers may employ the ADR system "only '***after*** the conduct of audits as authorized by' the statute." (*Id.* at 21 (quoting 42 U.S.C. § 256b(d)(3)(A)) (emphasis added by AbbVie)).) According to AbbVie, drug manufacturers cannot access the federal ADR system unless they show "good cause" to obtain the right to an audit, and it will not be able to show the requisite "good cause" unless it is permitted to demand claims data and other documents from covered entities and their contract pharmacies. (*See id.* ("[M]anufacturers have only one avenue available to investigate and enforce suspected abuse of the 340B program—the ADR system—and to access that system, they must be able to provide reasonable cause of suspected violations in the form of claims data. Tennessee's law effectively forecloses the ADR process . . . .").)

More specifically, AbbVie contends that the three provisions referenced above collectively "bar[] manufacturers from demanding the claims data needed to conduct an audit, prohibit[]

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does not require the sale of drugs at the 340B price to contract pharmacies. Rather, it requires manufacturers to deliver 340B drugs purchased by covered entities to contract pharmacies designated by covered entities.

manufacturers from conducting the audits required to access the ADR system, and thwart[] attempts to resolve any potential claims in good faith—all steps required for manufacturers under the federal 340B statute prior to seeking redress through the ADR system." (*Id.* at 22.) Consequently, it argues, "S.B. 1414 'stand[s] as an obstacle' to Section 340B's twin purposes—"providing discounts to covered entities only and prohibiting fraud.'" (*Id.* (quoting *Morrisey*, 760 F. Supp. 3d at 452).)

The State responds to this argument by arguing, somewhat ineffectually, that the Act does not "prevent AbbVie from gathering information about potential diversions" but instead only prevents it from "requiring 340B Hospitals to assume self-auditing burdens" that are "not imposed on other pharmacies or providers." (Doc. No. 23 at 23 (citation modified).) It asserts that AbbVie can obtain claims data and other information "by other means and through other parties" (without identifying such other means or other parties) and that, if it wants to impose requirements related to audits, it can do so for "*all* healthcare 'providers' and 'in the normal course of business.'" (*Id.* quoting S.B. 1414 § 1(a)(2), (4)).) It also argues that, even if the court views these provisions as imposing a "meaningful hurdle to AbbVie's self-help," that alone is not sufficient to find that the statute poses an obstacle to federal enforcement, because, as AbbVie itself recognizes, Congress vested the executive branch with "exclusive authority to protect the 340B program's integrity." (*Id.* (citation modified).)

More persuasively, the Brief of Amici Curiae points out that nothing in S.B. 1414 prevents manufacturers from *asking* for needed information about disputed drug reimbursement claims—it simply prevents them from *requiring* it as a condition of providing 340B drugs to a designated contract pharmacy. Amici also assert that, while the ADR guidelines require "reasonable cause" for seeking an audit, this standard is "not overly burdensome" and does not "present any barriers

to a manufacturer's ability to perform an audit of a covered entity." (Doc. No. 40 at 16 (quoting 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 FR 28643-01 ("ADR Rule"), at 28,646 (April 19, 2024)); *see id.* (noting that, in the preceding five years, "HRSA has not denied a request for a manufacturer audit of a covered entity" (citing ADR Rule at 28,646)).) In addition, the "reasonable cause" standard required for requesting an audit is broadly defined to mean "that a reasonable person could believe that a covered entity may have violated [certain provisions of the 340B statute]." (*Id.* (quoting 1996 Guidance at 65,406, 65,409).) Amici further posit that manufacturers "can meet this standard in various ways that require little evidence (and certainly do not require claims data)—for example, by pointing to '[s]ignificant changes in quantities of specific drugs ordered by a covered entity,' or by citing 'complaints from patients/other manufacturers about activities of a covered entity.'" (*Id.* (quoting 1996 Guidance at 65,406).)

The plaintiffs rely heavily on *Morrisey*, an opinion from the Southern District of West Virginia addressing a statutory scheme similar to that at issue here. To the court's knowledge, *Morrisey* stands thus far as the sole judicial opinion ruling in favor of drug manufacturers challenging state laws seeking to limit the manufacturers' ability to impose delivery conditions on 340B drugs. The court there held that, "to fit comfortably within the federal law, a state law must not create an obstacle to [the] twin federal purposes" of the 340B program, which the court identified as "providing discounts to covered entities only and prohibiting fraud through duplicate discounts." 760 F. Supp.3d at 452. It found that West Virginia's "no audits" provision posed "an obstacle to both purposes."[10] *Id.*

[10] The "no-audits" provision in the West Virginia law states that "no manufacturer shall directly or indirectly 'require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless'

In particular, the court observed that the 340B program authorizes drug manufacturers to utilize the ADR system only after first conducting an audit, meaning that the audit "serves as a condition precedent" to the use of the federal ADR system. *Id.* at 453. And it read West Virginia's "no-audit" provision as "clearly restrict[ing] such a condition from being met," insofar as it "restrict[ed] the very method by which data collection is made," thus "frustrat[ing] drug manufacturers' ability to take the initial steps necessary to start the very audit required to access the [ADR] system." *Id.* The court also found insufficient the State's argument in response that the law did not prevent the plaintiffs from requesting or accessing "dispensing data" through "other lawful means," without actually explaining what other lawful means were available to the drug manufacturers, aside from simply requesting the data. *Id.* The court rejected mere "requests" as a meaningful avenue:

> What then happens if a covered entity declines such a request? Defendants offer no alternatives. In fact, given that the No-Audits Provision forbids manufacturers from "indirectly[] requir[ing] a 340B entity to submit claims utilization data," *see* W. Va. Code § 60A-8-6a(b)(2), it seems there is not much recourse available to a manufacturer. Instead, covered entities—who may be engaging in the kind of fraud that the 340B Program's alternative dispute resolution system is meant to prevent—will essentially be the ones determining whether or not they wish to give manufacturers the very data necessary to start such an audit. The 340B Program certainly did not establish a system where the fox guards the hen house. By restricting a practice that the industry utilizes in order to take the first step toward accessing the 340B Program dispute resolution system, S.B. 325 creates an impermissible obstacle to executing the federal program.

Id. at 453. Thus, in short, the court found that the West Virginia statute hampered drug manufacturers' ability to establish the "reasonable cause" necessary to support a request for an audit and, by impeding their ability to conduct an audit, completely obstructed their access to the ADR system. *Id.* The court therefore concluded that the no-audit provision did not simply create

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the data is required to be shared by federal law." *Morrisey*, 760 F. Supp. 3d at 449 (quoting W. Va. Code § 60A-8-6a(b)).

"tension with the federal objectives" but, instead, stood "as an obstacle to achieving the federal objective of preventing fraud in the 340B Program." *Id.* On this basis, the court held that the plaintiffs met their burden of demonstrating a substantial likelihood of success on the merits of their claim that the no-audits provision was preempted by the 340B program.

This court, however, is not bound by *Morrisey* and is not persuaded by its reasoning. First, notably, nothing in the federal program has ever *required* covered entities to provide claims data (or "clarification") or other documentation to drug manufacturers upon demand, yet the ADR system has nonetheless been in place and functioning adequately for many years in the absence of any such requirement. Consequently, a state law that prohibits drug manufacturers from imposing upon covered entities a requirement that they submit claims data or other documentation as a precondition to allowing them to purchase drugs at the 340B discount price does not substantially alter the federal system.

Second, the plaintiffs have not actually shown that they need claims data and the other documentation they purport to need in order either to request an audit or to attempt to resolve a dispute in good faith before proceeding to ADR. As set forth in the 1996 Guidance, only "reasonable cause" is required to support a manufacturer's request for an audit, to "ensure that the audits are performed where there are valid business concerns." 1996 Guidance at 65,406. "Reasonable cause" is not precisely defined, but the plaintiffs have not provided any evidence that the provision of claims data is necessary to establish such reasonable cause. Rather, according to HRSA, "[s]ignificant changes in quantities of specific drugs ordered by a covered entity" or "complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause." *Id.* In other words, if a manufacturer has an articulable basis for suspecting that a covered entity is engaging in prohibited conduct, it likely will have reasonable

cause to request an audit. And a good faith request by the manufacturer for documents from a covered entity—again, so long as it has an articulable basis for believing that the entity is not in "compliance with the prohibitions against drug diversion and the generation of duplicate drug rebates and discounts with respect to drugs of the manufacturer"—would satisfy its obligation to "attempt in good faith to resolve the matter" before accessing the dispute resolution system. *Id.* at 65,406, 65,410; *see also* 42 C.F.R. § 10.21(b)(4) ("A covered entity or manufacturer filing a claim must provide documentation of good faith efforts, including for example, documentation demonstrating that the initiating party has made attempts to contact the opposing party regarding the specific issues cited in the ADR claim.").

And finally, as Amici also point out, HRSA itself observed in April 2024 that the standards for initiating a manufacturer audit "are *not overly burdensome* [and do not] present any barriers to a manufacturer's ability to perform an audit of a covered entity." ADR Rule at 28,646 (emphasis added). The plaintiffs, in fact, have presented no evidence that they or other drug manufacturers have ever been denied the ability to conduct an audit upon request or that they have been required to submit the kind of claims data they claim to need in order to substantiate a request for an audit. Rather, claims data is more likely to be precisely the documentation that would be reviewed *in the course of conducting an audit*.

In sum, the court finds that the plaintiffs have not established a strong likelihood of success on the merits of their claim that Subsections (a)(1) and (2) are preempted by the 340B program. Regarding Subsection (a)(4), AbbVie has not suggested that its 340B policy contains any provisions relating to audits that would conflict with the state law; nor has it substantiated its argument that this provision actual conflicts with the federal ADR program.

ii. S.B. 1414 § 2—The State's Enforcement Scheme

The Act provides that a violation of § 1(a) or 1(c) constitutes an "unfair or deceptive act or practice affecting trade or commerce" that may entail a civil penalty of $50,000 "per violation." S.B. 1414 § 1(d)(1). "Each package of 340B drugs applicable to a violation . . . constitutes a separate violation." *Id.* § 1(d)(2). In addition, a violation of the Act also constitutes a violation of the TCPA, *id.* § 2, which not only authorizes the Attorney General to bring an investigation and a civil enforcement action, but also permits enforcement actions by private individuals who "suffer[] an ascertainable loss of money or property . . . as a result" of any person's use of a practice described as unfair or deceptive under the TCPA. *See generally* Tenn. Code Ann. § 47-18-109(a)(1). In other words, there is no question that a violation of S.B. 1414 may entail severe penalties.

AbbVie argues that the Supreme Court has confirmed that HHS, acting through HRSA, has sole responsibility for administering and enforcing the 340B program and that Congress provided the "specific enforcement tools and penalties" for doing so. (Doc. No. 33-1 at 23 (citing *Astra USA*, 563 U.S. at 120; 42 U.S.C. § 256b(d)(l)(B)(v), (vi), (d)(3)).) It contends that the Act "contravenes HRSA's exclusive enforcement authority by installing its own parallel enforcement regime" and that it is well established that "[c]onflict is imminent when two separate remedies are brought to bear on the same activity." (Doc. No. 33-1 at 23 (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 380 (2000)) (citation modified).) And AbbVie relies on the holding in *Morrisey* that West Virginia's parallel enforcement scheme undermines "what Congress contemplated when it centralized enforcement [of the 340B program] in the government." (*Id.* (internal quotation marks omitted) (quoting *Morrisey*, 760 F. Supp. 3d at 457 (S.D.W. Va. 2024)).)

McClain addressed a similar argument. The Arkansas statute at issue there "created [an] oversight and enforcement scheme by empowering a state agency to exact penalties on manufacturers who refuse to distribute to contract pharmacies." *McClain*, 95 F.4th at 1144. The court held that this scheme did not conflict with—and was not preempted by—the 340B program, which "addresses discount pricing" and grants HHS jurisdiction over "disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs." *Id.*

In *Morrisey*, on the other hand, the West Virginia court distinguished *McClain* on the grounds that the plaintiffs in the case before it had established that the West Virginia statute, even if it purported to address the delivery of 340B discounted drugs, in reality sought to "operate[] as a means to enforce the 340B ceiling price." *Morrisey*, 760 F. Supp. at 456. It explained this conclusion based on the defendant's acknowledgment of the "replenishment model," discussed above, as the "controlling drug distribution model in West Virginia." *Id.* at 455. The court explained its view that, under this model,

> [b]ecause the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about delivery of the drug. The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one. Put another way, the system is about delivery at a given price, not delivery *per se*.
>
> Price is what distinguishes between an "ordinary drug" and a 340B Program drug—a fact that seems to be reflected in the statute itself. [The plaintiffs assert] that S.B. 325 "has a substantial impact on the types of transactions that trigger the 340B discount under federal law and the volume of discounts manufacturers must offer." That is because "[their] wholesalers and retailers already deliver [their] drug products to contract pharmacies throughout West Virginia," irrespective of the ceiling price it may charge. Thus, a manufacturer risks violating S.B. 325 "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering its drugs to those pharmacies." None of the non-binding authority that Defendants cite as examples of similarly upheld statutes indicates that the replenishment model was considered by those respective courts.

Id. at 455–56 (internal citations omitted). Because *Astra* establishes that "[p]rice regulation is exclusively controlled by the federal statute," the court found that the state's enforcement of its own statute would "necessarily intrude on the federal scheme" and, therefore, that the plaintiffs were likely to succeed on the merits of their claim that the state's enforcement mechanism was preempted. *Id.* at 458.

The court also found that the fact that "differing state and federal adjudications may result" from the state's enforcement mechanism, because adjudication of claims for violation of the state law would necessarily require the state to "make some determinations of federal law." *Id.* Although the defendant argued that a claim of "diversion, which would be adjudicated through the federal dispute resolution system, might operate as a defense to the state's enforcement," the court noted that the state statute did not actually authorize such a defense and that it was more "likely that a drug manufacturer could both restrict distribution at the 340B price because of diversion concerns and be subject to sanction under S.B. 325." *Id.* at 458. The court concluded that "[t]his risk of conflicting results cuts against Congress's vision of 'centralized enforcement'" and that the state enforcement mechanism "present[ed] an obstacle to this centralized purpose." *Id.*

Morrissey's analysis of the potential conflict focused on the replenishment model and the procedure for enforcing the West Virginia provision equivalent to S.B. 1414 § 1(c)—that is, the delivery restrictions that are, as discussed above, unlikely to be enforced against AbbVie in light of the grandfather clause that pertains to the application of § 1(c). This court nonetheless would take issue with *Morrissey*'s characterization of that provision as controlling *price* rather than *delivery*. The Tennessee statute says nothing about price, and, even under the replenishment model, covered entities are the only entities entitled to the 340B discount. Section 1(c), if it applied to AbbVie, would prohibit it from imposing restrictions on where it is willing to *deliver* drugs that

have been purchased by covered entities under the 340B discount. The amount of the discount is not at issue and is not affected by the state scheme.

The claims documentation and audit provisions are also clearly related to delivery rather than price. They restrict drug companies from conditioning the delivery of 340B drugs to a covered entity or any designated outside pharmacy upon the provision of such documentation. They directly implicate AbbVie's policy, which purports to condition delivery to any outside pharmacy upon the submission of certain claims data. Tennessee's enforcement mechanism would be related to the imposition of such *requirements* by a drug company, and the plaintiffs have not articulated how enforcement of that mechanism would in any way interfere with or overlap the federal enforcement procedures related to "disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs." *McClain*, 95 F.4th at 1144. Nor have they suggested how a manufacturer's suspicion of "diversion" of 340B-discounted drugs, *per se*, would constitute a defense to a state claim based on a violation of § 1(a)(1).[11] In other words, the state's system is not about diversion, and fears of diversion would not justify failure to comply with the state law. Enforcement of the penalties and mechanisms for addressing diversion would instead be pursued—entirely separately—through the federal ADR system. The plaintiffs have not shown a substantial likelihood of success on the merits of their claim that the state enforcement mechanism conflicts with, poses an obstacle to, or is preempted by the federal ADR system embodied in the 340B program.

[11] *Morrisey* provides no support for its presumption that the 340B program authorizes drug manufacturers to simply "restrict distribution at the 340B price because of diversion concerns." 760 F. Supp. 3d at 458. Rather, manufacturers apparently must be able to articulate reasonable cause for such concerns, seek an audit, and pursue informal dispute resolution and then resolution of a diversion dispute through ADR, as discussed above.

2. The Takings Clause

The Takings Clause, which is "applicable to the States through the Fourteenth Amendment," *Cedar Point Nursey v. Hassid*, 594 U.S. 139, 147 (2021), provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend. V. The "classic taking [is one] in which the government directly appropriates private property for its own use." *Horne v. Dep't of Agric.*, 576 U.S. 350, 357 (2015) (quoting *Tahoe–Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 324 (2002)). The Takings Clause does not distinguish between personal property and real property. *Id.* at 358. Thus, an appropriation of either type of property "is a *per se* taking that requires just compensation." *Id.*

AbbVie argues that, even if it is not preempted, S.B. 1414 violates the Takings Clause, insofar as it "compels AbbVie and other manufacturers to sell their products at 340B-discounted prices, allowing contract pharmacies and covered entities to reap windfall profits." (Doc. No. 33-1 at 25.) AbbVie's takings theory is that the Act "violates [the] principle" that the government "may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." (*Id.* at 26.) In particular, according to AbbVie, § 1(c) of the Act

> forbids AbbVie from "deny[ing]," "restrict[ing]," "prohibit[ing]," or "otherwise limit[ing]" the "acquisition of a 340B drug by" a "340B entity," including contract pharmacies and any "other location that is under contract with" a 340B entity. Telling manufacturers that they cannot include certain conditions on the sale of their drugs and cannot interfere with the acquisition of their drugs by contract pharmacies is the same as forcing manufacturers to sell their drugs at confiscatory prices under conditions favored by the State. This is not a "public use" recognized in American law.

(*Id.* (quoting S.B. 1414 § 1(c)).)

There are many problems with AbbVie's analogy. First, the State does not require AbbVie to sell its drugs in Tennessee at all; AbbVie voluntarily chooses to participate in Medicare and

Medicaid and to participate in the 340B program as a condition of that choice. Second, the State regulations on delivery do not amount to taking possession of AbbVie's property or conveying it to a third party, and AbbVie's gripe with the whole system is that it does not like the volume of drugs being sold at the 340B discount price. It believes that covered entities' use of contract pharmacies, for inexplicable reasons, increases the quantity of drugs purchased by covered entities at the 340B discount price.

District courts in Mississippi, Louisiana, and Missouri have rejected nearly identical takings challenges, concluding that the laws of those states prohibiting drug manufacturers from limiting or restricting the number of contract pharmacies or locations to which they will deliver 340B-discounted drugs purchased by covered entities do not constitute either a *per se* taking or a regulatory taking and that, even if they did effect a taking, it was a taking for public use, not private use, as a result of which the equitable relief the plaintiffs sought would not be an available remedy. *See AbbVie Inc. v. Fitch*, 2024 WL 3503965, at * 19–20 (denying plaintiffs' preliminary injunction motion); *see also Astrazenca Pharms. LP v. Bailey*, No. 2:24-CV-04143-MDH, 2025 WL 644285, at *5–6 (W.D. Mo. Feb. 27, 2025) (dismissing takings claim); *Murrill*, 2024 WL 4361597, at *15 (granting summary judgment for the State on the plaintiffs' takings claim). These opinions are highly compelling and persuasive but ultimately of little relevance here, again because the court has found that AbbVie lacks standing to challenge the implementation or enforcement of § 1(c).

AbbVie does not argue that the provisions of § 1(a) constitute a taking. The court therefore finds that AbbVie has not established a substantial likelihood of success on its claim that S.B. 1414 effects an unconstitutional taking.

3. The Due Process Clause and Vagueness

AbbVie's Complaint sets forth a claim for relief under the Due Process Clause of the Fourteenth Amendment, based on allegations that §§ 1(a)(3), 1(a)(4), 1(a)(6), and 1(c) are

unconstitutionally vague on their face. (Doc. No. 1 ¶¶ 179–88.) Its Motion for Preliminary Injunction argues perfunctorily that subsections 1(a)(3) and (a)(6) are unconstitutionally vague and that their lack of precision is rendered more egregious by the fact that S.B. 1414 "grants the Tennessee Attorney General *criminal* enforcement authority." (Doc. No. 33-1 at 29.)

The State contends that the statute is not untenably vague, as it provides ample notice of what constitutes a violation, and, even if the language of the Act arguably "leave[s] some wiggle room," the Attorney General is required to give notice of a potential violation before pursuing an enforcement action. (Doc. No. 23 at 17–18.) It also points out that, as discussed above, the Act does not actually give the Attorney General criminal enforcement authority. Rather, both S.B. 1414 and the TCPA give the Attorney General civil enforcement authority only.

If a challenged statute does not implicate First Amendment rights or impose criminal sanctions, a plaintiff "only has standing to challenge its purported vagueness as applied to the facts of her case." *Johnson v. Morales*, 946 F.3d 911, 928–29 (6th Cir. 2020). And in that situation, a statute is unconstitutionally vague only "if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or "if it authorizes or even encourages arbitrary and discriminatory enforcement." *Id.* at 929 (citing *Hill v. Colorado*, 530 U.S. 703, 732 (2000)).

The court has already found that the TCPA does not authorize the Attorney General to bring criminal enforcement proceedings and that, in any event, the plaintiff lacks standing to challenge the criminal enforcement provision, because it has not named the state District Attorneys as defendants; nor has it addressed the likelihood that they ever do or would bring criminal charges under the TCPA. Accordingly, the court finds that the standard articulated in *Johnson* applies, and the plaintiffs have the burden of establishing that people of ordinary intelligence would not

understand what the Act prohibits or showing that the Act authorizes or encourages arbitrary enforcement. In addition, the void-for-vagueness doctrine applies less strictly to economic regulations. *Id.* (citing *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498–99 (1982)). In that context, the standard asks whether a "*business person* of ordinary intelligence would understand" the conduct prohibited. *Hoffman*, 455 U.S. at 501 (emphasis added).

Here, the plaintiffs challenge S.B. 1414 § 1(a)(4) as unconstitutionally vague, insofar as it bars drug manufacturers from "impos[ing] any requirements relating to inventory management systems of 340B drugs, unless such requirement is required by [HHS] or applicable state law." (*See* Doc. No. 33-1 at 28.) They object that this subsection leaves manufacturers to guess the meaning of the terms "requirement," "relate," and "inventory management system." They contend that they could be "exposed to liability for routine supply-chain practices, operational policies, or even basic compliance steps—without any clear way to know whether those practices 'relate' to inventory systems under the statute." (*Id.* at 28–29.)

The plaintiffs also object to the "catch-all" provision in § 1(a)(6), which prohibits "any" conduct that the Attorney General deems to "interfere[] with the ability of a 340B entity to access discounts provided under the 340B program. They argue that this provision "impermissibly delegates open-ended enforcement discretion to a state official and invites 'arbitrary, discriminatory and overzealous enforcement.'" (Doc. No. 33-1 at 28 (quoting *Leonardson v. City of E. Lansing*, 896 F.2d 190, 198 (6th Cir. 1990)).) They further contend that the term "interference" itself is amorphous and utterly lacking in standards, unmoored to any objective criteria.

The court finds that these 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)(4) 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 (2023), *reh'g denied*, 144 S. Ct. 629 (2024)).

The Fourteenth Amendment does not require precision. *See Theunick*, 651 F.3d at 585 ("[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. Under this standard, the court finds that AbbVie has not established a substantial likelihood of success on the merits of its claim that subsections 1(a)(4) and 1(a)(6) are unconstitutionally vague, either because the provisions themselves fail to provide adequate notice of what conduct is prohibited or because they invite arbitrary enforcement.

4. Dormant Commerce Clause

Under the Commerce Clause, Congress has the power "[t]o regulate Commerce with foreign Nations, and among the several States." U.S. Const. art. I, § 8, cl. 3. On its face, the text of the so-called Commerce Clause affirmatively grants Congress the power to "regulate interstate and foreign commerce"; in addition, the Clause has "long been recognized as a self-executing limitation on the power of the States to enact laws imposing substantial burdens on such commerce." *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 644 (6th Cir. 2010) (quoting *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 87 (1984)). The "dormant" Commerce Clause thus "limits the power of states 'to erect barriers against interstate trade.'" *Id.* (quoting *Lewis v. BT Inv.*

Managers, Inc., 447 U.S. 27, 35 (1980)).

The dormant Commerce Clause primarily targets state laws that "discriminate[] against out-of-state goods or nonresident economic actors." *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 588 U.S. 504, 518 (2019); *see also Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 369 (2023) ("[T]his antidiscrimination principle lies at the 'very core' of our dormant Commerce Clause jurisprudence." (citation omitted)). While the Clause also has been construed to invalidate any state law that has "the practical effect of controlling commerce that occurs entirely outside of the state in question," *Int'l Dairy Foods*, 622 F.3d at 644, the Supreme Court has more recently declined to recognize an "'almost *per se*' rule against state laws with 'extraterritorial effects." *Nat'l Pork Prods.*, 598 U.S. at 373, 376; *see id.* at 371 (explaining that its prior decisions that focused on the extraterritorial *effect* of challenged laws were nonetheless motivated by the antidiscrimination principle). Even following *National Pork Products*, however, courts have continued to hold that "a statute [that] has the specific extraterritorial effect of controlling the price of wholly out-of-state transactions" will violate the dormant Commerce Clause. *Ass'n for Accessible Medicines v. Ellison*, No. 24-1019, 2025 WL 1660112, at *3 (8th Cir. June 12, 2025). In addition, the dormant Commerce Clause bars "attempts to give local consumers an advantage over consumers in other States." *N.J. Staffing All. v. Fais*, 110 F.4th 201, 207 (3d Cir. 2024) (quoting *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 580 (1986)).

In this case, AbbVie contends only that S.B. 1414 impermissibly burdens out-of-state commerce. In support of this claim, AbbVie argues, in two brief paragraphs, that (1) Tennessee courts decline to apply a presumption against extraterritoriality when interpreting Tennessee statutes; (2) S.B. 1414 includes no express language indicating the legislature's intent to limit its scope to intrastate commerce; and (3) by its plain terms, the Act "prohibits *any* manufacturer across

the country from imposing conditions on transactions between itself and *any* covered entity, pharmacy, or 'other location' authorized by the covered entity across the country, regardless of that manufacturer's or entity's connections to Tennessee." (Doc. No. 33-1 at 30.) According to AbbVie, the "practical effect" of the statute is to "directly control[] commerce occurring wholly outside [the state's] boundaries," making the law unconstitutional, irrespective of the legislature's actual intent. (*Id.* (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989); *Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 373 (6th Cir. 2013)).)

But, according to *National Pork Products*, the dormant Commerce Clause does not prohibit laws solely because they have extraterritorial reach, absent protectionist intent or effect. 598 U.S. at 373. AbbVie has not alleged either. Moreover, aside from that problem, AbbVie's initial premise is incorrect, as a result of which the argument collapses under its own weight. Tennessee *does*, and has for more than one hundred years, applied a presumption against extraterritoriality. The single case AbbVie cites to the contrary, *Freeman Industries, LLC v. Eastman Chemical Co.*, 172 S.W.3d 512 (Tenn. 2005), did not expressly address extraterritoriality and has not been subsequently construed by any Tennessee court as overruling more than a century of controlling precedent on the topic.

In *Freeman Industries*, the Tennessee Supreme Court was presented with the question of whether an indirect purchaser could bring an action under the Tennessee Trade Practices Act ("TPPA") against defendants involved in a price-fixing scheme. The court answered that question in the affirmative and held that an indirect purchaser could bring suit under the TPPA, even if he was not a resident of the state. *Freeman Indus.*, 172 S.W.3d at 520. Then, to determine whether the conduct at issue fell within the scope of the TPPA, the court applied a "substantial effects" standard, requiring courts to decide "whether the alleged anticompetitive conduct affects

Tennessee trade or commerce to a substantial degree." *Id.* at 522–23. It ultimately held that the plaintiff "fail[ed] to establish how the defendants' anticompetitive conduct affected Tennessee commerce to a substantial degree." *Id.* at 524.

However, as the Tennessee Court of Appeals explained in a very recent opinion, although "[n]othing in the [*Freeman Industries*] opinion mentions extraterritoriality," a 2020 law review article identified Tennessee as "among the states that have 'rejected a presumption against extraterritoriality,' even though 'there are older cases articulating a presumption against extraterritoriality.'" *Renel v. Drexel Chem. Co.*, No. W2023-01693-COA-R3-CV, 2025 WL 1604377, at *7 n.7 (Tenn. Ct. App. June 6, 2025) (quoting William S. Dodge, *Presumptions Against Extraterritoriality in State Law*, 53 U.C. Davis L. Rev. 1389, 1417–18, 1451 (2020)). In *Drexel*, the court expressly "decline[d] to interpret the [Tennessee Supreme] Court's silence in the same manner," citing numerous cases standing for the propositions that (1) silence on an issue should not be construed as overruling prior "unequivocal statements," *id.*, and (2) "Tennessee courts have repeatedly recognized the principle of extraterritoriality," pursuant to which courts presume that "[a] local statute has no extraterritorial force, and can be exercised only upon persons and property within the jurisdiction of the state where such statute is enacted," *id.* at *4 (quoting *Kirkland v. Calhoun*, 248 S.W. 302, 304 (Tenn. 1923), and collecting cases). The court also concluded that, to rebut the presumption against extraterritorial application, the statute at issue must "contain a clear affirmative indication that it applies extraterritorially." *Id.* at *8. That is, the "pivotal question" under Tennessee law "is whether the statute itself . . . purports to apply extraterritorially." *Id.*

Here, the plaintiffs do not contend that S.B. 1414 contains language affirmatively indicating that it is intended to be applied extraterritorially. Instead, they argue that it contains no

language *limiting* its extraterritorial application and therefore must be construed as "sweep[ing] broadly to include covered entities and contract pharmacies without any geographic limitation." (Doc. No. 33-1 at 30.) The court declines to construe the statute to apply extraterritorially. To read it thus would contravene both Tennessee's presumption against extraterritoriality and the "well established" canon of construction "that statutes should be construed to avoid constitutional questions if such a construction is fairly possible." *Boos v. Barry*, 485 U.S. 312, 333 (1988); *see also In re Schafer*, 689 F.3d at 605 ("Where, as here, a statute is challenged as unconstitutional, we construe the statute to avoid constitutional infirmity when fairly possible." (internal quotation marks and citation omitted)).

The plaintiffs have not established a substantial likelihood of success on their dormant Commerce Clause claim.

5. The First Amendment's Petition Clause

The plaintiffs argue that the Petition Clause of the First Amendment protects their "right to meaningfully access the federal government's established 340B dispute-resolution process" and that S.B. 1414 violates that right by "effectively barring" them from accessing that process. (Doc. No. 33-1 at 31 (citing *Holzemer v. City of Memphis*, 621 F.3d 512, 521 (6th Cir. 2010)).) The defendant responds that this argument is nothing more than an "ambitious repackaging" of AbbVie's preemption argument and that, regardless, it fails to state a cognizable claim under the First Amendment.

The First Amendment prohibits state actors from "abridging the freedom of speech . . . or the right of the people . . . to petition the Government for a redress of grievances." U.S. Const. amend. I. "[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)). Thus, for example, such activities as "fil[ing] a citizen complaint" with a police department and "request[ing] public records about that complaint" constitute conduct protected by the Petition Clause. *Id.* at 514.

For the same reasons propelling the court to reject AbbVie's preemption claim rooted in the same allegations, the court finds that S.B. 1414 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, such as, for example, "[s]ignificant changes in quantities of specific drugs ordered by a covered entity" or "complaints from patients/other manufacturers about activities of a covered entity," 1996 Guidance at 65,406—would be sufficient to establish such reasonable cause. And the plaintiffs have not pointed to any 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.

The court finds that the plaintiffs have not established a substantial likelihood of success on the merits of their First Amendment Petition Clause claim.

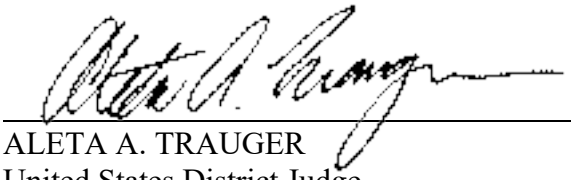
C. Other Elements of Preliminary Injunction Inquiry

As set forth above, if a plaintiff fails to establish a substantial likelihood of success on the merits, the court's inquiry ends, because, without a substantial likelihood of success on the merits,

a plaintiff will not be able to establish a substantial risk of irreparable harm or that the public interest weighs in favor of granting relief. Having concluded that AbbVie has not established a substantial likelihood of success on the merits of any of its constitutional claims, the court does not reach the other factors of the preliminary injunction standard and finds instead that AbbVie's failure to establish a substantial likelihood of success on any of claim is fatal to the Motion for a Preliminary Injunction.

V. CONCLUSION

For the reasons set forth herein, the plaintiffs' Motion for a Preliminary Injunction (Doc. No. 17) will be denied. An appropriate Order is filed herewith.



ALETA A. TRAUGER
United States District Judge