U.S. DISTRICT COURT
DISTRICT OF VERMONT
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UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. JULIE AREL, in her official capacity as Interim Commissioner of Health for the State of Vermont, Defendant.	)	Case No. 2:25-cv-00600

ORDER DENYING PHARMACEUTICAL RESEARCH AND MANUFACTURER'S MOTION FOR PRELIMINARY INJUNCTION AND GRANTING DEFENDANT'S PARTIAL MOTION TO DISMISS
(Doc. 8 and Doc. 21)

Pharmaceutical Research and Manufacturers of America ("Plaintiff" or "PhRMA") brings this action against Julie Arel (the "Commissioner" or "Defendant"), in her official capacity as Interim Commissioner of Health for the State of Vermont, to challenge to constitutionality of Vermont House Bill 266 ("H.B. 266"). (Doc. 1.) On July 29, 2025, Plaintiff moved for a preliminary injunction asking this court to enjoin enforcement of H.B. 266 which will be found in 18 V.S.A., Chapter 91, subchapter 6. (Doc. 8.) On September 2, 2025, the Commissioner moved to dismiss all aspects of the Plaintiff's complaint, except for Plaintiff's preemption claim as to 18 V.S.A. § 4682(d). (Doc. 21.)

On December 29, 2025, the court granted in part the Plaintiff's Motion for Preliminary Injunction as to the enforcement of 18 V.S.A. § 4682(d). (Doc. 55.) Defendant did not oppose a time-limited preliminary injunction as to that section. (Doc. 22 at 12.) On June 12, 2026, Defendant notified the court that the Vermont Legislature repealed Section 4682(d), the one section of the codified law as to which Defendant had neither sought dismissal nor opposed entry

of a time-limited preliminary injunction. (Doc. 57; *see* 2026 Vt. Acts & Resolves, No. 120, § 2 (June 8, 2026) (codified at 18 V.S.A. § 4682).*

Background

Section 340B of the Public Health Service Act requires drug manufacturers who participate in Medicare Part B and Medicaid to sell certain drugs at discounted prices to select healthcare providers known as "covered entities." 42 U.S.C. § 256(b); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455 (D.C. Cir. 2024). Covered entities include Indian health centers, Disproportionate Share Hospitals, which mainly serve low-income patients who are uninsured or enrolled in Medicare and Medicaid, and Ryan White HIV/AIDS program grantees. Health Res. & Servs. Admin., *340B Eligibility: Who Can Participate in the 340B Drug Pricing Program?*, U.S. Dep't of Health & Hum. Servs., https://www.hrsa.gov/opa/eligibility-and-registration [https://perma.cc/GT9Z-XMD5] (last visited Sep. 30, 2026); *see also* Health Res. & Servs. Admin., *Disproportionate Share Hospitals: Eligibility*, U.S. Dep't of Heath & Hum. Servs., https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals [https://perma.cc/J8NA-PATY] (last visited Sep. 30, 2026). Section 340B helps these providers serve low-income and rural patients by allowing them to turn a profit when insurance companies reimburse them for the discounted drugs at full price and by allowing them to provide drugs to uninsured patients "at little or no cost." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023).

The terms of Section 340B require these manufacturers to enter into agreements with the Secretary of Health and Human Services "under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed

* The court understands that Defendant did not move for dismissal of Count I because of this statutory section. Although the court was notified that the statute was repealed, Defendant has not sought dismissal of Count I.

an amount" called the "ceiling price." 42 U.S.C. § 256b(a)(1). After an amendment by the Affordable Care Act, Section 340B further provides that each agreement "shall require that the manufacturer 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." *Id.* "The ceiling price is fixed by a statutory formula strikingly generous to purchasers." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 456 (citing 42 U.S.C. § 256b(a)(2)).

The Health Resources and Services Administration ("HRSA") has issued guidance on "interpreting and implementing" the Section 340B program. *Id.* The initial guidance from 1994 stated "that a covered entity may use a 'purchasing agent.' According to the guidance, manufacturers may ship discounted drugs to this agent, which then must ship them to the covered entity for dispensing to patients." *Id.* (citation omitted). In 1996, HRSA released guidance stating they "recognized that many covered entities use outside pharmacies to distribute drugs to their patients. To accommodate them, HRSA stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Id.* at 457 (citation omitted).

Then, in 2010, HRSA shifted its position and allowed covered entities to begin contracting with an unlimited number of contract pharmacies. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 457. The new guidance allowed the providers to contract with as many outside pharmacies as necessary, "regardless of whether the entities have in-house pharmacies," reasoning that "contract pharmacies enable covered entities to 'create wider patient access by having more inclusive arrangements in their communities.'" *Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 457 (quoting 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010)). "[T]he

outsourcing of pharmacy services has allowed for drug dispensation closer to where low-income patients reside." *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024).

After the issuance of the 2010 guidance, the use of contract pharmacies "increased twentyfold." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th at 700; *see also Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 457 ("The 2010 Guidance prompted a significant expansion in the section 340B program. According to the Government Accountability Office, the number of covered entities participating in the program increased from about 9,700 to 13,000 between 2010 and 2019." (citing GAO Report No. 20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, at 2 (2020)). The number of contract pharmacies participating in the program marked another significant change after the 2010 Guidance was issued. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 457.

The process by which discounted drugs have been distributed has also evolved under the new scheme. *Id.* One common system that has become well-known across the various litigations nationwide is the "replenishment model." Under the replenishment model, the contract pharmacies use a general inventory to fill prescriptions versus maintaining an inventory of 340B drugs. *AbbVie, Inc. v. Brown*, 809 F. Supp. 3d 1341, 1351–52 (D. Utah 2025). The contract pharmacies will then "retroactively determine which prescription sales qualify for 340B discounts." *Id.* at 1352. After a "sufficient number of eligible 340B sales have accumulated, the covered entity orders additional quantities of the relevant drugs at 340B prices to replenish the contract pharmacy's inventory." *Id.* Additionally, once "both [the] drug and patient have left the pharmacy[,]" the contract pharmacy "replaces its distributed drug with a new one ordered by the

covered entity at the 340B price." *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 447 (S.D.W. Va. 2024), *aff'd sub nom. Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, 171 F.4th 675 (4th Cir. 2026), *reh'g en banc granted*, 176 F.4th 830 (4th Cir. 2026).

In 2025, Vermont followed several states that enacted legislation attempting to fill the gap in federal law to ensure covered entities could retain access to the Section 340B financial resources. The Vermont Legislature enacted Vermont House Bill 266 ("H.B. 266"), which states:

> A manufacturer or its agent shall not deny, restrict, prohibit, or otherwise interfere with, directly or indirectly, the acquisition of a 340B drug by or delivery of a 340B drug to a 340B contract pharmacy on behalf of a 340B covered entity unless receipt by the 340B contract pharmacy is prohibited by the U.S. Department of Health and Human Services.

Vt. Stat. Ann. Tit. 18, § 4682(a). H.B. 266 further provides "[a] manufacturer or its agent shall not directly or indirectly require a 340B covered entity to submit any claims, utilization, encounter, purchase, or other data as a condition for allowing the acquisition of a 340B drug by or delivery of a 340B drug to a 340B contract pharmacy" and that "[a] manufacturer or its agent shall not interfere with the ability of a pharmacy contracted with a 340B covered entity to dispense 340B drugs to eligible patients of the 340B covered entity." *Id.* §§ 4682(b)–(c)

The Commissioner of Public Health reports violations of H.B. 266, which can lead to the enforcement of civil penalties. *Id.* § 8. A violation of H.B. 266 can subject manufacturers to a penalty up to $100 for each time a prohibited act is committed, meaning "each package of 340B drugs that is subject to a discriminatory action by a manufacturer or its agent." *Id.* §§ 4684(b), 7. Additionally, a "340B covered entity, 340B contract pharmacy, or other person" who is injured by a manufacturer's violation of H.B. 266 can file a private suit in Superior Court. *Id.* § 4684(a).

Conclusions of Law and Analysis

I. Preliminary Injunction

A. Legal Standard

"A preliminary injunction is an extraordinary remedy never awarded as of right." *JTH Tax, LLC v. Agnant*, 62 F.4th 658, 666–67 (2d Cir. 2023) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008)). "Its purpose 'is merely to preserve the relative positions of the parties until a trial on the merits can be held.'" *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)). A party seeking a preliminary injunction must establish a likelihood of success on the merits, a likelihood of irreparable harm if preliminary relief is not granted, that the "balance of [hardships] tips in the [movant's] favor, and that an injunction is in the public interest." *Daileader v. Certain Underwriters at Lloyds London Syndicate 1861*, 96 F.4th 351, 356 (2d Cir. 2024) (citing *JTH Tax*, 62 F.4th at 667). When the government is the opposing party, the last two factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

B. Likelihood of Success on the Merits

First, a plaintiff must establish a substantial likelihood of prevailing on the merits of their claims. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 650 (2d Cir. 2015). Here, Plaintiff argues that H.B. 266 is preempted under both field and conflict preemption principles. (Doc. 8-10 at 17.) "The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citing U.S. Const. art. VI, cl.2). "Under this principle, Congress has the power to preempt state law." *Id.* In recognition of the "vital underlying system of state law," every

preemption case requires the court to determine whether Congress intended to exercise its "important and sensitive" power. *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 725 F.3d 65, 96 (2d Cir. 2013). States are independent sovereigns and "the historic police powers of the States [are] not to be superseded by [federal law] unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citation modified). The party asserting federal preemption bears the burden of establishing preemption. *MTBE*, 725 F.3d at 96.

There are three instances in which courts should find that Congress intended to preempt state law. These include express preemption, field preemption, and conflict preemption. *MTBE*, 725 F.3d at 96–97. Because there is no argument that Section 340B contains an express statement of intent to preempt state law, only the latter two circumstances are relevant to this action.

1. Field Preemption

Field preemption exists where Congress's "framework of regulation [is] so persuasive that Congress left no room for the States to supplement it," or the "federal interest is so dominant" that the existence of a federal scheme can be "assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. at399 (citation modified). These are "rare cases." *Kansas v. Garcia*, 589 U.S. 191, 208 (2020). The presumption against preemption is particularly strong when the state action falls within a state's historic powers. *MTBE*, 725 F.3d at 96.

Plaintiff argues that H.B. 266 is field preempted because Vermont, through H.B. 266, is "trying to alter . . . the bargained-for consideration of an exclusively federal contract, by requiring drug manufacturers to offer steeply reduced pricing even when the 340B program does not require them to do so." (Doc. 8-10 at 20.) Plaintiff argues Congress intended Section 340B be "administered 'harmoniously and on a uniform, nationwide basis.'" (*Id.* at 19 (quoting *Astra USA,*

Inc. v. Santa Clara Cnty., Cal., 563 U.S. 110, 120 (2011)). Additionally, Plaintiff contends Vermont did not have the power or authorization to impose additional procedures and conditions governing manufacturers' participation in 340B, which is a federal spending power program. (*Id.* at 20.) Defendant counters that Congress' deliberate decision not to address the issue of delivery of drugs and pharmacy distribution indicates the "Section 340B Program is not 'so pervasive that Congress left no room for the States to supplement it." (Doc. 22 at 7 (citation modified)).

In support of its argument, Plaintiff relies on the United States Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County., California.* In *Astra USA, Inc.*, the Supreme Court considered "whether 340B entities, though accorded no right to sue for overcharges under the statute itself, may nonetheless sue allegedly overcharging manufacturers as third-party beneficiaries of the [Pharmaceutical Pricing Agreements] to which the manufacturers subscribed." 563 U.S. at 113. The Supreme Court held Congress had the "vested authority to oversee compliance with the 340B Program in [the U.S. Department of Health and Human Services ("HHS")] and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. The *Astra* Court opined that Congress specifically "opted to strengthen and formalize HRSA's enforcement authority," and specifically "to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA[.]" *Id.* at 121–22 (citations omitted). Importantly, the Court's holding was limited to concluding that 340B entities cannot bring an independent cause of action to enforce ceiling-price contracts entered into by drug manufacturers and the Secretary of HHS. *Id.* at 113.

While Plaintiff reads this holding to mean Congress "intended that the federal agency running Medicare, Medicaid, and 340B—the ["HHS"]—would 'hold the control rein,'" this court disagrees. (Doc. 8-10 at 9 (citation modified.)) The Supreme Court did not discuss preemption,

340B entities' use of contract pharmacies, or drug distribution systems. The legislation adopting and implementing the 340B programs is silent as to the distribution of drugs to patients or the use of contract pharmacies. *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th at 1143–44; *see also Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th at 703–04.

This silence is important in determining whether Congress intended to preempt the state from regulating pharmacy distribution. *See Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th at 1143. In *McClain*, the Eighth Circuit considered Arkansas legislation, Ark. Code Ann. § 23-92-604(c), similar to H.B. 266. The Eighth Circuit concluded that the legislation creating the 340B program did not result in field preemption. This court finds its analysis persuasive:

> Pharmacies have always been an essential part of the 340B Program. Yet, the text of 340B "is silent about delivery" of drugs to patients. *Sanofi Aventis U.S. LLC*, 58 F.4th at 703. This silence contrasts with 340B's provisions that directly address distribution by third-party wholesalers. *See., e.g.*, 42 U.S.C. § 256b(a)(8). Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field.
>
> Furthermore, "the practice of pharmacy is an area traditionally left to state regulation." *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021). Indeed, when it comes to pharmaceuticals, the federal government has "'traditionally regarded state law as a complementary form of drug regulation' and has 'long maintained that state law offers an additional, and important, layer of consumer protection that complements [federal] regulation.'"

Id. at 1143 (citation omitted). Finding that Congress knew the role of pharmacies and state laws, its "silence on pharmacies" meant Congress did not intend to preempt the field. *Id.* at 1144.

This court joins the many district courts and circuit courts that have also held Congress did not intend for Section 340B to preempt the field. *AbbVie Inc. v. Skrmetti*, No. 3:25-cv-00519, 2025 WL 1805271, at *12–13 (M.D. Tenn. June 30, 2025) ("[T]he court was required to 'assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted.' . . . For the same reasons, this court finds that Congress did not intend

to preempt the field." (citations omitted)); *Pharm. Rsch. & Mfrs. of Am. v. Bailey*, No. 2:24-cv-04144, 2025 WL 644281, at *5 (W.D. Mo. Feb. 27, 2025); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657, 662–65 (S.D. Miss. 2024); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131, 2025 WL 489881, at *3–4 (W.D. Mo. Feb. 13, 2025) ("The practice of pharmacy is an area traditionally left to state regulation and that the case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in field of federal interest and has nonetheless decided to stand by both concept and to tolerate whatever tension there is between them." (citation modified)); *Pharm. Rsch. & Mfrs. of Am. v. Weiser*, No. 1:25-cv-02437, 2026 WL 763970, at *5 (D. Colo. Mar. 18, 2026), *appeal dismissed*, No. 26-1086, 2026 WL 2741370 (10th Cir. Sep. 11, 2026) ("Thus, the Eighth Circuit found that Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." (citation modified)).

2. Conflict Preemption

Plaintiff also argues H.B. 266 is preempted by Section 340B under conflict preemption principles. (Doc. 8-10 at 21.) Conflict preemption exists where a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). "[T]he conflict between state law and federal policy must be a 'sharp' one." *Marsh v. Rosenblum*, 499 F.3d 165, 178 (2d Cir. 2007) (citing *Boyle v. United Tech. Corp.*, 487 U.S. 500, 507 (1988)). Establishing conflict preemption is not an easy burden to overcome—the "mere fact of 'tension' between federal and state law is generally not enough to establish an obstacle supporting preemption . . . ." *MTBE*, 725 F.3d at 101–02 (quoting *Madeira v. Affordable Hous. Found., Inc.*, 469 F.3d 219, 241 (2d Cir. 2006)). "[T]he repugnance or conflict" must be "so direct

and positive that the two acts cannot be reconciled or consistently stand together." *Kelly v. State of Washington ex rel. Foss Co.*, 302 U.S. 1, 10 (1937) (citation modified).

In support of its conflict preemption claim, Plaintiff makes three arguments: (1) H.B. 266 impermissibly expands the scope of federal Section 340B obligations; (2) H.B. 266 unlawfully limits access to claims data; and (3) H.B. 266 conflicts with the federal enforcement regime. (Doc. 8-10 at 21, 24, 26.)

a. Scope of 340B Obligations

Plaintiff claims H.B. 266 conflicts with Section 240B because it "unlawfully expands the scope of the federal subsidy by requiring additional 340B-priced transactions." (Doc. 8-10 at 21.) Plaintiff asserts that Congress structured drug manufacturers' obligations under the 340B program to allow manufacturers some control over how they sell 340B-priced drugs, and H.B. 266 interferes or undermines that control. (*Id.*) Plaintiff relies on the United States Court of Appeals for the D.C. Circuit's decision in *Novartis Pharms. Corp.* to support its claim that H.B. 266 reworks and overrules manufacturers' obligations under the 340B program. (*Id.* at 22.)

The D.C. Circuit was asked to decide whether federal statutes creating the 340B program prevented manufacturers from contractually limiting the number of contract pharmacies to which they would send 340B-priced drugs. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 455. The D.C. Circuit held that "[S]ection 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." *Id.* at 464. In so doing, the *Novartis* Court recognized that 340B's implementing statutes are silent regarding distribution of drugs to patients. *Id.* at 460.

Plaintiff argues this holding means that H.B. 266 interferes impermissibly with manufacturers' control over how 340B-priced drugs are sold by "compelling transactions at the

340B price that would not otherwise occur under federal law[.]" (Doc. 8-10 at 24.) H.B. 266 does not compel transactions, however. Similar to the Arkansas law at issue in *McClain*, H.B. 266 "does not require manufacturers to provide 340B pricing discounts to contract pharmacies." *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th at 1145. H.B. 266 "does not set or enforce discount pricing." *Id.*

The relevant question for the court is whether H.B. 266 conflicts with Section 340B's requirement to sell 340B drugs at the statutorily-determined price. H.B. 266 prohibits a manufacturer from preventing or placing limits on a contract pharmacy or a location otherwise authorized by a 340B covered entity from obtaining 340B-priced drugs. This does not conflict with Section 340B's mandate. Instead, H.B. 266 and Section 340B work in tandem to "provide more comprehensive services and reach more eligible patients." *Pharm. Rsch. & Mfrs. of Am. v. Weiser*, 2026 WL 763970, at *6.

b. Access to Claims Data

One provision in H.B. 266 bars manufacturers from "directly or indirectly requir[ing] a 340B covered entity to submit any claims, utilization, encounter, purchase or other data as a condition for allowing the acquisition of a 340B drug by or delivery of 340B drug to a 340B contract pharmacy[.]" Vt. Stat. Ann. tit. 18, § 4682(b). Plaintiff asserts this limitation on the "collection of claims data" is preempted by Section 340B. (Doc. 8-10 at 24.) The statute continues to say: "*unless* the claims or utilization data sharing is required by the U.S. Department of Health and Human Services." Vt. Stat. Ann. tit. 18, § 4682(b) (emphasis added).

Plaintiff submits that manufacturers must audit covered entities prior to filing an alternative dispute resolution ("ADR") claim. (Doc. 8-10 at 25 (citing 42 U.S.C. §§ 256b(a)(5)(C), (d)(3)(B)(iv)). Plaintiff further asserts that conducting such an audit requires manufacturers to

have access to documentation maintained by the covered entity. (*Id.*) Since H.B. 266 restricts manufacturers' ability to receive this data, Plaintiff argues the statute is preempted.

Manufacturers are only authorized to conduct an audit where they "can demonstrate . . . that there is 'reasonable cause,' supported by 'sufficient facts and evidence[.]'" *Eli Lilly & Co. v. Kennedy*, No. 21-cv-02608, 2025 WL 1423630, at *2 (D.D.C. May 15, 2025), *appeal dismissed in part sub nom. Novartis Pharms. Corp. v. Kennedy*, No. 25-5177, 2025 WL 3779095 (D.C. Cir. July 18, 2025), *aff'd sub nom. Novartis Pharms. Corp. v. Kennedy*, 182 F.4th 1027 (D.C. Cir. 2026). The district courts that have ruled on this issue have "found that manufacturers have not demonstrated that the 'reasonable cause' standard is particularly burdensome, or that manufacturers cannot find reasonable cause to perform an audit without requiring claims-data from covered entities or contract pharmacies." *AstraZeneca Pharms. LP, v. Weiser*, No. 25-cv-02685, 2025 WL 3653161, at *10 (D. Colo. Dec. 17, 2025) (citing *AbbVie Inc. v. Skremetti*, 2025 WL 1805271, at *16–16).

In sum, H.B. 266 does not cut off access to claims data completely. It merely precludes the manufacturers from requiring the submission of claims data as a precondition to the acquisition or delivery of a 340B-priced drug. It does not prevent manufacturers from participation in the audit process when the manufacturers have "reasonable cause" to believe that a violation has occurred. H.B. 266 does not create any conflict regarding access to claims data.

c. Federal Enforcement Regime

Plaintiff argues H.B. 266 conflicts "with the exclusive federal administrative and enforcement regime." (Doc. 8-10 at 26.) Plaintiff contends that (1) H.B. 266 "permits private suits in state courts to enforce 340B," while Congress does not; and (2) that H.B. 266 "conflicts with Congress's chosen scheme of exclusive federal oversight for 340B." (*Id.* at 27.)

The Supreme Court held that 340B covered entities cannot file a cause of action directly against drug manufacturers for charging prices that exceed price limits contained in the contract between drug manufacturers and the Secretary of HHS. *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. at 113. The enforcement action authorized by H.B. 266, however, is quite distinct. The actions authorized by H.B. 266 do not authorize enforcement of the discount pricing of the 340B program. Instead, H.B. 266 authorizes a cause of action to protect the distribution and delivery of the drugs. The reasoning of the Eighth Circuit in *McClain* continues to be persuasive.

> PhRMA conflates the two statutes. [The Arkansas law] ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies. The 340B Program, on the other hand, addresses discount pricing. Therefore, HHS has jurisdiction over different disputes: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs.

Pharm. Rsch. & Mfrs. of Am. v. McClain, 95 F.4th at 1144 (citation omitted).

To establish "conflict preemption," Plaintiff bears the heavy burden to demonstrate more than mere tension; the conflict must so direct that the two acts are irreconcilable. Such is not the case here.

Plaintiff contends H.B. 266 is conflicted because the state enforcement mechanism would be forced to confront the federal defenses asserted by the manufacturer. (Doc. 8-10 at 28.) State courts, however, are "competent to apply federal law, to the extent it is relevant." *Link Motion Inc. v. DLA Piper LLP*, 103 F.4th 905, 915 (2d Cir. 2024) (quoting *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 701 (2006)); *see also In re C & M Props., L.L.C.*, 563 F.3d 1156, 1167 (10th Cir. 2009) ("[S]tate courts are regularly and rightly called on to decide questions of federal law, as they have throughout our history.")

Plaintiff has not met its heavy burden of establishing that H.B. 266 is preempted through either field preemption or conflict preemption. Therefore, Plaintiff has not demonstrated a likelihood of success on the merits.

C. Irreparable Harm

A showing of irreparable harm "is the single most important prerequisite for the issuance of a preliminary injunction." *State Farm Mut. Auto. Ins. Co. v. Tri-Borough NY Med. Prac. P.C.*, 120 F.4th 59, 80 (2d Cir. 2024) (citation modified). "To satisfy the irreparable harm requirement, Plaintiffs must demonstrate that absent a preliminary injunction they will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm." *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007) (citation modified). Irreparable harm is an injury "for which a monetary award cannot be adequate compensation." *Tom Doherty Assocs., Inc. v. Saban Ent., Inc.*, 60 F.3d 27, 37 (quoting *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979)).

Plaintiff claims its manufacturer members will suffer irreparable harm in the form of irrecoverable costs from price reductions to time and resources devoted to complying with H.B. 266. (Doc. 8-10 at 30.) The District Court in the Southern District of West Virginia found harm for a West Virginia code, similar to H.B. 266, which subjected violators to a $50,000 penalty for each violation. *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d at 463; *see* W. Va. Code § 60A-8-6a(c)(1)(A), (c)(2). Here, the penalty for each violation amounts to a maximum of $100. Vt. Stat. Ann. tit. 18, § 7. While this is still a monetary inconvenience, Plaintiff provides no evidence to suggest this rises to the level of an irreparable injury.

Further, Plaintiff provides no evidence to demonstrate the "imminent" and "actual" requirement to support a preliminary injunction. Plaintiff contends the manufacturers will have an

"inability to recover millions in 340B price reductions" is not persuasive without a more specificity of the "actual harm." (*See* Doc. 8-10 at 30.) Accordingly, this court finds Plaintiff has failed to establish irreparable harm.

D. Balance of Hardships and Public Interest

Plaintiff's final paragraph argues the "balance of harms and public interest also favor relief" because granting the preliminary injunction "preserves the status quo" with HHS being the regulator of Section 340B in Vermont. (*Id.* at 31.) Defendant responds that enjoining H.B. 266 would prevent filling 340B prescriptions at 340B prices, and therefore harm both healthcare providers and the rural and low-income communities they serve. (Doc. 22 at 16–17.) While the patients themselves do not directly benefit from the Section 340B program, the services the covered entities provide directly serve the community and public interest. *C.f. Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d at 464. Additionally, although Section 340B does not automatically lead to "more access to drugs to participating patients," *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1281 (W.D. Okla. 2025), H.B. 266 supports the mission to maintain services and lowering drug costs by "working in conjunction with Section 340B by allowing contract pharmacies to become an agent of the covered entity and dispense 340B drugs to patients of the covered entity." *Pharm. Rsch. & Mfrs. of Am. v. Weiser*, 2026 WL 763970, at *8.

All factors weigh against imposition of a preliminary injunction. Accordingly, Plaintiff's Motion for Preliminary Injunction is DENIED.

II. Partial Motion to Dismiss

A. Legal Standard

Defendant has also moved under Federal Rule of Civil Procedure 12(b)(6) to dismiss Count II of the Complaint, which argues that H.B. 266 is void for vagueness under the Due Process Clause

of the Fourteenth Amendment. (Doc. 21.) On a motion to dismiss pursuant to Rule 12(b)(6), district courts are to accept as true all factual allegations in the complaint and to draw all reasonable inferences in the plaintiff's favor. *Goldstein v. Pataki*, 516 F.3d 50, 56 (2d Cir. 2008). This requirement, however, does not apply to legal conclusions, bare assertions or conclusory allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Indeed, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Accordingly, a plaintiff is required to support their claims with sufficient factual allegations to show "more than a sheer possibility that a defendant has acted unlawfully." *Id.* "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Twombly*, 550 U.S. at 557 (internal quotation marks omitted)).

B. Void for Vagueness

Plaintiff argues H.B. 266 is unconstitutionally vague because it fails to define the term "interfere." (Doc. 1 at 48–49, ¶ 145.) The statute prohibits drug manufacturers from "interfer[ing] with, directly or indirectly, the acquisition of a 340B drug by or delivery of a 340B drug to a contract pharmacy" or "interfer[ing] with the ability of a pharmacy contracted with a 340B covered entity[.]" (*Id.* at 48, ¶ 144.) In its motion to dismiss, Defendant contends that the legislation provides reasonable drug manufacturers with adequate notice of the scope of prohibited conduct. (Doc. 21-1 at 15.)

The Due Process Clause of the Fourteenth Amendment provides that no state may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. "As one of the most fundamental protections of the Due Process Clause, the void-for-vagueness

doctrine requires that laws be crafted with sufficient clarity to give the person of ordinary intelligence a reasonable opportunity to know what is prohibited and to provide explicit standards for those who apply them." *Thibodeau v. Portuondo*, 486 F.3d 61, 65 (2d Cir. 2007) (citation modified). The critical question is whether the statute conveys "sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices." *Rubin v. Garvin*, 544 F.3d 461, 467 (2d Cir. 2008) (citation modified). The words, however, are not expected to provide precise mathematical boundaries between prohibited and permissible conduct. *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972).

The degree of permissible vagueness varies depending on the type of statute, and the standards for evaluating vagueness should not be "mechanically applied." *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498 (1982). "[E]conomic regulations are subject to a relaxed vagueness test, laws with criminal penalties to a stricter one, and laws that might infringe constitutional rights to the strictest of all." *Rubin*, 544 F.3d at 467. The less stringent standard applicable to economic regulations reflects that "businesses, which face economic demands to plan behavior carefully, can be expect to consult relevant legislation in advance of action . . . [and] may have the ability to clarify the meaning of the regulation by its own inquiry, or by resort to an administrative process." *Hoffman Ests.*, 455 U.S. at 498. To prevail on its vagueness challenge, Plaintiff must demonstrate that H.B. 266 is "impermissibly vague in all of its applications." *Id.* at 495. The statute need not delineate the scope of prohibited conduct with exacting precision.

Plaintiff asserts that the H.B. 266 is subject to a stricter vagueness standard because "the statute implicates speech." (Doc. 39 at 39.) Although Plaintiff cites cases which apply this heightened standard, Plaintiff fails to explain how this statute implicates speech. The statute does not involve restrictions on decency on radio and television. *See F.C.C. v. Fox Television Stations,*

Inc., 567 U.S. 239 (2012). H.B. 266 does not impose criminal liability on the misuse of a flag. *Smith v. Goguen*, 415 U.S. 566 (1974). Plaintiff cites no cases to support its contention H.B. 266's prohibition on drug manufacturers from limiting the use of contract pharmacies by 340B covered entities implicates speech. Instead, Plaintiff puts forth a list of behaviors that it asserts would constitute interference under the statute, including "publicizing information about unlawful transfers or duplicate discounts at specific contract pharmacies or covered entities; auditing covered entities and their records related to contract pharmacies; filing complaints within the federal system; and requesting information from, and clarifying claims made by, covered entities and contract pharmacies." (Doc. 39 at 40.)

As has been found by other courts considering this issue, this court does not find that any of the above-listed behaviors are prohibited by the statute and finds no infringement on Plaintiff's First Amendment rights. *See Pharm. Rsch. & Mfrs. of Am. v. Fitch*, 2024 WL 3277365, *14. Accordingly, the court finds that H.B. 266 is an economic regulation, subject to the less stringent vagueness standard. The question then is whether the statute's use of the term "interfere" or "interference," without additional definition, fail to provide adequate notice of prohibited conduct.

H.B. 266 prohibits a drug manufacturer from interfering with the acquisition or delivery of a 340B drug to a contract pharmacy of a 340B entity and from interfering with the ability of a contract pharmacy to dispense 340B drugs to eligible 340B patients. "Interference" means "the act or process of obstructing normal operations or intervening or meddling in the affairs of others." *See Pharm. Rsch. & Mfrs. of Am. v. Fitch*, 2024 WL 3277365, at *14 (citation modified); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271, at *21. The text of the statute clearly intends to prohibit drug manufacturers from preventing the contract pharmacies of 340B entities from acquiring, delivering, or dispensing 340B-priced drugs to eligible patients.

Even in the context of criminal statutes, the United States Supreme Court has recognized that "few words possess the precision of mathematical symbols, most statutes must deal with untold and unforeseen variations in factual situations, and the practical necessities of discharging the business of government inevitably limit the specificity with which legislators can spell out prohibitions." *Boyce Motor Lines v. United States*, 342 U.S. 337, 340 (1952). The Court further states, "[c]onsequently, no more than a reasonable degree of certainty can be demanded." *Id.* This is even truer in the context of economic regulation governing a business. H.B. 266 provides sufficient notice of prohibited conduct and is not impermissibly vague.

ORDER

The court DENIES Plaintiff's Motion for Preliminary Injunction. (Doc. 8.) The Partial Motion to Dismiss is GRANTED. (Doc. 21.)

DATED at Rutland, in the District of Vermont, this 30th day of September 2026.

Mary Kay Lanthier
United States District Judge