UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

NOVARTIS PHARMACEUTICALS CORP.,	)	
Plaintiff	)	
v.	)	1:25-cv-00407-JCN
AARON FREY,	)	
Defendant	)	

ABBVIE INC., et al.,	)	
Plaintiffs	)	
v.	)	1:25-cv-00416-JCN
AARON FREY, et al.,	)	
Defendants	)	

ORDER ON MOTIONS FOR PRELIMINARY INJUNCTION

In two related cases, Plaintiffs, two pharmaceutical manufacturers and affiliated entities, challenge a Maine statute regarding the role of contract pharmacies within a federal drug discount program. (Complaints, 1:25-cv-00407-JCN, ECF No. 1; 1:25-cv-00416-JCN, ECF No. 1.)[1] Plaintiffs contend that the Maine statute is unconstitutional on multiple grounds: the statute is preempted by federal law, violates the commerce clause, constitutes an improper taking, and is impermissibly vague.

[1] Plaintiffs in case no. 1:25-cv-00416-JCN are AbbVie, Inc., Allergan, Inc., Durata Therapeutics, AbbVie Products LLC, Pharmacyclics LLC, and Allergan Sales, LLC (collectively, "Plaintiff AbbVie or AbbVie").

The matter is before the Court on Plaintiffs' motions for a preliminary injunction. (Motions, 1:25-cv-00407-JCN, ECF No. 17; 1:25-cv-00416-JCN, ECF No. 14.) The State opposes the motions. (Responses, 1:25-cv-00407-JCN, ECF No. 28; 1:25-cv-00416-JCN, ECF No. 27.)

After consideration of the parties' oral and written arguments, and following a review of the record, the Court denies the motions.

FACTUAL AND PROCEDURAL BACKGROUND[2]

A. The 340B Statute

In 1992, Congress created a drug discount program referred to as the 340B program. 42 U.S.C. § 256b. All drug manufacturers who want their drugs to be covered under Medicaid and Medicare Part B must enter into an agreement with the Secretary of Health and Human Services (HHS) to comply with 340B program requirements, including that drug manufacturers must sell covered outpatient drugs to covered entities at or below a ceiling price. *Id.* § 256b(a)(1). Among other provisions, the statute establishes a formula for calculating ceiling prices, *id.* § 256b(a)(2), defines covered drugs, *id.* § 256b(a)(3), (b)(2), and lists the types of healthcare facilities qualifying as covered entities, *id.* § 256(a)(4). The discounts in the program are significant, "typically knocking 20–50% off the drug's sticker price." *Amgen, Inc. v. Kennedy*, No. CV 24-3571 (JEB), 2025 WL 2206948, at *1 (D. D.C. Aug. 4, 2025).

[2] The following facts are derived primarily from public documents amenable to judicial notice and the affidavits and exhibits filed in connection with Plaintiffs' pleadings and motions.

Covered entities are types of facilities that generally provide care to underserved communities. *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011). "The discounts help uninsured patients, who can get cheaper drugs from covered entities. They also help covered entities themselves. The entities can buy drugs at a discount, get reimbursed by insurers for the drug's full price, and pocket the difference." *Amgen*, 2025 WL 2206948, at *1 (citations omitted).[3] Covered entities are prohibited from requesting the 340B discount for drugs that also qualify for a Medicaid rebate (referred to as a double discount), 42 U.S.C. § 256b(a)(5)(A), may not resell or otherwise transfer the discounted drugs to anyone who is not a patient of the covered entity (referred to as diversion), *id.* § 256b(a)(5)(B), and must allow the Secretary and manufacturers to audit their records according to procedures established by the Secretary, *id.* § 256b(a)(5)(C).

If the Secretary finds that a covered entity has engaged in double-discounting or diversion, the entity shall be liable to the manufacturer for the discounts it received improperly. *Id.* § 256b(a)(5)(D). In appropriate cases, the Secretary may also impose sanctions on a covered entity, which sanctions could include interest penalties,

[3] There may be some dispute about the extent to which insured patients benefit from the discount or whether the entire discount is retained by covered entities and others, like third-party administrators, who coordinate with covered entities. An insured patient may not benefit directly from the lower price if their out-of-pocket cost is the same, regardless of whether the drug is eligible for the discount, but there is evidently little or no dispute that some uninsured patients benefit directly and both uninsured and insured patients likely benefit indirectly because one purpose of allowing the covered entity to retain the amount of the discount is that they are able to use the extra funds in service of their patients. *See American Hospital Association v. HHS*, No. 4:20-CV-08806-YGR, 2021 WL 616323, at *1 (N.D. Cal. Feb. 17, 2021) ("covered entities . . . use the discounts to stretch scarce federal resources and serve a greater number of uninsured and under-insured patients"). The expert opinions in the record suggest the parties would dispute the extent of indirect benefits through charitable spending and other services. In any event, resolution of the dispute is not central to Plaintiffs' requests for a preliminary injunction.

disqualification of the entity for a period, and/or reference of the matter to other federal authorities. *Id.* § 256b(d)(2)(B)(v). The Secretary can also impose monetary sanctions on manufacturers for charging more than the ceiling price. *Id.* § 256b(d)(1)(B)(vi).

The 340B program "is superintended by the Health Resources and Services Administration (HRSA)," a sub-agency within HHS. *Astra USA*, 563 U.S. at 113. Several courts, however, have noted that Congress did not grant HHS broad authority to issue regulations. *See, e.g., American Hospital Association v. HHS*, No. 4:20-CV-08806-YGR, 2021 WL 616323, at *7 (N.D. Cal. Feb. 17, 2021). Rather, rulemaking authority is currently limited to "(1) establishment of [an administrative dispute resolution process (ADR)]; (2) drug-pricing methodology; and (3) imposition of monetary sanctions for violations." *Id.* (citing *Pharmaceutical Research & Manufacturers of America v. HHS*, 43 F. Supp. 3d 28, 41-45 (D. D.C. 2014).

B. The Role of Contract Pharmacies

In December 1993, HRSA proposed a guidance notice regarding the 340B program which, as relevant here, specified that a covered entity may enter into a written agreement with a purchasing agent to negotiate contracts or receive drug shipments for distribution to the entity. 58 Fed. Reg. 68922, 68925. In May 1994, HRSA issued a similar final guidance notice. 59 Fed. Reg. 25110, 25113. In response to comments requesting that manufacturers not be required to sell to intermediaries, HRSA advised that covered entities often use purchasing agents or contract pharmacies, and that by placing limitations on sales transactions, manufacturers could be discouraging covered entities from participating in the program.

In November 1995, HRSA proposed a guidance notice regarding the 340B program and contract pharmacy services. 60 Fed. Reg. 55586. In August 1996, HRSA issued a substantially similar final guidance notice. 61 Fed. Reg. 43,549. 43,555–56. The notices encouraged covered entities to sign a contract pharmacy service agreement with a contractor based on model agreement terms to facilitate participation in the 340B program by covered entities that lacked access to in-house pharmacy services. The model agreement terms included a limit for one contractor site and a procedure where the covered entity would purchase the drug, the manufacturer would bill the covered entity, but the drug would be shipped directly to the contract pharmacy. Other terms in the model agreement included a commitment not to divert drugs to individuals who are not patients of a covered entity and to be subject to audits.

In 2001, HRSA established Alternate Methods Demonstration Projects, which, among other things, allowed some covered entities to apply and be approved to use a contract pharmacy to supplement an in-house pharmacy and to use multiple contract pharmacy service sites instead of a single site. 72 Fed. Reg. 1540. In January 2007, HRSA proposed new guidance that would permit all covered entities to use multiple contract pharmacy sites and to use contract pharmacies to supplement an in-house pharmacy. *Id.* at 1541. In March 2010, HRSA issued final guidelines stating that covered entities are not limited to providing in-house or contract pharmacy services at one location. 75 Fed. Red. 10272, 10277–79. In the same month, as part of the Patient Protection and Affordable Care Act, Pub. L. 111–148, 124 Stat. 119 (2010), Congress expanded the 340B program, which expansion provided that "covered entities" would also include hospitals serving isolated

rural areas and added some of the enforcement provisions found in the current version of the statute.

Since 2010, the 340B program has grown significantly. According to Plaintiffs, the number of participating contract pharmacy sites increased from 1,300 in 2010 to more than 33,000 in 2024. Plaintiff AbbVie (AbbVie) asserts that the number of covered entities increased from 15,000 in 2010 to more than 50,000 by 2020. Plaintiffs attribute much of the growth to the unlimited use of contract pharmacies and suggest that some of the growth is a result of improper discount claims.[4]

Covered entities and pharmacies have also shifted away from segregated inventories for 340B drugs and other drugs and toward retroactive methods of claiming and tracking 340B discounts, including a method known as the replenishment model. Plaintiffs contend that the use of multiple contract pharmacies and retroactive accounting methods makes it more difficult to detect diversion and double discounting and increases the risk that diversion, double discounting, and wrongful discount requests will occur.

[4] There is likely some dispute about the extent and causes of this growth. For example, Plaintiff Novartis (Novartis) asserts that total spending in the 340B program was $6.6 billion in 2010 and increased by more than a factor of 10 by 2023, reaching $66.3 billion. AbbVie asserts that by 2024, 340B spending totaled $124 billion. Plaintiffs, however, do not state whether the figures account for other relevant factors, such as changes in the average price of drugs over time, inflation overall during the period, and other changes since 2010, namely the additional categories of covered entities and thus additional patients using drugs obtained through the program. Also, by way of example, AbbVie notes that in some cases covered entities have drugs delivered to pharmacies located more than 100 miles from the covered entity's location, which it evidently believes reflects claims that were not contemplated to be within the scope of the 340B program when it was enacted. Other courts have noted, however, that "some covered entities service large geographic areas and that contract pharmacies assist those providers in serving a dispersed population." *Pharmaceutical Research & Manufacturers of America v. Murrill,* No. 6:23-CV-00997, 2024 WL 4361597, at *1 (W.D. La. Sept. 30, 2024). As with some other matters that might be in dispute, the Court need not resolve the issue at this stage of the litigation.

The replenishment model works as follows: (1) The pharmacy purchases a quantity of a drug at market price and maintains it in common inventory; (2) the pharmacy dispenses drugs from the common inventory whenever a customer arrives with a prescription without regard to whether the customer is a patient of a covered entity; (3) an administrator later reviews claims data to analyze which transactions were for covered drugs to a patient of a covered entity and thus eligible for the discount; and (4) after enough qualifying transactions have occurred, the covered entity orders more units of the drug at the discounted price to replenish the units dispensed to patients of the covered entity.

C. HRSA Prohibition of Manufacturer Limits

In 2020, some manufacturers, including Novartis, began to limit both the number of pharmacies to which they would deliver drugs and the maximum distance between the covered entity and the pharmacy site. Some manufacturers also required covered entities to provide claims data to use contract pharmacies. Novartis initially requested but did not require that covered entities provide claims data.[5]

In December 2020, the HHS Office of the General Counsel issued an advisory opinion stating that the statute unambiguously obligated manufacturers to deliver drugs to contract pharmacies because the statute only required that drugs be purchased by a covered entity and set no other requirements for eligibility. Several manufacturers filed suit challenging the opinion. One district court struck down the advisory opinion under the Administrative Procedure Act, and the Office of the General Counsel withdrew the

[5] AbbVie evidently implemented similar policies later, in 2023.

advisory opinion in June 2021. *See AstraZeneca Pharmaceuticals LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021); *see also*, *Eli Lilly & Co. v. HHS*, No. 1:21-CV-00081-SEB-MJD, 2021 WL 5039566, at *9 (S.D. Ind. Oct. 29, 2021).

HRSA also sent letters to the manufacturers in May 2021 notifying them that by placing contract pharmacy and claims data limitations on covered entities, the manufacturers were in violation of the 340B program. HRSA ordered the manufacturers to sell discounted drugs to covered entities without contractual conditions, including by delivering the drugs to the pharmacies with which the covered entities contracted. The manufacturers again filed suit in several courts to challenge the alleged violations.

Most of the district courts to consider the legality of the violation letters vacated the letters, and two circuit courts ruled in favor of the manufacturers. In *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023), the Third Circuit reasoned that because HRSA had not been granted broad rulemaking authority, because the statute did not mention contract pharmacies or delivery locations, and because the statute "imposes only a price term for drug sales to covered entities, leaving all other terms blank," HRSA could not establish that the manufacturers violated 340B by imposing conditions on requests for delivery to contract pharmacies, which meant "the Violation Letters and Advisory Opinion are unlawful." *Id.* at 703–04, 706. In *Novartis Pharmaceuticals Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024), the D.C. Circuit determined that the district court properly set aside the violation letters because the statute merely requires that a manufacturer offer to sell drugs "at or below a specified monetary amount" and because the statute is "silent about delivery conditions," and "statutory silence implies that private parties may act

freely." *Id.* at 369, 373. The court noted that a manufacturer would likely violate the statute by imposing terms that are "unreasonable" or "onerous enough" to effectively increase the price above the statutory ceiling or fall short of a "bona fide offer," but the manufacturer's conditions were not so burdensome as to violate the statute on its face. *Id.* at 371–73.

D. State Statutes Prohibiting Manufacturer Limits

Approximately twenty states have enacted laws in response to the court decisions finding that HRSA lacked statutory authority to prohibit the manufacturers' policies. While differences exist among the state statutes, they share certain features, including prohibitions on certain manufacturer limits on covered entities and contract pharmacies, as well as alternative remedies for violations of the prohibitions. (*See* Complaint at 42–43, 1:25-cv-00416-JCN, ECF No. 1.) Drug manufacturers filed lawsuits challenging the state statutes and seeking injunctive relief. At least five district courts, either on a motion for preliminary injunction or a motion for summary judgment, largely or entirely denied injunctive relief against the enforcement of the relevant state statute after addressing similar legal claims to those Plaintiffs assert here; on appeal, the Eighth Circuit and Fifth Circuit upheld two of those decisions.[6] At least one district court enjoined enforcement of

[6] *See Pharmaceutical Research & Manufacturers of America v. McClain,* 645 F. Supp. 3d 890 (E.D. Ark. 2022) (denying plaintiff's motion for summary judgment on preemption); *Pharmaceutical Research & Manufacturers of America v. McClain,* 95 F.4th 1136 (8th Cir. 2024) (affirming conclusion that Arkansas statute is not preempted), cert. denied, 145 S. Ct. 768 (2024); *Novartis Pharmaceuticals Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024) (denying plaintiff's motion for preliminary injunction); *AbbVie, Inc., v. Fitch*, No. 24-60375, 2025 WL 2630900 (5th Cir. Sept. 12, 2025) (affirming denial of preliminary injunction); *Pharmaceutical Research & Manufacturers of America v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (denying plaintiffs' motions for summary judgment); *Astrazenca Pharmaceuticals LP v. Bailey*, No. 2:24-CV-04143-MDH, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025) (granting in part defendant's motion to dismiss plaintiff's complaint); *AbbVie Inc. v. Skrmetti*, No. 3:25-

a state statute based on similar arguments to those Plaintiffs raise here.[7] Many other similar cases are pending in other district courts.[8]

On June 20, 2025, Maine enacted a statute entitled the "Protect Health Care for Rural and Underserved Communities Act," which statute goes into effect on September 24, 2025. L.D. 210, Sec. P-5 (132nd Legis. 2025). The statute creates a new "Chapter 103" within the Maine Insurance Code, and includes the following provision:

> **§7753. Prohibition of certain discriminatory actions by manufacturer or agent related to 340B entities**
>
> **1. Interference with acquisition or delivery of 340B drugs prohibited.** A manufacturer or its agent may not deny, restrict, prohibit or otherwise interfere with, either 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 entity unless receipt of that 340B drug is prohibited by the United States Department of Health and Human Services.
>
> **2. Submission of claims or utilization data prohibited.** A manufacturer or its agent may not, either 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

CV-00519, 2025 WL 1805271 (M.D. Tenn. June 30, 2025) (denying plaintiffs' motion for preliminary injunction).

[7] *See Pharmaceutical Research & Manufacturers of America v. Morrisey*, 760 F. Supp. 3d 439 (S.D.W. Va. 2024).

[8] *See AbbVie, Inc. v. Weiser*, 1:25-cv-01847 (D. Co.); *AbbVie v. Lopez*, 1:25-cv-00230 (D. Haw.); *AbbVie, Inc. v. Kobach*, 6:24-cv-01111 (D. Kan.); *Novartis Pharmaceuticals Corp. v. Brown*, 1:24-cv-01557 (D. Md.); *AbbVie, Inc. v. Bailey*, 4:24-cv-00996 (E.D. Mo.); *AbbVie, Inc. v. Wrigley*, 1:25-cv-00081 (D. N.D.); *AbbVie, Inc. v. Hilgers*, 4:25-cv-03089 (D. Neb.); *AbbVie, Inc. v. Jackley*, 3:25-cv-03006 (D. S.D.); *Novartis Pharmaceuticals v. Brown*, 2:25-cv-00284 (D. Utah).

> unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.
>
> **3. Other interference prohibited.** A manufacturer may not otherwise interfere directly or indirectly with a 340B entity unless expressly authorized by the United States Department of Health and Human Services.

The statute defines a "340B entity" as "an entity participating or authorized to participate in the federal 340B drug discount program, as described in 42 United States Code, Section 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the federal 340B drug discount program." 24-A M.R.S.A. § 7752(7) (effective Sept. 24, 2025). A "340B drug" is defined as "a drug that is purchased or eligible for purchase under Section 340B of the federal Public Health Service Act, 42 United States Code, Section 256b(a)(3)." 24-A M.R.S.A. § 7752(6) (eff. Sept. 24, 2025). A "340B contract pharmacy" is defined as "a pharmacy that has a contract with a 340B entity to receive and dispense 340B drugs to the 340B entity's patients on behalf of the 340B entity." 24-A M.R.S.A. § 7752(5) (effective Sept. 24, 2025).

Each violation of Chapter 103 is "subject to enforcement under the Maine Unfair Trade Practices Act." 24-A M.R.S.A. §7757(1) (effective Sept. 24, 2025). The Maine Unfair Trade Practices Act permits the Attorney General to "bring an action in the name of the State," to seek an injunction and restitution for any person who has suffered an ascertainable loss, and the Act provides that one who violates an injunction can incur a civil penalty up to $10,000 per violation. 5 M.R.S.A. § 209.

Plaintiffs filed suit in this court in August 2025 and sought a preliminary injunction enjoining enforcement of the state statute. In September 2025, amici curiae the American

Hospital Association, 340B Health, the Maine Hospital Association, and the American Society of Health-System Pharmacists, filed briefs in opposition to Plaintiffs' motions for preliminary injunctions. (Amici Briefs, 1:25-cv-00407-JCN, ECF No. 35; 1:25-cv-00416-JCN, ECF No. 34.)

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. NRDC*, 555 U.S. 7, 24 (2008). A district court must decide whether the party seeking a preliminary injunction has carried the burden of establishing that the balance of four factors weighs in its favor:

> (1) the movant's likelihood of success on the merits, (2) whether and to what extent the movant will suffer irreparable harm in the absence of injunctive relief, (3) the balance of relative hardships, and (4) the effect, if any, that an injunction or the lack of one may have on the public interest.

Becky's Broncos, LLC v. Town of Nantucket, 138 F.4th 73, 77 (1st Cir. 2025) (quotation marks omitted). "[T]he four factors are not entitled to equal weight in the decisional calculus; rather, likelihood of success is the main bearing wall of the four-factor framework." *Corporate Technologies, Inc. v. Harnett*, 731 F.3d 6, 9–10 (1st Cir. 2013) (quotation marks and modifications omitted).

DISCUSSION

A. Likelihood of Success

1. Standing

The United States Constitution's limitation on the federal courts' jurisdiction to "Cases" and "Controversies" requires that a party invoking federal jurisdiction establish:

(1) an injury in fact that is concrete and particularized, and actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and conduct complained of; and (3) a likelihood that the injury could be redressed with a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). "The plaintiff bears the burden of establishing standing" at the time of filing "and maintaining it thereafter" and must "support each element of standing with the manner and degree of evidence required at the successive stages of the litigation." *Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (quotation marks omitted).

The State argues that Plaintiffs have not established that they have standing to pursue their claims because they are allegedly harmed only when a covered entity claims entitlement to more discount drugs than were dispensed to patients of the covered entity, which conduct is not caused by the enforcement of Maine's law. The State contends this harm would be the result of a violation of the provisions of 340B and not a consequence of Maine law.

"[A] plaintiff satisfies the injury-in-fact requirement where he [or she] alleges an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014). While pre-enforcement standing is ordinarily invoked in the face of criminal penalties, courts generally note that civil punitive statutes have a lesser but similar risk of harm and thus apply a similar inquiry for establishing standing in a pre-enforcement challenge. *See e.g.*, *New York Bankers Association, Inc. v. City of New York*, No. 13 CIV. 7212 KPF, 2014 WL 4435427, at *12

(S.D.N.Y. Sept. 9, 2014); *Ostergren v. McDonnell*, No. 3:08CV362, 2008 WL 3895593, at *4 (E.D. Va. Aug. 22, 2008) ("it is not also the case that pre-enforcement challenges are limited to criminal statutes") (collecting cases).

Here, Plaintiffs have demonstrated an intent to follow their policies restricting delivery to contract pharmacies and that following the policies would likely result in state sanctions, as the State has not represented that it would not enforce the Maine statute with its attendant penalties if Plaintiffs followed their policies after the effective date of the statute. *See New York Bankers Association*, 2014 WL 4435427, at *12 (noting presumption, in pre-enforcement context, that a government will enforce punitive statutes, civil or criminal). Plaintiffs need not show more at this stage of the litigation to establish that they have standing to assert their constitutional claims. *See Defenders of Wildlife*, 504 U.S. at 561–62 ("When the suit is one challenging the legality of government action or inaction, the nature and extent of facts that must be averred . . . in order to establish standing depends considerably upon whether the plaintiff is himself an object of the action (or forgone action) at issue. If he is, there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.").

2. Preemption Claims

Under the Supremacy Clause, the Constitution, treaties, federal statutes, and federal regulations preempt contrary state law because federal law is the "supreme Law of the Land[.]" U.S. Const. art. VI, cl. 2. "Express preemption occurs when congressional intent to preempt state law is made explicit in the language of a federal statute." *Tobin v. Federal*

Express Corp., 775 F.3d 448, 452 (1st Cir. 2014). There are also two types of implied preemption, "field preemption and conflict preemption." *Capron v. Office of Attorney General of Massachusetts*, 944 F.3d 9, 21 (1st Cir. 2019).

A "presumption against preemption" ordinarily applies to implied preemption claims, *id.*, because courts have long assumed that Congress is reluctant to displace the broad police powers of the states, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The presumption does not apply to express preemption claims, where courts instead "use the usual tools of statutory interpretation, focusing on the plain wording of the [preemption] clause, which necessarily contains the best evidence of Congress's preemptive intent." *Northwestern Selecta, Inc. v. Gonzalez-Beiro*, 145 F.4th 9, 15 (1st Cir. 2025) (quotation marks and modifications omitted). "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quotation marks and modifications omitted).

a. Field Preemption

Field preemption "can be inferred from a framework of regulation so pervasive that Congress left no room for the States to supplement it or where there is a federal interest so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quotation marks and modifications omitted). "Implied field preemption analysis has two parts: (1) defining the relevant regulatory field; and (2) evaluating the scope of federal regulation in that field." *Hall v. Delta Air Lines, Inc.*, No. 2:16-CV-00417-JAW, 2018 WL 1570788, at *19 (D. Me. Mar. 30, 2018).

Defining the relevant field at the proper level of generality can be challenging. Some level of specificity is required, *see Basiliali v. Allegiant Air, LLC*, No. 2:18-CV-03888-RGK-MRW, 2018 WL 6219951, at *2 (C.D. Cal. Aug. 30, 2018), but defining the field too narrowly "result[s] in an analysis that resembles conventional conflict preemption." *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 705 n.22 (3d Cir. 2016).

Assessing the 340B statute at the highest level of generality, courts and parties have examined proposed fields such as the "practice of pharmacy," (Defendant's Responses at 16*; Pharmaceutical Research and Manufacturers of America v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024), the "regulation of contract pharmacies," *Pharmaceutical Research & Manufacturers of America v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *6 (W.D. La. Sept. 30, 2024), and (somewhat more specifically) the provision of "discounted drugs for needy patients." *AbbVie, Inc., v. Fitch*, No. 24-60375, 2025 WL 2630900 at *6 (5th Cir. Sept. 12, 2025). The Maine law would fall within with the broadly defined fields, but as the other courts have found, there can be no inference of preemptive intent because there is no dominant federal interest in such broad fields and the scope and extent of the regulations found in the 340B statute cannot reasonably be characterized as comprehensive or pervasive relative to the breadth of the fields.

Assessing the 340B statute at a lower level of generality, some courts and parties have examined proposed fields such as "340B pricing or entity eligibility to access manufacturers' drugs at 340B discounted prices." *AbbVie Inc. v. Skrmetti*, No. 3:25-CV-00519, 2025 WL 1805271, at *12 (M.D. Tenn. June 30, 2025). Consistent with this view, Plaintiffs argue that the relevant field is defined by 340B, which focuses on the drug

manufacturers' principal obligation under 340B—to offer to provide discount drugs to covered entities. (*See e.g.*, AbbVie's Reply at 3, 1:25-cv-00416-JCN, ECF No. 37.) If the field were defined in this way (i.e., the terms by which manufacturers must offer discounted drugs under the 340B program), there would be no field preemption. As with the broader proposals of the relevant field, because 340B does not dictate many of the terms regarding manufacturers' obligation to offer and provide the drugs, the language of 340B is insufficient to imply a congressional intent to preclude all state regulation in the field. *See Sanofi Aventis*, 58 F.4th at 704 (regarding the terms of an offer, the 340B statute "imposes only a price term for drug sales to covered entities, leaving all other terms blank"); *Fitch*, 2025 WL 2630900 at *6 ("Congress chose not to regulate distribution to patients, indicating that it did not intend to occupy the entire field in this area. As the Supreme Court has held, matters left unaddressed in an otherwise comprehensive and detailed federal regulatory scheme are presumably left subject to the disposition provided by state law.") (quotation marks omitted).

The state law addresses covered entities' "distribution of drugs to patients and the role of pharmacies in such distribution," a subject that does not fall within a specific field that Congress manifested an intent occupy exclusively. *Fitch*, 2025 WL 2630900 at *7. There are evidently no cases where a court has found field preemption of a similar state statute.[9] Courts have consistently concluded that similar state laws are not within the more

[9] The one case in which a court found preemption involving a similar state statute, the court appears to have based the determination on a form of conflict preemption. *Pharmaceutical Research & Manufacturers of America v. Morrisey*, 760 F. Supp. 3d 439, 452, 458 (S.D.W. Va. 2024) (concluding that "[m]ost germane

narrowly defined field. *See e.g., Skrmetti*, 2025 WL 1805271, at *12 ("The primary problem with the plaintiffs' position is that" the state law does not "say[ ] anything about the pricing of 340B drugs" and only "concern[s] the delivery of 340B drugs."). While the silence in 340B as to delivery or distribution has been interpreted by some courts to permit drug manufacturers to impose "at least some delivery conditions" and not to require manufacturers to deliver to multiple contract pharmacies as a matter of federal law, *see Johnson*, 102 F.4th at 460, the silence has also been viewed by two circuit courts as reflecting that Congress did not intend to preclude state involvement. *Fitch*, 2025 WL 2630900 at *6; *McClain*, 95 F.4th at 1144.[10]

Given 340B's silence regarding the acts and transactions required to accomplish the objectives of the 340B program (e.g., the distribution of prescription medication at a discounted rate to covered entities), and given the sound reasoning of other courts on the field preemption issue presented here, the Court concludes that Plaintiffs have not established that they are likely to succeed on their field preemption claim.

b. Conflict Preemption

Conflict preemption occurs "where compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963), or where the state statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*

to the No-Audits Provision is obstacle preemption" and "the Enforcement Provisions present an obstacle to this centralized purpose").

[10] The D.C. Circuit in *Johnson* did not address whether state involvement was permissible.

v. National Foreign Trade Council, 530 U.S. 363, 373 (2000). Plaintiffs do not argue that it is impossible to comply with both the federal and state obligations. This is not a case where "federal law forbids an action that state law requires," or vice versa. *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 486 (2013).

When analyzing whether a state statute presents an obstacle to the objectives of Congress in the enactment of a statute, a court must identify the relevant purposes, goals, or objectives of the federal law, and weigh the magnitude of the burden or the degree of the interference resulting from the state law. *See Maine Forest Products Council v. Cormier*, 51 F.4th 1, 8 (1st Cir. 2022) (noting judicial concerns about "ascrib[ing] unenacted purposes and objectives to a federal statute" because "hidden legislative wishes" can be "difficult to discern" and the task "risks displacing the legislative compromises") (quotation marks omitted) (discussing *Virginia Uranium, Inc. v. Warren*, 587 U.S. 761, 778 (2019) (lead opinion of Gorsuch, J.); *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000) ("What is a sufficient obstacle is a matter of judgment").

The core congressional objective in this case is not difficult to discern. The program is designed to use two other large federal spending programs to incentivize manufacturers to provide a subsidy to healthcare entities caring for underserved patients.[11] *See Novartis*

[11] Plaintiffs contend that providing covered entities with discounted drugs is not the sole objective of the program. Congress placed some specific limitations on discount claims—a formula to calculate the amount of the discount, prohibitions on diversion and double discounting, and auditing requirements and penalties for violations. Plaintiffs maintain that the limitations and enforcement provisions demonstrate an intent to limit to some degree the number of claims that would be made by covered entities and to prevent covered entities from claiming more discounts than they are entitled to receive. Plaintiffs contend that 340B reflects Congress' intent to achieve an appropriate balance between providing discounted drugs to the covered entities and incentivizing manufacturers to participate in the program. In support of this view, Plaintiffs cite one court's conclusion that the 340B statute has "twin federal purposes" of providing discounts and

Pharms. Corp. v. Espinosa, No. 21-CV-1479-DLF, 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021) ("The purpose of Section 340B is clear—it provides discounts on drugs to certain kinds of healthcare facilities"). As the State argues, at least as an initial matter, there is little or no tension between the effect of the state law and the central objective of 340B. The effect of the state statute is to prevent limits on and preserve flexibility in the methods of distribution for covered entities, which is in harmony with the 340B goal of providing the entities with prescription drugs at the discounted price for the benefit (directly or indirectly) of underserved patients.

Plaintiffs argue that states have no role in implementing the 340B program and that Maine is categorically prohibited from adopting rules that add any requirements regarding a manufacturer's participation in the 340B program. In other words, Plaintiffs argue that any state rule related to the 340B program presents an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 373.

Courts might be less inclined to find implied preemption when the federal statute contemplates a state implementation role within the federal program and are more likely to find implied preemption when a federal statute does not specifically provide a role for states. *See Fresenius Medical Care Holdings, Inc. v. Francois*, 832 F. Supp. 2d 1364, 1368

protecting manufacturers or preventing fraud. *Morrisey*, 760 F. Supp. 3d at 452. Prevention of excess claims and fraud by covered entities is a discernible goal of the 340B statute, but the "twin federal purposes" suggests that the objectives are unrelated to or of equivalent importance as each other. In the crafting of most, if not all, federal legislation establishing a program with eligibility requirements, fraud prevention is a consideration. Ensuring that the program serves only those who are eligible is an ancillary goal of any such program. Here, protecting manufacturers against duplicate claims and otherwise preventing fraud are subsidiary goals to the objective of the 340B program, which is to subsidize the cost of drugs to underserved populations.

(N.D. Fla. 2011) (indicating that when a federal statute "has been recognized as a cooperative state-federal program . . . the case for federal preemption is less persuasive and difficult to establish"). Courts also might be more inclined to find preemption when a state law directly targets a federal program and be less inclined to infer congressional intent to preempt generally applicable state laws that impact federal programs incidentally. *Pedraza v. Shell Oil Co.*, 942 F.2d 48, 53–54 (1st Cir. 1991) (noting that federal law preempts state laws addressing occupational safety standards but finding no basis for preemption "in the workplace of private rights and remedies traditionally afforded by state laws of general application" or "state criminal laws of general application"); *compare Planned Parenthood of Houston & Southeast Tex. v. Sanchez*, 403 F.3d 324, 341 (5th Cir. 2005) (finding preemption more likely because "[the state] is attempting to impose regulations that restrict the scope of a federal program"), *with Deanda v. Becerra*, 96 F.4th 750, 762 n.9 (5th Cir. 2024) (finding preemption less likely because the state law did not target eligibility requirements of a federal program but was instead "a generally applicable state law").

The Supreme Court, however, has never adopted a categorical rule that requires a finding of preemption whenever a state law is addressed directly to those participating in a federal program where the federal statute does not rely on the state to implement the program. Instead, courts must determine whether the alleged obstacle presented by the state law is significant enough to compel preemption. The case of *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644 (2003) is particularly instructive.

In 2000, the Maine state legislature created the Maine Rx Program, which was intended to authorize anyone in the state to purchase prescription drugs at the lower prices negotiated on behalf of and available to those who purchase drugs through the Medicaid program. *Id.* at 649. Maine used the prospect of imposing prior authorization requirements on nonparticipating manufacturers selling drugs through the Medicaid program to convince drug manufacturers to participate in the state program and provide similar lower prices to the public. *Id.* at 649–50. The district court granted a preliminary injunction in favor of the drug manufacturers, precluding implementation of the program. *Pharmaceutical Research & Manufacturers of America v. Commissioner, Maine DHS*, No. CIV. 00-157-B-H, 2000 WL 34290605, at *6 (D. Me. Oct. 26, 2000). The district court found obstacle preemption because although the federal Medicaid statute allowed states to impose restrictions on drug distribution as necessary to assure that care and services would be provided in a manner consistent with the best interests of Medicaid's requirements, the federal law did not specifically permit the federal Medicaid program to be used to further the interests of non-Medicaid recipients. *Id.* at *5. The district court reasoned:

> No matter how modest an obstacle the new prior authorization amounts to (the parties disagree on the severity of the obstacle), it is an obstacle—drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed or prescribed—and therefore an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid.

Id. (quotation marks omitted).

"[P]erceiv[ing] no conflict between the [Maine Rx statute] and Medicaid's structure and purpose," the First Circuit reversed. *Pharmaceutical Research & Manufacturers of*

America v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001). The First Circuit noted that nothing in the text of the federal statute "prevents states from imposing prior authorization requirements; indeed, they are explicitly permitted," and after entertaining the argument that there were federal legislative purposes in "preventing abuse or overprescription of certain expensive medications," and in "achieving the best interests of the Medicaid recipient," the court expressed concerns about the possibility of obstruction but found an "insufficient basis" on the record of competing affidavits at that point in the proceedings to conclude that the statute presented more than a *de minimis* obstacle to achieving the goals that the plaintiff had identified. *Id.* at 75–78.

The Supreme Court affirmed the First Circuit's decision. *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644, 670 (2003). Reasoning that the district court erred when it observed that it was sufficient to show any impediment to a discernable federal goal, a plurality of justices concluded that obstacle preemption required a showing of more than a "modest" impediment or harm to a federal statutory goal. *Id.* at 665, 667 (opinion of Stevens, J.), 671 (Breyer, J., concurring); *compare Townsend v. Swank*, 404 U.S. 282, 286 (1971) (finding preempted an additional "state eligibility standard" that had the effect of excluding from welfare benefits a whole category of persons the federal program deemed eligible for assistance), *with New York State Department of Social Services v. Dublino*, 413 U.S. 405, 421–22 (1973) (not finding complimentary state law work requirements for welfare benefits preempted simply because they might become conditions for continued assistance for some individuals but remanding for further analysis of the eligibility implications of each specific work rule).

Plaintiffs contend that the impediment is sufficient to support a preemption finding because the use of the replenishment model, multiple pharmacies, and pharmacies located a considerable distance from a covered entity combine to expand the program beyond that contemplated by Congress, resulting in an unreasonable burden on manufacturers and a greater potential for fraud, which factors could limit manufacturers' involvement in the program. At this time on this record, the Court is not persuaded that the increase in the number of 340B claims with the use of multiple pharmacies is inconsistent with the objectives of the 340B program, provided the claims are made for drugs distributed to patients of covered entities.

Under the reasoning of the Third and D.C. Circuits, congressional silence regarding the conditions that drug manufacturers can include in their offers to sell the drugs to covered entities precludes HRSA from dictating the number of pharmacies to which the manufacturers must deliver on behalf of a covered entity. *Sanofi Aventis*, 58 F.4th 696; *Johnson*, 102 F.4th 452. The silence, however, does not necessarily reflect that Congress intended to prevent state involvement or somehow limit the number of legitimate discounted claims. *See Planned Parenthood of Indiana, Inc. v. Commissioner of Indiana State Department of Health*, 699 F.3d 962, 985 (7th Cir. 2012) ("The question is not whether [the federal law] expressly allows a recipient state to impose its own subgrant conditions . . . [i]nstead, the pertinent question is whether [the federal law] prohibits state-imposed eligibility conditions, either expressly or by necessary implication. As we have noted, congressional and regulatory silence usually defeats a claim of preemption, not the other way around"). The Court discerns nothing in 340B to suggest that Congress intended

to limit the number of patients for whom covered entities may prescribe drugs at the discounted rate. For instance, there is no persuasive evidence to suggest that Congress intended to limit the number of legitimate discounted claims to a subset of a covered entity's eligible patients that corresponds to patients living in the immediate vicinity of a single in-house or designated contract pharmacy. Rather than limit eligibility and participation, in 2010, Congress significantly increased the healthcare facilities that are considered covered entities.

Plaintiffs also assert there is a direct conflict because the state law remedy overlaps with the federal remedy—namely the ADR process to be followed by a judicial proceeding—and provides an additional enforcement mechanism beyond the federal remedy. Courts have recognized that state efforts to impose additional remedies for the same violations are more likely to be preempted. *See e.g.*, *Idaho Building & Construction Trades Council, AFL-CIO v. Inland Pacific Chapter of Associated Builders & Contractors, Inc.*, 801 F.3d 950, 961 (9th Cir. 2015) (finding preemption when a state added a criminal penalty for violating a federal program enforced by federal civil and administrative remedies); *Bessette v. Avco Financial Services, Inc.*, 230 F.3d 439, 447 (1st Cir. 2000), *amended on denial of rehearing* (Dec. 15, 2000) ("[T]he broad enforcement power under the Bankruptcy Code preempts virtually all alternative mechanisms for remedying violations of the Code."). The State argues there is no overlap because potential violations of the state statute would not involve the overcharging, diversion-related, and price disputes, all of which would be subject to the ADR process under the federal statute.

The ADR rule provides that ADR is available to a covered entity that "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21(a)(1). Plaintiffs argue that their contractual limitations on a covered entity's distribution of the drugs to patients through contract pharmacies, which is the subject of the Maine statute, could be challenged as a limitation on the ability to purchase drugs at or below the ceiling price under the federal law. The Court is not persuaded that such an interpretation presents a conflict because HRSA, the governing agency, has adopted a contrary view—a view consistent with the decisions of the Third and D.C. Circuits that 340B does not address distribution. At this stage, therefore, the alleged conflict is too speculative to support a finding that Plaintiffs are likely to prevail on the claim.

Plaintiffs further argue that the state law's requirement that manufacturers cannot condition participation in the program on the covered entities providing claims data impermissibly conflicts with 340B. A discernible secondary goal of 340B is to prevent excess claims and fraud, and the ADR process is evidently intended to assist in that objective. Plaintiffs submit that they need claims data to prevent fraud and meet the "reasonable cause" level of suspicion necessary to initiate an audit. Plaintiffs' concern regarding access to evidence of possible violations is not unreasonable. Plaintiffs, however, have not demonstrated that claims data are necessary to obtain an audit or that the proof necessary to obtain an audit is particularly onerous. For instance, Plaintiffs have not shown that the trends upon which they rely to support their injury-in-fact standing argument would be insufficient to obtain an audit. The 340B program and the audit process

have existed for many years, but Plaintiffs have not identified cases where a manufacturer had requested but been denied an audit due to a lack of relevant claims data. On the current record, the alleged impediment is too speculative to support a finding that Plaintiffs are likely to prevail on their claim.

Finally, the "subtle refram[ing]" of the obstacle preemption inquiry, which the First Circuit has identified in more recent Supreme Court opinions, does not assist Plaintiffs. *Maine Forest Products Council v. Cormier*, 51 F.4th 1, 8 (1st Cir. 2022). According to the First Circuit, the Supreme Court has asked whether the federal statute "implicitly confer[s] a right" to engage in certain conduct subject only to certain federal standards and be free from the state law regulation. *Id.* (discussing *Kansas v. Garcia*, 589 U.S. 191, 210 (2020) and *Murphy v. National Collegiate Athletic Association*, 584 U.S. 453, 479 (2018)). As discussed above, the limited specified requirements of the 340B program and Congress's silence on all other aspects of the transactions necessary to accomplish the objectives of 340B do not imply that Congress intended to confer on manufacturers a right to be free from all state law requirements regarding drug distribution to patients, contract pharmacies, and claims data.

In sum, at this stage of the proceedings on the current record, which includes competing affidavits, the Court is not convinced that it is more likely than not that Plaintiffs will establish that Maine's statute represents more than a modest impediment to drug manufacturers' participation in and the goals of 340B. As related to obstacle conflict preemption, the Court is not persuaded that there is a significant risk that the state law is likely to cause manufacturers to withdraw from or not participate in the 340B program such

that the core objectives of the program would be compromised. Plaintiffs, therefore, have failed to establish a likelihood of success on their obstacle preemption claim.

3. Dormant Commerce Claim

"The Commerce Clause provides that Congress shall have power to regulate commerce with foreign Nations, and among the several States, and with the Indian Tribes." *Association To Preserve & Protect Local Livelihoods v. Sidman*, 147 F.4th 40, 55 (1st Cir. 2025) (quotation marks and modifications omitted) (quoting U.S. Const. art. I, § 8, cl. 3). Although the text is framed as a grant of power to Congress, the Supreme Court has long "held this language to contain a further, negative command, known as the dormant Commerce Clause, prohibiting certain state [regulation] even when Congress has failed to legislate on the subject." *Oklahoma Tax Commission v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995).

The doctrine primarily "bars states and localities from pursuing economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Becky's Broncos, LLC v. Town of Nantucket*, 138 F.4th 73, 78 (1st Cir. 2025) (quotation marks omitted). "To ascertain whether a regulatory measure is so designed, we look for evidence of either discriminatory purpose or discriminatory effect, recognizing the primacy of the latter in the dormant Commerce Clause analysis of facially neutral legislation." *Id.* (quotation marks and modifications omitted).

Plaintiffs argue that the state statute discriminates against out-of-state manufacturers for the benefit of in-state providers and pharmacies. Even assuming the

burdens and benefits are as Plaintiffs assert, Plaintiffs are not likely to prevail on their claim. The question "is not whether a statute discriminates at all, but whether it discriminates between substantially similar entities in a single market. Indeed, the principle that any notion of discrimination assumes a comparison of substantially similar entities is a fundamental element of dormant Commerce Clause jurisprudence." *American Trucking Associations, Inc. v. Rhode Island Turnpike & Bridge Authority*, 123 F.4th 27, 37 (1st Cir. 2024) (quotation marks and citations omitted). Although Plaintiffs contend that contract pharmacies and manufacturers compete for customers "vertically" in a single market, they do not explain why they are substantially similar. In practice, the manufacturers create the drugs and sell them to covered entities for patients, the covered entities buy drugs from the manufacturers and distribute them to patients at an equivalent or reduced cost, and pharmacies act as the conduit for distribution. The roles are meaningfully different and cannot be viewed as similar entities.

Plaintiffs cite *Healy v. Beer Institute*, 491 U.S. 324, 336 (1989), for the proposition that states may not regulate transactions occurring wholly outside their borders. The Supreme Court, however, has arguably limited the concerns about extraterritorial price impacts identified in *Beer Institute*. *See National Pork Producers Council v. Ross*, 598 U.S. 356, 143 (2023) (rejecting "'almost per se' rule against laws that have the 'practical effect' of 'controlling' extraterritorial commerce").

In addition, in *Walsh*, the First Circuit and the Supreme Court rejected the argument that requiring certain discounts for in-state drug transactions had extraterritorial impacts

based on the series of upstream transactions involving out of state middlepersons before a drug is finally distributed to the consumer.

> [A]s the Court of Appeals correctly stated, unlike price control or price affirmation statutes, "the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. Similarly, Maine is not tying the price of its in-state products to out-of-state prices." 249 F.3d, at 81–82 (footnote omitted). The rule that was applied in *Baldwin* and *Healy* accordingly is not applicable to this case.

Walsh, 538 U.S. at 669. The Court is not convinced that a different analysis applies in this case.

Plaintiffs also invoke the balancing test of *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970) to support the commerce clause claim. Under *Pike*, a court is asked "to determine whether a facially non-discriminatory local measure violates the Dormant Commerce Clause" by inquiring "whether the burdens (if any) that the measure imposes on interstate commerce are clearly excessive in relation to the claimed local benefits that it secures." *Sidman*, 147 F.4th at 64. Plaintiffs, however, have not demonstrated that they are likely to establish that the Maine statute imposes an excessive burden on interstate commerce. As Plaintiffs correctly note, despite the language of the Maine statute, there are no 340B drugs. Rather, the drugs that are covered by the 340B program are the same drugs that Plaintiffs manufacture and sell for patients of all healthcare providers. The 340B program simply contemplates that a portion of the drugs that Plaintiffs manufacture and sell would be sold at a discounted rate to covered entities. The Maine statute, therefore, is unlikely to affect significantly the quantity of drugs that will be sold in interstate commerce. Plaintiffs' principal concern is that under the Maine statute, their

administrative costs will increase, and they will be required to sell more drugs at a discounted rate. In other words, Plaintiffs would be harmed in the form of a reduction in their profits. A reduction in Plaintiffs' profitability, if proven, would not constitute an excessive burden on interstate commerce. *See Construction Materials Recycling Association Issues & Education Fund, Inc. v. Burack*, 686 F. Supp. 2d 162, 172 (D.N.H. 2010) ("A dormant Commerce Clause claim, however, cannot be based merely on a showing that a challenged statute will cause individual out-of-state businesses to lose profits"). In short, Plaintiffs have not established that they are likely to succeed on their dormant commerce claims.

4. Takings Claim

AbbVie contends that "Maine's law effects a physical taking of AbbVie's property by forcing AbbVie to transfer its pharmaceutical products to private third parties for discounted prices." (AbbVie Motion at 18.)

The Fifth Amendment prohibits "private property" from being "taken for public use, without just compensation." U.S. Const. amend. V. The Fifth Amendment applies to the federal government, but "[t]hat prohibition . . . applies against the States through the Fourteenth Amendment." *Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 160 (1980). "When the government physically takes possession of an interest in property for some public purpose, it has a categorical duty to compensate the former owner, regardless of whether the interest that is taken constitutes an entire parcel or merely a part thereof." *Tahoe-Sierra Preservation Council, Inc. v. Tahoe Regional Planning Agency*, 535 U.S. 302, 322 (2002) (citation omitted).

"When an entity voluntarily participates in a federal program, it forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." *Astrazenca Pharmaceuticals LP v. Bailey*, No. 2:24-CV-04143-MDH, 2025 WL 644285, at *4 (W.D. Mo. Feb. 27, 2025). A government does not take property by creating a "financial inducement" to comply voluntarily. *See Pharmaceutical Research & Manufacturers of America v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *14 (W.D. La. Sept. 30, 2024); *see also*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) ("as long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking").

The voluntary nature of the 340B program, therefore, would appear to present an impediment to AbbVie's takings claim. AbbVie asserts that the voluntariness of the federal program does not impact the analysis at least in part because there was no independent state law benefit offered with the state requirements. AbbVie relies on cases finding that alleged benefit was illusory and thus the program was not truly voluntary, *see Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023) (discussing *Horne v. Department of Agriculture*, 576 U.S. 350 (2015)), but AbbVie does not provide any persuasive authority to support the contention that each new regulatory condition must be accompanied by a separate benefit to maintain the voluntary nature of the program for

purposes of a takings claim. Because AbbVie can choose not to participate in the 340B program, AbbVie has not demonstrated a likelihood of success on its takings claim.[12]

5. Vagueness Claim

AbbVie maintains that Maine's statute is impermissibly vague because there is little or no guidance for what it means to "interfere" with covered entities and the delivery of covered drugs to contract pharmacies on behalf of covered entities. Under the Due Process Clauses of the Fifth and Fourteenth Amendments, "[a] statute is impermissibly vague if (1) 'it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits' or (2) 'it authorizes or even encourages arbitrary and discriminatory enforcement.'" *March v. Frey*, 458 F. Supp. 3d 16, 39 (D. Me. 2020) (quoting *Hill v. Colorado*, 530 U.S. 703, 732 (2000)). However, legislatures need not attempt to achieve "semantic certainty," *Draper v. Healey*, 827 F.3d 1, 4 (1st Cir. 2016), because "words are rough-hewn tools, not surgically precise instruments." *URI Student Senate v. Town of Narragansett*, 631 F.3d 1, 14 (1st Cir. 2011).

[12] AbbVie primarily argues the state law effects a physical taking rather than a regulatory taking. The Supreme Court has also recognized that even without taking physical possession, "if regulation goes too far it will be recognized as a taking." *Id.* at 326 (quoting *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). A regulatory taking occurs "where government requires an owner to suffer a permanent physical invasion of her property," or "completely deprive[s] an owner of all economically beneficial use of her property," or demands an exaction as a condition to approving development, such as a public easement, that is disproportionate to the impact of the proposed development. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538–39, 546–48 (2005) (quotation omitted). When presented with a regulatory takings claim that does not implicate one of the situations identified in *Lingle*, courts employ a "more nuanced, three-pronged inquiry into (1) the extent to which the regulation interferes with the claimant's reasonable investment-backed expectations; (2) the regulation's economic impact on the property owner; and (3) the character of the government action." *Maine Education Association Benefits Trust v. Cioppa*, 695 F.3d 145, 153 (1st Cir. 2012) (citing *Penn Central Transportation Co. v. City of New York,* 438 U.S. 104, 124 (1978)). To the extent that AbbVie asserted during oral argument that under a regulatory takings analysis, Maine's law constitutes a taking, the voluntariness issue likely still bars the claim, and even if it did not, the Court is not persuaded that AbbVie is likely to satisfy the stringent requirements of a regulatory takings claim.

While courts have acknowledged that terms like "interfere with" can be indefinite enough to create vagueness concerns if read in a vacuum, *see Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023), "[h]ere . . . the challenged [terms] do not appear in a vacuum" because the statute "contains additional terms that supply concrete guidance," at least to some degree, "as to the behavior that it prohibits and the circumstances in which it can be enforced." *URI Student Senate*, 631 F.3d at 14. The statute's language that manufacturers "may not deny, restrict, [or] prohibit" the "acquisition" or "delivery" of certain drugs, and the title of the provision addressing "discriminatory actions by manufacturer or agent related to 340B entities" narrow the scope of the term "interfere" considerably. Nearby provisions in Chapter 103 also use the word "interfere" in the context of discriminatory policies that impose conditions on 340B participants that are not imposed on comparable nonparticipants. *See* 24-A M.R.S.A. §7754(4)–(5) (effective Sept. 24, 2025). The statute itself, therefore, provides reasonable guidance and notice to AbbVie and those similarly situated.

Several other important factors undermine the void-for-vagueness claim here. First, perhaps because imprecise terms can "take on definiteness and clarity" when "directed to a discrete professional group," *In re Bithoney*, 486 F.2d 319, 324 (1st Cir. 1973), "the doctrine is applied more leniently in the sphere of economic regulation of sophisticated parties." *FERC v. Silkman*, 177 F. Supp. 3d 683, 702 (D. Mass. 2016) (citing *U.S. v. Lachman*, 387 F.3d 42, 56–57 (1st Cir. 2004)). AbbVie certainly qualifies. Second, the harm resulting from a lack of specificity is lessened "by the scienter requirement" that must be satisfied before drug manufacturers would face civil penalties. *Id.*; *March*, 458 F. Supp.

3d at 39.[13] Third, statutory imprecision is less likely to offend due process when there is a method "to allow private parties to obtain an official government answer on whether [the conduct] is covered" before facing penalties, *United States v. Zhen Zhou Wu*, 711 F.3d 1, 15 (1st Cir. 2013), and the enforcement mechanism contains that opportunity before it creates a risk of financial penalties. Fourth, federal courts are less likely to find a state statute to be unconstitutionally vague in a pre-enforcement context where a plaintiff brings the case before the state court had the opportunity to interpret the state law. *See Donovan v. City of Haverhill*, 311 F.3d 74, 78 (1st Cir. 2002) (courts should "presume that state courts will give [challenged provision] a limiting construction that will preserve its facial constitutionality"); *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 450 (2008) (treading carefully when the state courts "have had no occasion to construe the law in the context of actual disputes . . . or to accord the law a limiting construction"). Fifth, "the [Supreme] Court has expressed greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe." *Sessions v. Dimaya*, 584 U.S. 148, 156 (2018) (quotation marks omitted).

Finally, except in the First Amendment context, a plaintiff is not generally permitted to pursue facial pre-enforcement vagueness challenges and courts instead "consider

[13] It appears that state enforcement of the Maine statute effectively requires a willful violation before the imposition of monetary penalties. As the Court reads the statute, to enforce the statute, the state attorney general would initiate a state court proceeding after first providing notice and conferring with the manufacturer, which lawsuit might then lead to an injunction from the state court against the offending practice, and the manufacturer would only face monetary penalties if it continued the offending conduct in violation of the injunction.

whether a statute is vague as applied to the particular facts at issue, for a plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others." *Holder v. Humanitarian Law Project*, 561 U.S. 1, 18–19 (2010) (quotation marks omitted). AbbVie asserts an as applied argument. Notably, AbbVie has not argued that it is uncertain whether the state statute prohibits the policies it has implemented in recent years. All parties acknowledge that the Maine statute and similar statutes enacted in other states are designed to prevent manufacturers from maintaining the restrictive policies employed by AbbVie.

In sum, the word "interfere" is not so indefinite in the context of the state statute and the 340B program that it presents constitutional concerns at this stage. All the relevant factors suggest that AbbVie is not likely to succeed on its void-for-vagueness claim.

B. Other Factors

Because Plaintiffs have failed to establish that they will likely succeed on the merits of their preemption, commerce clause, takings, or vagueness claims, the Court need not dwell on the remaining preliminary injunction factors. Where Plaintiffs have failed to demonstrate a likelihood of success on their claims, irreparable harm, the balance of hardships, and the public interest are inconsequential. *See New Comm Wireless Services, Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002) ("The sine qua non of this four-part inquiry is likelihood of success on the merits: if the moving party cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity").

CONCLUSION

After an assessment of the factors relevant to Plaintiffs' requests for a preliminary injunction, the Court concludes that Plaintiffs are not entitled to preliminary injunctive relief. Accordingly, the Court denies Plaintiffs' motions for a preliminary injunction.

/s/ John C. Nivison
U.S. Magistrate Judge

Dated this 23rd day of September, 2025.