

UNITED STATES DISTRICT COURT  
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH	)	
AND MANUFACTURERS	)	
OF AMERICA,	)	
	)	
Plaintiff	)	
	)	
v.	)	1:25-cv-00469-JCN
	)	
AARON FREY, et al.,	)	
	)	
Defendants	)	

**ORDER ON MOTION FOR PRELIMINARY INJUNCTION**

Plaintiff, a trade association representing biopharmaceutical research companies, challenges a Maine statute related to the role of contract pharmacies within a federal drug discount program. (Complaint, ECF No. 1.) Plaintiff contends that the Maine statute violates the Supremacy Clause and constitutes an extraterritorial regulation. The matter is before the Court on Plaintiff’s motion for a preliminary injunction. (Motion, ECF No. 14.) Defendants oppose the motion.<sup>1</sup> (Response, ECF No. 22.)

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

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<sup>1</sup> Plaintiff named Aaron Frey, Maine’s Attorney General, and Bob Carey, the Superintendent of the Maine Bureau of Insurance, as defendants.

## FACTUAL AND PROCEDURAL BACKGROUND<sup>2</sup>

### 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 (the Secretary or 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).

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

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<sup>2</sup> The following facts are derived primarily from public documents amenable to judicial notice and the declarations filed in connection with Plaintiff’s motion. The Court also reiterates herein some of the background summary and legal analysis included in its decision in two related cases in which two manufacturers asserted similar claims in their challenges to the same Maine statute. *See Novartis Pharms. Corp. v. Frey*, No. 1:25-cv-00407-JCN, 2025 WL 2813787 (D. Me. Sept. 23, 2025).

WL 2206948, at \*1 (citations omitted).<sup>3</sup> 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, 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*, 563 U.S. at 113. Several courts, however, have noted that Congress did not grant HHS broad authority to issue

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<sup>3</sup> 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 uninsured patients arguably benefit directly and both uninsured and insured patients arguably 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”). In any event, the potential dispute is not central to Plaintiff’s request for a preliminary injunction.

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) the establishment of an administrative dispute resolution process [ADR];” (2) drug-pricing methodology; and (3) imposition of monetary sanctions for violations. *Pharmaceutical Research & Manufacturers of America v. HHS*, 43 F. Supp. 3d 28, 41 (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, 68924. 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 limiting those sales transactions, manufacturers could be discouraging covered entities from participating in the program. *Id.* at 25111.

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. 43549. 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. *Id.* at 43555. 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 a contract pharmacy. *Id.* 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. *Id.*

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. Reg. 10272, 10277. 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. *Id.* §§ 7101-7102.

Since 2010, the 340B program has grown significantly. Plaintiff and drug manufacturers 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. 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. Plaintiff contends 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.

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 a 340B 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 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 be eligible to use contract pharmacies. 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 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).

In the meantime, HRSA sent letters to 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 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,” *id.* at 703-04, 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 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, *id.* at 373, 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. 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 manufacturers’ conditions in that case were not so burdensome as to violate the statute on its face. *Id.* at 371–73.

#### **D. State Statutes Prohibiting Manufacturer Limits**

In June 2025, Maine enacted a statute entitled the “Protect Health Care for Rural and Underserved Communities Act,” which statute went into effect in September 2025. 2025 Me. Legis. Serv. Ch. 388 (H.P. 132) (L.D. 210) Sec. P-5 (West). The statute created a new “Chapter 103” within the Maine Insurance Code, and includes the following provision:

##### **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

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.

24-A M.R.S.A. § 7753.

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). 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). 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).

Each violation of Chapter 103 is “subject to enforcement under the Maine Unfair Trade Practices Act[.]” 24-A M.R.S.A. §7757(1). 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 a person who violates an injunction imposed under the Act can incur a civil penalty up to \$10,000 per violation. 5 M.R.S.A. § 209.

Approximately twenty states, including Maine, 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. Drug manufacturers filed lawsuits challenging the state statutes and seeking injunctive relief. At least nine district courts (including this Court), either on a motion for preliminary injunction or a motion for summary judgment, have declined to enjoin the enforcement of the relevant state statute after considering similar legal claims to those Plaintiff asserts here; on appeal, the Eighth Circuit and Fifth Circuit upheld two of those decisions.<sup>4</sup> Other appeals are pending. At least three district courts have denied a motion to dismiss or

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<sup>4</sup> 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. 1:24-CV-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024) (same); *AbbVie, Inc. v. Fitch*, 152 F.4th 635 (5th Cir. 2025) (affirming denial of preliminary injunction); *Murrill*, No. 6:23-CV-00997, 2024 WL 4361597 (denying plaintiffs' motions for summary judgment); *Astrazeneca 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-CV-00519, 2025 WL 1805271 (M.D. Tenn. June 30, 2025) (denying plaintiffs' motion for preliminary injunction); *Novartis Pharmaceuticals Corp. v. Frey*, No. 1:25-cv-00407-JCN, 2025 WL 2813787 (D. Me. Sept. 23, 2025) (denying plaintiffs' motions for preliminary injunction); *AbbVie, Inc. v. Weiser*, No. 25-CV-1847-WJM-KAS, 2025 WL 3041825 (D. Colo. Oct. 31, 2025) (same); *Astrazeneca Pharmaceuticals v. Weiser*, No. 25-CV-02685-PAB-STV, 2025 WL 3653161 (D. Colo. Dec. 17, 2025) (same); *AbbVie v. Hilgers*, No. 4:25CV3089, 2025 WL 3688051 (D. Neb. Dec. 19, 2025) (same); *AbbVie, Inc. v. Jackley*, No. 3:25-CV-03006-RAL, 2025 WL 3706066 (D. S.D. Dec. 22, 2025) (same).

preliminarily enjoined enforcement of a state statute, accepting similar arguments to those Plaintiff raises here.<sup>5</sup> Other comparable cases are pending in other district courts.<sup>6</sup>

#### 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).

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<sup>5</sup> See *AbbVie, Inc. v. Brown*, No. 2:25-CV-00271-RJS-DAO, 2025 WL 3228898 (D. Utah Nov. 19, 2025) (denying motion to dismiss plaintiffs’ Supremacy Clause and Takings claims); *AbbVie Inc. v. Drummond*, No. CIV-25-1156-PRW, 2025 WL 3048929 (W.D. Okla. Oct. 31, 2025) (granting plaintiffs’ motions for preliminary injunction in part and enjoining enforcement of select provisions of state law); *Pharmaceutical Research & Manufacturers of America v. Morrissey*, 760 F. Supp. 3d 439 (S.D.W. Va. 2024) (granting plaintiffs’ motions for preliminary injunction).

<sup>6</sup> See, e.g., *AbbVie v. Lopez*, 1:25-cv-00230 (D. Haw.); *AbbVie, Inc. v. Bailey*, 4:24-cv-00996 (E.D. Mo.); *AbbVie, Inc. v. Wrigley*, 1:25-cv-00081 (D. N.D.).

## DISCUSSION

### A. Likelihood of Success

In Count I of the complaint, Plaintiff asserts a Supremacy Clause claim. In Count II of the complaint, Plaintiff alleges an extraterritorial regulation claim pursuant to the Due Process Clause, the Commerce Clause, and other provisions. Plaintiff's arguments in support of the motion for a preliminary injunction concern only Count I.

Under the Supremacy Clause, the Constitution, treaties, federal statutes, and federal regulations are the "supreme Law of the Land[.]" U.S. Const. art. VI, cl. 2. "State law may run afoul of the Supremacy Clause in two distinct ways:" by violating the intergovernmental immunity doctrine or the doctrine of preemption. *North Dakota v. United States*, 495 U.S. 423, 434-36 (1990). While Plaintiff ultimately proposes an expansive non-targeting rule distilled from parts of the two separate lines of cases, the Court declines Plaintiff's invitation to so combine and extend the "distinct" doctrines. *See United States v. California*, 921 F.3d 865, 880 & 884 n.9 (9th Cir. 2019) (deeming the doctrines "distinct" and cautioning against the failure to "accurately distinguish between the doctrines of intergovernmental immunity and obstacle preemption"). As explained below, because neither doctrine applies here, Plaintiff has not established a likelihood of success on its Supremacy Clause claim.

#### 1. Intergovernmental Immunity

A state law offends the modern intergovernmental immunity doctrine "only if it regulates the United States directly or discriminates against the Federal Government or those with whom it deals." *North Dakota v. United States*, 495 U.S. 423, 435 (1990). A

state law within the scope of the doctrine is invalid under the Supremacy Clause, “unless Congress provides clear and unambiguous authorization for such regulation.” *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 180 (1988) (quotation marks omitted).

An impermissible direct regulation occurs when a state places a tax “on the United States itself, or on an agency or instrumentality so closely connected to the Government that the two cannot realistically be viewed as separate entities, at least insofar as the activity being taxed is concerned[,]” *United States v. New Mexico*, 455 U.S. 720, 735 (1982), or when a state “places a prohibition on the Federal Government,” *Hancock v. Train*, 426 U.S. 167, 180 (1976) (quotation marks and footnote omitted). “[A] state law discriminates against the Federal Government or its contractors if it singles them out for less favorable treatment, or if it regulates them unfavorably on some basis related to their governmental status.” *United States v. Washington*, 596 U.S. 832, 839 (2022) (quotation marks, citations, and modifications omitted).

To the extent Plaintiff argues that the Maine statute directly regulates the federal government, the argument lacks merit. On its face, Maine’s statute does not place any tax, prohibition, or mandate on the federal government or its functions. This is also not a case where a state statute carefully avoids facial restrictions or mandates on the federal government but still interferes directly because it applies to public or private individuals or entities only when they are carrying out the functions of the federal government that the state seeks to restrict. *Cf. CoreCivic, Inc. v. Governor of New Jersey*, 145 F.4th 315, 320-21 (3d Cir. 2025) (finding an impermissible direct regulation when a state statute prohibited all contracting services for civil immigration detention).

Plaintiff’s primary argument is that because its members contract with HHS, its members are “contractors” subject to a discriminatory state statute. Whether an individual or entity is protected under the intergovernmental immunity doctrine depends on the nature of the contract or relationship with the federal government. *See Geo Group, Inc. v. Newsom*, 50 F.4th 745, 755 (9th Cir. 2022) (recognizing different degrees of protection under the Supremacy Clause against state laws addressing federal instrumentalities, employees, suppliers, and contract workers). Here, the Pharmaceutical Pricing Agreements between Plaintiff’s members and HHS are not ordinary “transactional, bargained-for contracts[,]” *Astra*, 563 U.S. at 113, subject to ordinary contract rules because they “have no negotiable terms” and merely “serve as the means by which drug manufacturers opt into the statutory scheme[,]” *id.* at 118. Drug manufacturers participating in the 340B program agree to provide discounts in the marketplace to certain other private entities; the manufacturers do not agree to perform any function of the federal government or provide any goods or services to the federal government. Plaintiff cites no persuasive authority that would support a finding that the mere participation in a regulatory program or receipt of government incentives confers on the participant a contractor status with the federal government. Plaintiff’s members, therefore, do not fall within any of the recognized categories of entities with whom the government “deals” for purposes of intergovernmental immunity, such as employees, contract workers, suppliers, or instrumentalities.

Even if Plaintiff could establish the requisite relationship between the manufacturers’ agreements and the performance of federal government functions, Plaintiff

has not demonstrated that Maine's statute violates the relevant antidiscrimination rule. Courts do not examine any one provision in isolation but instead examine the broader regulatory context, *North Dakota*, 495 U.S. at 435, to determine whether the economic burden of a state's rules are "imposed equally on other similarly situated constituents of the State[,]" *id.* at 438. "The State does not discriminate against the Federal Government and those with whom it deals unless it treats someone else better than it treats them." *Washington v. United States*, 460 U.S. 536, 544-45 (1983) (footnote omitted).

Plaintiff has not proposed a relevant or workable set of comparators. To the extent Plaintiff maintains that the set of similarly situated entities is comprised of all drug manufacturers doing business in Maine and participating in the 340B program, there is no discernible discrimination because the state statute does not make any other distinctions among the participants. To the extent Plaintiff contends that the set of similarly situated entities consists of all drug manufacturers, Plaintiff evidently argues that the relevant distinction would be participation or nonparticipation in the 340B program. Plaintiff, however, has not argued or provided evidence that there are any such nonparticipating drug manufacturers doing business in Maine. Even if such evidence were presented, Plaintiff has not established that its additional rules for 340B participants are sufficiently burdensome to support a finding that Maine seeks to improperly favor nonparticipating manufacturers over participating manufacturers. *See Dawson v. Steager*, 586 U.S. 171, 177 (2019) ("Whether a State treats similarly situated state and federal employees differently depends on how the State has defined the favored class."); *McHenry County. v. Raoul*, 44 F.4th 581, 594 (7th Cir. 2022) (concluding that a state statute's impact on federal

domain “is not enough to establish discrimination” for purposes of the intergovernmental immunity doctrine if a plaintiff “cannot identify any actors similarly situated . . . that receive more favorable treatment” under the state statute); *California*, 921 F.3d at 880–81 (noting that the intergovernmental immunity doctrine is concerned with state rules that burden the federal government and reasoning that a state rule does not “burden” the federal government or those with whom it does business just because the state rule “targets” federal rules).

In sum, the intergovernmental immunity doctrine does not invalidate Maine’s statute or Maine’s rules for contract pharmacies. The Court declines to extend the doctrine to cover any state law that adds a requirement for participants in a federally regulated market or under a federal program.<sup>7</sup> Because the intergovernmental immunity doctrine does not apply as broadly as Plaintiff contends, Plaintiff’s claim to any further degree of

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<sup>7</sup> The evolution of the doctrine of the doctrine weighs against a broad application of the doctrine. The intergovernmental immunity doctrine developed in the state taxation context, *see McCulloch v. Maryland*, 17 U.S. 316 (1819), and the Supreme Court once applied a broad rule prohibiting “taxes on those who had contractual relationships with the Federal Government or with its instrumentalities whenever the effect of the tax,” even an indirect effect, “was or might be to increase the cost to the Federal Government of performing its functions.” *United States v. Fresno County*, 429 U.S. 452, 460 (1977). The rationale was that “although a tax was collected from an independent private party, the tax was considered to be ‘on’ the government because the tax burden might be passed on to it through the contract.” *South Carolina v. Baker*, 485 U.S. 505, 518 (1988). The Supreme Court later recognized that the approach was untenable and “repudiated” the broader rule in a series of cases beginning in the 1930s. *Id.* at 520–21 (“The thoroughness with which the Court abandoned the burden theory was demonstrated most emphatically when the Court upheld a state sales tax imposed on a Government contractor even though the financial burden of the tax was entirely passed on, through a cost-plus contract, to the Federal Government”). Plaintiff does not argue that Maine’s statute would directly or even indirectly increase costs to the federal government. The lack of any clear or apparent impact on federal government costs underscores the conclusions above, including that 340B participants do not qualify as contractors for the federal government and that Maine’s contract pharmacy rules do not discriminate in the relevant sense against drug manufacturers or the federal government.

protection from the state statute “must be resolved under principles of congressional pre-emption.” *North Dakota*, 495 U.S. at 435.

## 2. Preemption

“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 Basilioli 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,” *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*, 152 F.4th 635, 646 (5th Cir. 2025). The Maine law would fall within with the broadly defined fields, but as 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, Plaintiff proposes that the relevant field is the key terms of the 340B statute, namely “eligibility for reduced pricing, the content of a drug manufacturer’s 340B offer . . . and the administration and enforcement of the statute’s requirements.” (Motion at 18.) Yet even if the field were defined in this way, 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 covered drugs, the language of 340B is insufficient to suggest 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*, 152 F.4th at 646 (“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,” which is a subject that does not fall within a specific field that Congress manifested an intent occupy exclusively. *Fitch*, 152 F.4th at 647. The Court is not aware of a case where a court found that field preemption applied to

a similar state statute.<sup>8</sup> Courts have consistently concluded that similar state laws are not within the more 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, that silence has also been viewed by two circuit courts as suggesting that Congress did not intend to preclude state involvement. *Fitch*, 152 F.4th at 647; *McClain*, 95 F.4th at 1144.<sup>9</sup>

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 Plaintiff has not established that it is likely to succeed on its field preemption claim.

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<sup>8</sup> In the three cases where courts have been persuaded by manufacturer’s preemption arguments and either granted a preliminary injunction or denied a motion to dismiss involving a similar state statute, the basis for the determination was a form of conflict preemption. *See Morrissey*, 760 F. Supp. 3d at 458; *Drummond*, No. CIV-25-1156-PRW, 2025 WL 3048929, at \*7; *Brown*, No. 2:25-CV-00271-RJS-DAO, 2025 WL 3228898, at \*9.

<sup>9</sup> The D.C. Circuit in *Johnson* did not address whether state involvement was permissible.

*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 v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000). While Plaintiff contends that “Maine’s process seeks to punish drug manufacturers for obeying federal law,” (Motion at 20), Plaintiff does 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) (observing that the Supreme Court has recently questioned “efforts to ascribe 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) (citing *Virginia Uranium, Inc. v. Warren*, 587 U.S. 761, 778 (2019) ; *see also 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 340B 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.<sup>10</sup> See *Novartis Pharmaceuticals 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 Defendants argue, 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. The harmonious goals of the federal and state are suggestive but not determinative, however. See *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (“it is not enough to say that the ultimate goal of both federal and state law” is the same because “[a] state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal”).

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<sup>10</sup> Some manufacturers have argued 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. Some manufacturers 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. The manufacturers have argued 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. One court’s conclusion in support of this view is that the 340B statute has “twin federal purposes” of providing discounts and 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” notion suggests that these objectives are unrelated to each other, or of equal importance. 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. 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.

Plaintiff argues there is a sufficient obstacle to warrant preemption here because the state statute applies only to participants in the federal 340B program, which program does not rely on the states to implement. According to Plaintiff, state rules are always preempted if they target a federal program by adding requirements for participants. Plaintiff relies on two Supreme Court cases, *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988) and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), to support its argument.

The *Boyle* case addressed one of the “few areas” involving “uniquely federal interests” that “are so committed. . . to federal control” that state law can be preempted by judge-made “federal common law,” *Boyle*, 487 U.S. at 504, when there is “a significant conflict” with “an identifiable federal policy or interest,” *id.* at 507 (internal quotation marks omitted). Because the procurement of equipment by the federal government is an area of uniquely federal interest, the Supreme Court held that state tort liability against contractors for design defects in military equipment is preempted “when (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States.” *Id.* at 512.

In *Buckman*, the Supreme Court held that the Federal Food, Drug, and Cosmetic Act preempted state law fraud claims by patients against medical companies for alleged misrepresentations to the Food and Drug Administration while seeking approval for medical devices. *Buckman*, 531 U.S. at 343–44. The *Buckman* Court reasoned that “the federal statutory scheme amply empower[ed] the FDA to punish and deter fraud against the Administration” through investigative tools backed by criminal punishment, injunctive

relief, and civil penalties, and the agency decided whether and how to pursue the available remedies based on a “delicate balance of statutory objectives” that was likely to be disrupted by allowing private parties to bring “fraud-on-the-FDA claims under state tort law.” *Id.* at 348–49.

Plaintiff evidently relies on these cases in part because the Supreme Court did not apply the usual presumption against preemption and thus applied a lower threshold for finding preemption than in many other cases. The *Boyle* Court reasoned that in an area of uniquely federal interest, “[t]he conflict with federal policy need not be as sharp as that which must exist for ordinary pre-emption when Congress legislates in a field which the States have traditionally occupied.” *Boyle*, 487 U.S. at 507 (quotation marks omitted). Similarly, the *Buckman* Court declined to apply the presumption against preemption because “[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied,” and it cited *Boyle* while noting that “the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.” *Buckman*, 531 U.S. at 347 (quotation marks omitted).

The circumstances here are not similar and do not represent a situation where courts have disregarded or should disregard the presumption against preemption. Maine’s statute does not regulate the relationship between the federal agency (HHS/HRSA) and the entity it regulates (a drug manufacturer or a covered entity). Maine’s statute addresses the relationship between regulated entities and other private entities. There is no dispute that

states have traditionally had a regulatory role addressing the transactions and relationships among drug companies, medical providers, and pharmacies.

This is also not one of the “few areas” where there are “uniquely federal interests” comparable to the terms of the federal government’s procurement contracts or the liability of federal officers for actions taken in the course of their duties. As discussed above, the agreements between drug manufacturers and the Secretary are not analogous to many other contracts, including employment or procurement contacts with the federal government. *See Astra*, 563 U.S. at 113. To the extent Plaintiff argues that there are always “uniquely federal interests” in the legal requirements governing participants in a federal program, that fact alone is insufficient for a court to ignore the presumption against preemption. The argument would expand a limited exception to ordinary preemption principles potentially applicable in only a “few areas,” *Boyle*, 487 U.S. at 504, to include many contexts where there is understandable and necessary concurrent federal and state regulation.

Even if the Court were to accept Plaintiff’s contention regarding the effect of the federal interests on the presumption against preemption, that would “not . . . end the inquiry,” *Boyle*, 487 U.S. at 507, or imply that a state law is always preempted if it targets participants in a federal program. Under *Boyle*, a state law is only displaced if it causes “a significant conflict” with or would “frustrate specific objectives” of the federal policy. *Id.* (quotation marks omitted). In other words, the most that can be reasonably inferred from *Boyle* and *Buckman* is that for preemption, courts might reasonably require less evidence of preemptive intent or a lesser obstacle to federal purposes when there are stronger federal interests and weaker state interests; the Supreme Court 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. *See id.* at 507–08 (“Or to put the point differently, the fact that the area in question is one of unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can. But conflict there must be.”).

The reasoning of other courts also militates against the broad reading of *Boyle* and *Buckman* that Plaintiff proposes. For instance, courts have found it less tenable to infer that Congress intended to preempt a state statute when the federal statute contemplates a state implementation role within the federal program, while implied preemption is more plausible when a federal statute does not provide any role for states. *See Fresenius Medical Care Holdings, Inc. v. Francois*, 832 F. Supp. 2d 1364, 1368 (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”) (quotation marks omitted). Courts also more readily find implied preemption when a state law directly targets a federal program and are less likely to find implied preemption when a general state law impacts a federal program only incidentally. *See Pedraza v. Shell Oil Co.*, 942 F.2d 48, 53–54 & n.5 (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 preemptive intent less likely because the state law did not target eligibility requirements of a federal program but was instead “a generally applicable state law”).

Because there is no categorical rule for state statutes targeting participants in federal programs, a court must still determine in each case whether the alleged obstacles presented by the state law are 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.” *Id.* 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,” *id.* at 76-77, 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 77.

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 in concluding 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 665-67 (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).

Plaintiff contends that by requiring drug manufacturers to provide 340B-priced drugs to multiple pharmacies, the Maine statute impermissibly expands the obligations of manufacturers and, therefore, conflicts with federal law. According to Plaintiff, 340B allows manufacturers to determine the conditions of its offers to sell discounted drugs, which conditions may include requiring claims data and limiting a covered entity to the use of a single contract pharmacy. Plaintiff maintains that the Maine statute “vastly expands the number of 340B transactions[,]” (Motion at 22), and “fundamentally alters the bargain struck by Congress with manufacturers for participation in 340B, Medicare, and Medicaid.” (*Id.* at 23.)

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. That silence, however, does not necessarily mean 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. The Court likewise discerns nothing in 340B to suggest that Congress intended for manufacturers to have an unfettered right to adopt policies with the purpose of limiting the number of its patients for whom a covered entity may prescribe drugs at the discounted rate. For instance, Plaintiffs have offered no reason to believe 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 or a certain radius from the facility. Instead of limiting eligibility and participation, in 2010, Congress significantly increased the number of healthcare facilities that are considered covered entities, an expansion that included rural facilities serving patients over a greater geographic area.

Second, Plaintiff asserts there is a significant 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 for the same conduct. Plaintiff contends that “[t]he Supremacy Clause does not permit Maine to adopt a scheme that eviscerates the uniformity Congress intended and upsets the bargain Congress set for a federally-created benefit program.” (Motion at 29.)

When a federal statute provides a unified administrative remedial scheme for violations of the federal statute, courts typically disfavor statutory interpretations that permit alternate remedies for the same violations, such as implied private rights of action. *See Armstrong v. Exceptional Child Center, Inc.*, 575 U.S. 320, 329 (2015) (concluding that the complexity of enforcing the federal statute “coupled with the express provision of an administrative remedy . . . shows that the [statute] precludes private enforcement of [the provision] in the courts”); *Astra*, 563 U.S. at 120. Similarly, courts have recognized that state efforts to impose additional state law remedies for the same violations of federal law are more likely to be preempted due to the potential to disrupt the tradeoffs embodied in the federal remedial scheme. *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); *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 193 (4th Cir. 2007) (noting that “the [federal statute] does not explicitly authorize states to create alternative remedies” for violations of the federal statute, and concluding that “in view of the [federal statute]’s unusually elaborate enforcement scheme, there cannot be the exceptionally strong presumption against preemption of such state remedies that would be warranted if the [federal statute]

did not provide federal 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.”).

Defendants argue, however, that the Maine statute does not provide additional overlapping remedies for the same federal violations because alleged violations of the state law would not be based on the same overcharging, diversion, and price disputes that are enforced through the federal administrative process. Defendants’ argument has merit. Federal violations like overcharging and diversion are not enforced under the state statute. *See Tompkins v. United Healthcare of New England, Inc.*, 203 F.3d 90, 96 (1st Cir. 2000) (noting that a state law can impair a federal law “to the extent that the [state law] provides a means of enforcing [the federal law’s] commands” but there is no impairment if “the practices made unlawful under [the state law] were not unlawful under [the federal law]”) (summarizing *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983)).

Plaintiff argues that there is the potential for conflicting adjudications because a manufacturer might assert as an affirmative defense in a state enforcement proceeding that the covered entity’s drugs which the manufacturer refused to deliver or distribute through a contract pharmacy were not required to be sold at the 340B price under federal law, but it is far from obvious whether or how often such questions would arise. At least at this stage, the alleged conflict is too speculative to support a finding that Plaintiff is likely to prevail. *See English v. General Electric Co.*, 496 U.S. 72, 90 (1990) (finding prospect of overlapping state and federal enforcement proceedings “too speculative a basis on which

to rest a finding of pre-emption” because the Supreme Court “has observed repeatedly that pre-emption is ordinarily not to be implied absent an ‘actual conflict’”).

It is also not clear on this record whether there are any federal remedies available for the conduct the state statute prohibits. 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). Manufacturers have argued that contractual policies limiting a covered entity’s distribution of the drugs to patients through contract pharmacies (the subject of the Maine statute) could be challenged in a federal agency proceeding as a limitation on the ability of the covered entity to purchase drugs at or below the ceiling price under the federal law. The Court is not persuaded that such an interpretation presents a significant 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 the federal remedy is not available for such conduct because 340B does not address distribution. Again, the alleged conflict is too speculative currently to support a finding that Plaintiff is likely to prevail on the merits of its claim.

Third, Plaintiff argues 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 improper claims and fraud, and the ADR process is evidently intended to assist in that objective. Manufacturers have argued they need claims data to prevent fraud and meet the “reasonable cause” level of suspicion necessary to initiate an audit. The concern regarding

access to evidence of possible violations is not unreasonable. But neither Plaintiff nor the manufacturers have demonstrated that claims data are necessary to obtain an audit or that the proof necessary to obtain an audit is particularly onerous. For instance, the 340B program and the audit process have existed for many years, but there are apparently no cases where a manufacturer requested but was denied an audit due to a lack of relevant claims data. As with the other enforcement arguments, on the current record, the alleged impediment is too speculative to support a finding that Plaintiff is likely to prevail on its claim.<sup>11</sup>

Furthermore, the “subtle refram[ing]” of the obstacle preemption inquiry, which the First Circuit has identified in more recent Supreme Court opinions, does not assist Plaintiff. *Cormier*, 51 F.4th at 8. 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 challenged state regulation. *Id.* (citing *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

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<sup>11</sup> Plaintiff argued previously that there could be a conflict for those manufacturers participating in HRSA’s rebate pilot program because its rules require the collection of some claims data. The State suggested that there would likely be no conflict because under the savings clause of the state statute, the collection of claims data is not prohibited when it is required under federal law. The Court need not address the issue further as the parties later stipulated that the issue was resolved when the State determined that Chapter 103 is not violated when a manufacturer within the rebate pilot program requires the submission of the specified claims data. (Stipulation at 3–4, ECF No. 47.)

intended to confer on manufacturers a right to be free from all state law requirements regarding drug distribution to patients, delivery of a covered entity's property to contract pharmacies, and collection of claims data.

Finally, the other prominent case Plaintiff cites, *Forest Park II v. Hadley*, 336 F.3d 724 (8th Cir. 2003), is not to the contrary. In *Hadley*, the operator of an apartment building financed through a federal subsidized housing program sought to prepay its mortgage and withdraw from the federal program. *Id.* at 727. Although the operator met the federal withdrawal requirements, a state statute imposed additional conditions and different time schedules for withdrawing from the federal program. *Id.* at 730. The Eighth Circuit declined to apply the presumption against preemption based on *Buckman* and found the state statute preempted. *Id.* at 731, 734.

Plaintiff points to certain broad language in the opinion. *See id.* at 732 (“Simply, state statutes may not interfere with the implementation of a federal program by a federal agency.”) But other portions of the decision demonstrate that the Eighth Circuit did not adopt the categorical non-targeting rule that Plaintiff contends should apply here. *See id.* at 734 (“We do not suggest that all state attempts at preserving existing federally subsidized, low-income housing are preempted. Nothing . . . indicates that states are prohibited from instituting their own incentive plans or other programs to preserve low-income housing within the framework of the federal prepayment scheme.”).

Unlike in this case, the state statute in *Forest Park* imposed requirements inconsistent with the federal rules because they “restrict[ed] the exercise of the participants’ federally granted prepayment rights” and used different timelines than the

federal law, “creat[ing] delays in the prepayment process.” *Id.* at 734. In addition, unlike here, that state statute regulated the relationship between the federal agency and the regulated entity rather than relationships between private parties. *See id.* at 732 (“[T]he state law forces the federal government to continue to provide financial assistance to the participant when both the federal government and the participant have chosen to end their relationship.”). In other words, the state statute was preempted in *Forest Park* not because of a categorical non-targeting rule but because the degree of conflict or interference was of a far greater magnitude than Plaintiff has shown here.

In sum, on the record at this stage of the proceedings, which record includes competing sworn declarations, the Court is not convinced that Plaintiff is more likely than not to 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 the state statute interferes with or undermines the available federal remedies or 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. Plaintiff has failed to establish a likelihood of success on its obstacle preemption claim. *See Fitch*, 152 F.4th at 647–48; *McClain*, 95 F.4th at 1145.

## **B. Other Factors**

Because Plaintiff has failed to establish that it will likely succeed on the merits of its intergovernmental immunity or preemption claims, the Court need not address the remaining preliminary injunction factors (irreparable harm, the balance of hardships, and

the public interest). “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.” *New Comm Wireless Services, Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002).

#### CONCLUSION

After an assessment of the factors relevant to Plaintiff’s request for a preliminary injunction, the Court concludes that Plaintiff is not entitled to preliminary injunctive relief. Accordingly, the Court denies Plaintiff’s motion for a preliminary injunction.

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

Dated this 23rd day of January, 2026.