2026 WL 2145194
Only the Westlaw citation is currently available.
United States District Court, D. Maine.

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff

v.

AARON FREY, et al., Defendants

1:25-cv-00495-JCN
|
Filed 07/27/2026

Attorneys and Law Firms

Allon Kedem, Pro Hac Vice, Jeffrey L. Handwerker, Pro Hac Vice, Samuel I. Ferenc, Pro Hac Vice, Arnold & Porter Kaye Scholer LLP, Washinton, DC, Carmela T. Romeo, Pro Hac Vice, Nicole L. Masiello, Pro Hac Vice, Arnold & Porter Kaye Scholer LLP, New York, NY, Jeffrey D. Talbert, Arnold & Porter Kaye Scholer LLP, Newark, NJ, for Plaintiff.

Kimberly L. Patwardhan, Michael T. Devine, Sean D. Magenis, Office of the Attorney General, Augusta, ME, for Defendants.

Alyssa Howard, Pro Hac Vice, William B. Schultz, Pro Hac Vice, Zuckerman Spaeder LLP, Washington, DC, Edward S. MacColl, Thompson, MacColl & Bass LLC, P.A., Portland, ME, for Amici American Hospital Association, 340B Health, American Society of Health System Pharmacists.

Edward S. MacColl, Thompson, MacColl & Bass LLC, P.A., Portland, ME, for Amicus Maine Hospital Association.

ORDER ON MOTION TO DISMISS

John C. Nivison U.S. Magistrate Judge

***1** Plaintiff, a biopharmaceutical company, challenges a Maine statute (Chapter 103 in the Maine Insurance Code) related to the role of contract pharmacies within a federal drug discount program (the 340B program).[1] (Complaint, ECF No. 1.) Plaintiff contends that the Maine statute is preempted, substantially impairs its contract with the federal government, and represents a taking of property without compensation. The matter is before the Court on Defendants' motion to dismiss. (Motion, ECF No. 18.) Plaintiff opposes the motion. (Response, ECF No. 25.)

1 Plaintiff named Aaron Frey, Maine's Attorney General, and Bob Carey, the Superintendent of the Maine Bureau of Insurance, as defendants.

Following a review of the complaint and after consideration of the parties' arguments and relevant legal authority,[2] the Court grants the motion and dismisses the complaint.

2 Some of the issues presented in this case and by Defendants' motion to dismiss have been considered and are continuing to be considered by multiple courts. At the conclusion of oral argument, the Court invited the parties to submit for the Court's consideration any relevant decisions that are issued after oral argument and before the Court rules on the motion to dismiss. The parties submitted some additional decisions, which the Court has considered.

Background[3]

3 The following facts are derived primarily from the complaint and public documents amenable to judicial notice. The Court also reiterates herein some of the background summary and legal analysis included in its decisions in three related cases challenging the same state statute. *See* *Novartis Pharmaceuticals Corp. v. Frey*, No. 1:25-cv-00407-JCN, 2025 WL 2813787 (D. Me. Sept. 23, 2025); *AbbVie Inc. v. Frey*, No. 1:25-cv-00416-JCN, 2025 WL 2813787 (D. Me. Sept. 23, 2025); *Pharmaceutical Research & Manufacturers of America v. Frey,* No. 1:25-cv-00469-JCN, 2026 WL 184504 (D. Me. Jan. 23, 2026).

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, which provide 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 WL 2206948, at *1 (citations omitted).[4] 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).

4 The parties in this and the other related cases evidently dispute 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. Plaintiff alleges that contract pharmacies often receive a fee of twenty percent of the sale price. (Complaint ¶ 36.) An insured patient might not benefit directly from the lower price if the patient's out-of-pocket cost is the same, regardless of whether the drug is eligible for the discount, but uninsured patients often benefit directly, (*id.* ¶ 40), and both uninsured and insured patients arguably benefit indirectly because one purpose of allowing the covered entity to retain a portion of the price difference is that the entity can use the 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 potential dispute is not material to the pending motion because Plaintiff's legal claims do not depend on the extent to which patients experience the benefits of the program.

***2** 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 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.

***3** Since 2010, the 340B program has grown significantly. Drug manufacturers attribute much of the growth to the unlimited use of contract pharmacies. Covered entities and pharmacies have also moved away from a segregated inventory for drugs available under the 340B program 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, including Plaintiff, 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.[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, including Plaintiff, 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).

5 Plaintiff evidently adopted such a policy later, in October 2024. (Complaint ¶¶ 68, 74.)

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

***4** 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.

Many 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. Multiple district courts (including this Court) have denied injunctive relief or granted judgment in favor of a state after considering similar legal claims to those Plaintiff asserts here; three of those decisions were affirmed on appeal. *See, e.g.*, *AbbVie, Inc. v. Murrill*, No. 24-30645, 2026 WL 1947948, at *1 (5th Cir. July 6, 2026); *AbbVie, Inc. v. Fitch*, 152 F.4th 635 (5th Cir. 2025); *Pharmaceutical Research & Manufacturers of America v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *AbbVie, Inc. v. Skrmetti*, No. 3:25-CV-00519, 2026 WL 542712, at *4 (M.D. Tenn. Feb. 26, 2026) (collecting cases). A few district courts have enjoined similar state statutes or denied motions to dismiss claims similar to Plaintiff's. *See, e.g.*, *AbbVie Inc. v. Drummond*, No. CIV-25-1156-PRW, 2025 WL 3048929, at *6 (W.D. Okla. Oct. 31, 2025). Other comparable cases are pending in other district courts, and other appeals are also pending.[6]

6 A divided panel of the Fourth Circuit initially affirmed on preemption grounds a preliminary injunction against the enforcement of a similar state statute, but the panel's decision was vacated when the full court granted en banc review. *Pharmaceutical Research and Manufacturers of America. v. McCuskey*, 171 F.4th 675 (4th Cir. 2026), *rehearing en banc granted*, 176 F.4th 830 (4th Cir. 2026); Fourth Circuit Local Rule 40(e).

Standard of Review

***5** In reviewing a motion to dismiss under Rule 12(b)(6), a court "must evaluate whether the complaint adequately pleads facts that 'state a claim to relief that is plausible on its face.' " *Guilfoile v. Shields*, 913 F.3d 178, 186 (1st Cir. 2019) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In doing so, a court must "assume the truth of all well-pleaded facts and give the plaintiff the benefit of all reasonable inferences therefrom," but need not "draw unreasonable inferences or credit bald assertions [or] empty conclusions." *Id.* (alteration in original) (internal quotation marks omitted); *see also Bruns v. Mayhew*, 750 F.3d 61, 71 (1st Cir. 2014) ("[A] court is 'not bound to accept as true a legal conclusion couched as a factual allegation.' " (quoting *Twombly*, 550 U.S. at 555)). Federal Rule of Civil Procedure 12(b)(6) "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To evaluate the sufficiency of the complaint, therefore, a court must "first, 'isolate and ignore statements in the complaint that simply offer legal labels and conclusions or merely rehash cause-of-action elements,' then 'take the complaint's well-pled (i.e., non-conclusory, non-speculative) facts as true, drawing all reasonable inferences in the pleader's favor, and see if they plausibly

narrate a claim for relief.' " *Zell v. Ricci*, 957 F.3d 1, 7 (1st Cir. 2020) (alteration omitted) (quoting *Zenon v. Guzman*, 924 F.3d 611, 615-16 (1st Cir. 2019)).

Discussion

As noted above, Plaintiff challenges the Maine law on grounds that the law (a) is preempted under federal law, (b) violates the Contracts Clause of the United States Constitution, and (c) constitutes a taking in violation of the Fifth Amendment to the United States Constitution. Defendants move to dismiss all the claims.

A. Obstacle Preemption Claims

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. "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).

Plaintiff does not assert a field preemption claim. Rather, Plaintiff alleges conflicts with two different federal statutes. 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). 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).

***6** 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[.]").

1. The 340B Statute

a. Primary Purpose

The core congressional objective in this case is not difficult to discern. The 340B program is designed to use access to two other large federal spending programs to incentivize manufacturers to provide a subsidy to healthcare entities caring for underserved

patients. *See Fitch*, 152 F.4th at 639 ("In 1992, Congress created the Section 340B program to ensure that uninsured and low-income individuals can access the medications they need and to ensure that medical providers serving these individuals receive crucial subsidies"); *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 purpose and effect of the state law and the central objective of 340B. The primary 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 populations. *See Murrill*, 2026 WL 1947948 at *8 ("the two laws work in tandem to advance Congress's central aim"); *McClain*, 95 F.4th at 1144–45 ("[the state law] assists in fulfilling the purpose of 340B").

The harmonious goals of the federal and state statutes 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"). Regardless of the consistency between the main goals of the federal and state statutes, Plaintiff contends that Maine's statute is preempted because there are several ways the statute interferes with the chosen methods and subsidiary goals of 340B. The Court addresses each argument below.

b. Presumption Against Preemption and Proposed No-Targeting Rule

Plaintiff asserts that preemption is required because the state statute applies only to participants in the federal 340B program, but the 340B program does not rely on the states for implementation. 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.

In *Boyle*, the Supreme Court 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.

***7** 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 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 the cases in part because the Supreme Court did not apply the presumption against preemption and thus applied a lower threshold for finding preemption than in many other cases. The Supreme 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, in *Buckman*, the 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." *Buckman*, 531 U.S. at 347 (quotation

marks omitted). The Court 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." (*Id.*)

The circumstances here are not similar and are not the type 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. *See Murill*, 166 F.4th at 539, 542 (declining a manufacturer's urging to dispense with the presumption against preemption and noting that "[t]he statute does not disturb the federally regulated relationship between manufacturers and covered entities"). 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 disregard 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 situations 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 less significant 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.").

***8** 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").

As this Court has previously observed, the case of *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644 (2003) is 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.

***9** The Supreme Court affirmed the First Circuit's decision. *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644, 670 (2003). Finding 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).

Because there is no categorical rule for obstacle preemption (even for state statutes targeting a federal program), a court must determine in each case whether the alleged obstacles presented by the state law are significant enough to compel preemption. The Court considers the magnitude of each alleged impediment.

c. Added Costs from Legitimate Transactions

Plaintiff contends that Chapter 103 "vastly expand[s]" the number of 340B transactions, "drastically increasing [manufacturers'] costs[.]" (Complaint ¶¶ 6, 89.) Compared to the approach that Chapter 103 preserves, where a covered entity can use any number of pharmacies to distribute drugs to the covered entity's patients, Plaintiff alleges that it would save $300,000 per month (equivalent to $3.6 million per year) if it could limit covered entities to using a single pharmacy. (Complaint ¶ 98.) According to Plaintiff, the costs of allowing covered entities to use more than one contract pharmacy fundamentally alter the bargain struck by Congress with manufacturers for participation in 340B, Medicare, and Medicaid.

As applied to otherwise legitimate discounted transactions, the argument is unpersuasive. There is nothing in the language of 340B to suggest that Congress intended to afford manufacturers an unfettered right (and free from state law rules)[7] to place conditions on its offer for the purpose of significantly limiting or reducing the number of otherwise qualifying transactions at the discount price. Plaintiff has alleged no facts nor offered any reasonable argument to suggest that Congress' objective was to limit non-duplicative discounts to any subset of a covered entity's patients, such as those living in the immediate vicinity or a certain radius from the facility. To the contrary, after HRSA proposed the multiple-contract-pharmacy rule, rather than attempting to reduce the size of the 340B program or limit eligibility and participation, in 2010, Congress significantly increased the number of healthcare facilities that are considered covered entities, and the expansion included rural facilities serving patients over a greater geographic area.

7 The First Circuit has identified a "subtle refram[ing]" of the obstacle preemption inquiry. *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 in more detail below, 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 and pharmacies.

***10** Plaintiff implies that states are improperly attempting to overrule the decisions of the Third and D.C. Circuits, but the Third and D.C. Circuits never suggested that Congress wished to limit the number of otherwise legitimate sales to the patients of covered entities. According to the Third and D.C. Circuits, congressional silence regarding the ordinary terms and conditions that drug manufacturers might 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. Congressional silence, however, does not necessarily mean that Congress intended to prevent state involvement or to ensure that manufacturers had an unrestricted right to adopt contractual terms with the intended or foreseeable effect of drastically curbing the number of otherwise legitimate discount 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."); *Murrill*, 2026 WL 1947948 at *8 ("Congress decided not to undertake regulation of the delivery of 340B drugs or the role of pharmacies in that process—thereby leaving, absent congressional amendment, those matters to state law").[8]

8 It is also noteworthy that the manufacturers' preemption challenges are premised on the prior statutory interpretation of the Third and D.C. Circuits, but the manufacturers' allegations here regarding the magnitude of the impact of their contract pharmacy policies appear to be in tension with the arguments the manufacturers made in those cases and the caveats in the courts' interpretation. For example, the D.C. Circuit accepted the delivery conditions as legal under federal law but reasoned that "more onerous conditions might violate the statute," such as if they did not amount to a "bona fide" offer or "effectively increase the contract 'price[.]' " *Johnson*, 102 F.4th at 462, 464. In other words, the argument for the federal legality of the delivery conditions was that they represented reasonable business terms with a modest impact on the scope of the program, whereas manufacturers now argue that a state law prohibiting the same delivery conditions represents a vast and drastic expansion of the scope of the program.
Neither Defendants nor HRSA continue to dispute the interpretation of the Third and D.C. Circuits, so the Court assumes without deciding that the interpretation of federal law is correct. The Court notes only that the other circuits have not considered whether the 340B statute should be interpreted to allow manufacturers to adopt conditions on its offer to sell for the purpose of significantly reducing the number of otherwise qualifying discounted transactions, and the Supreme Court has not conclusively answered the question.

Plaintiff alleges that the larger number of discounted sales occurring in a distribution system involving multiple contract pharmacies discourages manufacturers from continuing to participate in the 340B program. (*Id.* ¶ 94.) As mentioned above, Plaintiff alleges that it would save $300,000 per month (equivalent to $3.6 million per year) if it could limit covered entities

to using a single pharmacy. (Complaint ¶ 98.) Plaintiff also submitted arguments from the Government in another case, which arguments included the alleged possibility that costs might outstrip profits for some manufacturers, who would then withdraw from the program. (Amicus Brief at 24–26, ECF No. 28-1.)

The Court agrees that if a state adopted rules targeting transactions in the 340B program which were burdensome enough that they risked eliminating the overall financial incentive for manufacturers to participate, it would present an impermissible obstacle to the goals of the 340B, resulting in preemption. The nonconclusory facts alleged here, however, such as Plaintiff's alleged profit reduction of $300,000 per month, do not plausibly support a conclusion that the pharmacy distribution rules like Chapter 103 are burdensome enough to threaten the financial incentive for manufacturers to participate in the 340B program.[9]

9 Because a district court considering a motion to dismiss must accept as true all well-pleaded factual allegations, the Court assumes for purposes of the motion the truth of the more specific statements in the complaint, such as the estimated $300,000 per month financial impact of a multiple pharmacy requirement, the growth of the program, and the increase in the number of contract pharmacies since 2010. However, Plaintiff's caveats and predictions about the possible future conduct of other manufacturers and the potential impact of that predicted conduct on the goals of the federal program do not appear to be based on Plaintiff's personal knowledge but rather involve a series of proposed deductions, inferences, and legal determinations. In any event, the assertions are "the type of conclusory statement[s] that need not be credited at the Rule 12(b)(6) stage," and must instead be assessed for their plausibility based on the more specific factual matter in the complaint. *A.G. by & through Maddox v. Elsevier, Inc.*, 732 F.3d 77, 80 (1st Cir. 2013); *see also*, *Shay v. Walters*, 702 F.3d 76, 82 (1st Cir. 2012) (noting that district courts should "strip away and discard" conclusory statements); *Sullivan v. City of Springfield*, 561 F.3d 7, 14 (1st Cir. 2009) (noting that courts need not credit statements in a pleading that involve "conclusory allegations, improbable inferences, [or] unsupported speculation").

***11** Plaintiff failed to allege any facts regarding its profits or the industry's profits from Medicare and Medicaid to permit a comparison or assessment of the alleged financial burden imposed by the use of multiple pharmacies as contemplated by Chapter 103. Notably, Plaintiff has not alleged that it intends to withdraw from the program if it must distribute discounted drugs to covered entities' patients through multiple pharmacies. In fact, Plaintiff's allegations suggest that manufacturers evidently continued to participate in the period after 2010 when federal law was understood to allow covered entities to use an unlimited number of pharmacies and after 2020 when states began enacting laws like Maine's statute. The allegations, therefore, do not support a plausible inference that contract pharmacy rules like Chapter 103 expand manufacturer obligations to a degree that fundamentally alters the bargain Congress established regarding 340B costs and Medicare and Medicaid profits such that manufacturers would withdraw from the program.

The Court concludes that even after assuming the truth of the facts alleged in the complaint and drawing all reasonable inferences in Plaintiff's favor, the allegations would not support a finding that the financial impact of Chapter 103 represents more than a modest impediment to the goals of the 340B statute.

d. Added Costs from Illegitimate Transactions

Plaintiff also contends that its argument regarding the likely increase in the number of discounts applies to improper transactions under the federal statute. The argument has more merit as applied to illegitimate discount claims. The prohibitions on diversion and double discounting combined with the auditing process and penalties for violations demonstrate a subsidiary congressional objective of protecting manufacturers against improper claims and fraud. Mitigating the circumvention of eligibility rules is a discernible ancillary goal of virtually any such program.

The alleged nonconclusory facts, however, would not support a finding that Chapter 103 presents more than a modest impediment to the goal of preventing double discounts or diversion. Plaintiff suggests that some (unspecified) portion of the growth of the 340B program since 2010 is attributable to the use of multiple contract pharmacies making it more difficult to detect abuse, but the complaint contains no facts to permit an assessment of the size of the alleged problem as compared to the growth attributable to other causes.[10] Likewise, Plaintiff alleges that the use of multiple pharmacies facilitates diversion

and duplicate discounts, (Complaint ¶ 43), but Plaintiff provides no alleged facts or figures to permit an assessment of the magnitude of the alleged facilitation relative to other causes and the scale of the program overall.[11] Plaintiff also does not allege which portion (or any) of its expected savings of $300,000 per month are attributable to reduced fraud or abuse as opposed to an expected reduction in otherwise proper discounted transactions. In sum, Plaintiff has not alleged facts that would support a finding that Maine's statute presents more than a "modest" impediment to the goals of the 340B objectives.[12] *Walsh*, 538 U.S. at 665-67.

10 For example, in support of its conclusion that the use of multiple pharmacies causes abuse, Plaintiff only includes figures showing that there was an increase in the number of contract pharmacy arrangements since 2010, but that result is not surprising and is not suggestive of abuse because HRSA endorsed the use of multiple pharmacies beginning that year and at approximately the same time that Congress expanded the categories of covered entities that could participate. (Complaint ¶¶ 30–32, 46.)

11 For example, Plaintiff cites a 2018 Government Accountability Office report observing that approximately two-thirds of the diversion findings in HRSA audits between 2012 and 2017 involved drugs distributed through contract pharmacies, (Complaint ¶ 48), but that fact alone is not suggestive of an overwhelming or even disproportionate contribution to abuse because Plaintiff did not allege what portion of overall distribution during those years occurred through contract pharmacies rather than through in house pharmacies. If more than two-thirds of covered entities' patients received their medications through contract pharmacies, the fact that only two-thirds of the diversion findings involved contract pharmacies would suggest a fraud prevention effect rather than facilitation.
HRSA posts some information on its website about the results of two hundred audits of covered entities it conducts each year. Plaintiff cites one year, 2019, and notes that nineteen covered entities had permitted an unspecified amount of diversion through contract pharmacies. (Complaint ¶ 48.) Again, because Plaintiff offers no information regarding the amount of diversion that occurred for even those entities and no way to compare the rates of diversion for covered entities utilizing multiple contract pharmacies rather than a single contract pharmacy or an in house pharmacy, the alleged fact alone does not make it plausible to conclude that a state law rule allowing multiple outside pharmacies would present more than a *de minimis* obstacle to achieving the antifraud goals that Plaintiff has identified.

12 As the other manufacturers made explicit in the prior related cases, the most plausible inference from the specific factual matter contained in the complaint is that most (or the vast majority) of the estimated financial impact underlying Plaintiff's preemption claim rests on an expected reduction in otherwise qualifying transactions rather than savings from preventing diversion or double discounting.

***12** Plaintiff further 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. As discussed above, 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 or illegitimate claims 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. Plaintiff, however, has not alleged facts showing 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 Plaintiff has not cited a case where a manufacturer requested but was denied an audit due to a lack of relevant claims data. Some covered entities have used contract pharmacies for decades, and the manufacturers evidently did not previously assert that they needed claims data to establish cause to obtain an audit (wherein they will get claims data).

Plaintiff argues that there could be a conflict for manufacturers participating in HRSA's rebate pilot program because its rules require the collection of some claims data. Plaintiff has not established an actual conflict, however, because Defendants have consistently asserted that under the savings clause of the state statute the collection of claims data is not prohibited when it is required under federal law. To that end, Defendants stipulated in a prior related case that Chapter 103 is not violated when a manufacturer within the rebate pilot program requires the submission of the specified claims data, and Defendants have reiterated that position in this case. (Motion at 13–14.) Plaintiff has not argued or alleged any facts to suggest that Defendants have brought or intend to bring enforcement proceedings against it or any other manufacturer based on a different interpretation of Chapter 103 and the pilot program.[13]

13 Furthermore, HRSA has not begun to implement the proposed rebate pilot program as it has been the subject of legal challenges and further administrative consideration. *See, e.g.*, *American Hospital Association v. Kennedy*, No. 2:25-cv-00600-LEW, 2026 WL 372131 (D. Me. Feb. 10, 2026).

In sum, the alleged burden from Chapter 103 on the subsidiary antifraud goal of the 340B statute is too speculative to support a finding that the state statute represents more than a modest impediment.

e. Alternate Remedies

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 the Supremacy Clause does not permit Maine to adopt a scheme that defeats the uniformity that Congress intended and upsets the bargain Congress set for a federally created benefit program.

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.").

***13** 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 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 Plaintiff's assertions do not support a plausible claim. Because the alleged conflict involves questions that would likely arise (if at all) as a hypothetical affirmative defense to a future enforcement proceeding, the alleged conflict is too speculative to support a finding of preemption here. *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 preemption" because the Supreme Court "has observed repeatedly that pre-emption is ordinarily not to be implied absent an 'actual conflict' ").

Plaintiff's complaint also does not include facts to suggest that there are available federal remedies for the conduct that 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 to support a finding of preemption.

* * *

In sum, the allegations, if proven, would not establish that Chapter 103 represents more than a modest impediment to drug manufacturers' participation in and the goals of 340B. As related to the 340B obstacle conflict preemption claim that Plaintiff asserts in the complaint, the Court is not persuaded that Plaintiff has alleged sufficient facts to support a finding that the state statute substantially interferes with or undermines the core objective, the subsidiary objectives, or the chosen remedies for violations of the federal statute. Plaintiff's 340B preemption claim, therefore, fails. *See Murrill*, 2026 WL 1947948 at *8; *Fitch*, 152 F.4th at 647–48; *McClain*, 95 F.4th at 1145.

2. Patent Law

Plaintiff claims that Chapter 103 is preempted by federal patent laws. "[T]he field of federal patent law preempts any state law that purports to define rights based on inventorship." *University of Colorado Foundation, Inc. v. American Cyanamid Co.*, 196 F.3d 1366, 1372 (Fed. Cir. 1999). Plaintiff does not allege that Chapter 103 alters intellectual property ownership, but Plaintiff claims that Chapter 103 is nevertheless preempted because it allegedly creates an impermissible obstacle to federal patent laws through its price impacts on some transactions involving some patented drugs.

***14** The Supreme Court has acknowledged that state regulations can present obstacles to federal intellectual property statutes and has identified three central objectives of the federal patent laws: (1) granting a temporary right of exclusion to enhance the financial reward of inventions, (2) requiring adequate and full disclosure so that others can utilize inventions after the expiration of the period of exclusion, and (3) ensuring that knowledge in the public domain cannot be removed. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974). Plaintiff's argument implicates the first of the identified objectives. Federal courts have found impermissible obstacles from certain state statutes attempting to regulate the price of patented drugs. For example, Plaintiff cites *Biotechnology Industry Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (hereinafter "*BIO*"), which invalidated legislation making it unlawful to sell "a patented prescription drug" in D.C. "for an excessive price." *Id.* at 1365.

As compared with cases like *BIO*, which found the statutes preempted, the alleged facts in this case reveal a lesser degree of impact and a more attenuated chain of causation regarding the financial incentive to invent. Chapter 103 does not "affect[ ] only patented products," *id.* at 1373, it "neither caps the price of patented drugs nor penalizes high prices as such, and it applies regardless of whether the drugs are subject to patent." *AstraZeneca Pharmaceuticals LP v. Lopez*, No. 25-00369 MWJS-WRP, 2026 WL 497141, at *17 (D. Haw. Feb. 23, 2026). Other courts have correctly noted that state contract pharmacy laws "do[ ] not cap the price of patented drugs—Section 340B does." *AstraZeneca Pharmaceuticals LP v. Weiser*, No. 25-CV-02685-PAB-STV, 2025 WL 3653161, at *10 (D. Colo. Dec. 17, 2025).[14] Further, it is insufficient to show an indirect profit reduction through an impact on the number of sales in a highly regulated market in which Plaintiff participates voluntarily. *See Lopez*, 2026 WL 497141, at *17 (rejecting similar argument because "[u]nder that theory, any [state] regulation increasing the cost of selling or distributing patented goods would be per se invalid").

14 The Court also notes that manufacturers' attempts to characterize contract pharmacy statutes like Chapter 103 as price regulations rather than distribution or delivery regulations are suspect particularly given that the Third Circuit and D.C. Circuits evidently relied on manufacturers' contrary arguments that their contract pharmacy policies were merely distribution or delivery conditions rather

than substantive measures implicating drug pricing. *See Johnson*, 102 F.4th at 463 (characterizing the contract pharmacy policies as "delivery conditions" or "distribution conditions" but noting that onerous conditions could effectively impact "price").

The allegations in the complaint, therefore, would not support a finding that Chapter 103 presents more than a modest impediment to the objectives of federal patent laws. Accordingly, Plaintiff's patent law preemption claim fails.

B. Contracts Clause Claim

The Contracts Clause provides that "[n]o State shall ... pass any ... Law impairing the Obligation of Contracts." U.S. Const. art. 1, § 10, cl. 1. "The origins of the Clause lie in legislation enacted after the Revolutionary War to relieve debtors of their obligations to creditors." *Sveen v. Melin*, 584 U.S. 811, 818 (2018). When analyzing a Contracts Clause claim, a court must determine "[1] whether there is a contractual relationship, [2] whether a change in law impairs that contractual relationship, and [3] whether the impairment is substantial," *Maine Association of Retirees v. Board of Trustees of Maine Public Employees Retirement System*, 758 F.3d 23, 29 (1st Cir. 2014), and if so, "[4] whether the impairment was reasonable and necessary to serve an important government interest." *Vazquez-Velazquez v. Puerto Rico Highways & Transportation Auth.*, 73 F.4th 44, 51 (1st Cir. 2023); *see also*, *McGrath v. Rhode Island Retirement Board*, 88 F.3d 12, 16 (1st Cir. 1996). Here, the Court need not assess the more complex final step because the allegations are insufficient to satisfy each of the first three considerations.

***15** First, although the Contracts Clause is not limited to its original debtor-credit context and applies to other types of contracts, *Sveen*, 584 U.S. at 818, it does not apply to all representations, agreements, or authorizations upon which a person might rely. *See, e.g.*, *Cherokee Nation Businesses, LLC v. Arkansas*, No. 4:24-CV-969-DPM, 2025 WL 849181, at *1 (E.D. Ark. Mar. 18, 2025) (noting that government licences, charters, and grants are generally not contracts for purposes of the Contracts Clause); *Horan v. Coen*, No. 122CV01120JDBJAY, 2023 WL 9751502, at *2 (W.D. Tenn. Dec. 21, 2023) (noting that consensual custody orders and settlement orders are not contracts for purposes of the Contracts Clause); *Avery v. Sanders*, No. 4:22-CV-00560-LPR, 2023 WL 166469, at *2 (E.D. Ark. Jan. 11, 2023) (noting that plea bargains are contract-like for some purposes like rules of interpretation but are not contracts for purposes of the Contracts Clause); *Banerjee v. Town of Wilmot, NH*, No. 13-CV-203-PB, 2013 WL 4787220, at *2 (D.N.H. Sept. 6, 2013) (noting that building permits are a government authorization to build but not a contract).

The Supreme Court teaches that a Pharmaceutical Pricing Agreement (PPA) is merely "a form" that manufacturers use to opt into the 340B program. *Astra USA*, 563 U.S. at 113. Each PPA "simply incorporate[s] statutory obligations and record[s] the manufacturers' agreement to abide by them." *Id.* at 118. The Supreme Court declined to apply the usual contract enforcement rules to PPAs in part because they "contain no negotiable terms," and they "are not transactional, bargained-for contracts." *Id.* at 113, 118. Plaintiff has not alleged or argued that its PPA creates obligations that could be enforced through a contract claim or that it would be entitled to damages for any breach on the part of HHS. *See Redondo Const. Corp. v. Izquierdo*, 662 F.3d 42, 48 (1st Cir. 2011) ("A contract creates alternative obligations: performance or payment of damages for breach"). Under the Supreme Court's reasoning in *Astra*, a breach of contract suit is likely unavailable because a suit to enforce a PPA "is in essence a suit to enforce the statute itself," *id.* at 115, and because a manufacturer's remedy for alleged violations of 340B is instead an administrative proceeding "subject to judicial review under the Administrative Procedure Act." *Id.* at 118.[15] The Court concludes, therefore, that PPAs are not contracts capable of generating a Contracts Clause claim.

15 Because the Supreme Court concluded that a suit to enforce a PPA would amount to an attempt to enforce the statute, it is also noteworthy that courts are precluded from "finding that a statute creates a binding contract absent a clear and unequivocal expression of intent by the legislature to so bind itself," and the First Circuit has "[n]ever once ... found that state or federal legislation clearly and unequivocally expressed a legislative intent to create private contractual rights enforceable as such against the state." *Cranston Firefighters, IAFF Loc. 1363, AFL-CIO v. Raimondo*, 880 F.3d 44, 48 (1st Cir. 2018).

Second, even if PPAs did qualify as contracts for purposes of the Contracts Clause, the nonconclusory allegations in the complaint do not demonstrate that Chapter 103 impairs its relationship with HHS. Maine's statute "does not alter the terms, rights, or obligations of AstraZeneca's PPA with the federal government" because the state statute "addresses acquisition and delivery of discounted drugs to contract pharmacies," a topic on which "the PPAs are silent." *Murrill*, 2026 WL 1947948 at *11.

Because the federal government and the manufacturers have long been aware that a significant portion of distribution between covered entities and patients involves outside pharmacies subject to state law regulations, and yet they never chose to make "delivery logistics ... part of the federal pricing agreements," Chapter 103's requirement that manufacturers not interfere with a covered entity's decision to use certain pharmacies "does not alter the contractual bargain between AstraZeneca and the federal government." *Id.* at 545.

***16** Third, even if there was some impairment, the degree of the impairment is not substantial. "The parties' reasonable expectations are central to the issue of substantiality." *Alliance of Automobile Manufacturers v. Gwadosky*, 430 F.3d 30, 42 (1st Cir. 2005). The most substantial impairments occur when a state law makes a sudden and unanticipated retroactive change to the parties' obligations. *See Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 249 (1978).

There is no retroactive effect here. Chapter 103 has no impact upon and adds no obligations for conduct or transactions that occurred before the state statute took effect, and Plaintiff has no obligation under the PPA or the 340B statute to continue participating in the future. *See Local Division 589, Amalgamated Transit Union, AFL-CIO, CLC v. Massachusetts*, 666 F.2d 618, 639 (1st Cir. 1981) (noting that courts typically uphold state laws where reliance interests are weak, "such as where a law would have basically prospective application"); *Easthampton Savings Bank v. City of Springfield*, 736 F.3d 46, 51 n.5 (1st Cir. 2013) ("Ordinarily ... a state law with only prospective effect will not violate the Contracts Clause").

Chapter 103 also cannot be characterized as completely unanticipated. Plaintiff chooses to participate in the business of pharmaceutical sales and distribution, which is a "heavily regulated industry in which state and federal oversight have long coexisted." *Murrill*, 2026 WL 1947948 at *12. "Because the agreements say nothing about delivery at all, AstraZeneca could not reasonably expect that delivery obligations would arise exclusively from federal law." *Id.*

Plaintiff, therefore, has failed to allege an actionable Contract Clause claim.

C. Takings Clause Claim

Plaintiff contends that Maine's law constitutes a physical appropriation of its property because it will have to sell a greater quantity of its pharmaceutical products to private third parties at discounted prices. "The Takings Clause of the Fifth Amendment, which applies to the states through the Fourteenth Amendment, prohibits the taking of private property for public use without just compensation." *Franklin Memorial Hospital v. Harvey*, 575 F.3d 121, 125 (1st Cir. 2009). "The Supreme Court has recognized two types of takings: physical takings and regulatory takings." *Asociacion De Subscripcion Conjunta Del Seguro De Responsabilidad Obligatorio v. Flores Galarza*, 484 F.3d 1, 27–28 (1st Cir. 2007).

A physical taking occurs when the government "uses its power of eminent domain to formally condemn property," when it "physically takes possession of property without acquiring title to it" or "when it occupies property[.]" *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147–48 (2021). The Supreme Court has found an "occupation" physical taking occurred where (a) recurring flooding resulted from the building of a dam, *see United States v. Cress*, 243 U.S. 316 (1917), (b) cable companies were allowed to install cables and electronics boxes on rental property, *see Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982), (c) a building permit was conditioned on a landowner granting the public an easement for beach access, *see Nollan v. California Coastal Commission*, 483 U.S. 825 (1987), (d) a labor relations board required that a business owner permit labor organizers regular access to meet with workers, *Cedar Point Nursery*, 594 U.S. 139, and, (e) aircraft flew frequently at low-altitude, *United States v. Causby*, 328 U.S. 256 (1946). A regulatory taking occurs when the government places significant restrictions on the owner's use of the property, which inquiry requires "a careful examination and weighing of all the relevant circumstances," including the burdens and economic impacts of the regulation. *Maine Education Association Benefits Trust v. Cioppa*, 695 F.3d 145, 153 (1st Cir. 2012) (discussing *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104, 124 (1978)). Plaintiff alleges a physical taking, not a regulatory taking.

***17** Courts have long recognized that "where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking." *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009). Chapter 103 only applies to

a manufacturer if it chooses to participate in the drug discount program. Plaintiff does not argue that there is any requirement that manufacturers continue participating. Plaintiff presumably chooses to participate and forego certain profits from the 340B discounts in order to obtain other profits from selling through Medicare and Medicaid. Because Chapter 103 only applies if Plaintiff continues to opt in to the program to obtain other public funds, Plaintiff's voluntary choice "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); *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"); *Pharmaceutical Research & Manufacturers of America v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *14 (W.D. La. Sept. 30, 2024) (rejecting a similar takings claim because a government does not take property by creating a "financial inducement" to comply voluntarily).

Plaintiff argues 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. Plaintiff relies on cases finding that the 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 Plaintiff provides no 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. Likewise, the Court is aware of no binding or persuasive authority that provides that any new regulation bearing on a voluntary program from a different sovereign must be accompanied by a separate benefit to preserve the voluntary nature of the program. Because Plaintiff can choose not to participate in the 340B program, the state has not taken its property.

Even if its voluntary participation did not defeat Plaintiff's takings claim, other courts have persuasively explained why similar state statutes do not constitute a physical taking. Chapter 103 "simply imposes on drug manufacturers a negative obligation of non-interference with covered entities' arrangements with contract pharmacies, by preventing them from refusing to sell Section 340B drugs to covered entities that have arrangements with contract pharmacies and from restricting what covered entities can do with Section 340B drugs after they have purchased them." *Fitch*, 152 F.4th at 643. In other words, because Plaintiff has no right to adopt conditions to reduce the number of legitimate purchases that covered entities might make, "[Chapter 103] does not deprive [Plaintiff] of anything to which § 340B entitles it." *Murrill*, 166 F.4th at 543.

Plaintiff's takings argument is also unavailing for an additional (though related) reason. If Plaintiff's argument was correct, an unconstitutional taking would occur whenever a new regulation had an impact, even indirectly, on the number of transactions expected to occur in a price-regulated market. The argument would have far-reaching implications, and the Supreme Court has never endorsed such an expansive approach in its physical takings cases.

Conclusion

Following a review of the complaint and after consideration of the parties' arguments, for the reasons explained herein, Plaintiff's nonconclusory factual allegations fail to state an actionable preemption claim, Contracts Clause claim, or Takings Clause claim. Accordingly, the Court grants Defendants' motion and dismisses the complaint.

***18** Dated this 27th day of July, 2026.

All Citations

Slip Copy, 2026 WL 2145194

End of Document