2026 WL 1752214
Only the Westlaw citation is currently available.
United States District Court, D. New Mexico.

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff,

v.

Raúl TORREZ, in is official capacity as Attorney General of the State of New Mexico, Defendant,

Case No. 1-25-cv-01225-MIS-JHR
|
Filed 05/26/2026

Attorneys and Law Firms

Erin E. Murphy, Pro Hac Vice, Clement & Murphy, PLLC, Alexandria, VA, Matthew Rowen, Pro Hac Vice, Alexandria, VA, Philip Hammersley, Pro Hac Vice, Clement & Murphy PLLC, Alexandria, VA, Alex Cameron Walker, Modrall, Sperling, Roehl, Harris & Sisk, P.A., Albuquerque, NM, for Plaintiff.

Alfred A. Park, Taylor M. Lueras, Park & Associates, LLC, Albuquerque, NM, for Defendant.

ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION

MARGARET STRICKLAND, UNITED STATES DISTRICT JUDGE

***1 THIS MATTER** is before the Court on Plaintiff's Motion for Preliminary Injunction ("Motion"), ECF No. 11, filed December 16, 2025. Defendant, New Mexico Attorney General Raúl Torrez (New Mexico), filed a Response in Opposition to the Motion ("Response"), ECF No. 22, on January 26, 2026, to which Plaintiff filed a Reply ("Reply"), ECF No. 23, on February 9, 2026.

Upon review of the Parties' submissions, the record, and the relevant law, the Court will **DENY** Plaintiff's Motion for a Preliminary Injunction.

I. Background

The Pharmaceutical Research and Manufacturers of America (PhRMA or "Plaintiff") filed the instant lawsuit on December 16, 2025, seeking to enjoin the enforcement of Chapter 91 of the 2025 New Mexico Session Laws, codified as N.M. Stat. § 26-1-27 (1978). For purposes of the instant Motion, the following facts are undisputed.[1]

1 The facts are gleaned from the Parties Briefings: Plaintiff's Complaint, ECF No. 1; Plaintiff's Motion for Preliminary Injunction, ECF No. 11; Defendant's Answer to Complaint, ECF No. 21; Defendant's Response, ECF No. 22; in combination with the background sections reciting the 340B program's history in numerous federal court decisions throughout the country. See e.g., AbbVie, Inc. v. Weiser, 811 F. Supp. 3d 1264, 1269-72 (D. Colo. 2025); AbbVie, Inc. v. Fitch, 152 F.4th 635, 639-42 (5th Cir. 2025); AbbVie, Inc. v. Brown, 809 F. Supp. 3d 1341, 1348-53 (D. Utah 2025); and AbbVie Inc. v. Drummond, 808 F. Supp. 3d 1266, 1270-74 (W.D. Okla. 2025).

The 340B program is a federal drug program created pursuant to 42 U.S.C. § 256b that imposes ceilings on the prices drug manufacturers may charge for medications sold to specified "covered entities" that focus on providing "safety-net services" to the poor, such as public hospitals, community health centers and other healthcare providers. Astra USA, Inc. v. Santa Clara County, 563 U.S. 110, 113 (2011). The 340B program is overseen by the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS). Id.

Under the program, drug manufacturers that participate in Medicaid and Medicare Part B are incentivized to offer certain drugs at discount prices to healthcare providers that serve uninsured and low-income individuals. However, the manufacturers can only opt-in to the program if they enter into a 340B program contract with HHS dubbed a Pharmaceutical Pricing Agreement (PPA) under which manufacturers "agree to charge covered entities no more than predetermined ceiling prices, derived from the 'average' and 'best' prices and rebates calculated under the Medicaid Drug Rebate Program." Id. at 115 (quoting 42 U.S.C. § 256b(a)(1)). In turn, the program also places several restrictions on covered entities including – among other things – (1) prohibiting covered entities from seeking both the 340B discount and the Medicaid rebate on the same drug (i.e., duplicate discounts); (2) barring covered entities from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity; and (3) requiring covered entities to permit HHS and drug manufacturers to audit their records for compliance. AbbVie, Inc. v. Fitch, 152 F.4th 635, 640 (5th Cir. 2025).

***2** Early in the program's history HRSA issued guidance that allowed covered entities lacking an in-house dispensing pharmacy to contract with a single third-party commercial pharmacy to assist with dispensing 340B drugs to patients; however, in 2010, HRSA took it a step further, issuing additional guidance allowing covered entities to "contract with an unlimited number of outside pharmacies to distribute Section 340B drugs." Id. (citing Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010)). This led to a significant spike in the number of contract pharmacies working with covered entities,[2] and in response – citing fears this spike would lead to an increase in diversion and duplicate discounts – manufacturers started adopting policies that limited the ability of covered entities to partner with contract pharmacies. Fitch, 152 F.4th at 640-641.

2 *See* U.S. Gov't Accountability Off., GAO-20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement 2 (2020) (reporting that the number of contract pharmacies working with covered entities increased by more than 20,000 in a ten-year span).

HHS then attempted to combat these restrictive contract pharmacy policies by issuing an advisory opinion that suggested "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." Advisory Op. 20-06 on Contract Pharmacies under the 340B Program, 2020 WL 11422965, at *1 (HHS Dec. 30, 2020). However, HHS then withdrew that advisory opinion after manufacturers successfully argued their restrictive contract pharmacy policies were consistent with the federal Section 340B statute. See Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 704 (3d Cir. 2023) (finding that Section 340B's statutory text says nothing about delivery and the federal statute does not require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies) (emphasis added); Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 464 (D.C. Cir. 2024) (holding that Section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities).

In response New Mexico, and more than a dozen other states, enacted statutes attempting to fill what local legislators perceived to be a gap in federal law.[3] Generally, legislators framed these laws as statutes governing delivery, with states aiming to support contract pharmacies and patients by prohibiting manufacturers from refusing to sell 340B drugs to covered entities. For New Mexico, this took the form of N.M. Stat. Ann. § 26-1-27(1978), titled "Prohibition of discrimination against 340b entities." The operative statutory text of Section 26-1-27 reads as follows:

> A manufacturer, a manufacturer's agent or an affiliate of a manufacturer shall not directly or indirectly:

(1) deny, restrict, prohibit or interfere with the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy contractually obligated with an applicable entity and is authorized to receive and dispense 340B drugs on behalf of the applicable entity unless receipt of the 340B drugs is prohibited by the United States department of health and human services;

(2) interfere with the ability of a pharmacy contracted with an applicable entity to dispense 340B drugs to the applicable entity's eligible patients; or

(3) require an applicable entity to submit any claims, utilization, purchasing or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, an applicable entity unless the sharing of claims or utilization data is required by federal law.

***3** N.M. Stat. Ann. § 26-1-27(B) (1978).

3 See N.M. Stat. Ann. § 26-1-27; Utah Code Ann. § 31A-46-311; Colo. Rev. Stat. § 10-16-1505; N.D. Cent. Code § 43-15.3-08; Or. Rev. Stat. § 743A.062; S.D. Codified Laws § 58-29G-2; Tenn. Code Ann. § 47-18-136; Vt. Stat. Ann. tit. 18 § 4682; W. Va. Code § 60A-8-6a; Ark. Code Ann. § 23-92-604; Haw. Rev. Stat. § 2; La. Stat. Ann. § 40:2884; Md. Code Ann., Health Occ. § 12-6C-09.1; Mo. Rev. Stat. § 376.414; Minn. Stat. § 62J.96; Miss. Code Ann. § 41-149-5; Neb. Rev. Stat. LB 168 § 3.

On December 8, 2025, PhRMA filed its Complaint for Declaratory and Preliminary and Permanent Injunctive Relief. ECF No. 1. On December 16, 2025, it filed a separate motion for a preliminary injunction. ECF No. 11. New Mexico filed a Response, ECF No. 22, to which PhRMA filed a Reply, ECF No. 23. On April 13, 2026, the Court held a hearing on the Motion. See ECF No. 26. This Order follows.

II. Legal Standard

A movant can establish a right to a preliminary injunction if they demonstrate the following four factors weigh in their favor: "(1) [the movant] is substantially likely to succeed on the merits; (2) [the movant] will suffer irreparable injury if the injunction is denied; (3) [the movant's] threatened injury outweighs the injury the opposing party will suffer under the injunction; and (4) the injunction would not be adverse to the public interest." Awad v. Ziriax, 670 F.3d 1111 (10th Cir. 2012) (quoting Beltronics USA, Inc. v. Midwest Inventory Distrib., LLC, 562 F.3d 1067, 1070 (10th Cir. 2009)). If a court finds against the movant on one factor, the other factors need not be addressed. Dominion Video Satellite, Inc. v. Echostar Satellite Corp., 356 F.3d 1256, 1266 n.8 (10th Cir. 2004).

Further, a preliminary injunction is an " 'extraordinary remedy' that is granted only when 'the movant's right to relief [is] clear and unequivocal.' " First W. Cap. Mgmt. Co. v. Malamed, 874 F.3d 1136, 1145 (10th Cir. 2017) (alteration in original) (quoting Wilderness Workshop v. U.S. Bureau of Land Mgmt., 531 F.3d 1220, 1224 (10th Cir. 2008); see also United States ex rel. Citizen Band Potawatomi Indian Tribe of Okla. v. Enter. Mgmt. Consultants, Inc., 883 F.2d 886, 888–89 (10th Cir. 1989) ("Because it constitutes drastic relief to be provided with caution, a preliminary injunction should be granted only in cases where the necessity for it is clearly established.").

III. Analysis

Plaintiff's Motion can be resolved by addressing the first prong of the preliminary injunction inquiry. As such, the Court's analysis focuses exclusively on the question of whether plaintiff has demonstrated a substantial likelihood of success on the merits of its claim such that the extraordinary remedy requested is warranted.

Plaintiff advances two primary arguments to support their Motion. One argument, which PhRMA and other drug manufacturers have argued in many districts throughout the country, is that the federal 340B statute preempts laws such as N.M. Stat. Ann. § 26-1-27 (1978). Mot. at 27-34. Plaintiff also argues that that New Mexico's law violates the Supremacy Clause by discriminating against those the federal government deals with, regulating the activities of the federal government and intruding on an enclave

of "uniquely federal interests." Id. at 16-25. Thus, under Plaintiff's alternative argument, the Supremacy Clause in and of itself forecloses laws such as Section 26-1-27.

***4** For the reasons that follow, the Court finds that Plaintiff has failed to demonstrate a substantial likelihood of success on the merits of their claims.

a. The 340B Statute does not preempt N.M. Stat. Ann. § 26-1-27 (1978)

The Supremacy Clause provides that the laws of the United States "shall be the supreme Law of the Land; ... anything in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Under this provision, Congress has the power to enact statutes that preempt state law. Nw. Cent. Pipeline Corp. v. State Corp. Comm'n of Kan., 489 U.S. 493, 509, (1989). Generally, there are three types of preemption: express, field, and conflict. US Airways, Inc. v. O'Donnell, 627 F.3d 1318, 1324 (10th Cir. 2010). Plaintiff argues that field and conflict preemption are relevant in the instant case.

1. Field Preemption

Field preemption exists where Congress intends for the federal government to exclusively occupy and regulate conduct in a particular field. Id. at 1324-25. This intention can be inferred when the framework of a federal law or regulation is "so pervasive ... that Congress left no room for the States to supplement it[.]" Arizona v. United States, 567 U.S. 387, 399 (2012) (alteration in original) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); see also English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990).

Plaintiff argues that the 340B program originates from, is governed by, and terminates according to federal law, and contends that the states have no role to play in its operation because "Congress did not give the states any role to play in administering or enforcing it." Mot. at 27. Moreover, Plaintiff argues that any gaps in the federal 340B program are gaps that represent a conscious choice by Congress to not impose any additional obligations on manufacturers "rather than an invitation for states to insert themselves into this exclusively federal program." Id. Therefore, Plaintiff alleges that these facts support the conclusion that Congress intended to occupy the field and preempt laws such as N.M. Stat. Ann. § 26-1-27 (1978). Id.

New Mexico counters that Plaintiff's field preemption theory has been frequently rejected and "[c]ourts have uniformly held that the 340B statute is silent on delivery logistics and does not occupy the field of drug distribution." Resp. at 15 (citations omitted). Moreover, New Mexico argues that because regulation of pharmacies traditionally occurs at the state level and the federal 340B statute is silent as to pharmacy distribution, it would be improper for the Court to find that Congress decided to occupy the field. Id. at 8-9. The state points to the 8th Circuit's ruling in McClain to further bolster their position. See id. at 9 (quoting Pharm. Rsch. & Mfrs. of Am. v. McClain, 95 F.4th 1136, 1143 (8th Cir. 2024) ("[W]hen it comes to pharmaceuticals, the federal government has traditionally regarded state law as a complementary form of drug regulation and has long maintained that state law offers an additional, and important, layer of consumer protection that complements [federal] regulation.").

Plaintiff's preemption theory has been litigated with some frequency over the last several years as more than a dozen states adopted laws like Section 26-1-27. Generally, attempts by manufacturers to preliminarily enjoin enforcement of these laws have failed. See AbbVie Inc. v. Skrmetti, No. 3:25-CV-00519, 2025 WL 1805271 at *12-13 (M.D. Tenn. June 30, 2025) (finding a similarly drafted Tennessee statute was not field preempted because it was only concerned about delivery of 340B drugs and "Congress did not intend to preempt the field"); AbbVie, Inc. v. Brown, 809 F. Supp. 3d 1341, 1348 (D. Utah 2025) (holding that the federal 340B statute only regulates drug pricing and is silent about delivery, thus a Utah state statute regulating 340B drug distribution is not field preempted); Pharm. Rsch. & Mfrs. of Am. v. Bailey, No. 2:24-CV-04144-MDH, 2025 WL 644281, at *5 (W.D. Mo. Feb. 27, 2025) (finding no field preemption based on McClain); AstraZeneca Pharms. LP v. Fitch, 766 F. Supp. 3d 657, 665 (S.D. Miss. 2024) (denying a motion for preliminary injunction and finding field preemption did not apply to a similar Mississippi statute); Pharm. Rsch. & Mfrs. of Am. v. Murrill, No. 6:23-CV-00997, 2024 WL 4361597, at *8 (W.D. La. Sep. 30, 2024) (same).

***5** Often the decisions reached by these courts is grounded in the statutory silence of the federal statute, as both the Third and D.C. Circuits have held that the federal 340B statute is "silent about delivery." Sanofi Aventis, 58 F.4th at 703; Johnson, 102 F.4th at 461. The Tenth Circuit has yet to weigh in on the issue; however, several sister districts have mostly rejected Plaintiff's field preemption arguments. See AbbVie, Inc. v. Weiser, 811 F. Supp. 3d 1264, 1274-77 (D. Colo. 2025) (denying preliminary injunction and finding a pharmaceutical manufacturer's argument that a similar Colorado statute was neither field nor conflict preempted by the federal 340B statute); Brown, 809 F. Supp. 3d at 1356-58 (D. Utah 2025) (granting in part and denying in part Utah's Motion to Dismiss a manufacturers claims, finding that a similar Utah statute was not field preempted but may be conflict preempted). Still, the Court also notes that at least one district in the Tenth Circuit has found that the federal 340B statute preempted a similar Oklahoma law. AbbVie Inc. v. Drummond, 808 F. Supp. 3d 1266, 1279 (W.D. Okla. 2025).

Here, the Court believes that an analysis by the Eighth Circuit examining an Arkansas statute similar to the one at issue in the current litigation, though not controlling, is quite instructive and ultimately persuasive. Arkansas's statute barred pharmaceutical manufacturers from

> (1) Prohibit[ing] a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or (2) Deny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

Ark. Code Ann. § 23-92-604(c).

In its analysis, the Eighth Circuit noted that "the 340B Program is not 'so pervasive ... that Congress left no room for the States to supplement it' " McClain, 95 F.4th at 1143 (quoting Arizona, 567 U.S. at 399). Moreover, the Eighth Circuit also highlighted the history of contract pharmacies going back to the 340B program's early days and noted that such pharmacies "have always been an essential part of the 340B Program" and that the program's "silence" regarding the delivery of drugs to patients "contrasts with 340B's provisions that directly address distribution by third-party wholesalers." Id. (citing 42 U.S.C. § 256b(a)(8)). The Eighth Circuit also noted that "the practice of pharmacy is an area traditionally left to state regulation" and that the court was required to "assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted[,]" Id. at 1143, 1144 (first quoting and then citing Pharm. Care Mgmt. Ass'n v. Wehbi, 18 F.4th 956, 972 (8th Cir. 2021)). This led the court to conclude that "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." Id. at 1143.

Here, Section 26-1-27 places restrictions on manufacturers that are not materially different from those at play in Arkansas. Further, the New Mexico statute on its face also appears structured as a delivery statute. For example, the first provision of the statute by its plain language focuses on the "acquisition of a 340B drug by, or delivery of a 340B drug" to a pharmacy contractually obligated with an applicable covered entity whereas the second provision appears to focus on the distribution of said drugs to eligible patients of the covered entity. N.M. Stat. Ann. § 26-1-27(B)(1) (1978). Neither of those provisions speak explicitly to price, which is the focus of the federal 340B statute. Given that, coupled with the statutory silence with respect to delivery noted by many courts, the fact the federal statute elsewhere contemplates distribution, and, as the Eighth Circuit noted, that the practice of pharmacies is an area traditionally regulated by states and contract pharmacies appeared a necessity for the 340B program's operation during its early days, it is difficult for the Court to infer that Congress intended to field preempt statutes such as Section 26-1-27.

***6** Therefore, for the foregoing reasons, the Court concludes that PhRMA has not demonstrated a substantial likelihood of success on the merits of its field preemption claim.

2. Conflict Preemption

Conflict preemption occurs when compliance with both federal and state regulations is "a physical impossibility, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Mount Olivet Cemetery Ass'n v. Salt Lake City, 164 F.3d 480, 486 (10th Cir. 1998). Determining what constitutes "a sufficient obstacle

is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects[.]" Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000).

Plaintiff argues that the federal 340B statute preempts New Mexico's law on conflict preemption grounds. Mot. at 28-34. More specifically, Plaintiff argues that Section 26-1-27 conflicts with the federal statute in three respects. One, it impedes the "discretion" manufacturers have to impose reasonable conditions on offers to sell drugs to covered entities at 340B prices. Mot. at 28-30. Two, it "makes it virtually impossible" for drug manufacturers to initiate Administrative Dispute Resolution ("ADR") under the federal 340B statute because the state law makes it more difficult to initiate an audit given the limitations the state law imposes on accessing claims data. Id. at 30-32. And three, it interferes with the 340B program's "exclusively federal enforcement regime" as HRSA is the entity tasked with enforcing federal 340B regulations and New Mexico's law opens the doorway for "conflicting adjudications" between state and federal enforcement authorities. Id. at 33. Further, Plaintiff contends that state enforcement proceedings would likely involve manufacturers invoking federal defenses and, as such, various proceedings related to state laws in New Mexico and elsewhere could create "conflicting determinations by state and federal actors." Id.

New Mexico counters that the state statute does not compel manufacturers to sell drugs in New Mexico, it simply prohibits manufacturers who choose to participate in the 340B program from engaging in discriminatory conduct or interfering with drug delivery to covered entities. Resp. at 15. Moreover, New Mexico again points to the silence in the 340B statute regarding delivery, and since there is no federal law regulating delivery, there is nothing with which a state law governing delivery can conflict. Id. at 17. Finally, the state argues Section 26-1-27 does not create any additional obstacles or burdens on the federal program or the federal enforcement regime, including with respect to federal claims data rights as access is expressly reserved in the statute. Id.

Before diving into the individual conflicts Plaintiff alleges, the Court begins its inquiry by looking at what the federal 340B statute sought to accomplish. Here, the Eighth Circuit is again helpful as they concisely summarized the program in McClain:

> The 340B Program "has three basic parts: (1) a cap on drug makers' prices, (2) restrictions on covered entities, and (3) compliance mechanisms" for both covered entities and manufacturers. Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 699 (3d Cir. 2023). First, as a condition of participating in Medicaid, drug manufacturers must "opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement" with the Secretary of HHS. Astra USA, Inc., 563 U.S. at 113, 131 S.Ct. 1342. The Pharmaceutical Pricing Agreement requires manufacturers to sell drugs to covered entities at a discounted "ceiling price." 42 U.S.C. § 256b(a)(1). The ceiling price is determined by a statutory formula. 42 U.S.C. §§ 256b(a)(2), 1396r-8(c). The second part of 340B mandates that discounted prices are only made available to covered entities. Id. § 256b(a). Covered entities are defined by statute to include fifteen different types of public and not-for-profit hospitals, community centers, and clinics that are "dominantly, local facilities that provide medical care for the poor." Astra USA, Inc., 563 U.S. at 115, 131 S.Ct. 1342; see also 42 U.S.C. § 256b(a)(4).
>
> ***7** Finally, the 340B Program includes compliance mechanisms, penalties for noncompliance or abuse by manufacturers and covered entities, and a dispute resolution process through HHS. See, e.g., Astra USA, Inc., 563 U.S. at 115–16, 131 S.Ct. 1342; Sanofi Aventis U.S. LLC, 58 F.4th at 701–02. Manufacturers are required to report their 340B ceiling prices to the HRSA on a quarterly basis and are subject to auditing. 42 U.S.C. § 256b(a)(1), (a)(5)(C).

McClain, 95 F.4th at 1141.

Plaintiff's conflict preemption argument, much like its field preemption argument, is not entirely new. In fact, Plaintiff and another pharmaceutical manufacturer unsuccessfully pursued a very similar line of argument when challenging a Colorado law that uses effectively identical language to that in N.M. Stat. Ann. § 26-1-27 (1978). See generally Weiser, 811 F. Supp. 3d at 1277-80; Astrazeneca Pharms. LP v. Weiser, No. 25-CV-02685-PAB-STV, 2025 WL 3653161, at *7-10 (D. Colo. Dec. 17, 2025).

From the outset, the Court is unconvinced that New Mexico's law directly impedes the ability of drug manufacturers to pursue an audit and launch the federal resolution process by restricting access to claims data. Although the New Mexico statute prohibits manufacturers from requiring an applicable entity to submit claims and other varieties of data as a condition for acquiring or receiving delivery of 340B drugs, it explicitly states the prohibition applies "unless the sharing of claims or utilization data is required by federal law." N.M. Stat. Ann. § 26-1-27(B)(3) (1978) (emphasis added). On its face, that provision seems to allow manufacturers to still acquire claims data if that is what is required by federal law. However, if federal law does not necessitate the provision of claims data, manufacturers cannot impose such a requirement as a condition of delivery. Thus, it appears there is an explicit carveout in the statute for manufacturers to acquire whatever claims data is needed to engage in an audit and ultimate resolution process under federal law.

Plaintiff's argument that New Mexico's statute creates an obstacle or additional responsibilities for the federal enforcement regime also appears speculative. It is true that Congress entrusted HHS with authority to oversee compliance with the 340B Program. Santa Clara County, 563 U.S. at 113. It is also worth recognizing that that the U.S. Supreme Court expressed concerns about allowing 340B entities in and of themselves to bring private suits as intended beneficiaries of 340B PPA agreements and emphasized that "Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." Id. at 121 (citing 124 Stat. 823–827, 42 U.S.C. § 256b(d)). However, as New Mexico noted, neither Section 26-1-27 nor Section 26-1-26 (the accompanying penalties provision) create a private right of action for covered entities, nor does it create additional penalties for manufacturers who charge covered entities prices that are more than the price ceiling imposed by the federal 340B statute. Resp. at 20. In fact, New Mexico's law does not appear to provide covered entities or manufacturers any remedies for violations of the federal 340B statute. Rather, New Mexico's law imposes penalties on manufacturers who interfere with the ability of covered entities and their pharmacy partners to receive delivery of and ultimately distribute drugs they are authorized to receive under the 340B program. If a manufacturer engages in that prohibited conduct they could be "guilty of a fourth degree felony and shall be punished by a fine of not less than one thousand dollars ($1,000) or more than five thousand dollars ($5,000) or by imprisonment for not less than one year or both." N.M. Stat. Ann. § 26-1-26(A). Therefore, it would appear that the federal enforcement regime targets disputes and compliance issues related to pricing under the 340B program, whereas the New Mexico law focuses on imposing criminal penalties on manufacturers who interfere with the abilities of authorized covered entities to accept delivery of and ultimately distribute discounted drugs.

***8** Lastly, Plaintiff argues that New Mexico's statute interferes with the discretion manufacturers were afforded in imposing conditions on 340B offers and thus is conflict preempted. Mot. at 28-30. More specifically, Plaintiff contends that Congress did not expressly allow HRSA to restrict a manufacturer's discretion to impose reasonable conditions on their 340B offers, let alone states. Mot. at 30. Moreover, Plaintiff notes that prior court rulings have found that while "some conditions are compatible with the federal 340B statute, other unreasonable conditions might be statutorily foreclosed." Id. at 28 (citing Novartis, 102 F.4th at 464; Sanofi, 58 F.4th at 706). Thus, under Plaintiff's theory, it is impermissible for state statutes to bar manufacturers from imposing restrictions on delivery to contract pharmacies, as is alleged with New Mexico's law.

Plaintiff's argument is not infallible though, especially given the limited record before the Court at this juncture. Plaintiffs' interpretation of Novartis and Sanofi seems a step too far because neither of those cases suggest that manufacturers are free to impose any restrictions they desire, nor do they speak to whether states have the authority to prohibit manufacturers from imposing certain conditions on the delivery of pharmaceuticals. Rather, both cases speak to the federal statute simply being silent as to the issue. As the court states in Novartis, it "cannot plausibly interpret statutory silence to subject manufacturers to whatever delivery conditions any covered entity might find most convenient," 102 F.4th at 461, and "the silence preserves — rather than abrogates—the ability of sellers to impose at least some delivery conditions[,]" id. at 460 (emphasis added). The absence of a federal prohibition on the conduct New Mexico is targeting, however, does not equate to a bar on states like New Mexico exercising their ability to legislate in an area that is within the traditional police powers of the state. As the Court noted earlier, the practice of a pharmacy is traditionally left to state regulation, and "when it comes to pharmaceuticals, the federal government has traditionally regarded state law as a complementary form of drug regulation and has long maintained that state law offers an additional, and important, layer of consumer protection that complements [federal] regulation." McClain, 95 F.4th

at 1143 (internal quotation marks and citation omitted). Although the Eighth Circuit raises this point in the context of its field pre-emption analysis, it remains notable here because the Supreme Court has suggested that the presumption that the historic police powers of states are not superseded by federal act still applies in cases involving implied conflict pre-emption. Wyeth v. Levine, 555 U.S. 555, (2009) ("[I]n all pre-emption cases ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' ") (emphasis added).

Thus, even here, the Court cannot read congressional silence to find implied conflict pre-emption. Therefore, PhRMA has not met its burden to demonstrate a substantial likelihood of success on the merits of its conflict preemption claims.

b. The Supremacy Clause in and of itself does not preempt Section 26-1-27

In addition to the preemption claim, Plaintiff also argues that the Supremacy Clause itself forecloses laws such as Section 26-1-27. Mot. at 16-25. More specifically, PhRMA argues that New Mexico's statute violates the Supremacy Clause itself by discriminating against those the federal government deals with, regulating the activities of the federal government and intruding on an enclave of "uniquely federal interests." Id. at 25-27. Essentially, Plaintiff argues that New Mexico's statute discriminates against those with whom the government deals because it only applies to manufacturers who participate in the 340B program and thus it is exclusively targeting a federal program. Id. at 18. Further, Plaintiff argues the law impermissibly regulates the federal government by interfering with federal contracting decisions and "expanding HRSA's regulatory responsibilities." Id. at 23. And lastly, Plaintiff contends New Mexico's law intrudes on an area of uniquely federal interest because it "intrudes on the federal government's uniquely federal interest in defining — clearly—the limits of its spending programs." Id. at 26.

***9** New Mexico counters that Plaintiff's Supremacy Clause argument is essentially repackaging an argument that "manufacturers have lost on consistently" in the preemption context. Resp. at 10 n.3; id. at 7-8. The State argues that New Mexico's statute "does not regulate the federal government, federal officers, or federal programs, and it does not discriminate against entities based on their federal affiliations." Id. at 8. Rather, New Mexico argues, the statute is simply a healthcare regulation governing distribution of pharmaceuticals within state borders which falls well within the areas of traditional state police power regulations, whereas the federal 340B statute is a pricing statute. Id. Therefore, according to the state, the strong presumption against preemption principle applies. Id. Further, New Mexico argues that N.M. Stat. Ann. § 26-1-27 (1978) does not discriminate against or regulate the federal government because pharmaceutical manufacturers are not working as traditional federal contractors; nor are they agents of the federal government within the 340B context; nor does the statute create additional enforcement obligations or otherwise alter the enforcement approach currently taken by the federal government. Id. at 12-13.

The Supremacy Clause generally immunizes the federal government from state laws that directly regulate or discriminate against it. See United States v. Washington, 596 U.S. 832, 835 (2022). The Supreme Court has recognized a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 715 (1985). And, as previously noted, the operation of pharmacies is an area traditionally left to state regulation and there is an assumption that state statutes that impact health and welfare are not preempted. McClain, 95 F.4th at 1143.

From the outset, the Court notes Plaintiff's Supremacy Clause argument is not all that dissimilar from preemption arguments that have already been rejected, and it appears that the attempt to reframe Section 26-1-27 as violative of the Supremacy Clause itself is an attempt, at least in part, to get around the presumption against preemption. Although Plaintiff claims the presumption against preemption canon should be irrelevant to determining whether the Supremacy Clause itself forecloses laws such as Section 26-1-27, Mot. at 17, Plaintiff fails to provide a citation that definitively supports such an assertion. Moreover, principles of federalism further counsel against adopting Plaintiff's reading.

Turning to Plaintiff's argument that the statute interferes with federal contracting decisions and expands the federal government's regulatory responsibilities, as this Court previously stated in its preemption analysis, it is unclear what additional responsibilities – if any – are foisted on the federal government as a result of New Mexico's law. New Mexico state actors appear to be the

individuals tasked with enforcing the law, and given the statute possesses a carveout for manufacturers to access claims data it is unclear how New Mexico – or for that matter the more than a dozen other states that enacted similar laws – are creating a greater caseload for HRSA. Moreover, nothing in New Mexico's statue speaks to regulating 340B drug pricing, and since the federal 340B statute governs a drug pricing program that manufacturers must opt-into, it's not yet clear New Mexico's law will impact bargaining.

The Court is also skeptical of Plaintiff's claim that New Mexico is intruding on an enclave of uniquely federal interests. The Court is simply not persuaded that Section 26-1-27 intrudes upon Congress's spending power with regard to Medicare and Medicaid; New Mexico's statute simply does not affect that power. Moreover, this Court has already noted the complementary nature of how federal law and state law have regulated drug distribution. Thus, the Court cannot find that Congress's spending power preempts state laws governing pharmaceutical distribution. Plaintiff claims that "the practical result" of New Mexico's law is to discourage manufacturers from participating in the 340B program" and by extension Medicaid and Medicare. Mot. at 26. However, at this juncture, there is nothing in the record to render such an assertion as more than speculation. And in fact, one might argue that since more than a dozen states have pursued this path and the federal government has yet to intervene in the prior litigation, one could infer that such an outcome is not anticipated.

***10** Lastly, the Court is unpersuaded by Plaintiff's discrimination theory and finds its reliance on Washington unpersuasive. The underlying facts of Washington are materially different from the case at hand, as the discriminatory statute the state of Washington enacted exclusively focused on federal contractors working on federal public lands. 596 U.S. at 835-36. Manufacturers opting into the 340B program are quite simply not federal contractors. Moreover, Plaintiff claims that New Mexico's statute "imposes unanticipated costs on both manufacturers and the federal government, which now must police parties and transactions that otherwise would not exist for program compliance." Mot. at 21. However, this claim is speculative at best as New Mexico's law is apparently enforced purely by state actors and does not appear to carry any enforcement burdens or obligations for HRSA on its face. Further, though Plaintiff implies that the state law targeting a federal program inherently violates the nondiscrimination rule, 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 where the federal statute does not rely on the state to implement the program. Instead, courts must determine whether the alleged obstacle presented by the state law is significant enough to compel preemption." Novartis Pharms. Corp. v. Frey, No. 1:25-CV-00407-JCN, 2025 WL 2813787 at *10 (D. Me. Sep. 23, 2025).

Therefore, given the limited record before the Court, PhRMA has not met its burden to demonstrate a substantial likelihood of success on the merits of its Supremacy Clause claim.

IV. Conclusion

Accordingly, it is **HEREBY ORDERED** that Plaintiff's Motion for Preliminary Injunction, ECF No. 11, is **DENIED.**

All Citations

Slip Copy, 2026 WL 1752214

End of Document