

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

ABBVIE INC., et al.,

Plaintiffs,

v.

No. 1:25-cv-01230-KG-JHR

RAUL TORREZ, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Plaintiffs’ Motion for a Preliminary Injunction, Doc. 7, Defendants’ Response, Doc. 30, and Plaintiffs’ Reply, Doc. 34. For the reasons below, the motion is denied. The Court grants the Motion for Leave to File Amicus Curiae Brief by the American Hospital Association, 340B Health, and the American Society of Health-System Pharmacists, Doc. 31, and has considered that brief in resolving the preliminary injunction motion. *See, e.g., Colorado Christian Univ. v. Weaver*, 2006 WL 2255900, at *1 (D. Colo.).

I. Background¹

A. The 340B Program

In 1992, Congress enacted the 340B program as part of the Veterans Health Care Act, 42 U.S.C. § 256b. The 340B program allows qualifying healthcare providers, known as “covered

¹ Many federal courts, including the Supreme Court, have already summarized the history of the 340B Program and relevant United States Department of Health and Human Services (“HHS”) guidance. *See Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110 (2011); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *AbbVie, Inc. v. Fitch*, 152 F.4th 635 (5th Cir. 2025); *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep’t of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023); *AbbVie, Inc. v. Weiser*, 811 F. Supp. 3d 1264 (D. Colo. 2025); *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266 (W.D. Okla. 2025). The Court incorporates the eloquent background set forth in those decisions where applicable and adds further detail from the parties’ briefing.

entities,” to purchase outpatient drugs from pharmaceutical companies like AbbVie at a “discount negotiated by the Secretary of Health and Human Services.” *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1270 (W.D. Okla. 2025). There are sixteen different categories of covered entities, including “public hospitals and community health centers, many of them providers of safety-net services to the poor.” *AbbVie, Inc. v. Weiser*, 811 F. Supp. 3d 1264, 1269 (D. Colo. 2025). The 340B program benefits covered entities in two ways: first, by giving them “extra revenue” when “insurance companies reimburse them at full price that they bought at the 340B discount,” *id.*; and second, by giving uninsured patients “drugs at little or no cost.” *Id.*

The Health Resources and Services Administration (“HRSA”) is an agency within HHS that administers the 340B program. *See Drummond*, 808 F. Supp. 3d at 1271. Pharmaceutical companies opt into the program by signing a “non-negotiable” Pharmaceutical Pricing Agreement (“PPA”) with HHS. Doc. 7 at 3. A pharmaceutical company’s eligibility to participate in Medicaid and Medicare Part B “is conditioned on [its] entry into PPAs for covered drugs purchased by [covered] entities.” *Weiser*, 811 F. Supp. 3d at 1270. The PPA obligates manufacturers to offer “each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price” set by HHS. *Id.*

In 2024, HHS created a new administrative dispute resolution system (“ADR”) for “resolving 340B-related disputes” between covered entities and manufacturers. Doc. 7 at 17; *see* 89 Fed. Reg. 28643 (Apr. 19, 2024). Examples of permitted claims include “claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug,” and “claims that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price.” 89 Fed. Reg. 28649.

B. The Rise of Contract Pharmacies

Covered entities originally distributed “340B drugs from their [in-house] pharmacies.” *Drummond*, 808 F. Supp. 3d at 1271. For many covered entities, “building or maintaining [an in-house] pharmacy is cost-prohibitive.” *PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024). As a result, in 1996 HRSA issued guidance that allowed each covered entity to contract with a single outside pharmacy, or “contract pharmacy,” to dispense drugs purchased through the 340B program so long as the covered entity did not “transfer title to any discounted drugs to the contract pharmacy.” *Drummond*, 808 F. Supp. 3d at 1271; *see* 61 Fed. Reg. 43549 (Aug. 23, 1996). Covered entities “still order and pay for the drugs, but they [are] shipped directly to the [contract] pharmacies.” *Sanofi Aventis U.S. LLC v. U.S. Dep’t of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023). Beyond avoiding the costs of building or maintaining an in-house pharmacy, contract pharmacies also enabled covered entities with large, rural service areas to dispense drugs “closer to where [their] low-income patients reside.” *McClain*, 95 F.4th at 1139. In 2010, HRSA issued new guidance allowing covered entities to contract with an “unlimited number of contract pharmacies for purposes of 340B prescription fulfillment.” *Drummond*, 808 F. Supp. 3d at 1271; *see* 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010).

After the 2010 guidance, the use of contract pharmacies exploded, and the average number of contract pharmacies per covered entity reached “20.7 by 2024.” *Drummond*, 808 F. Supp. 3d at 1271. The increased use of contract pharmacies proved profitable: while patients and insurers generally pay normal market prices in the 340B program, the covered entities that purchase the drugs at a discount “pocket the spread between the discounted purchase and sale prices” and divvy up the profits between themselves, contract pharmacies, and third-party administrators. *Id.* at 1273 n.29.

Pharmaceutical companies became increasingly concerned that “contract pharmacies were driving up duplicate discounting and diversion.” *Weiser*, 811 F. Supp. 3d at 1271–72; *see* Doc. 7 at 5. As a result, pharmaceutical companies began adopting policies “that limited or prohibited covered entities from contracting with outside pharmacies for the dispensation of 340B drugs to patients.” *McClain*, 95 F.4th at 1139. AbbVie’s policy is known as its “340B Program Integrity Initiative.” Doc. 7 at 6; *see* Doc. 7-1. Under the 2025 iteration of the policy, “non-hospital covered entities”² may “place orders at the 340B price for direct shipment to an unlimited number of contract pharmacies” only if the covered entity submits “prescription-level information” known as “claims data” to AbbVie. Doc. 7 at 6. This policy is enforced “at the offer stage,” and “is a condition that covered entities must agree to before AbbVie sells them drugs at the 340B discount price.” *Id.*

HHS “acted quickly to prohibit [pharmaceutical companies] from imposing these restrictive contract-pharmacy policies.” *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 641 (5th Cir. 2025). It issued an advisory opinion stating that, “to the extent contract pharmacies are acting as agents of a covered entity, a [pharmaceutical company] 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.” *Id.*; *see also Advisory Op. 20-06 on Contract Pharmacies under the 340B Program*, 2020 WL 11422965, at *1.

Pharmaceutical companies challenged HHS’s advisory opinion, and several circuits sided with them, reasoning that “Congress never said that drug makers must *deliver* discounted 340B drugs to an unlimited number of contract pharmacies.” *Sanofi Aventis*, 58 F.4th at 707; *see also*

² AbbVie’s policy has a separate provision for *hospital* covered entities, but the contested New Mexico statute does not extend to those entities. Doc. 7 at 6 n.5.

Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 455 (D.C. Cir. 2024). As a result, pharmaceutical companies could impose conditions on the delivery of drugs to contract pharmacies because the 340B statute only requires that covered drugs be *offered* to covered entities at a discount. *See Sanofi Aventis*, 58 F.4th at 703. HHS subsequently withdrew the advisory opinion. *See Fitch*, 152 F.4th at 641.

C. The Inflation Reduction Act’s Drug Price Negotiation Program

In 2022, Congress created the Medicare Drug Price Negotiation Program (“DPNP”) “to limit the federal government’s spending on prescription drugs under Medicare.” *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 150 F.4th 76, 81 (2d Cir. 2025); *see* 42 U.S.C. § 1320f. Under the DPNP, HHS sets “a maximum fair price (‘MFP’) for certain selected drugs,” which pharmaceutical companies must make available to individuals insured by Medicare. *Weiser*, 811 F. Supp. 3d at 1280. If a drug implicated by the DPNP is simultaneously sold to a covered entity under 340B, pharmaceutical companies must “provide the lower of the two price concessions.” *Id.*

In response to “widespread concern” about the difficulty of complying with both programs without providing duplicate discounts, HHS “announced a new rebate-model pilot program” (the “Rebate Program”). Doc. 7 at 10; *see* 90 Fed. Reg. 36163–65. Under the Rebate Program, pharmaceutical companies that sell drugs priced under an MFP to a covered entity “issue rebates for the difference between the commercial price and the 340B ceiling price.” *Id.* HHS paused the program after it was enjoined by another court. *See American Hosp. Ass’n v. Kennedy*, 820 F. Supp. 3d 30, 36 (D. Me. 2025). HHS then announced a new iteration of the program that is set to go into effect in 2027. *See* Doc. 42; 91 Fed. Reg. 48883 (Aug. 3, 2026).

D. H.B. 78

Following the Third and D.C. Circuits’ decisions permitting pharmaceutical companies to impose delivery conditions on 340B drugs, several states passed laws to protect covered entities’ partnerships with contract pharmacies, “attempting to do by statute what HHS had done in its advisory opinion.” *Fitch*, 152 F.4th at 641. New Mexico passed H.B. 78, “which prohibits [pharmaceutical companies] from imposing restrictions or data conditions not required under federal law” when selling drugs to 340B covered entities. Doc. 30 at 6; *see* NMSA 1978, § 26-1-27 (Cum. Supp. 2025). The statute states:

B. 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 [HHS];

(2) interfere with the ability of a pharmacy contracted with an applicable entity to dispense 340B drugs to the applicable entity to dispense 340 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 of utilization data is required by federal law.

Id. The law delegates enforcement to New Mexico’s Attorney General. Doc. 7 at 13. A violation of H.B. 78 is “a misdemeanor for the first offense and for second and subsequent offenses is [] a fourth-degree felony.” Doc. 30 at 7.

E. Procedural History

AbbVie now seeks a preliminary injunction against H.B. 78, arguing that it is constitutionally infirm and preempted by federal law. *See* Doc. 7 at 13. Defendants argue that H.B. 78 “does not conflict with federal law” and operates within “New Mexico’s well-

established authority to regulate drug distribution and prevent discriminatory practices.” Doc. 30 at 21. AbbVie has also filed notices of supplemental authority. *See* Docs. 37, 39, 40, 42.

II. Legal Standard

A preliminary injunction is an “extraordinary remedy” that is “the exception rather than the rule.” *Free the Nipple-Fort Collins v. City of Fort Collins*, 916 F.3d 792, 797 (10th Cir. 2019). A plaintiff seeking a preliminary injunction must establish that: (1) they are likely to succeed on the merits, (2) they are likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in their favor, and (4) an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 19 (2008). The third and fourth factors merge when the government is the opposing party. *Denver Homeless Out Loud v. Denver*, 32 F.4th 1259, 1278 (10th Cir. 2022) (citation omitted).

The Supremacy Clause of the United States Constitution “provides a clear rule that federal law ‘shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.’” *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. Const. art. VI, cl. 2). Courts have construed the Supremacy Clause as empowering Congress to preempt state laws. *Id.* Every preemption inquiry begins with “the presumption that federal law does not override the historic police powers of the States” absent the “clear and manifest” intent of Congress. *Bradshaw v. Am. Airlines, Inc.*, 123 F.4th 1168, 1173 (10th Cir. 2024). The party claiming preemption bears the burden of showing that Congress intended to preempt state law. *Day v. SkyWest Airlines*, 45 F.4th 1181, 1184 (10th Cir. 2022).

III. Analysis

For the reasons below, the Court concludes that AbbVie has not established a substantial likelihood of success on its federal preemption claims under either (A) field preemption or (B) conflict preemption principles.

A. H.B. 78 is not field preempted.

First, AbbVie has not demonstrated a substantial likelihood of success in showing that H.B. 78 is field preempted. In the absence of an express preemption provision, state law may be impliedly preempted in two circumstances.³ Field preemption precludes states from regulating conduct where “a framework of regulation of a field is so pervasive that it leaves no space for state supplementation.” *Bradshaw*, 123 F.4th at 1173. Field preemption also exists where the federal interest “is so dominant that the existence of a federal scheme can be assumed to preclude enforcement of state laws on the same subject.” *Id.*

AbbVie contends that H.B. 78 is field preempted because the 340B program “reflects Congress’s judgment about the price of entry for Medicaid and Medicare Part B,” and, along with the program’s “comprehensive enforcement apparatus,” is “so pervasive that there is no room for the States to supplement it.” Doc. 7 at 22. In AbbVie’s view, because the 340B program regulates “which drugs are covered, the prices that manufacturers must charge, to which entities manufacturers must offer those prices, and what covered entities must do to continue receiving the drugs,” Congress left no room for states to regulate the conditions of the *delivery* of 340B drugs. *Id.* at 22–23. The Court disagrees with that view.

³ Congress may “withdraw specific powers from the States by enacting a statute containing an express preemption provision.” *Arizona*, 567 U.S. at 399; *see, e.g., Chamber of Commerce v. Whiting*, 563 U.S. 582, 592 (2011). No such express provision is at issue here. *See generally* Doc. 7. Accordingly, the Court considers whether H.B. 78 is subject to implied preemption.

AbbVie’s field preemption theory fails because the federal scheme it identifies does not occupy the field H.B. 78 regulates—the acquisition and delivery of 340B drugs to contract pharmacies. *See Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 325 (2016) (noting “the State’s traditional power to regulate in the area of public health”). H.B. 78 regulates the “acquisition,” “delivery,” and ability to “dispense” 340B drugs, but does not set or enforce discount pricing. § 26-1-27. The 340B program, on the other hand, is “silent about delivery.” *Sanofi Aventis*, 58 F.4th at 703; *Novartis Pharms.*, 102 F.4th at 461 (agreeing with *Sanofi Aventis*); *McClain*, 95 F.4th at 1143 (relying on *Sanofi Aventis*). The 340B program “regulates neither the distribution of drugs to patients nor the role of pharmacies in [that] distribution.” *Fitch*, 152 F.4th at 646. Indeed, the fact that “Congress chose not to regulate [drug] distribution...indicat[es] that it did not intend to occupy the entire field in this area.” *Fitch*, 152 F.4th at 646. In case after case, pharmaceutical companies asked courts to characterize the 340B program as regulating the terms on which manufacturers must *offer* drugs, rather than the subsequent delivery of those drugs. AbbVie cannot now treat the 340B program as occupying the separate field of drug *delivery*.

AbbVie’s reliance on the 340B program’s “comprehensive enforcement apparatus” similarly fails to transform an unregulated field into an occupied one. Doc. 7 at 22. Congress has comprehensively regulated the terms on which manufacturers must offer discounted drugs to covered entities but has left unregulated the delivery of those drugs to contract pharmacies. That silence “will not be presumed to mandate preemption.” *Paul v. Monts*, 906 F.2d 1468, 1475 n.8 (10th Cir. 1990). Field preemption does not apply.

B. H.B. 78 is not conflict preempted.

Next, AbbVie has not demonstrated a substantial likelihood of success in showing that H.B. 78 is conflict preempted. State law is also impliedly preempted where it conflicts with

federal law, either because “(1) compliance with both federal and state regulations is a physical impossibility,” or because the state law “(2) stands as an obstacle to the accomplishment and execution of the full purposes and objectives of federal law.” *United States v. Supreme Ct. of N. M.*, 839 F.3d 888, 918 (10th Cir. 2016).

AbbVie argues that H.B. 78 improperly alters the terms of the 340B program by imposing obligations beyond those Congress required, interferes with the program’s centralized federal enforcement scheme, and restricts its ability to obtain claims data necessary to invoke the federal administrative dispute-resolution process. *See* Doc. 7 at 15–20. AbbVie further contends that H.B. 78 conflicts with the federal Rebate Program because it prohibits pharmaceutical companies from requiring claims data that federal law contemplates they will receive. *Id.* at 20–22. AbbVie therefore maintains that these state-law requirements disrupt the federal scheme Congress created and, in some instances, make simultaneous compliance with state and federal law impossible. The Court disagrees. None of AbbVie’s asserted conflicts warrants preemption of H.B. 78. The Court addresses each argument in turn.

1. H.B. 78 does not impermissibly regulate the 340B Program.

AbbVie first argues that H.B. 78 is preempted because it is “entirely dependent upon federal law.” Doc. 7 at 15. As a result, if Congress repealed the 340B program, “H.B. 78 would regulate nothing.” *Id.* AbbVie contends that this dependence establishes preemption under *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001), and *McCulloch v. Maryland*, 17 U.S. 316 (1819). *Id.* It is not.

Buckman did not hold that a state law is preempted merely because federal law is essential to its operation. There, the federal Food, Drug, and Cosmetic Act preempted state fraud claims because the federal statute “amply empowers the FDA to punish and deter fraud.”

Buckman, 531 U.S. at 348. The Court explained 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.* at 347. Allowing state tort actions for fraud against the FDA would interfere with the FDA’s ability to administer and enforce its own regulations. *Id.* at 348–53.

H.B. 78 is different. The statute does not authorize New Mexico to police whether pharmaceutical companies have complied with duties owed to the federal government under the 340B program. Federal law identifies the drugs, manufacturers, and covered entities to which H.B. 78 applies; state law supplies the independent prohibition governing the separate acquisition, delivery, and dispensing of those drugs. *See* § 26-1-27. That New Mexico, along with a slew of other states, chose to define the scope of its regulation by reference to a federal program does not, on its own, establish conflict preemption. *See generally Kansas v. Garcia*, 589 U.S. 191, 211 (2020) (“The mere fact that state laws...overlap to some degree with federal [law] does not even begin to make a case for conflict preemption.”). AbbVie “cannot circumvent its burden to identify a compelling federal interest warranting preemption by pointing to the mere existence of a federal statute.” *Weiser*, 811 F. Supp. 3d at 1276.

AbbVie’s reliance on *McCulloch* fares no better. *See* Doc. 7 at 15. *McCulloch* held that Maryland could not impose a tax upon the Bank of the United States because a state may not “impede, burden, or in any manner control” the operations of the federal government. *McCulloch*, 17 U.S. at 317. H.B. 78, however, does not impose a tax or regulatory burden upon the United States, HHS, or a federal instrumentality. It regulates private pharmaceutical companies that operate within New Mexico. *See* § 26-1-27. AbbVie does not explain how its participation in a federal pricing program transforms it into a federal instrumentality such as the

Bank of the United States in *McCulloch*, nor does *McCulloch* establish that private parties become immune from otherwise permissible state regulation because they also happen to participate in a federal program. Accordingly, the fact that H.B. 78 incorporates aspects of the federal 340B program does not itself establish a conflict with federal law.

AbbVie next contends that the obligations imposed by H.B. 78 “change[] the terms of the 340B Program” and, therefore, interfere with the federal statutory scheme. Doc. 7 at 15. It views the 340B program as “contractual [in] nature.” *Id.*; see *Barnes v. Gorman*, 536 U.S. 181, 186 (2002) (noting that “Spending Clause legislation [is] much in the nature of a *contract*”). In AbbVie’s view, pharmaceutical companies undertake a defined set of obligations to the federal government in exchange for participation in the 340B program, and H.B. 78 impermissibly changes “the terms of the 340B program” by adding obligations Congress did not impose. Doc. 7 at 15–16. AbbVie cites *Sanofi Aventis* and *Novartis* for the proposition that federal law only requires it to “offer” covered outpatient drugs to covered entities under the 340B program at a set price, not to offer those drugs unconditionally. *Id.* at 16. H.B. 78, then, allegedly alters the bargain by obligating delivery of discounted drugs on terms Congress did not require. *Id.*

AbbVie mistakes its obligations under federal law—established by multiple federal courts of appeals—for an affirmative federal right to be free from additional state regulation. As discussed, *Novartis* and *Sanofi Aventis* both held that the 340B statute is silent as to the delivery of discounted drugs. See *Novartis Pharms.*, 102 F.4th at 461; *Sanofi Aventis*, 58 F.4th at 703. Congress’s decision not to impose a particular delivery obligation through the 340B statute, however, is not equivalent to a congressional decision that manufacturers must remain free from such obligations under state law.

AbbVie’s contention that Congress’s silence regarding delivery “preserve[d]...the ability of sellers to impose at least some delivery conditions” fares no better. Doc. 7 at 16. Nothing in the statutory text affirmatively guarantees manufacturers the right to impose delivery conditions notwithstanding state law. Accordingly, H.B. 78 does not alter the terms Congress articulated in the 340B program merely because it imposes an independent state-law obligation that Congress did not impose.

2. H.B. 78 does not conflict with enforcement of the 340B Program.

The Court also rejects AbbVie’s argument that Congress vested “HHS with exclusive authority to oversee compliance with the 340B program.” Doc. 7 at 16. As discussed, H.B. 78 does not enforce the same legal obligations as the 340B program. It follows, then, that New Mexico’s enforcement regime does not provide a separate remedy for violation of the same federal obligation. *See Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 380 (2000).

AbbVie’s heavy reliance on *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 117 (2011), is misplaced. There, the Supreme Court rejected covered entities’ attempt to enforce Section 340B’s ceiling-price obligations through third-party-beneficiary suits under state contract law as “incompatible with the [federal] statutory regime.” *Id.* at 113. The Court observed that Congress vested HHS with authority to oversee compliance with the 340B program and sought “centralized enforcement in the government.” *Id.* at 119. H.B. 78, however, does not authorize New Mexico to enforce Section 340B’s drug-pricing obligation or impose penalties because a pharmaceutical company violated its obligations under a federal PPA. It imposes a separate state-law prohibition on restricting the acquisition and delivery of 340B drugs. *See* § 26-1-27(B). A pharmaceutical company may therefore comply fully with its obligations under Section 340B but still violate H.B. 78. Unlike the statutory and contractual

obligations at issue in *Astra*, then, the federal and state obligations here are not “one and the same,” and New Mexico’s penalties are aimed only “at activity that falls outside the purview of 340B.” *Astra*, 563 U.S. at 114; *see, e.g., McClain*, 95 F.4th at 1145; *Fitch*, 152 F.4th at 647.

AbbVie’s arguments about HHS’s ADR process do not compel a different conclusion. AbbVie is correct that the ADR regulations permit covered entities to bring overcharge claims against manufacturers, including 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); Doc. 7 at 17. As a result, a pharmaceutical company’s contract-pharmacy restrictions that impact drug prices may be presented to HHS as the basis for a claim in the ADR process. The availability of that federal forum, though, does not transform a state law regulating the same underlying conduct into an impermissible means of enforcing Section 340B. An ADR panel determines whether a pharmaceutical company violated its obligations under *federal* law, while enforcement of H.B. 78 is limited to violations of New Mexico’s own restrictions on the acquisition and delivery of 340B drugs. The fact that the same conduct may give rise to both inquiries does not convert the state-law proceeding into an alternative means of enforcing a federal obligation. *See Weiser*, 811 F. Supp. 3d at 1278.

AbbVie separately argues that H.B. 78 conflicts with the federal enforcement scheme because it restricts “manufacturers’ access to the federal ADR scheme.” Doc. 7 at 19. To commence an ADR action, a manufacturer must first “conduct an audit.” 42 U.S.C. § 256b(d)(3)(B)(iv). AbbVie says it relies on claims data—which H.B. 78 prohibits it from requiring covered entities to provide—to identify audit targets. Doc. 34 at 9. The record does not establish, however, that claims data are necessary to initiate an audit. HRSA has explained that the “reasonable cause” standard for obtaining an audit does not “present any barriers to a

manufacturer’s ability to perform an audit of a covered entity,” and reasonable cause may be established through information other than claims data. *See* 89 Fed. Reg. 28643, 28646 (Apr. 19, 2024); *see also* Doc. 31-1 at 20–21. Even assuming that claims data are required to pursue an audit or ADR proceeding, H.B. 78 expressly permits pharmaceutical companies to require such data when “required by federal law.” § 26-1-27(B)(3). So, if federal law requires claims data as a prerequisite to accessing the federal enforcement process, H.B. 78 does not prohibit their collection. If not, then AbbVie cannot establish conflict preemption merely because claims data would make it easier to identify potential audit targets. *See PhRMA v. Torrez*, 2026 WL 1752214, at *10 (D.N.M.) (concluding the same).

AbbVie’s argument that New Mexico courts will be forced to resolve substantive questions of federal 340B law and create conflicting interpretations is overstated. *See* Doc. 34 at 7–8. An enforcement action under H.B. 78 asks whether a pharmaceutical company violated New Mexico’s restrictions on the acquisition and delivery of 340B drugs, not whether Section 340B has been violated. *See* § 26-1-27(B). To the extent that applying H.B. 78 requires resolving threshold questions defined by federal law, such as whether a drug or entity falls within the 340B program, that reference does not transform the State’s proceeding into one enforcing federal obligations. *See generally* Doc. 31-1 at 20.

AbbVie’s final conflict preemption argument concerns HHS’s Rebate Program. *See* Doc. 7 at 20–22. AbbVie contends that H.B. 78 “squarely conflicts with the Rebate Program” because “[w]ithout claims data, AbbVie cannot feasibly participate...and risks compromising” the program’s integrity. *Id.* at 20. This argument fares no better than AbbVie’s ADR argument. First, the Rebate Program is not currently operative. As the State points out, implementation of the pilot program was halted by federal court orders, and manufacturers presently remain subject

to the existing upfront-discount model. *See* Doc. 30 at 16–17. No operative conflict currently exists. The existence “of a hypothetical or potential conflict is insufficient to warrant the preemption of [a] state statute.” *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982).

Second, even assuming the revised Rebate Program takes effect in 2027, H.B. 78 expressly permits pharmaceutical companies to require claims or utilization data when that information is “required by federal law.” § 26-1-27(B)(3). Thus, to the extent future participation in the Rebate Program requires AbbVie to obtain claims data from covered entities, H.B. 78 does not prohibit that collection. *See* Doc. 30 at 16–17; Doc. 31-1 at 22–23; *Weiser*, 811 F. Supp. 3d at 1281.

The Court acknowledges AbbVie’s concern that the Attorney General “refused to provide” “assurance that H.B. 78’s carveout covered the Rebate Program.” Doc. 34 at 10. Even so, H.B. 78 provides that its prohibition on requiring claims or utilization data does not apply when the sharing of such data is “required by federal law.” § 26-1-27(B)(3). If the revised Rebate Program imposes such a federal requirement, the exception applies by its plain terms. The Attorney General’s refusal to provide advance assurance does not render a presently hypothetical conflict actual. *See United States v. Kansas*, 810 F.2d 935, 938 (10th Cir. 1987) (“We should not seek out conflicts between state and federal regulations where none clearly exist”).

IV. Conclusion

Having concluded that Plaintiffs have not demonstrated a substantial likelihood of success on the merits, the Court need not address the remaining preliminary injunction factors. *See Warner v. Gross*, 776 F.3d 721, 736 (10th Cir. 2015). Plaintiffs’ Motion for a Preliminary

Injunction, Doc. 7, is denied. The Motion for Leave to File Amicus Curiae Brief, Doc. 31, is granted.

IT IS SO ORDERED.

/s/Kenneth J. Gonzales
CHIEF UNITED STATES DISTRICT JUDGE

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