**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLORADO**
**Judge Regina M. Rodriguez**

Civil Action No. 1:25-cv-02437-RMR-STV

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado; and KRISTEN WOLF, RYAN LEYLAND, PATRICIA EVACKO, AVANI SONI, MICHAEL SCRUGGS, ALEXANDRA ZUCCARELLI, and JAYANT PATEL, in their official capacities as Members of the Colorado State Board of Pharmacy,

Defendants.

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**ORDER**

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This matter comes before the Court on Plaintiff's Motion for Preliminary Injunction, Hearing Requested, ECF No. 10. Defendants filed a Response, ECF No. 33, and Plaintiffs filed a Reply, ECF No. 46. Additionally, the Court has reviewed numerous decisions from other federal courts related to nearly identical issues and has determined that a hearing on the issue is unnecessary. For the reasons explained below, the Motion is DENIED.

## I. BACKGROUND[1]

The high cost of prescription drugs has led to concerns over affordability and access. Several states have passed legislation to address this issue. Colorado recently passed its version in Colorado Senate Bill 25-071 ("SB25-71"), now codified as the Colorado 340B Contract Pharmacy Protection Act, Colorado Revised Statutes (C.R.S.) §§ 6-29-101 *et seq.* (2025). Plaintiff asserts Colorado's Act is preempted by federal law, specifically, Section 340B of the Public Health Services Act ("Section 340B"), and therefore, this Court should enjoin its enforcement.

### A. Section 340B

Section 340B requires drug companies that participate in Medicaid and Medicare Part B to offer discounts on certain outpatient drugs to "covered entities," including public hospitals, community health centers, and other entities providing care for low-income and rural patients. 42 U.S.C. §§ 256b; *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023). Section 340B allows providers "to support their missions by maintaining services and lowering medication costs for patients" through revenue generated from the program and up-front savings realized on the cost of drugs. Gov't Accountability Off., *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17 (GAO-11-836, Sept. 2011). "Drug manufacturers also must follow certain 340B program

[1] The following facts are from the "Background" sections of the parties' briefing, ECF Nos. 10, 33, 46, in combination with the summaries of the history of the 340B Program provided in numerous federal court decisions. The Court has reviewed Defendants' Notice of Related Cases, ECF No. 27, and in particular leverages the background sections from *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024) and *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024).

requirements. Specifically, they must sell outpatient drugs to covered entities at or below the statutorily determined price." Gov't Accountability Off., *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 13 (GAO-11-836, Sept. 2011). "The ceiling price is fixed by a statutory formula strikingly generous to purchasers." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024).

In 1994, the Health Resources and Services Administration's ("HRSA") "initial guidance stated that a covered entity may use a 'purchasing agent.' According to the guidance, manufacturers may ship discounted drugs to this agent, which then must ship them to the covered entity for dispensing to patients." *Id.* Then in 1996, "HRSA recognized that many covered entities use outside pharmacies to distribute drugs to their patients. To accommodate them, HRSA stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Id.* at 457. Fourteen years later, HRSA "opined that covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies," reasoning that "contract pharmacies enable covered entities to 'create wider patient access by having more inclusive arrangements in their communities.'" *Id.* (quoting Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,273). "[T]he outsourcing of pharmacy services has allowed for drug dispensation closer to where low-income patients reside." *PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024).

**B. Colorado's Act SB25-71**

Today, covered entities rely on the use of contract pharmacies to take full advantage of Section 340B. ECF No. 33 at 5. As covered entities increased their use of contract pharmacies, pharmaceutical companies responded by restricting covered entities from contracting with outside pharmacies for Section 340B drug dispensation. *Id.* In response, states began enacting state laws to fill the gap in federal law to ensure that covered entities in their states could retain access to the Section 340B financial resources. *Id.* at 6. In 2025, the Colorado General Assembly enacted the Colorado 340B Contract Pharmacy Protection Act ("SB25-71"), which states "a manufacturer, third-party logistics provider, or repackager . . . shall not, directly or indirectly, deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B covered entity, a pharmacy contracted with a 340B covered entity, or a location otherwise authorized by a 340B covered entity to receive and dispense 340B drugs." Colo. Rev. Stat. § 6-29-105(1)(a). SB25-71 also states "a manufacturer shall not directly or indirectly require, including as a condition, a 340B covered entity, a pharmacy contracted with a 340B covered entity, or any other location authorized to receive 340B drugs by a 340B covered entity to submit any health information, claims or utilization data . . . or other data that does not relate to a claim submitted to federal health care program, unless such data is voluntarily furnished by such covered entity or otherwise required to be furnished under applicable federal law. Colo. Rev. Stat. § 6-29-105(1)(b).

A violation of SB25-71 is an unfair or deceptive trade practice under the Colorado Consumer Protection Act ("CCPA"), and the violator is subject to the CCPA's enforcement

and penalty provisions. § 6-29-105(3)(a). A person regulated by Colorado's State Board of Pharmacy who violates the CCPA provisions may be subject to Pharmacy Board discipline. § 6-29-105(3)(d).

**C. Related Cases and Court Decisions**

There are two pending related cases in this district: *AbbVie Inc. v. Weiser, et al.*, Case No. 25-cv-01847-WJM-KAS, filed June 12, 2025; and *AstraZeneca Pharmaceuticals LP v. Weiser, et al.*, Case No. 25-cv-02685-PAB, filed August 27, 2025. In *AbbVie*, Judge Martinez denied AbbVie's Motion for Preliminary Injunction, finding that it had not established a substantial likelihood of success on the merits of its preemption or Takings Clause claims. *AbbVie, Inc. v. Weiser*, No. 25-CV-1847-WJM-KAS, 2025 WL 3041825, at *5 (D. Colo. Oct. 31, 2025). On November 19, 2025, AbbVie filed a Notice of Appeal as to Judge Martinez's order denying the preliminary injunction, and the issue is currently on appeal in the Tenth Circuit. In *AstraZeneca*, Judge Brimmer also denied AstraZeneca's Motion for Preliminary Injunction after analyzing likelihood of success on its preemption and other related claims. *Astrazeneca Pharms. LP v. Weiser*, No. 25-CV-02685-PAB-STV, 2025 WL 3653161, at *11 (D. Colo. Dec. 17, 2025). Two days later, AstraZeneca filed its Notice of Appeal as to Judge Brimmer's order denying the preliminary injunction, and the issue is also on appeal in the Tenth Circuit. Similar cases challenging comparable state laws brought by these and other pharmaceutical companies

have been filed in several federal district courts. *AbbVie*, 2025 WL 3041825, at *4. The majority of these lawsuits have been unsuccessful.[2] *Id.* (compiling cases).

Other circuit courts have affirmed the lower court decisions regarding whether or not Section 340B preempts state laws, like Colorado's SB25-71, that prohibit manufacturers from limiting covered entities from contracting with outside pharmacies. Most recently, the Fifth Circuit reviewed the plaintiffs' federal preemption, unconstitutional taking, and unconstitutional vagueness claims in their motion for summary judgment and found none prohibited the Louisiana state law, affirming the lower court's denial of plaintiff's motion. *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 537, 549 (5th Cir. 2026). Likewise,

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[2] In addition to the cases compiled by Judge Martinez, the Court is also aware of the following cases: *AbbVie, Inc., et al. v. Skrmetti*, No. 25-cv-00519, 2026 WL 542712 (M.D. Tenn. Feb. 26, 2026) (granting motion to dismiss); *AstraZeneca Pharmaceuticals LP v. Lopez*, No. 25-cv-00369 (D. Haw. Feb. 23, 2026) (denying motion for preliminary injunction); *AbbVie, Inc., et al. v. Brown*, Nos. 25-cv-0071, 25-cv-00284, 25-cv-00308, 2025 WL 3228898 (D. Utah Nov. 19, 2025) (granting in part motion to dismiss Due Process and Commerce Clause claims and denying in part motion to dismiss with respect to Supremacy Clause and Takings claims); *AbbVie Inc. et al. v. Drummond*, Case Nos. Civ-25-726, Civ-25-727, Civ-25-1156 (W.D. Okla. Oct. 31, 2025) (granting in part and denying in part preliminary injunction).

The cases compiled by Judge Martinez include: *AbbVie Inc. v. Neronha*, 1:25-cv-00388-JJM-AEM (D.R.I. Sept. 30, 2025) (denying preliminary injunction as to Rhode Island law); AbbVie, Inc. v. Frey, 2025 WL 2813787, at *1 (D. Me. Sept. 23, 2024) (same as to Maine law); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657, 664–65 (W.D. Miss. 2024) (same as to Mississippi law); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737, 749–50 (S.D. Miss. 2024) (same); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271, at *18 (M.D. Tenn. June 30, 2025) (same as to Tennessee law); *AstraZeneca Pharms. LP v. Bailey*, 2025 WL 644285, at *3 (W.D. Mo. Feb. 27, 2025) (granting motion to dismiss manufacturer's claims that Missouri law was preempted and violated the Takings Clause); *PhRMA v. Murrill*, 2024 WL 4361597, at *8–9 (W.D. La. Sept. 30, 2024) (granting summary judgment in favor of State on manufacturers' claims that Louisiana law was preempted and violated the Takings Clause); *AbbVie Inc. v. Fitch,* 2024 WL 3503965, at *12 (S.D. Miss. July 22, 2024) (denying preliminary injunction as to Mississippi law), *aff'd* 152 F.4th 635 (5th Cir. 2025); *PhRMA v. Fitch,* 2024 WL 3277365, at *11 (S.D. Miss. July 1, 2024) (same); *PhRMA v. McClain,* 645 F. Supp. 3d 890 (E.D. Ark. 2022) (granting summary judgment in favor of Arkansas official on manufacturers' claim that Arkansas law was preempted), *aff'd* 95 F.4th 1136 (8th Cir. 2024), *cert. denied* 145 S.Ct. 768 (2024); *but see AstraZeneca Pharms. LP v. Harris,* No. 4:24-cv-00268-KGB (E.D. Ark. Sept. 30, 2025), ECF No. 141 (denying judgment on the pleadings as to manufacturer's claim that Arkansas law violated Takings Clause); *PhRMA v. Morrisey,* 760 F. Supp. 3d 439, 452–60 (S.D.W. Va. 2024) (granting preliminary injunction as to West Virginia law and denying the defendants' motion to dismiss).

in *Novartis*, the District of Columbia Circuit held "that Section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 464. The Eighth Circuit has also held that Arkansas' state law is not preempted by Section 340B or the Federal Food, Drug, and Cosmetic Act's Risk Evaluation and Mitigation Strategies. *McClain*, 95 F.4th at 1146.

## II. LEGAL STANDARD

Federal Rule of Civil Procedure 65 authorizes a district court to enter preliminary injunctions. Fed. R. Civ. P. 65(a). "Preliminary injunctions are extraordinary remedies requiring that the movant's right to relief be clear and unequivocal." *Planned Parenthood of Kan. v. Andersen*, 882 F.3d 1205, 1223 (10th Cir. 2018). A party seeking preliminary injunctive relief must satisfy four factors: (1) a likelihood of success on the merits; (2) a likelihood that the movant will suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the movant's favor; and (4) that the injunction is in the public interest. *Petrella v. Brownback*, 787 F.3d 1242, 1257 (10th Cir. 2015). A party seeking an injunction must demonstrate that "all four of the equitable factors weigh in its favor," *Sierra Club, Inc. v. Bostick*, 539 F. App'x 885, 888 (10th Cir. 2013), and a "plaintiff's failure to prove any one of the four preliminary injunction factors renders its request for injunctive relief unwarranted." *Vill. of Logan v. U.S. Dep't of Interior*, 577 F. App'x 760, 766 (10th Cir. 2014).

In addition to the four factors, a district court must also consider whether the movant's request falls within one of the "disfavored injunction" categories. Those

categories of disfavored injunctions include those that will (1) alter the status quo, (2) mandate an affirmative act by the defendant, or (3) afford all the relief that the movant could expect to win at trial. *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1259 (10th Cir. 2004). Here, Plaintiff's motion requests a disfavored injunction. Accordingly, Plaintiff "must make a strong showing both on the likelihood of success on the merits and on the balance of the harms." *Colo. v. E.P.A.*, 989 F.3d 874, 884 (10th Cir. 2021) (quotation omitted).

## III. ANALYSIS

The Court has reviewed Plaintiff's Motion and Complaint, Defendants' response, and Plaintiff's Reply. For the reasons stated below, the Court finds that Plaintiff has failed to meet its burden of showing that a preliminary injunction is warranted.

### A. Likelihood of Success on the Merits

First, a plaintiff must establish a substantial likelihood of prevailing on the merits of his claims. *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1246 (10th Cir. 2001). Here, Plaintiff argues that SB25-71 is preempted under both field and conflict preemption principles. ECF No. 10 at 11-23. Defendants contest both field and conflict preemption exists and assert that Plaintiff lacks standing. ECF No. 33 at 9-22. With regard to standing, Defendants contend that PhRMA characterizes an economic injury that cannot be traceable to Defendants, because SB25-71 "neither compels PhRMA members to participate in 340B nor directs PhRMA members to sell 340B drugs directly to pharmacies." ECF No. 33 at 12-14. PhRMA emphasizes that it need only show an injury is "fairly traceable" and that "[e]conomic injury is quintessential Article III injury." ECF No. 46 at 18. PhRMA argues SB71-25 "forces manufacturers to provide 340-priced drugs

where they would otherwise not be required to do so." *Id.* at 19. While SB71-25 does not impact the price of Section 340B drugs, it does affect the overall cost of PhRMA's participation in Section 340. This economic injury is sufficiently "concrete and particularized" and "fairly traceable" to SB71-25 to establish standing. *See Astrazeneca*, 2025 WL 3653161, at *5. Having demonstrated standing, "the party claiming preemption . . . bears the burden of showing with specificity that Congress intended to preempt state law." *Day v. SkyWest Airlines*, 45 F.4th 1181, 1184 (10th Cir. 2022) (citation omitted). "Congress's intent to preempt state law can be shown 'through a statute's express language' or implied 'through its structure and purpose.'" *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008)).

**1. Field Preemption**

"The Supremacy Clause 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.' Under this principle, Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting Art. VI, cl. 2.). "Field preemption is one variety of implied preemption. It exists where 'a framework of regulation' of a field is 'so pervasive' that it leaves no space for state supplementation or 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.'" *Bradshaw v. Am. Airlines, Inc.*, 123 F.4th 1168, 1173 (10th Cir. 2024) (quoting *Arizona*, 567 U.S. at 399).

PhRMA argues that SB25-71 is "field preempted because it regulates in an exclusively federal field (a program that is the product of Congress's spending power) where Congress has set the terms of participation and obligations incurred." ECF No. 10 at 17. PhRMA contends that "Congress deemed it essential that 340B be administered 'harmoniously and on a uniform, nationwide basis.'" ECF No. 10 at 20 (quoting *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 120 (2011)). According to PhRMA, Congress did not "authorize states to alter the procedures and conditions governing manufacturers' voluntary participation in 340B (and, by extension, Medicare and Medicaid)." *Id.* Defendants counter that "Congress did not intend for 340B to preempt the field" and that the Section 340B is "not so pervasive that Congress left no room for the States to supplement it." ECF No. 33 at 17 (citations omitted, cleaned up).

First, the Court notes that *Astra*, which PhRMA relies on, discusses the similar but unique issue of whether or not "340B entities, though accorded no right to sue for overcharges under the statute itself, may nonetheless sue allegedly overcharging manufacturers as third-party beneficiaries of the PPAs (Pharmaceutical Pricing Agreements) to which the manufacturers subscribed." *Astra*, 563 U.S. at 113. In *Astra,* the Supreme Court held that "suits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS ["Health and Human Services"] are incompatible with the statutory regime." *Id.* Specifically, the Supreme Court determined that "Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions." *Id.* at 114. PhRMA interprets this holding to mean that 340B, as a whole, is "a matter for Congress alone." ECF No. 10 at 21. The

Court disagrees. The Supreme Court determined in *Astra* that "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Astra*, 563 U.S. at 117. *Astra* specifically held that Congress intended to "strengthen and formalize HRSA's enforcement authority" of PPAs and "to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA." *Id.* at 121-22. The *Astra* decision did not discuss or contemplate whether there was room in the 340B program itself for state supplementation, the field preemption issue in the instant case.

Second, while not controlling, the Court finds the Eight Circuit's analysis of Section 340B and the Arkansas law comparable to SB25-71, Ark. Code Ann. § 23-92-604(c) ("Act 1103"), compelling on the issue. *See Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir.). Like SB25-71, "Act 1103 prohibits manufacturers from limiting covered entities' ability to contract with outside pharmacies." *Id.* at 1139. The Eighth Circuit helpfully summarized the 340B program:

> 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*, 563 U.S. at 113. 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*, 563 U.S. at 115; *see also* 42 U.S.C. § 256b(a)(4). 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*, 563 U.S. at 115-16; *Sanofi Aventis*, 58 F.4th at 701-2. 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).

*Id.* at 1141. The Eighth Circuit agreed with the Third Circuit in that "the 340B Program is silent about delivery and distribution of pharmaceuticals to patients." *Id.* at 1142 (citation omitted). Indeed, Judge Martinez confirmed that "federal Circuit Courts of Appeal now concur that Section 340B is silent about delivery.'" *Abbvie*, 2025 WL 3041825, at *6 (citing *Sanofi Aventis*, 58 F.4th at 702; *Novartis Pharms.*, 102 F.4th at 461; *Fitch*, 152 F.4th at 646).

Like SB25-71, Act 1103 "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying the pharmacy access to a covered entity's 340B drugs" and "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying 340B drug pricing to covered entities who use contract pharmacies for distribution." *Id.* at 1143. PhRMA argued in *McClain*, as it does here, that Act 1103 was field preempted by Section 340B. *Id.* The Eighth Circuit disagreed, explaining that "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." *Id.* at 1143-44 (quoting *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 940-41 (8th Cir. 2011)). Thus, the Eight Circuit found 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.

Finally, the Court reiterates that the majority of other courts have also found that Congress did not intend for Section 340B to preempt the field. *See AbbVie Inc. v. Skrmetti*, No. 3:25-CV-00519, 2025 WL 1805271, at *13 (M.D. Tenn. June 30, 2025) ("The primary problem with the plaintiff's position is that neither AbbVie's policy nor S.B. 1414 says anything about the *pricing* of 340B drugs; both entirely concern the *delivery* of 340B drugs. . . . [T]his court finds that Congress did not intend to preempt the field."); *Pharm. Rsch. & Manufacturers of Am. v. Bailey*, No. 2:24-CV-04144-MDH, 2025 WL 644281, at *5 (W.D. Mo. Feb. 27, 2025) ("The Eighth Circuit found that a statute which establishes enforcement for the distribution of 340B drugs and the federal 340B law's enforcement scheme address two completely different issues and thus Congress did not inten[d] to preempt the field with its 340B legislation."); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657, 665 (S.D. Miss. 2024) ("The Eighth Circuit and this Court have previously held that Congress did not intend to preempt the field when it enacted 340B."); *Pharm. Rsch. & Manufacturers of Am. v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *8 (W.D. La. Sept. 30, 2024) ("[T]he Court concludes that Plaintiffs cannot establish that "Congress has unmistakably so ordained" that state regulatory power be displaced with respect to contract pharmacies under the Section 340B program."). The Court interprets Section 340B the same way and finds that it was not intended to preempt the field.

Thus, the Court concludes that PhRMA is unlikely to succeed on the merits of its field preemption claim.

**2. Conflict Preemption**

PhRMA also argues that SB25-71 conflicts with Section 340B. Conflict preemption exists when a state-law provision conflicts with federal law either because "(1) compliance with both federal and state regulations is a physical impossibility, or because the provision (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 New Mexico*, 839 F.3d 888, 918 (10th Cir. 2016). PhRMA makes three arguments to support its conflict preemption claim: (1) SB25-71 impermissibly expands the scope of federal Section 340B obligations; (2) SB25-71 unlawfully limits access to claims data; and (3) SB25-71 conflicts with the federal enforcement regime. ECF No. 10 at 16-23.

**a. Scope of 340B Obligations**

First, PhRMA argues that SB25-71 conflicts with Section 340B's "offer-and-acceptance mechanism and unlawfully expand the scope of the federal subsidy by requiring additional 340B-priced transactions." ECF No. 10 at 16. According to PhRMA, SB25-71 "directly interferes with the methods by which the federal statute was designed to achieve its purposes and reworks manufacturers' 340B obligations." *Id.* PhRMA relies on *Novartis*, which held that "[S]ection 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 464 (D.C. Cir. 2024). PhRMA attempts to extend this holding to mean that SB25-71 impermissibly interferes with manufacturers'

"control over how they sell 340B-priced drugs." ECF No. 10 at 22. The Court disagrees. SB25-71 does not alter the definitions of "covered entity" or "340B drug." Colo. Rev. Stat. § 6-29-105(1)(a). Instead, it prohibits a manufacturer from preventing or limiting the acquisition of a 340B drug to a contract pharmacy or a location otherwise authorized by a 340B covered entity. *Id.* On its face, this requirement does not conflict with Section 340B's requirement to sell 340B drugs at the statutorily determined price. "When covered entities enter into agreements with contract pharmacies, these pharmacies do not become beneficiaries of the 340B program. . . . Covered entities using contract pharmacies still order and pay for the drugs, but they are shipped directly to the pharmacies." *McClain*, 95 F.4th at 1142 (citations omitted, cleaned up). When a covered entity uses a contract pharmacy, "the pharmacy becomes an agent of the covered entity with the authorization to dispense 340B drugs to patients of the covered entity pursuant to a prescription." *Id.* In other words, SB25-71 works in concert with Section 340B to "provide more comprehensive services and reach more eligible patients." ECF No. 33 at 18 (citing *McClain*, 95 F.4th at 1144-45). Judge Brimmer similarly found "no preemption issue raised by S.B. 71 attaching itself to Section 340B" because SB25-71 helps accomplish Section 340B's mission to help "healthcare providers reach more eligible patients and provide more comprehensive services." *AstraZeneca*, 2025 WL 3653161, at *8.

Thus, the Court finds that PhRMA has not demonstrated a likelihood of success on the merits of its preemption claim based on SB25-71's purported expansion of the scope of Section 340B obligations.

**b. Claims-Data Restriction**

Second, PhRMA argues that SB25-71 "unlawfully limits access to claims data." ECF No. 10 at 25. SB25-71 bars manufacturers from "requir[ing], including as a condition, a 340B covered entity, a pharmacy contracted with a 340B covered entity, or any other location authorized to receive 340B drugs by a 340B covered entity to submit any health information, claims or utilization data, purchasing data, payment data, or other data that does not relate to a claim submitted to a federal health care program, unless such data is voluntarily furnished by such covered entity or otherwise required to be furnished under applicable federal law." Colo. Rev. Stat. § 6-29-105(1)(b). PhRMA contends that "[u]nder the federal regime, a manufacturer must first audit a covered entity before initiating ADR ("alternative dispute resolution") claim." ECF No. 10 at 26 (citing 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv)). According to PhRMA, SB25-71 is preempted, because it prevents manufacturers from obtaining audit documents and "hides this information, limiting manufacturers' access to evidence of federal violations and handicapping manufacturers' use of the exclusive federal resolution process." ECF No. 10 at 27.

SB25-71 goes on to state that "subsection (1) of this section does not prohibit a manufacturer from requiring health information or other data that a covered entity is required to furnish to a manufacturer under applicable federal law, including data relating to an audit in accordance with procedures established by the Federal Department of Health and Human Services under 42 U.S.C. Sec. 256b(a)(5)(C)." Colo. Rev. Stat. § 6-29-105(5). SB25-71 does not *prohibit* the audit required under Section 340B. Instead, it simply does not permit manufacturers to *require* such claims data unless federal law

mandates it. Thus, like Judge Brimmer and other judges addressing this argument, the Court does not find that PhRMA has demonstrated a likelihood of success on the merits of its preemption claim based on SB25-71's claim-data restriction. *See AstraZeneca*, 2025 WL 3653161, at *10.

Additionally, PhRMA's arguments that the Medicare Drug Negotiation Program necessitates claims data fails. Under this program, HHS is required to negotiate maximum fair prices with manufacturers for certain drugs. 42 U.S.C. § 1320f-3(a). Manufacturers need claims data to avoid providing duplicative price reductions. PhRMA alleges that SB25-71's claim-data restriction "hides that data." ECF No. 10 at 27. The Court disagrees. Because SB25-71's claims-data restriction does not apply if the data is "otherwise required to be furnished under applicable federal law," manufacturers may access the claims data necessary to appropriately participate in the Medicare Drug Negotiation Program.

Accordingly, the Court is not persuaded by PhRMA's second conflict preemption argument based on SB25-71's claim-data restriction.

**c. Federal Enforcement Regime**

Third, PhRMA argues that SB25-71 "conflicts with the exclusive federal administrative and enforcement regime." ECF No. 10 at 28. Again, PhRMA repurposes conflict preemption arguments presented in other similar federal cases. PhRMA contends that (1) SB25-71 allows private entities to file suit while Congress does not; and (2) HHS has authority to address the issues SB25-71 targets. *Id.* at 28-29. AstraZeneca has similarly argued (1) "S.B. 71 authorizes the Colorado Attorney General and district

attorneys to bring civil actions to enjoin violations and recover penalties" and (2) "SB25-71 would require state adjudicators to consider and resolve questions of federal law to determine whether a manufacturer violated the statute. *AstraZeneca*, 2025 WL 3653161, at *9. Judge Brimmer found—and this Court agrees—that SB25-71 creates enforcement authority for violations of SB25-71 itself, not Section 340B, and state courts are regularly called to decide questions of federal law. *Id.* Thus, the enforcement authority under SB25-71 does not conflict with that of Section 340B.

Accordingly, the Court concludes that PhRMA is unlikely to succeed on the merits of its conflict preemption claim.

**B. Irreparable Harm**

The Tenth Circuit has explained that "[t]o merit preliminary injunctive relief, a movant must present a significant risk it will experience harm that cannot be compensated after the fact by money damages. . . . The injury must also be of such imminence that there is clear and present need for equitable relief to prevent irreparable harm." *State v. U.S. Env't Prot. Agency*, 989 F.3d 874, 884 (10th Cir. 2021) (citations omitted, cleaned up). PhRMA argues that its members suffer "irreparable harm in the form of unrecoverable compliance costs and unrecoverable lost resources" absent relief. ECF No. 10 at 30. It also contends that its "members have and will continue to expend significant time and financial resources in analyzing the effects of the Act, determining how to comply with both it and federal law." *Id.* "[T]o constitute irreparable harm, an injury must be imminent, certain, actual, and not speculative." *Id.* at 886 (citation omitted). PhRMA does not provide specific evidence to demonstrate "imminent, certain and actual

harm." Without more, PhRMA fails to establish irreparable harm to support its claim for preliminary injunction.

### C. Balance of Hardships and Public Interest

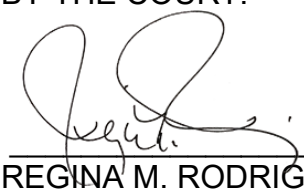
PhRMA argues, in a single paragraph, that the "balance of harms and public interest also favor relief." ECF No. 10 at 31. PhRMA states that "the federal government has long regulated 340B exclusively, and PhRMA's members operated under that scheme and relied on its exclusively federal nature." *Id.* However, PhRMA ignores that fact that the purpose of Section 340B is to allow providers "to support their missions by maintaining services and lowering medication costs for patients" through revenue generated from the program and up-front savings realized on the cost of drugs. Gov't Accountability Off., *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17 (GAO-11-836, Sept. 2011). As described above, SB25-71 supports this mission by working in conjunction with Section 340B by allowing contract pharmacies to become an agent of the covered entity and dispense 340B drugs to patients of the covered entity. Thus, the Court is unpersuaded by PhRMA's argument that balance of harms and public interest favor relief.

## IV. CONCLUSION

For the reasons stated herein, Plaintiff's Motion for Preliminary Injunction, ECF No. 10, is DENIED.

DATED: March 18, 2026

BY THE COURT:



REGINA M. RODRIGUEZ
United States District Judge