IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

ABBVIE INC., *et al.*, Plaintiffs, v. GENTNER DRUMMOND, in his official capacity as ATTORNEY GENERAL, Defendant.	)	Case No. CIV-25-726-PRW
NOVARTIS PHARMACEUTICALS COPRORATION, Plaintiff, v. GENTNER DRUMMOND, in his official capacity as ATTORNEY GENERAL, Defendant.	)	Case No. CIV-25-727-PRW
ASTRAZENECA PHARMACEUTICALS LP Plaintiff, v. GENTNER DRUMMOND, in his official capacity as ATTORNEY GENERAL, *et al.* Defendants.	)	Case No. CIV-25-1156-PRW

ORDER

Before the Court are three motions for preliminary injunction (Case No. CIV-25-726, Dkt. 7; Case No. CIV-25-727, Dkt. 15; and Case No. CIV-25-1156, Dkt. 13). Plaintiffs AbbVie Inc., *et al.*, Novartis Pharmaceuticals Corporation, and AstraZeneca Pharmaceuticals LP each moved for a preliminary injunction under Federal Rule of Civil Procedure 65. Defendant Gartner Drummond, in his official capacity as Attorney General of Oklahoma, filed responses in opposition to AbbVie and Novartis's Motions. For the reasons that follow, Plaintiffs' Motions are **GRANTED IN PART AND DENIED IN PART**.

Background[1]

In 1992, Congress created what would become the most important drug pricing scheme virtually no one has heard of: the 340B Program. The 340B Program, unlike Medicare and Medicaid, was designed for the direct benefit of healthcare providers rather than their patients.[2] Indeed, a patient would generally have no reason to know that the 340B Program played any role in their prescription. The patient pays the same price, for the same drug, from the same pharmacy as they would if their prescription wasn't covered by the 340B Program.

Congress enacted the 340B Program as part of the Veterans Health Care Act to help qualifying healthcare providers ("covered entities") stay afloat by allowing them to

[1] Unless otherwise noted, the information in this section is drawn from the uncontested statements of facts in the parties' pleadings.

[2] *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3rd Cir. 2023).

purchase certain outpatient drugs from manufacturers who participate in Medicaid and Medicare Part B at a discount negotiated by the Secretary of Health and Human Services.[3] The 340B Program requires drug manufacturers to subsidize covered entities by forcing the drug manufacturers to sell deeply discounted drugs to those entities, who then turn around and sell them to their patients at full price and pocket the difference. And when those covered entities bill their patients' insurance providers for qualifying 340B drugs, the insurance companies reimburse the covered entities at the non-discounted price, and again, the covered entities pocket the spread. Covered entities are not obligated to pass any of this windfall on to patients. They are free to do whatever they like with it, whether that be putting the profits towards general operating expenses or new capital projects.

There are sixteen different categories of covered entities, ranging from Disproportionate Share Hospitals ("DSHs"), which essentially are non-profit or public hospitals serving high numbers of Medicare or Medicaid recipients,[4] to Indian health centers and Ryan White HIV/AIDS Program grantees.[5] Commercial pharmacies are not covered entities.

The Health Resources and Services Administration ("HRSA"), an agency of the United States Department of Health and Human Services ("HHS"), administers the

[3] *Sanofi*, 58 F.4th at 699–700.

[4] Health Res. & Servs. Admin., *Disproportionate Share Hospitals: Eligibility*, U.S. Dep't of Health & Hum. Servs., https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals (last visited Oct. 9, 2025).

[5] Health Res. & Servs. Admin., *340B Eligibility: Who Can Participate in the 340B Drug Pricing Program*, U.S. Dep't of Health & Hum. Servs., https://www.hrsa.gov/opa/eligibility-and-registration (last visited Oct. 9, 2025).

program. Initially, the covered entities were distributing 340B drugs from their inhouse pharmacies, but in 1996, acknowledging that not every covered entity could support a pharmacy, HRSA allowed each covered entity to begin working with one outside "contract pharmacy" (think Walgreens or CVS), so long as the covered entity did not transfer title to any discounted drugs to the contract pharmacy.[6] In 2010, HRSA allowed covered entities to begin contracting with an *unlimited* number of contract pharmacies for purposes of 340B prescription fulfillment.[7]

After that 2010 change, the average number of contract pharmacies engaged with each covered entity began to rapidly rise, reaching 20.7 by 2024.[8] Coinciding with the relaxed rules around contract pharmacies, covered entities themselves began proliferating.[9] Offshoots of covered entities, such as separately located urgent care centers, are in some cases deemed "child sites" and eligible for 340B pricing.[10] These child sites, it turns out, are often not located in socioeconomically challenged areas.[11] As of 2023, only 30% of 340B-eligible child sites are located in counties with either poverty rates higher than Oklahoma's statewide poverty rate or with median incomes lower than the state's median income.[12] Meanwhile, 52% of 340B-eligible hospitals and federal grantees are located in

[6] 61 Fed. Reg. 43549, 43551–53 (Aug. 23, 1996).

[7] 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010).

[8] Chen Expert Rep. (Case No. CIV-25-726, Dkt. 7, Ex. 24), at 20.

[9] *Id.* at 19.

[10] *Id.* at 6.

[11] *Id.* at 30.

[12] *Id.* at 37.

such counties.[13] Further, covered entities are no longer contracting with just local pharmacies. The University of Oklahoma Medical Center, for example, has its 340B-discounted drugs shipped to contract pharmacies in far-flung places like Orlando, Florida; Las Vegas, Nevada; and Carolina, Puerto Rico.[14]

Unsurprisingly, this proliferation attracted third parties looking to share in the profits from the rapidly growing 340B market. A cottage industry of "third-party administrators" began offering their services to covered entities to cull through records from prescription sales by contract pharmacies to match those sales up with possible 340B eligibility.[15] Then, the covered entities purchase drugs from the manufacturers that are delivered to the contract pharmacies at 340B prices to backfill the inventory depleted as a result of qualifying 340B customer sales. The new inventory of drugs purchased at 340B prices is comingled with the rest of the inventory not purchased through the 340B Program. The contract pharmacies, third-party administrators (often subsidiaries of the contract pharmacies), and the covered entities each divvy up the profits from the 340B sales.[16] This has been termed the "replenishment model." In 2023, Walgreens made $382 million dollars just through its third-party data processing subsidiary for administering the 340B

[13] *Id.*

14 Plf.s' Ex. 43 (Case No. CIV-25-726, Ex. 43), at 3–5.

[15] Chandra Expert Rep. (Case No. CIV-25-726, Dkt. 7, Ex. 25), at 42–43.

[16] *Id.*

Program.[17] What's more, fees accounting for as much as 20% of the reimbursements paid by insurers are paid out to the contract pharmacies.[18]

Drug manufacturers complained about what they perceived as a lack of transparency in the process by which these third-party administrators were identifying qualifying 340B prescriptions.[19] After all, part of the bargain Congress struck in creating the 340B Program was that manufacturers would be required to "offer" their drugs at a discounted price to the *covered entities,*[20] not their contract pharmacies.[21] And in exchange for offering that discount, the drug manufacturers could participate in Medicaid and Medicare Part B, but covered entities would not be able to double-dip and claim a Medicaid rebate from the manufacturer on top of the discounted price from the manufacturer.[22] Nor would covered entities be able to sell ("divert") the discounted drugs to patients not eligible to participate in the 340B Program.[23] The manufacturers complained that the lack of transparency in the replenishment model put them at a disadvantage by making it impossible for them to determine if double-dipping and diversion of discounted drugs was occurring. And some *was* occurring. Some 15% of HRSA audits had identified diversion violations, 6% had

[17] *Id.* at 42

[18] *Id.* at 42–43.

[19] Pl.s' Mot. Summ. J. (Dkt. 7), at 5–6.

[20] 42 U.S.C. § 256b(1).

[21] *Id.*

[22] 42 U.S.C. § 256b(a)(5)(A)(i).

[23] 42 U.S.C. § 256b(a)(5)(B).

identified double-dipped discounts, and almost 30% of HRSA audits had identified a combination of both.[24]

Congress responded to these complaints by granting both the HHS Secretary and manufacturers the ability to audit covered entities.[25] When an audit shows that a covered entity diverted discounted drugs or double-dipped on a discount and rebate, the covered entity can be required to pay a fine to the manufacturer or even face expulsion from the 340B Program or exclusion from Medicaid.[26] Further, Congress required that covered entities and manufacturers participate in administrative dispute resolution in the event they face disagreements over pricing, payment, diversion, or double-dipping with Medicaid rebates.[27] A prerequisite to ADR, however, is a manufacturer's audit of the covered entity.[28]

Drug manufacturers also began both limiting the number of contract pharmacies with which covered entities could engage for filling of 340B prescriptions and requiring certain claims data in exchange for transferring the 340B drugs to those contract pharmacies.[29] HHS moved to halt these efforts by the manufacturers, issuing an advisory

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[24] Chen Expert Rep. (Case No. CIV-25-726, Dkt. 7, Ex. 24), at 29.

[25] 42 U.S.C. § 256b(a)(5)(C).

[26] 42 U.S.C. § 256b(d)(1).

[27] 42 U.S.C. § 256b(d)(3).

[28] 42 U.S.C. § 256b(d)(3)(B)(iv).

[29] These limitations imposed upon covered entities and contract pharmacies do not increase the prices *patients* pay for drugs. Remember, the patient and insurance company always pay normal market prices in the 340B Program—it's the covered entities who purchase the drugs at a discount and who are entitled to pocket the spread between the discounted purchase and sales prices. And unless a covered entity outright refused to write a

opinion prohibiting manufacturers from limiting contract pharmacy arrangements.[30] Drug manufacturers responded with lawsuits, and the Third Circuit and D.C. Circuit both ultimately sided with the manufacturers.[31] The Third Circuit held that the language of Section 340B does not require manufacturers to offer drugs to contract pharmacies at a discount. HHS relied on the silence of the statute to support its order, but the Third Circuit disagreed. "If drug makers make drugs available to anyone at any price, they must 'offer' those drugs to 'covered entities' at a discount."[32] The text of Section 340B does not contemplate contract pharmacies.[33] In light of this silence, the Third Circuit found that covered entities are not entitled to force manufacturers to "deliver goods wherever and to whomever the buyer demands."[34] The D.C. Circuit employed similar reasoning in its subsequent decision.[35]

In 2025, Oklahoma followed a slew of states that enacted legislation attempting to do what those federal courts had said HHS could not lawfully do. The Oklahoma Legislature enacted House Bill 2048 and overrode a governor's veto of its efforts. The

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prescription for filling at a pharmacy from which it didn't reap a 340B profit, these manufacturer-imposed restrictions in no way make it harder for patients to get their prescriptions filled.

[30] HHS Advisory Opinion No. 20-06 (Dec. 30, 2020), https://tinyurl.com/2ca6rmnm.

[31] *Sanofi*, 58 F.4th at 696; *Novartis Pharmaceuticals Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024).

[32] *Sanofi*, 58 F.4th at 703.

[33] *Id.*

[34] *Id.*

[35] *Novartis,* 102 F.4th at 461.

relevant portion of the statute is codified at 36 O.S. § 5400 *et seq.*, which goes into effect on November 1, 2025. Oklahoma argues its law merely regulates *delivery* of drugs in a legislative void left by Congress's silence on the issue. Oklahoma fills that void by requiring manufacturers to deliver drugs at the 340B discount to as many contract pharmacies a covered entity wishes to designate. H.B. 2048 also creates its own enforcement scheme whereby violations of H.B. 2048 can result in both civil fines of up to $10,000 per violation and criminal sanctions. In short, H.B. 2048 expands drug manufacturer's obligations under the federal 340B program, which consequently raises a manufacturer's price of admission to participate in Medicaid and Medicare Part B.

AbbVie, Novartis, and AstraZeneca, in separate cases, now seek a preliminary injunction against H.B. 2048, arguing that it is constitutionally infirm.

Analysis

The purpose of a preliminary injunction is "to enjoin, pending the outcome of the litigation, action that [the movant] claims is unlawful."[36] A preliminary injunction is an "extraordinary remedy" that is never "awarded as of right."[37] An injunction is appropriate only when monetary or other traditional remedies are inadequate, and "the right to relief [is] clear and unequivocal."[38]

The Court may enter a preliminary injunction if (1) Plaintiffs are substantially likely to succeed on the merits; (2) Plaintiffs will suffer irreparable injury if the injunction is

[36] *Grupo Mexicano de Desarrollo, S.A. v. All. Bond Fund, Inc.*, 527 U.S. 308, 314 (1999).

[37] *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 24 (2008).

[38] *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1258 (10th Cir. 2005).

denied; (3) Plaintiffs' threatened injury outweighs the injury Defendant will suffer under the injunction; and (4) the injunction would not be adverse to the public interest.[39] "The third and fourth prongs 'merge when the Government is the opposing party.'"[40] As the movants, it is Plaintiffs' burden to establish that each factor tips in its favor.[41]

I. Plaintiffs are substantially likely to succeed on the merits.

a. H.B. 2048 is preempted.

The Constitution empowers Congress to pass legislation, as "the supreme Law of the Land[,]" preempting state law.[42] However, before courts determine that state law is preempted by federal law, courts presume that "the historic police powers of the States," are undisturbed by federal law, barring "the 'clear and manifest' intent of Congress."[43] In every question of preemption, then, "congressional intent [is] 'the ultimate touchstone[.]'"[44] Courts thus ascertain congressional intent either "'through a statute's express language" or infer it "'through its structure and purpose.'"[45]

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[39] *Fish v. Kobach*, 840 F.3d 710, 723 (10th Cir. 2016).

[40] *Does 1-11 v. Board of Regents of University of Colorado*, 100 F.4th 1251, 1267 (10th Cir. 2024) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009).

[41] *Heideman v. S. Salt Lake City*, 348 F.3d 1182, 1188 (10th Cir. 2003).

[42] *Bradshaw v. American Airlines, Inc.*, 123 F.4th 1168, 1173 (10th Cir. 2024) (citing *Arizona v. United States*, 567 U.S. 387, 399 (2012)).

[43] *Id.* at 1173 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

[44] *Id.* (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 (2009)).

[45] *Id.* (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008)).

Preemption comes in different flavors,[46] but central to the claims here are theories of field and conflict preemption. Courts infer a statute is preempted under a theory of field preemption "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.'"[47] Conflict preemption, on the other hand, "forces a state law to yield to federal law either when it is impossible to comply with both laws or when the state law thwarts the federal law's purposes and intended effects."[48]

i. H.B. 2048's delivery requirement is preempted.

It is undisputed that Congress did not expressly preempt H.B. 2048.[49] Instead, the Court must determine if H.B. 2048 is implicitly pre-empted.[50] Both in its briefs and at oral arguments, Oklahoma has asserted that H.B. 2048 is a "delivery" regulation, not a "pricing" regulation.[51] This matters because the Eighth Circuit recently relied on that distinction in concluding that a similar Arkansas law was not preempted by federal law.[52]

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[46] *State of Kan. ex. rel. Todd v. United States*, 995 F.2d 1505, 1509 (10th Cir. 1993).

[47] *Bradshaw*, 123 F.4th at 1173 (quoting *Arizona*, 567 U.S. at 399).

[48] *Pharmaceutical Care Management Association v. Mulready*, 78 F.4th 1183, 1193 (10th Cir. 2023) (citing *Arizona*, 567 U.S. at 399–400).

[49] *ONEOK, Inc., v. Learjet, Inc.*, 575 U.S. 373, 376 (2015).

[50] *Id.*

[51] *See, e.g.,* Def.'s Resp. (Case No. CIV-25-726, Dkt. 26), at 11–12.

[52] *Pharmaceutical Research and Manufacturers of America v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024).

Arkansas's law provides that:

> (c) A pharmaceutical manufacturer shall not:
> (1) Prohibit 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 or prohibit 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.[53]

The Eighth Circuit echoed an observation from the Third Circuit that "the 340B Program 'is silent about delivery' and distribution of pharmaceuticals to patients."[54] The Eighth Circuit casts the Arkansas law as one that simply prohibits manufacturers from either "interfering in a covered entity's agreement with a contract pharmacy by denying the pharmacy access to a covered entity's 340B drugs[]" or "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."[55] Because, according to the Eighth Circuit, "[contract p]harmacies do not purchase 340B drugs, and they do not receive the 340B price discounts[,]"Arkansas's law is simply aimed at regulating pharmacy, a field traditionally within the province of a state's police power.[56] This supposed distinction between "delivery" and "price" regulations, however, strikes this Court as artificial.

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[53] *Id.* at 1142–43 (quoting Ark. Code. Ann. § 23-92-604(c)).

[54] *Id.* at 1142 (quoting *Sanofi*, 58 F.4th at 703)).

[55] *Id.* at 1143.

[56] *Id.* at 1144.

First of all, how Oklahoma describes its regulation doesn't end the matter;[57] an examination of how the regulation actually operates is necessary. A hypothetical might help illustrate the point: imagine if Congress passed a law requiring pizza parlors to sell pizzas at a 50% discount to anyone named John. If a state then passed a law requiring those pizza parlors to also deliver half-priced pies to any other person that John told them to, could that state law possibly be described as a mere "delivery" regulation? Of course not; the effect of the law is to reduce the price of pies that would otherwise be sold to non-John's at full price. That's a law regulating pricing, and H.B. 2048 is just that kind of law.

And while the record is not yet clear whether the agreements between the covered entities and contract pharmacies in Oklahoma that participate in the 340B Program require the covered entities to maintain title in the 340B discounted drugs when they are at the contract pharmacies (Plaintiffs believe they don't), the practical effect either way is that H.B. 2048 requires manufacturers to deliver drugs to contract pharmacies at a discounted price when they would otherwise be delivered at full price. And why? Because Oklahoma wants drug manufacturers to maximally subsidize Oklahoma covered entities.

This artificiality of this pricing/delivery distinction is underscored by the fact that federal law doesn't use the term "340B drug," and that's because that term is really a misnomer. The drug is the same whether sold under the 340B Program or otherwise. All

[57] *See Bailey v. Drexel Furniture Co.*, 259 U.S. 20, 36 (1922) (holding that a "so-called tax" was in substance a penalty to coerce activities otherwise outside Congress's ability to regulate) and *N.F.I.B. v. Sebelius*, 567 U.S. 519, 563–64 (2012) (holding that a provision labeled a penalty is a valid exercise of Congress's taxing power despite the label).

the 340B Program does is set the price for certain sales of drugs. So when H.B. 2048 defines a "340B drug" as a "drug that has been subject to any offer for reduced prices by a manufacturer pursuant to [42 U.S.C. § 256b] and is purchased by a covered entity as defined in [42 U.S.C. § 256b(a)(4).],"[58] it does so in recognition of the fact that the only difference between a "340B drug" and a non-340B drug is…it's price. H.B. 2048's mandate that "[a] manufacturer shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to a 340B entity, unless such receipt is prohibited by [HHS]" thus isn't really regulating the delivery of drugs to those contract pharmacies, but rather the *price* at which those drugs must be sold.[59]

In a similar case, the United States District Court for the Southern District of West Virginia granted a preliminary injunction after concluding that if a comparable West Virginia law "is an attempt to enforce 340B's pricing scheme, then the statute would be preempted according to existing Supreme Court precedent."[60] The District Court also noted that while district courts considering similar statutes had generally upheld those laws, those

[58] 36 O.S. § 5401(1).

[59] 36 O.S. § 5403(A).

[60] *Pharmaceutical Research and Manufacturers of America v. Morrisey*, 760 F. Supp. 3d 439, 455 (S.D.W. Va. 2024). That Supreme Court precedent was a 2011 decision in a non-preemption case where the Court concluded that third parties—in this instance, a county operating 340B entities—could not enforce the 340B Program because Congress "'centralized enforcement [of the pharmaceutical pricing agreements between manufacturers and HRSA] in the [federal] government.'" *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011) (citation omitted).

courts hadn't considered the implications of the replenishment model,[61] and that matters because the replenishment model significantly muddies the waters as to who is the actual purchaser of the 340B drugs: the contract pharmacy or the covered entity? Recall, there are only sixteen designated types of covered entities and contract pharmacies are not among them.[62] And the 340B Program does not require drug manufacturers to offer discounted drugs to anyone other than covered entities. So where H.B. 2048 effectively expands the definition of "covered entity" to include contract pharmacies, that expansion is "contrary to federal law," and accordingly "must yield."[63]

Congress, after all, struck a delicate balance with the federal 340B Program. The Program is a bargain between drug manufacturers and the federal government whereby, in exchange for access to the lucrative Medicaid and Medicare Part B markets, manufacturers help subsidize certain healthcare providers.[64] Because drug manufacturers aren't forced to participate, Congress limited the scope of the 340B Program to ensure that the price of admission wasn't too high, which might have the deleterious effect of causing drug manufacturers to opt out of Medicaid and Medicare Part B.[65] No statute "pursues its

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[61] *Morrisey*, 760 F. Supp. 3d at 456.

[62] Health Res. & Servs. Admin., *340B Eligibility: Who Can Participate in the 340B Drug Pricing Program*, U.S. Dep't of Health & Hum. Servs., https://www.hrsa.gov/opa/eligibility-and-registration (last visited Oct. 9, 2025).

[63] *Remund v. State Farm Fire and Cas. Co.*, 483 Fed. Appx. 403, 407 (10th Cir. 2012) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1962)).

[64] *Morrisey*, 760 F. Supp. 3d at 452 (noting the "twin federal purposes" of the program).

[65] Transcript (Case No. CIV-25-726, Dkt. 78), at 62 (noting that one manufacturer has done just that, due to the rising costs of the 340B Program).

purposes at all costs," and that is especially so with respect to the 340B Program's subsidy scheme.[66]

Further, the District Court in *Morrisey* found that a state attempt to enforce 340B Program's pricing requirements would likewise impinge on Congress's intent to "'centralize[] enforcement in the government[.]'"[67] In *Astra*, the Supreme Court rejected an attempt by a county government to enforce the 340B Program by way of a third-party beneficiary theory in contract, which the Court deemed "in essence a suit to enforce the statute itself," which wasn't allowed.[68] Accepting that Oklahoma's delivery regulation in the context of the replenishment model operates as a price regulation, Oklahoma stands functionally in the same place that the county did in *Astra*, enforcing the 340B Program itself, in contravention of what "Congress contemplated when it 'centralized enforcement in the government.'"[69] And under the replenishment model, in the event that a manufacturer "den[ies], restrict[s], prohibit[s], or otherwise interfere[s] with . . . the acquisition of a 340B drug by, or delivery of a 340B drug to a 340B entity," Oklahoma regulators won't be questioning whether the drug reached a pharmacy—they'll be questioning the price at which it was delivered. This is materially the same as the

[66] *Rodriguez v. United States,* 480 U.S. 522, 525–526 (1987).

[67] *Morrisey*, 760 F. Supp. 3d at 457 (citation omitted).

[68] *Astra*, 563 U.S. at 118.

[69] *Morrisey*, 760 F. Supp. 3d at 456 (quoting *Astra*, 563 U.S. at 119).

unconstitutional third-party enforcement scheme that the Supreme Court dispatched with in *Astra.*[70]

Oklahoma has also stipulated that H.B. 2048 prohibits manufacturers from conditioning the delivery of the 340B discount on the provision of claims data from covered entities and contract pharmacies.[71] Plaintiffs argue that this creates a conflict with federal law in inhibiting their ability to access the 340B Program's ADR process.

Recall, before a manufacturer may access the federal ADR scheme, 42 U.S.C. § 256b(d)(3)(A) requires the manufacturer to seek an audit in compliance with § 256b(a)(5)(C). And in order to trigger an audit, a manufacturer must first demonstrate there is "reasonable cause" to believe a covered entity is violating the terms of the conditions of 340B participation either through diversion or double-discounting.[72] At an evidentiary hearing, AbbVie provided compelling testimony supporting its argument that claims data is necessary to establish the reasonable cause required to trigger an audit.[73] Essentially, AbbVie argues that the claims data clarifies otherwise opaque transaction information that has been used recently to determine that 340B transactions have been

[70] *Astra*, 563 U.S. at 113.

[71] Def.'s Resp. (Dkt. 26), at 17.

[72] 61 Fed. Reg. 65,406 (Dec. 12, 1996).

[73] Transcript (Case No. CIV-25-726, Dkt. 78), at 53–54.

unlawfully duplicated.[74] Without the claims data from the covered entity, such detection would be "impossible."[75]

Oklahoma responds that (1) the implementing regulation does not *require* claims data in order to trigger an audit and (2) HRSA has never actually utilized the "reasonable cause" standard to deny a manufacturer's request for an audit. But that response ignores the obvious: without suspicion-raising claims data, how would a manufacturer know to ever ask for an audit? The claims data, as far as the Court can tell, would be *the* way to detect possible diversion or double-dipping on discounts. The barrier to access that data created by H.B. 2048 thus stands in direct conflict with the 340B Program's dispute resolution mechanism.[76]

Accordingly, the Court finds that Plaintiffs are likely to prevail on their claim that 36 O.S. § 5403 is preempted by federal law.

ii. H.B. 2048's parallel enforcement provision is preempted.

Finally, Plaintiffs argue that Oklahoma's separate enforcement scheme, vested in the Attorney General, creates another conflict. [77] As previously stated, the Supreme Court has found that Congress provided HHS with the sole authority to "oversee compliance with

[74] *Id.*

[75] *Id.*

[76] *Atchison, Topeka and Santa Fe Ry. Co. v Lennen*, 732 F.2d 1495, 1506 (10th Cir. 1984).

[77] While AstraZeneca has named the Insurance Commissioner as a defendant, the Court notes that the provision, 36 O.S. § 5404(A), providing the Commissioner with enforcement power would not reach AstraZeneca, as that provision is aimed at "health insurers."

the 340B Program,"[78] and gave the HHS Secretary the authority to promulgate rules "in order to prevent overcharges[.]"[79] The Secretary subsequently implemented rules vesting the power to adjudicate "[c]laims by covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers" as well as "[c]laims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity . . . that a covered entity may have violated the prohibitions against duplicate discounts or diversion[,]" in the 340B ADR Panel.[80]

H.B. 2048 meanwhile vests in the Oklahoma Attorney General the authority to investigate violations of its requirements and punish those with both civil fines of up to $10,000 and criminal sanctions.[81] And disputes under H.B. 2048 related to the delivery of a "340B drug" necessarily raise a question as to whether the covered entity or contract pharmacy in question was delivered drugs at the discounted rate, which is an attempt by Oklahoma to police potential overcharges.

Further, Plaintiffs have raised non-speculative concerns about the possibility of state and federal regulators providing conflicting interpretations of federal law. For instance, in a situation where a manufacturer denies a 340B discount to an entity suspected of illegally diverting drugs to non-340B patients, an Oklahoma regulator and a federal regulator might reach a conflicting conclusion as to the patient's 340B eligibility. This isn't a farfetched

[78] *Astra*, 563 U.S. at 117.

[79] 42 U.S.C. § 256b(d)(1)(A).

[80] 42 C.F.R. § 10.3 (2024).

[81] 36 O.S. § 5404(B).

scenario, as Novartis has convincingly argued that such eligibility is subject to "a number of malleable factors" that could very easily lead to differing determinations.[82] Because the analysis is not a mere mechanical application of federal law, the potential for conflicting determinations raises the specter that Congress's intended *uniform* scheme would be derailed.[83]

Accordingly, the Court finds that Plaintiffs are likely to succeed on the merits of their claim that 36 O.S. § 5404 is preempted by federal law.

b. H.B. 2048 forces sales at confiscatory prices, resulting in unconstitutional takings.

"The Takings Clause of the Fifth Amendment provides that private property shall not 'be taken for public use, without just compensation.'"[84] Nor can the government "avoid the categorical duty to pay just compensation for a physical taking of property by reserving to the property owner a contingent interest in a portion of the value of the property, set at the government's discretion."[85]

When Congress created the 340B Program, it offered drug manufacturers the choice of participating in the Program as a cost of admission to the broader Medicaid and Medicare Part B markets. That exchange of value (i.e., offer discounted drugs to certain buyers for

[82] Plf.'s Brief (Case No. CIV-25-727, Dkt .16), at 24–25.

[83] *See Colorado Public Utilities Com'n v. Harmon*, 951 F.2d 1571, 1583 n. 14 (10th Cir. 1991).

[84] *Murr v. Wisconsin*, 582 U.S. 383, 392 (2017) (quoting U.S. Const. amend. V).

[85] *Horne v. Department of Agriculture*, 576 U.S. 350, 362–63 (2015) (internal quotation marks omitted).

access to the government-created market) meant the Takings Clause wasn't a barrier. H.B. 2048, however, isn't Oklahoma charging admission to a market of its own creation, but rather Oklahoma demanding a ransom in exchange for continued access to another's market. There is no exchange of value because Oklahoma isn't giving the drug manufacturers anything they don't already have (i.e., access to the federal market) as compensation for forcing them to make discounted sales, for prohibiting them from requiring claims data, and for making them subject to civil and criminal penalties (amongst other things). Oklahoma is instead raising the cost of exercising a "basic and familiar use[] of property"—its sale, while offering nothing in return. The Supreme Court has made clear that selling one's product in interstate commerce "although certainly subject to reasonable government regulation, is . . . not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection."[86]

Nor is the Court satisfied that there is adequate evidence to conclude that this taking is being done for a public, rather than private, purpose. Even in *Kelo v. City of New London,* the high watermark of government takings power, the Supreme Court was satisfied that the City of New London's economic development plan that undergirded the city's condemnation claims of the petitioners' properties "was not adopted to benefit a particular class of identifiable individuals."[87] And the lower courts in *Kelo* had found "no evidence

[86] *Horne*, 576 U.S. at 366.

[87] *Kelo v. City of New London*, 545 U.S. 469, 478 (2005) (quoting *Hawaii Housing Authority v. Midkiff*, 467 U.S. 229, 245 (1984)) (internal quotation marks omitted).

of an illegitimate purpose"—i.e., "to bestow a private benefit."[88] But even under *Kelo's* permissive definition of "public use," H.B. 2048 seems to effectuate a taking for purposes of bestowing a private benefit.[89] Oklahoma is taking away property from *A*, the pharmaceutical manufacturers, and giving it to *B*, the covered entities (or the contract pharmacies) to sell for windfall profits and with no requirement to put those profits towards any particular public good. The evidentiary hearing made abundantly clear that the contract pharmacies and third-party administrators keep a slice of those profits, which those private businesses do whatever they want with. The hospitals are not required to deploy 340B profits towards charity care, nor is there convincing evidence before the Court that covered entities would cease to serve high-needs patients but for the 340B profits from sales at unlimited numbers of contract pharmacies. H.B. 2048 is thus a transfer of property "adopted[,]" to some extent, "to benefit a particular class of identifiable individuals."[90] This is verboten.

Further, even if the Court were convinced there was sufficient evidence before it to conclude that H.B. 2048 served a *Kelo*-kosher public purpose, there is still the question of just compensation. The heavily discounted prices set by the 340B Program (up to 100% discounts) are confiscatory when required by Oklahoma for the merely incremental purpose of not being subject to state penalties.[91]

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[88] *Kelo*, 545 U.S. at 478.

[89] *Id. at* 483.

[90] *Id.* at 478 (quoting *Midkiff*, 467 U.S. at 245).

[91] *See Horne*, 576 U.S. at 362–63.

Accordingly, the Court finds that Plaintiffs have established a likelihood of success on the merits of their claim that 36 O.S. § 5403 effects an unconstitutional taking.

c. The Court delays ruling on Plaintiffs' other claims.

Plaintiffs put forward a variety of other claims for relief, including arguments that H.B. 2048 violates the dormant Commerce Clause, violates the Contracts Clause, is void for vagueness, and is preempted by federal patent law. Because Plaintiffs have demonstrated a likelihood of success on the merits such that the Court is able to grant interim relief on the conflict preemption and Fifth Amendment claims, the Court reserves a decision on the other substantive claims for the merits stage.

II. Plaintiffs will suffer irreparable harm in the event H.B. 2048 goes into effect.

Plaintiffs risk civil fines of up to $10,000 and possible criminal sanctions for violating H.B. 2048 after it goes into effect on November 1, 2025. If Plaintiffs choose to avoid doing business in Oklahoma, Plaintiffs risk disqualification from Medicare Part B and Medicaid. If Plaintiffs submit to H.B. 2048, they face large financial losses with little practical likelihood of recovering in the event the Court permanently enjoins enforcement of H.B. 2048 against them. Moreover, deprivation of a constitutional right is a prototypical irreparable injury.[92]

[92] *Free the Nipple-Fort Collins v. City of Fort Collins*, 916 F.3d 792, 806 (10th Cir. 2019).

Oklahoma argues that the state will suffer its own irreparable injury by being barred from enforcing state law.[93] But the Court is already persuaded that there's a substantial showing that H.B. 2048 violated the Constitution. So that's not enough to counsel against a preliminary injunction.[94] Oklahoma next argues that an injunction threatens the health and safety of Oklahomans by cutting off a revenue stream for covered entities, but Oklahoma offered no credible evidence in support.[95]

Accordingly, the Court finds that Plaintiffs will suffer irreparable harm such that interim relief is necessary.

III. The public interest weighs in favor of granting a preliminary injunction.

Finally, Plaintiffs have demonstrated that the public interest weighs in favor of enjoining H.B. 2048's various provisions pending final resolution of this case. As previously stated, the state lacks "an interest in enforcing a law that is likely constitutionally infirm[.]"[96] Plus, the 340B Program does not automatically lead to discounted drugs or more access to drugs to participating patients. So, the status quo here, allowing the manufacturers to continue to impose restrictions that are valid under federal law, is unlikely to harm Oklahoma patients. The ball is in the covered entities' courts to

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[93] Def.'s Resp. (Case No. CIV-25-726, Dkt. 26), at 24) (quoting *Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018).

[94] *See Chamber of Commerce v. Edmondson*, 594 F.3d 742, 771 ("Oklahoma does not have an interest in enforcing a law that is likely constitutionally infirm.").

[95] *See, e.g.,* Chandra Expert Rep. (Case No. CIV-25-726, Dkt. 7, Ex. 25), at 34–35 (finding that increased 340B profits do not lead to better patient outcomes).

[96] *Edmondson*, 594 F.3d. at 771.

decide whether they will write scripts to be fulfilled at the pharmacies individual patients prefer. Further, because 340B participants (as well as the contract pharmacies and their third-party administrators) are free to do whatever they choose with 340B profits, it does not follow that loss of the additional profits Oklahoma seeks to funnel those entities will harm the public, and Oklahoma has provided no evidence establishing a likelihood of such harm.

IV. The Court only enjoins 36 O.S. §§ 5403, 5404(B).

As to severability, "[t]he question of whether an unconstitutional provision of state law is severable from the remainder of the enactment is a matter of state law."[97] H.B. 2048 provides:

> If any provision of this act, an amendment made by this act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this act, the amendments made by this act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.[98]

The Court reads this provision to allow it to enjoin only 36 O.S. §§ 5403, 5404(B). The remainder of the statute, by all appearances, will be able to operate without the two enjoined provisions going into effect on November 1, 2025, as the remainder of the law is aimed at "health insurance issuer[s], pharmacy benefits manager[s], other third-party payor[s], or [their] agent[s.]"[99]

Conclusion

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[97] *Bishop v. Smith*, 760 F.3d 1070, 1093 (10th Cir. 2014) (citations omitted).

[98] 36 O.S. § 5405.

[99] 36 O.S. § 5402(A).

For the reasons stated above, the Court **GRANTS IN PART AND DENIES IN PART** Plaintiffs' various motions for preliminary injunctions (Case no. 25-cv-726, Dkt. 7; Case no. 25-cv-727, Dkt. 15; Case no. 25-cv-1156, Dkt. 13), **DISMISSES** Defendant's Motion for Judgment on the Pleadings (Case no. 25-cv-726, Dkt. 36), and **ENJOINS** the Attorney General from enforcing 36 O.S. §§ 5403, 5404(B) against Plaintiffs while these cases are pending.

Because it would be impossible, based on the record before the Court, to quantify the damage done, if any, to Defendant as a result of this injunction, the Court **ORDERS** that the security bond required by Federal Rule of Civil Procedure 65(c) be set at **ZERO**.[100]

IT IS SO ORDERED this 31st day of October 2025.

PATRICK R. WYRICK
UNITED STATES DISTRICT JUDGE

[100] *ETP Rio Rancho Park, LLC v. Grisham*, 522 F. Supp. 3d 966, 1014 (D.N.M 2021).