2025 WL 3688051
Only the Westlaw citation is currently available.
United States District Court, D. Nebraska.

ABBVIE INC., a Delaware corporation; ALLERGAN, INC., a Delaware corporation; DURATA THERAPEUTICS, INC., a Delaware corporation; ABBVIE PRODUCTS LLC, a Georgia limited liability company; PHARMACYCLICS LLC, a Delaware limited liability company; and ALLERGAN SALES, LLC, a Delaware limited liability company; Plaintiffs,

v.

MIKE HILGERS, in his official capacity as Attorney General of the State of Nebraska; Defendant.

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff,

v.

MIKE HILGERS, in his official capacity as Attorney General of Nebraska; Defendant.

4:25CV3089, 4:25CV3163
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Filed: 12/19/2025

MEMORANDUM AND ORDER

Susan M. Bazis United States District Judge

***1** This matter is before the Court on Plaintiffs' Motion for a Preliminary Injunction. (Filing No. 56).[1] For the reasons explained below, the motion will be denied.

BACKGROUND

In 1992, Congress enacted Section 340B of the federal Public Health Service Act, which established the "340B Program." *See* 42 U.S.C. § 256b. In exchange for participation in federal Medicaid and Medicare programs, the statute requires drug manufacturers to sell their drugs at a discounted "ceiling price" to qualifying healthcare providers ("covered entities"). 42 U.S.C. § 256b(a)(1). "Covered entities" include, among others, federally qualified health centers and rural hospitals. 42 U.S.C. § 1396r-8(a)(5)(B); 42 U.S.C. § 256b(a)(4). Commercial pharmacies are not "covered entities" under the Act.

The statute prohibits covered entities from "resell[ing] or otherwise transfer[ing]" drugs they purchased at a discount to "a person who is not a patient of [a covered] entity—a practice often referred to as "diversion." 42 U.S.C.§ 256b(a)(5)(B). Covered entities are also prohibited from requesting or receiving "duplicate discounts or rebates" that may be available for drugs obtained via 340B. 42 U.S.C. § 256b(a)(5)(A). Congress vested the United States Department of Health & Human Services ("HHS") and its subagency, the Health Resources and Service Administration ("HRSA"), with the authority to enforce and administer the 340B Program through audits and a federal Administrative Dispute Resolution ("ADR"). In addition to the Secretary of HHS, drug manufacturers are authorized to audit covered entities to ensure compliance with the diversion and duplicate rebate provisions. 42 U.S.C. § 256b(a)(5)(C).

In 1996, HRSA issued non-binding guidance opining that covered entities lacking an in-house dispensing pharmacy should be permitted to contract with a single pharmacy to dispense 340B-priced drugs to their patients. 61 Fed. Reg. 43549, 43550–55 (Aug. 23, 1996). Then, in 2010, HRSA allowed all covered entities to contract with an unlimited number of contract pharmacies, rather than just one local pharmacy. 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010). "A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy." 75 Fed. Reg. at 10277.

Drug manufacturers participating in the 340B Program began implementing distribution policies that limited covered entities from contracting with outside pharmacies for the dispensation of 340B drugs. (Filing No. 1; Filing No. 45.) For instance, if a covered entity has an in-house pharmacy, Plaintiff AbbVie will only take orders for the in-house pharmacy. (Filing No. 1; Filing No. 45.) However, "if a covered entity does not have an in-house pharmacy ... [it] will take orders for direct delivery to one designated contract pharmacy, provided that the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site, and the covered entity submits limited claims data on 340B utilization for that pharmacy location." (Filing No. 1; Filing No. 45.) Plaintiffs maintain this policy is meant to curb the diversion that has resulted from covered entities contracting with an unlimited number of outside pharmacies. (Filing No. 1; Filing No. 45.)

***2** In 2025, the Nebraska Legislature passed L.B. 168—the 340B Contract Pharmacy Protection Act. L.B. 168, 109th Leg., 1st Sess. (Neb. 2025). L.B. 168 provides, in pertinent part, that "[a]ny manufacturer ... shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of any 340B drug by or delivery of any 340B drug to any location authorized by any 340B entity to receive such 340B drug, unless receipt of such 340B drug is prohibited by federal law." L.B. 168, § 3(1). Significant to this motion—Section 3 of L.B. 168 also restricts manufacturers' right to require submission of claims data ("claims-data provision"): "Any manufacturer ... shall not, either directly or indirectly, require any 340B entity to submit any data, including any claim data, utilization data, encounter data, medical data, purchasing data, or other data, as a condition for allowing the acquisition of any 340B drug by or delivery of any 340B drug to any 340B entity or to any location authorized by any 340B entity to receive such 340B drug, unless such data is required by federal law." *Id*. at § 3(2). L.B. 168 authorizes the Nebraska Attorney General or any county attorney to institute an action "for an injunction or other process to restrain or prevent any violation" of the Act. *See* L.B. 168, § 4. L.B. 168 also contains a clause providing that nothing in the Act "shall be construed or applied to conflict with federal law or any other law of the State of Nebraska, if such law is compatible with applicable federal law." L.B. 168, § 5.

Following the passage of L.B. 168, Plaintiffs instituted this action against Mike Hilgers—the Attorney General of the State of Nebraska ("Defendant"), asking that L.B. 168 be declared unconstitutional and seeking an injunction against its enforcement. (Filing No. 1; Filing No. 45.) Plaintiffs argue that L.B. 168 (1) is an unconstitutional taking; (2) is preempted by federal law; (3) violates the dormant Commerce Clause; and (4) is unconstitutionally vague. (Filing No. 1; Filing No. 45.) Defendant subsequently filed a motion to dismiss which is presently pending before the Court. (Filing No. 26.)

On November 11, 2025, Plaintiffs filed a motion for a limited preliminary injunction. (Filing No. 56.) Plaintiffs request that the Court enjoin Defendant from enforcing L.B. 168's claims-data provision against them in a way that obstructs their ability to participate in a federal 340B Rebate Pilot Program ("Rebate Program"), which commences on January 1, 2026. Plaintiffs assert that HHS announced the Rebate Program to help pharmaceutical manufacturers comply with overlapping federal discount programs without providing duplicate discounts. 90 Fed. Reg. 36163 (Aug. 1, 2025).

Plaintiffs manufacture a drug called Imbruvica that, beginning January 1, 2026, will be subject to federal price concessions under both the federal 340B program and the Inflation Reduction Act ("IRA"), 42 U.S.C. §§ 1320f *et seq*. While the 340B Program requires manufacturers to offer drugs to covered entities at a calculated "ceiling price," the IRA's Drug Price Negotiation Program ("DPNP") requires HHS to set a maximum fair price ("MFP") for certain drugs, which manufacturers must then make available to certain Medicare-covered individuals at the MFP. *Id*. Under the DPNP's nonduplication provision, manufacturers must provide the lower of the two price concessions—not both. *Id*. Plaintiffs contend the Rebate Program will allow them to offer 340B discounts on Imbruvica sales to eligible recipients through a rebate mechanism, as opposed to an up-front discount, to prevent duplicate discounts. (Filing No. 57.) Plaintiffs claim that to participate in the program, they need "prescription-level 'claims data' (such as the prescriber's identity and the date of service) in order to determine whether a rebate is appropriate." (Filing No. 57.) Plaintiffs maintain they sought a temporary non-enforcement agreement from Defendant that would allow Plaintiffs to continue requiring claims data solely for Imbruvica 340B sales within the context of the federal Rebate Program, but Defendant refused. (Filing No. 57.) Hence, the request for a preliminary injunction.

DISCUSSION

Plaintiffs' Complaint seeks declaratory relief invalidating and a permanent injunction preventing enforcement of all L.B. 168's provisions. (Filing No. 1; Filing No. 45.) However, the relief Plaintiffs request through their present motion is narrower—it only seeks to enjoin Defendant from enforcing L.B. 168's claims-data provision in such a way that prevents Plaintiffs from collecting the data they need to participate in the Rebate Program. (Filing No. 56.)

***3** In deciding a motion for injunctive relief, a court considers (1) the probability that the movant will succeed on the merits; (2) the threat of irreparable harm to the movant; (3) the state of balance between this harm and the injury that granting the injunction will inflict on other parties; and (4) the public interest. *Ng v. Bd. of Regents of the Univ. of Minn.*, 64 F.4th 992, 997 (8th Cir. 2023) (quoting *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981)). When a plaintiff seeks to restrain governmental action, the balance of equities and public interest factors merge. *Eggers*

v. Evnen, 48 F.4th 561, 564 (8th Cir. 2022). Because a preliminary injunction is an extraordinary remedy, the movant bears the burden of establishing its propriety under these factors. *Roudachevski v. All-Am. Care Centers, Inc.*, 648 F.3d 701, 705 (8th Cir. 2011). "No single factor is determinative." *WWP, Inc. v. Wounded Warriors, Inc.*, 566 F. Supp. 2d 970, 974 (D. Neb. 2008).

Likelihood of success on the merits is the most significant factor in the determination of whether a preliminary injunction should be issued. *Laclede Gas Co. v. St. Charles Cty*, 713 F.3d 413, 419-20 (8th Cir. 2013). When a party seeks to enjoin a government regulation that is "based on presumptively reasoned democratic processes," a heightened standard applies, requiring the moving party to show they are "likely to prevail on the merits" of their claims. *Firearms Regulatory Accountability Coalition, Inc. v. Garland*, 112 F.4th 507, 517 (8th Cir. 2024) (quoting *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732 (8th Cir. 2008) (en banc)). "The Eighth Circuit has clarified that this 'more-likely-than-not standard' applies when 'a preliminary injunction is sought to enjoin the implementation of a duly enacted state statute.' " *Iowa Ass'n of Business and Industry v. Ommen*, No. 4:25-cv-00211, 2025 WL 2888377, at *6 (S.D. Iowa July 21, 2025) (quoting *Rounds*, 530 F.3d at 732)). For purposes of this motion, Plaintiffs argue that they are likely to succeed on the merits because they will be able to show that L.B. 168 conflicts with the Rebate Program and is therefore preempted.

Conflict preemption occurs when "compliance with both federal and state regulations is a physical impossibility" or when a state regulation "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012); *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 884 (2000). State laws that conflict with federal law are "without effect." *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 479-80 (2013). However, "a court should not find preemption too readily in the absence of clear evidence of a conflict." *Geier*, 529 U.S. at 885. "A hypothetical or theoretical conflict is insufficient to warrant preemption." *Flying J, Inc. v. Van Hollen*, 621 F.3d 658, 662 (7th Cir. 2010). "[T]he proper approach is to reconcile the operation of both statutory schemes with one another rather than holding one completely ousted." *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117, 127 (1973).

Plaintiffs assert that L.B. 168's claims-data provision is preempted because it substantially interferes with the HHS's Rebate Program. (Filing No. 57.) Plaintiffs maintain that the "Rebate Program expressly contemplates that participating manufacturers will obtain claims data from covered entities" and that "rebates hinge on this exchange of data." (Filing No. 57.) Plaintiffs assert that because covered entities rarely provide claims data voluntarily or upon request, Plaintiffs have conditioned 340B pricing under the Rebate Program upon covered entities providing this data. (Filing No. 57.) Plaintiffs argue enforcement of the claims-data provision, which prohibits Plaintiffs from requiring covered entities to "submit any data, including any claim data, utilization data, encounter data, medical data, purchasing data, or other data," would prevent them from gathering the information they require to participate in the Rebate Program. (Filing No. 57.)

***4** Based on the record before the Court at this point, it certainly appears that Plaintiffs will be required to submit claims data of the variety covered by L.B. 168 to participate in the Rebate Program. A recent notice from HHS about the Rebate Program provides: "Manufacturers will be *required* to submit data ... on a monthly basis to ensure program integrity and to provide transparency in the 340B Program" and "Covered entities are *required* to provide specific data to participating manufacturers in order for the manufacturers to provide rebates to effectuate the 340B discount on the entities' covered outpatient drug purchases." 90 Fed. Reg. 44197, 44198 (Sept. 12, 2025) (emphasis added). Per HHS, the data required could include things such as dates of service, prescription dates, prescription numbers, prescriber IDs, as well as other types of data. 90 Fed. Reg. 38165 (Aug. 7, 2025). Therefore, if Defendant attempted to enforce L.B. 168 in such a way that prevents Plaintiffs from obtaining the required information, a compelling preemption argument could certainly be made.

At this point, however, the Court is unable to conclude Plaintiffs have shown a likelihood of success on the merits. The Rebate Program does not begin until January 1, 2026. The degree to which covered entities will voluntarily produce the claims data, or if Defendant will attempt to enforce the claims-data provision in L.B. 168 despite possible conflicting federal requirements, is unknown. Defendant has stated that L.B. 168 does not establish a blanket ban on obtaining claims data from covered entities and has acknowledged that L.B. 168 contains a clause that expressly provides that nothing in the Act "shall be construed or applied to conflict with federal law or any other law of the State of Nebraska." (Filing No.

70.) The Court cannot issue a preliminary injunction based on hypotheticals or speculation that Defendant will step outside the bounds of L.B. 168 through impermissible enforcement actions, particularly where Defendant has represented that L.B. 168 is not an obstacle to the collection of claims data when required by federal law. *See AbbVie, Inc. v. Weiser*, No. 25-cv-1847, 2025 WL 3041825 (D. Colo. Oct. 31, 2025) (denying a preliminary injunction based on argument that a Colorado state law similar to L.B. 168 was preempted by the Rebate Program where the state law contained a provision stating that its claims-data prohibition was inapplicable if it conflicted with federal law).

For similar reasons, the Court cannot conclude that Plaintiffs will suffer irreparable harm without a preliminary injunction. "[I]rreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." *Grasso Enters., LLC v. Express Scripts, Inc.*, 809 F.3d 1033, 1040 (8th Cir. 2016) (quotation omitted). However, the mere "possibility of irreparable harm" will not suffice. *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 22 (2008). The harm shown must be more than mere speculation. *MPAY Inc. v. Erie Custom Comput. Applications, Inc.*, 970 F.3d 1010, 1020 (8th Cir. 2020). The movant "must show harm that is certain and great and of such imminence that there is a clear and present need for equitable relief." *H&R Block, Inc. v. Block, Inc.*, 58 F.4th 939, 951 (8th Cir. 2023) (quotation omitted). "[F]ailure of a movant to show irreparable harm is an independently sufficient basis upon which to deny a preliminary injunction." *Beber v. NavSav Holdings, LLC*, 140 F.4th 453, 461 (8th Cir. 2025) (quotation omitted). Again, at this point, there is only speculation that Plaintiffs will sustain irreparable harm without injunctive relief.

The last two factors of the preliminary injunction analysis —balance of the equities and public interest—fare no better for Plaintiffs. In balancing the equities, the Court weighs "the threat of irreparable harm shown by the movant against the injury that granting the injunction will inflict on [the] other part[y] litigant[s]." *MPAY*, 970 F.3d at 1020 (quotation omitted). To prevail, the movant must show that "the balance of equities so favors [the movant] that justice requires the court to intervene to preserve the status quo until the merits are determined." *Sessler v. City of Davenport*, 990 F.3d 1150, 1157 (8th Cir. 2021) (quotation omitted). The Court agrees with Defendant that displacing L.B. 168 through a preliminary injunction could introduce uncertainty regarding the legitimacy of L.B. 168 in contravention of the public interest, especially when it is unknown how the Rebate Program and L.B. 168 will (or can) operate in tandem. This is left to be seen.

***5** Accordingly,

IT IS ORDERED:

1. Plaintiffs' Motion for a Preliminary Injunction (Filing No. 56; Filing 30, Case No. 4:25CV3163) is denied.

2. Defendant's Motion to Stay Briefing, Consolidate, and Construe Plaintiffs' Motion as a Motion to Expedite (Filing No. 61) is denied as moot.

Dated this 19th day of December, 2025.

All Citations

Slip Copy, 2025 WL 3688051

Footnotes

1 The above-captioned actions were consolidated. Case No. 4:25CV3089 was designated as the "Lead" case. The filing numbers cited throughout this Memorandum and Order are taken from the "Lead" case, unless stated otherwise. Also, the plaintiffs in each action are collectively referred to herein as "Plaintiffs."

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