No. _____

In the
Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

ALAN MCCLAIN, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE ARKANSAS INSURANCE DEPARTMENT, COMMUNITY HEALTH CENTERS OF ARKANSAS, AND PIGGOTT COMMUNITY HOSPITAL,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This Nation's second largest drug program, the federal 340B Drug Pricing Program (340B), is administered by the U.S. Department of Health and Human Services (HHS) and effectuated through a contract between the federal government and drug manufacturers. It requires manufacturers to offer heavily discounted prescription drugs to certain statutorily enumerated healthcare entities called "covered entities." The D.C. and Third Circuits have held that HHS cannot require drug manufacturers to deliver 340B-priced drugs to an unlimited number of third-party "contract pharmacies," because Congress "preserved" manufacturers' ability to impose conditions on the delivery of 340B-priced drugs as part of their offers, including as to the use of contract pharmacies. And this Court has previously held that the federal government alone possesses exclusive administrative and enforcement authority over 340B. Nevertheless, Arkansas and a growing number of other States have enacted laws forbidding manufacturers from imposing contract-pharmacy conditions—something even HHS cannot do. In the decision below, the Eighth Circuit blessed Arkansas's law, permitting the State to impose its own preferred obligations and enforcement scheme on 340B.

The question presented is:

Whether the Eighth Circuit erred in holding—in conflict with the decisions of other circuits and this Court—that a State may strip manufacturers of the ability preserved to them by 340B to impose conditions on the use of contract pharmacies as part of the offer to provide 340B-priced drugs and intrude on 340B's centralized enforcement scheme.

PARTIES TO THE PROCEEDING

Petitioner in this Court and Plaintiff-Appellant in the court of appeals is the Pharmaceutical Research and Manufacturers of America.

Respondent in this Court and Defendant-Appellee in the court of appeals is Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department; also Respondents in this Court and Intervenor-Appellees in the court of appeals are Community Health Centers of Arkansas and Piggott Community Hospital.

RELATED PROCEEDINGS

The following proceedings are directly related to this petition:

Pharmaceutical Research and Manufacturers of America v. McClain, No. 22-3675, United States Court of Appeals for the Eighth Circuit, judgment entered March 12, 2024 (95 F.4th 1136), rehearing denied May 2, 2024.

Pharmaceutical Research and Manufacturers of America v. McClain, Civil Action No. 4:21-cv-864-BRW, United States District Court for the Eastern District of Arkansas, order entered December 12, 2022 (645 F. Supp. 3d 890) and judgment entered December 29, 2022.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner the Pharmaceutical Research and Manufacturers of America respectfully petitions this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

OPINIONS AND ORDERS BELOW

The decision of the court of appeals (App. 1a-16a) is reported at 95 F.4th 1136, and the court of appeals' denial of rehearing (App. 37a-38a) is unreported. The decision of the district court (App. 17a-36a) is reported at 645 F. Supp. 3d 890.

JURISDICTION

The court of appeals entered judgment on March 12, 2024. App. 1a-16a. On May 2, 2024, the court of appeals denied petitioner's timely petition for rehearing. App. 37a-38a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Relevant statutory and regulatory provisions are reproduced in the petition appendix. App. 39a-65a.

INTRODUCTION

This case presents a recurring question of national importance regarding the operation of one of the Nation's biggest healthcare programs—the federal 340B Drug Pricing Program, 42 U.S.C. § 256b (340B)—that implicates a conflict of authority over the central requirements of that program. Under 340B, private pharmaceutical manufacturers are required to offer steep discounts on certain drugs, sometimes as low as a penny per unit, to statutorily enumerated healthcare entities, known as "covered entities." If manufacturers do not participate in 340B, their drugs cannot receive federal reimbursement under Medicare Part B and Medicaid, programs which ensure healthcare access for millions of vulnerable Americans and constitute "almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Human Servs.*, 58 F.4th 696, 699 (3d Cir. 2023). Yet manufacturers now face an increasingly difficult dilemma as to whether they can continue to participate in the program due to the explosion in the number of third-party "contract pharmacies" seeking to profit indirectly from the discounts that lie at the heart of 340B.

340B sharply limits what covered entities may do with 340B-priced drugs by barring them from "resell[ing]" or "transfer[ring]" drugs to any person who is not their patient, and thus contemplates the use of *in-house* pharmacies operated by covered entities themselves. Yet, national pharmacy chains independent from covered entities have contracted with covered entities in staggering numbers, sometimes as high as hundreds of pharmacies per covered entity, to profit from the discounts mandated

by 340B. At least in part due to this intervention, the program has grown from $4 billion in 2010 to $53.7 billion in 2022. Because of concerns over abuse stemming from the drastic increase in the use of contract pharmacies, manufacturers, in turn, have imposed various conditions on the use of contract pharmacies. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457-58 (D.C. Cir. 2024).

After examining the text and structure of 340B, two courts of appeals held that Congress "preserve[d] . . . the ability of [manufacturers] to impose at least some delivery conditions" on their statutorily required offer, including as to the use of contract pharmacies. *Id.* at 460; *see Sanofi*, 58 F.4th at 703-06. Based on that understanding, these courts concluded 340B bars the U.S. Department of Health and Human Services (HHS)—the federal administrator of 340B—from requiring manufacturers to offer 340B drugs free of any restrictions or conditions on the use of contract pharmacies. The Eighth Circuit's decision conflicts with those decisions by holding that States may strip manufacturers of the ability preserved to them by Congress to condition the offer of 340B drugs on the use of a limited number of contract pharmacies. The upshot is that the decision gives States a greater role in dictating the terms that may be imposed on 340B drugs than the Federal Government itself.

The Eighth Circuit's ruling contravenes this Court's precedent, too. In *Astra USA, Inc. v. Santa Clara County*, this Court held that, in enacting 340B, Congress established a system of "'centralized enforcement'" that gave the *Federal Government* "the control rein" over 340B. 563 U.S. 110, 119-20 (2011) (citation omitted). As the Court explained, this

exclusive authority is necessary to ensure uniformity in obligations and consistency in enforcement of the federal program. Likewise, this Court has held in other contexts that state laws that pose an obstacle to a uniform federal enforcement scheme are preempted. *Arizona v. United States,* 567 U.S. 387, 406-07 (2012). The Eighth Circuit's decision contravenes that precedent by holding that States may enact, and enforce, their own requirements on how 340B should operate and be enforced when it comes to contract pharmacies. That ruling eviscerates 340B's centralized enforcement scheme by essentially holding that the 50 States may each enact their own requirements and enforcement schemes for 340B, leading to 50 different enforcement regimes.

This Court's intervention is urgently required to ensure that States do not impermissibly interfere with, and upset the balance at the heart of, this critically important federal program. This case presents a timely and ideal vehicle in which to address this issue, resolve the aforementioned conflicts, and provide needed guidance. 340B touches, in some fashion, individuals and companies nationwide, from manufacturers to healthcare entities to patients. It is critical for this Court to resolve the question presented to prevent uncertainty and upheaval to a vital national program as a growing number of States, including Arkansas, seek to co-opt the centralized enforcement authority that Congress reserved in the Federal Government and impose conditions that the federal administrator cannot.

The petition should be granted.

STATEMENT OF THE CASE

A. Statutory Background

Congress enacted 340B as part of the Veterans Health Care Act of 1992. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992) (codified as amended at 42 U.S.C. § 256b). 340B generally provides that participating drug manufacturers "shall . . . offer" certain "covered outpatient drugs" at or below a substantially discounted "ceiling price" to specific "covered entities" for such drugs to receive reimbursement under Medicare Part B or the federal share of funding under Medicaid. 42 U.S.C. §§ 256b(a)(1), (5), 1396r-8(a)(1), (5).

340B was enacted as a response to the unintended consequences of Congress's 1990 passage of the Medicaid Drug Rebate Program (MDRP). *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (codified at 42 U.S.C. § 1395ww). Before MDRP, drug manufacturers voluntarily offered discounts to healthcare providers serving low-income and underinsured patients. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 29 (2019). But after MDRP, manufacturers were no longer incentivized to provide the same level of voluntary discounts. *Id.* at 29-30.

Congress enacted 340B to address this problem by tying eligibility for reimbursement of a manufacturer's covered outpatient drugs under Medicare Part B and eligibility of federal matching funds under Medicaid to the manufacturer's agreement to offer discounts on the price of these

drugs under 340B. 42 U.S.C. § 1396r-8(a)(1), (5). In doing so, Congress: (1) carefully defined and limited the participants in 340B; and (2) centralized administrative and enforcement power over 340B in the federal government through HHS.

To limit participants in 340B, Congress enumerated fifteen categories of healthcare providers, known as "covered entities," to which manufacturers "shall . . . offer" discounts and specified what those providers must do to maintain covered entity status. *Id.* § 256b(a)(1), (4)-(5); *see also* H.R. Rep. No. 102-384(II), pt. 2, at 12-13 (1992) (discussing the number of covered entities then in existence, which totaled about 2,700). Congress also barred covered entities from reselling or transferring 340B-priced drugs to any person other than their patients, known as "diversion," or from causing "duplicate discounts or rebates" under Medicaid for the same drug. 42 U.S.C. § 256b(a)(5), (d)(2)(A). Instead, the discounts are intended to benefit patients through discounts on drugs purchased by them or increased charity care, although the statute lacks a mechanism to make certain that occurs. These requirements ensure manufacturers need only offer discounts to a limited number of entities, limiting 340B's burden.

Congress also recognized the importance of keeping the program carefully managed. To that end, Congress put both administrative and enforcement power in the hands of HHS, a body that could administer 340B "with an eye towards any implications for" Medicare and Medicaid. *Astra*, 563 U.S. at 120 (citation omitted). HHS administers 340B through contracts between the Federal Government and manufacturers, commonly known as

Pharmaceutical Pricing Agreements, 42 U.S.C. § 256b(a)(1). And HHS enforces the program primarily through two methods: Statutorily specified remedies and penalties for noncompliance, and a unique Administrative Dispute Resolution (ADR) process designed to address specific disputes between 340B participants. *Id.* § 256b(a)(5)(D), (d). This "'centralized enforcement'" ensures that 340B, Medicare, and Medicaid are "administer[ed] . . . on a uniform, nationwide basis." *Astra*, 563 U.S. at 119-20.

B. Explosion Of Contract Pharmacies

A few years after 340B's enactment, the Health Resources and Services Administration (HRSA), a sub-agency of HHS, addressed concerns that certain covered entities might not have in-house pharmacies to dispense 340B-priced drugs. To facilitate participation in 340B by those entities while also keeping 340B circumscribed, HRSA issued non-binding guidance in 1996 explaining that a covered entity without an in-house pharmacy could enter a contractual relationship with *one* pharmacy, known as a "contract pharmacy," to dispense 340B-priced drugs to the covered entity's patients as the covered entity's "agent." *See* 61 Fed. Reg. 43,549, 43,550, 43,555 (Aug. 23, 1996). The limitation of one contract pharmacy per covered entity practically ensured that the pharmacy would act like an in-house pharmacy. *Id.* at 43,551, 43,553.

In 2010, however, HRSA lifted its one-contract-pharmacy limit. *See* 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). This opened the floodgates for enterprising commercial entities to exploit 340B for private gain and to expand the size of the program.

This increase in size, however, has not come with an increase in the charity care covered entities provide, despite Congress's intent. *See* Adam J. Fein, *340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019), https://www.drugchannels.net/2019/05/exclusive-340b-program-purchases-reach.html; *see also* Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 24, 2022), https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-/neighborhood.html.

Instead, many sophisticated for-profit pharmacies—including the Nation's largest pharmacy chains—recognized that if they could insert themselves into the 340B supply chain, they could sell 340B-priced drugs at or near full price and pocket a portion of the discount as profit, by receiving either a percentage of the sales price or a flat fee per prescription. *See* U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 20, 26-28 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf (GAO-18-480). Given the number of drugs sold under 340B, even small differentials add up to huge profits.

Predictably, the number of contract pharmacies participating in 340B exploded. According to the U.S. Government Accountability Office (GAO), between 2010 and 2018 the number of contract pharmacy arrangements increased "more than fifteen-fold, from about 1,300 to approximately 20,000." GAO-18-480 at 10. Some covered entities use *hundreds* of different contract pharmacies. *See id.* at 18 (explaining that

one covered entity used 439 contract pharmacies). This bears no similarity to the limited use of in-house pharmacies affiliated with the covered entities themselves that Congress intended when it enacted 340B.[1]

The explosion of contract pharmacies ballooned the program's size and increased the potential for abuse. When covered entities dispense 340B drugs, they are almost guaranteed to dispense those drugs to their patients. Not so with contract pharmacies, which serve both the average consumer and covered entities' patients. *See* U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf.

Predictably, given the increased numbers of contract pharmacies and, often, geographic distance between covered entities and their contract pharmacies, covered entities are unable to directly supervise contract pharmacy compliance. *See* Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, Berkeley Research Group (Oct. 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf (distance between hospital covered entities and contract pharmacies averaged 334 miles in 2020). No surprise, then, that

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[1] Covered entities have a financial incentive to leverage as many contract pharmacies as possible to fill as many prescriptions as possible—not to ensure that patients get the drugs, but to profit off of the 340B discounts. *See Novartis*, 102 F.4th at 457-58. Patients of covered entities will always have access to prescription drugs, whether or not covered entities use contract pharmacies. *See infra* at 11.

contract pharmacies accounted for nearly two-thirds of the violations for unlawful diversion (*i.e.*, unauthorized resales or transfers) of 340B-priced drugs uncovered by HRSA. GAO-18-480 at 44.

The opportunity for 340B abuse is even more acute given contract pharmacies' use of the "replenishment model." Using this model, contract pharmacies dispense drugs from their general inventories to *all* customers (whether or not a covered entity patient). *Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. on Health, Educ., Labor, & Pensions*, 115th Cong. 11-12 (2018) (statement of Ann Maxwell, Assistant Inspector Gen. for Evaluation & Inspections for Office of the Inspector General, Health and Human Services) (OIG Report).[2] On the backend, contract pharmacies use undisclosed algorithms to retroactively identify customers that may in theory have some relationship to a covered entity. *Id.* Contract pharmacies then restock their general inventories with 340B-priced drugs based on the outcome of the undisclosed algorithms. Krista M. Pedley Decl. ¶¶ 5-11, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2.

This black-box system—which does not require verification of covered-entity patient status when drugs are dispensed—creates even more opportunities for diversion of 340B-priced drugs. OIG Report at 11-12; 75 Fed. Reg. at 10,277-78. In addition, it results in greater profits for pharmacies and covered entities, creating an incentive to use

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[2] Available at https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/pdf/CHRG-115shrg30195.pdf.

more and more contract pharmacies and "catalog as many prescriptions as possible." *See Novartis*, 102 F.4th at 457-58.

To be clear, this is not about patients' ability to receive drugs. Any pharmacy can purchase a supply of drugs at *market* prices *outside* of 340B to fill prescriptions. And given the replenishment model, in which the discount is not applied until long after the patient leaves the pharmacy, most 340B discounts are not passed on to the patient. Rather, this dispute is about whether third-party pharmacies can profit off 340B by taking a cut of the revenue generated by selling heavily discounted drugs, to which they are not entitled, at a markup. *Supra* at 8-9.

C. Reaction By Manufacturers, HHS, And The Federal Courts

Faced with these developments and the increased risk of abuse, manufacturers individually adopted policies on the use of contract pharmacies to protect against abuse. *See, e.g.*, First Am. Compl. ¶¶ 48-50, *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27 (D. Del. Feb. 12, 2021), ECF No. 13. The contours of these policies differ by manufacturer, but each permits covered entities to purchase an unlimited number of 340B-priced drugs for delivery to the covered entity, while placing reasonable conditions on the use of contract pharmacies to check diversion and abuse. *Sanofi*, 58 F.4th at 701; *Novartis*, 102 F.4th at 463-64 (discussing two manufacturer policies).

In May 2021, after receiving complaints from covered entities and contract pharmacies, HRSA issued violation determinations to the manufacturers that had implemented these policies. *See, e.g.*, *Novartis*, 102 F.4th at 458-59. Around the same time,

HHS also issued a since-withdrawn Advisory Opinion that stated a covered entity may choose whatever delivery location it wants, "be it the lunar-surface, low-earth orbit, or a neighborhood pharmacy." Advisory Op. 20-06 on Contract Pharmacies Under the 340B Program 3, HHS (Dec. 30, 2020), https://bit.ly/3LkKn3s. Litigation ensued.[3] These suits challenged HRSA's conclusion that manufacturers had an obligation to provide 340B-priced drugs without condition to any and all contract pharmacies. *See, e.g.*, *Novartis*, 102 F.4th at 459.

Multiple federal courts have now concluded no such obligation exists—instead, 340B protects manufacturers' ability to impose reasonable conditions on their 340B offers, including as to contract pharmacy use. In *Novartis*, for example, the D.C. Circuit, in an opinion by Judge Katsas, held that the 340B statute "preserve[d]" manufacturers' ability to condition their offer of 340B drugs on the use of a limited number of contract pharmacies in dispensing 340B-priced drugs. *Id.* at 460. Although manufacturers must "offer" drugs at the discounted price, a manufacturer may include conditions concerning the use of contract pharmacies, and the Federal Government determines when that offer is

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[3] *Eli Lilly & Co. v. Health Res. & Servs. Admin.*, No. 1:21-cv-81 (S.D. Ind. filed Jan. 12, 2021); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027 (D. Del. filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. United States Dep't of Health & Human Servs.*, No. 3:21-cv-00634 (D.N.J. filed Jan. 12, 2021); *Novo Nordisk Inc. v. United States Dep't of Health & Human Servs.*, No. 3:21-cv-00806 (D.N.J. filed Jan. 15, 2021); *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C. filed May 31, 2021); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686 (D.D.C. filed June 23, 2021).

"bona fide." *Id.* at 462-64. The Third Circuit reached a similar conclusion in construing the statute's "offer" language in *Sanofi*, and likewise held that HHS could not "requir[e] delivery of discounted drugs to an unlimited number of contract pharmacies." 58 F.4th at 706.

Both courts thus rejected HRSA's efforts to read into the "shall offer" provision a requirement that manufacturers offer 340B-priced drugs free of any conditions regarding the use of contract pharmacies, and recognized the preservation of manufacturers' ability to impose reasonable conditions.

D. States' Intervention In The Federal Program

Meanwhile, covered entities and national pharmacy chains that have profited from the unlimited use of contract pharmacies began lobbying States to impose the same contract pharmacy obligation on manufacturers that federal courts held HHS lacks the authority to impose.

On May 3, 2021, Arkansas became the first State to enact a law that imposes a contract pharmacy requirement. Act 1103, entitled the "340B Drug Pricing Nondiscrimination Act," includes two provisions concerning contract pharmacies. The first provision bars manufacturers from "[p]rohibit[ing] a pharmacy from contracting" with a covered entity "by denying access to [their] drugs." Ark. Code Ann. § 23-92-604(c)(1). The second forbids manufacturers from "[d]eny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy that receives drugs" pursuant to "a 340B drug pricing contract pharmacy arrangement." *Id.* § 23-92-604(c)(2). These two provisions, together, require that manufacturers

deliver 340B-priced drugs to all of a covered entity's contract pharmacies in Arkansas—no matter how many it uses.

Not long after the passage of Act 1103, the Commissioner of the Arkansas Insurance Department (AID) promulgated a rule that designated the penalties for violating Act 1103. *See* App. 60a-65a. The rule provides that "[t]he penalties, actions or orders, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule." *Id.* at 65a. Under Ark. Code Ann. § 23-66-210, AID may issue a cease-and-desist order and require "[p]ayment of a monetary penalty of not more than one thousand dollars ($1,000) for each and every act or violation," with an aggregate cap "of ten thousand dollars ($10,000) unless the person knew or reasonably should have known he or she was in violation." Ark. Code Ann. § 23-66-210(a)(1). In the latter case, "the penalty shall be not more than five thousand dollars ($5,000) for each and every act or violation" and can be levied up to fifty thousand dollars ($50,000) "in any six-month period." *Id.*

AID itself recognized that the Arkansas statute raised serious preemption concerns. In an earlier version of its implementing rule, AID required a covered entity to use the federal ADR process to determine whether a drug manufacturer had "improperly denied a pharmacy 340B drug pricing" before it could use state enforcement mechanisms. App. 69a. AID explicitly stated that it included this limitation "due to concerns over federal pre-emption." App. 67a. But this requirement was removed from the final rule. *See* App. 60a-65a.

Following Arkansas's lead, seven other States enacted similar laws, including some that carry

criminal penalties for violation.[4] All have the same goal—to strip manufacturers of the ability that Congress reserved to them to place conditions on their provision of 340B-priced drugs to contract pharmacies and to mandate that manufacturers' drugs be provided to an unlimited number of contract pharmacies at the 340B price, rather than the prevailing market price. And that tide is growing: Twenty-two other States have or are currently considering similar laws.

E. This Litigation

Pharmaceutical Research and Manufacturers of America (PhRMA)—a voluntary nonprofit association that represents the Nation's leading pharmaceutical research companies—brought this suit challenging Act 1103 as preempted by 340B under the Supremacy Clause of the United States (U.S. Const. art. VI, cl. 2).[5] PhRMA argued that Act 1103 was impliedly preempted, both because 340B preempts the field of the operation of 340B and because it "stands as an

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[4] *See* S.B. 28 (Kan.), https://www.kslegislature.org/li/b2023_24/measures/documents/sb28_enrolled.pdf; H.B. 358, Reg. Sess. (La. 2023), https://www.legis.la.gov/Legis/ViewDocument.aspx?d=1332515; H.B. 1056, (Md. 2024), https://mgaleg.maryland.gov/2024RS/bills/hb/hb1056T.pdf; H.F. 4757, 93rd Leg. (Minn. 2024), https://www.revisor.mn.gov/bills/text.php?number=HF4757&type=bill&version=4&session=ls93&session_year=2024&session_number=0; H.B. 728, Reg. Sess. (Miss. 2024), https://legiscan.com/MS/text/HB728/2024; S.B. 751, 102nd Gen. Assemb., 2nd Reg. Sess. (Mo. 2024), https://www.senate.mo.gov/24info/pdf-bill/tat/SB751.pdf; S.B. 325, 86th Leg., Reg. Sess. (W. Va. 2024), https://www.wvlegislature.gov/Bill_Status/bills_text.cfm?billdoc=sb325%20intr.htm&yr=2024&sesstype=RS&i=325.

[5] PhRMA also challenged Act 1103 as preempted by the federal Risk Evaluation and Mitigation Strategies program. 21 U.S.C. § 355-1. That challenge is not presented here.

obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillman v. Maretta*, 569 U.S. 483, 490 (2013) (citation omitted).

The district court held that 340B was not preempted. As to field preemption, the district court found the presumption against preemption applied, and that because 340B did not explicitly address drug distribution, Arkansas was allowed to implement its own drug distribution system. And as to conflict preemption, the court reasoned that 340B regulated only pricing while Act 1103 regulated only distribution, as "[t]he drug-ceiling price has already been set at the point Act 1103 becomes applicable to any specific drug shipment." App. 34a.

The Eighth Circuit affirmed. App. 16a. It found that 340B did not preempt the field because it was "'silent" as to the requirements for delivery and Congress "was aware of the role of pharmacies" when implementing 340B. *Id.* at 11a-12a (citation omitted). It then went on to rely on the distinction between pricing and distribution advanced by the State. *Id.* at 12a-13a. Yet, it did not explain why pricing and delivery could so easily be separated, where the object of Act 1103 mandated the delivery of 340B-*priced* drugs, not just drugs in general. The Eighth Circuit declined to materially address this Court's decision in *Astra*, on which PhRMA heavily relied.

The Eighth Circuit also found that 340B and Act 1103 were not in conflict. Despite this Court's urging that conflicts may exist even where state and federal law "share the same goals" or work to "a common end," *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 379-80 (2000), it found that Act 1103 "assists in fulfilling the purpose of 340B" and therefore did not present an obstacle, App. 14a.

The Eighth Circuit denied PhRMA's timely filed petition for panel rehearing or rehearing en banc.

REASONS FOR GRANTING THE WRIT

This case satisfies the Court's criteria for certiorari. *See* Sup. Ct. R. 10(a). First, the question presented concerns a threat to the operation of critical federal drug programs on which millions of vulnerable Americans depend for their health care, and thus is exceptionally important to patients, healthcare providers, and manufacturers nationwide. Second, the Eighth Circuit's decision below conflicts with decisions from the D.C. and Third Circuits on the scope of manufacturers' obligations under 340B and cannot be reconciled with this Court's precedent holding that state laws that disrupt a uniform federal enforcement scheme are preempted. And, third, the question presented is cleanly presented and warrants resolution by this Court in this case.

I. The Question Presented Is Exceptionally Important

As the Federal Government has recognized, 340B has become a "critical part of the nation's healthcare safety net." Defs.' Opp. to Pl. Mot. Summ. J. and Cross-Mot. Summ. J. 1, 3, *Genesis Health Care, Inc. v. Becerra*, No. 4:19-cv-01531-RBH (D.S.C. July 28, 2023). 340B, Medicare, and Medicaid work in tandem to ensure that the most vulnerable in our society have access to affordable healthcare. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011). 340B embodies a delicate balance, one that requires private parties (drug manufacturers) to subsidize healthcare entities (covered entities) for Medicare Part B and Medicaid to cover a manufacturer's drugs. The viability of 340B is thus inextricably linked to the

health of Medicare and Medicaid—particularly the ability of Medicare and Medicaid patients to access a manufacturer's drugs at discounted prices.

Arkansas's Act 1103, and the growing number of other state laws that are following on its heels, threaten to fundamentally rework the bargain Congress struck by depriving manufacturers of the ability that Congress preserved for them to place reasonable conditions on their offer of 340B-priced drugs and stripping the Federal Government of its exclusive enforcement authority over 340B in favor of a myriad of state-level regimes. Ultimately, these state laws will not only frustrate the operation of 340B, but also jeopardize 340B's continued vitality. The question presented thus warrants review.

1. Even setting aside its connection to other drug programs, 340B is of significant national importance. Although Congress originally intended 340B to be small, H.R. Rep. No. 102-384(II), pt. 2, at 12-14 (1992), 340B is now the Nation's second largest federal drug program, Adam J. Fein, *The 340B Program Reached $54 Billion in 2022 – Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://tinyurl.com/2nrux6et (*Program Reached $54 Billion*); Berkeley Research Group, *340B Program at a Glance* (2021), https://tinyurl.com/ms2afa2y. By 2026, it will be the largest. As of 2020, 340B accounted for approximately $38 billion in drug sales, or about 7% of all prescription drug sales in the United States. Karen Mulligan, PhD, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics (Oct. 14, 2021), https://bit.ly/3FFSemV. And the program continues

to balloon: In 2022, 340B purchases reached a staggering $53.7 billion. Fein, *supra*, *Program Reached $54 Billion*; *see also id.* (the list price of those same 340B purchases was $106 billion).

2. Because 340B now plays such an important role in our healthcare system, it is crucial to protect what the Federal Government has referred to as 340B's "carefully calibrated scheme." *See* Oral Argument at 00:39-00:54, *Novartis Pharms. Corp. v. Johnson*, No. 21-5304 (D.C. Cir. Oct. 24, 2022) (lawyer for HHS), https://www.cadc.uscourts.gov/recordings/recordings2022.nsf/73100C5D19609A2C852588E50055A75E/$file/21-5299.mp3.

State efforts to rework 340B's obligations will place 340B and, by extension, the Medicaid and Medicare drug programs, in peril. The 50,000 covered entities currently participating in 340B, Mulligan, *supra*, are healthcare providers that receive a federal grant or other federal assistance or certain categories of hospitals, 42 U.S.C. § 256b(a)(4). To help fund those entities and ease its own burden, the Federal Government constructed a unique program: It mandated that participating manufacturers provide steep discounts on drugs to covered entities. These discounts are set by statute and are a fraction of the price the drugs would be on the free market. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, Berkeley Research Group (Oct. 2020).

To back up that requirement, Congress threatened manufacturers with ineligibility for drug reimbursement under Medicare Part B and Medicaid, which constitute a huge swath of the United States drug market. But Congress also took care to balance

340B to maintain manufacturer participation and, by extension, access to manufacturers' drugs.

To that end, Congress carefully circumscribed the obligations and rights of manufacturers and covered entities. Congress (a) specifically enumerated the fifteen exclusive categories of healthcare providers that can qualify as covered entities and set forth criteria for assessing their continued eligibility to receive discounted drugs; (b) prohibited covered entities from reselling or transferring the discounted drugs to any person other than their patients; and (c) placed enforcement, administrative, and dispute-resolution authority over the program exclusively in the hands of HHS. 42 U.S.C. § 256b(a), (d). Congress thus ensured that only covered entities could benefit from 340B, and that the Federal Government could watch over the federal subsidy, as the "adjudication of rights under [340B] program must proceed with an eye towards any implications for" Medicare and Medicaid. *Astra*, 563 U.S. at 120 (citation omitted).

3. But certain for-profit entities had other ideas. A new group of entities—for-profit, contract pharmacies that are mostly part of large pharmacy chains—sought to work their way into the 340B system in increasing numbers. As of June 2018, five "pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—represented a combined 60 percent of 340B contract pharmacies," despite representing "only 35 percent of all pharmacies nationwide." U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 21 (June 2018) (GAO-18-480).

As the number of contract pharmacies grew, they developed multiple tactics to profit from their

participation. *See* GAO-18-480 at 26-28 (discussing payments contract pharmacies receive for dispensing 340B-priced drugs). Those tactics paid off: two of the five biggest pharmacy chains, CVS and Walgreens, have disclosed that 340B revenue is material to their profitability. *See* CVS Health Corp., Annual Report (Form 10-K) 26 (Feb. 7, 2024), http://bit.ly/4cUiv1L; Walgreens Boots Alliance, Inc., Annual Report (Form 10-K) 30 (Oct. 12, 2023), https://bit.ly/3VXFcez.

Participation by an unlimited number of contract pharmacies not only increased the program's size and allowed a significant amount of a manufacturer's subsidy to be siphoned off by for-profit pharmacies, but also increased the threat of 340B abuse. 340B prohibits covered entities from "resell[ing] or otherwise transfer[ring]" a 340B-priced drug "to a person who is not a patient of" a covered entity—known as diversion. 42 U.S.C. § 256b(a)(5)(B). But where the entity responsible for dispensing the drug (the contract pharmacy) is not the entity that treats the patient (the covered entity), the opportunity for diversion increases significantly. U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 32-33 (Sept. 2011). Data collected by Federal Government watchdogs bears this out. GAO-18-480 at 16, 38 (indicating that 66 percent of all diversion findings occurred at contract pharmacies, and that 33 percent of covered entities lack sufficient oversight of contract pharmacies).[6] And the specter of increased

[6] Contract pharmacies also contribute to duplicate discounting—that is, where covered entities get the 340B

profits incentivize categorization of prescriptions as 340B eligible. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457-58 (D.C. Cir. 2024) (covered entities [and] contract pharmacies "[e]ach . . . ha[ve] a financial incentive to catalog as many prescriptions as possible as eligible for the discount").

All these factors produced by unlimited contract pharmacies significantly increase the cost of the program for manufacturers and threaten to upset the delicate balance Congress created in 340B, putting at risk the vulnerable patient populations that rely on Medicaid and Medicare Part B to access drugs. In any event, the increasing costs of participation on manufacturers threatens both the viability of remaining in the program and their ability to invest the significant resources required to research and develop the next generation of innovative drug therapies. If they remain in the program, manufacturers may ultimately need to increase drug costs elsewhere to recoup the significant losses created by for-profit contract pharmacies if they wish to continue that critical research. This breakdown in research or a required shift in costs will ultimately negatively impact patients and potentially the Federal Government. *See Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 321 (2016).

4. Despite those risks, States, in ever-increasing numbers, are seeking to rework the federal program and impose their own preferred 340B obligations on manufacturers. In addition to Arkansas, seven States

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discount on drugs that also generate a Medicaid rebate. *See* 42 U.S.C. § 256b(a)(5)(A)(i); HHS Office of Inspector General, Memorandum Report: *Contract Pharmacy Arrangements in the 340B Program OEI 05-13-00431* at 13, 15 (Feb. 4, 2014), https://bit.ly/3eWKmBQ.

have enacted laws imposing a requirement that manufacturers provide 340B-priced drugs to any and all contract pharmacies that covered entities want. *See supra* at 14-15. And twenty-two others have or are currently considering similar laws. The resulting patchwork of obligations will dramatically ratchet up the cost of 340B participation for manufacturers.

The imposition of state enforcement schemes in addition to the federal scheme will also produce inconsistent results that make 340B participation difficult and force manufacturers to defend themselves in potentially fifty different fora, vastly increasing the costs, burdens, and complexity of participating in 340B. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008) (The increased costs of complying with tort law of fifty different States would stifle innovation.); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("[C]omplying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing" regulated entities, "burdens not contemplated by Congress . . . .").

Given the size of 340B, the ripple effects of Arkansas's law, and others like it, will be felt across the Nation, by manufacturers, healthcare entities, pharmacies, and patients alike. And those consequences will only intensify with each passing day, ratcheting up the threat to the program's future.

II. The Eighth Circuit's Decision Conflicts With The Decisions Of Other Circuits And This Court's Precedent

This Court's intervention is warranted to resolve the conflicts between the decision below and the decisions of other circuits and this Court, both as to

the rights preserved to manufacturers by 340B and when federal law preempts state law.

A. The Eighth Circuit's Decision Conflicts With Decisions Of The D.C. And Third Circuits

The Eighth Circuit's decision conflicts with decisions of other circuits on the central statutory question of whether 340B preserves the ability of manufacturers to place conditions on the use of contract pharmacies as part of its 340B offer.

1. After careful consideration of 340B's text and structure, both the D.C. and Third Circuits have answered that question affirmatively.

In *Novartis*, the D.C. Circuit, in a unanimous opinion authored by Judge Katsas, explained that the 340B statute's "shall offer" provision preserved manufacturers' ability to limit the number of contract pharmacies to which they would provide 340B-priced drugs. 102 F.4th at 460. The court analyzed the text of the 340B statute, which provides that manufacturers must "'offer each covered entity covered outpatient drugs for purchase' at or below a specified ceiling 'price.'" *Id.* (quoting 42 U.S.C. § 256b(a)(1)). And an "offer," according to ordinary contract principles, "may contain both price and non-price terms"—in fact, some non-price terms are required. *Id.* Because delivery provisions are typical of sales contracts, the court explained, Congress clearly "*preserve[d]*—rather than abrogate[d]—the ability of [manufacturers] to impose at least some delivery conditions" on their offers to sell to covered entities. *Id.* (emphasis added). Manufacturers' only requirement is to make covered entities a "bona fide" offer, which does not preclude the contract-pharmacy

conditions the manufacturers had imposed in that case. *Id.* at 462. Because the 340B statute specifically preserved manufacturers' ability to limit the number of contract pharmacies to which they would provide 340B-priced drugs, even the administering federal agency cannot require manufacturers to provide drugs to an unlimited number of contract pharmacies.

The Third Circuit, in an opinion authored by Judge Bibas, unanimously reached the same conclusion based on its own reading of 340B. In *Sanofi Aventis U.S. LLC v. United States Department of Health & Human Services*, the court rejected the notion that 340B mandated providing 340B-priced drugs to an unlimited number of pharmacies. 58 F.4th 696, 703 (3d Cir. 2023). Like the D.C. Circuit, the Third Circuit looked to the term "offer" and concluded a manufacturer still "offers" drugs to covered entities if it does so with a stipulation about where the drugs are to be delivered, and that there was no federal obligation to provide 340B-priced drugs when a covered entity was requesting delivery to multiple contract pharmacies. *Id.* The court further noted Congress had "expressly contemplate[d] drug makers selling discounted drugs through contract pharmacies" in a "neighboring provision" of that "same Veterans Health Care Act of 1992," indeed starting "on the very page of the Act where Section 340B ended." *Id.* at 704-05. The Third Circuit concluded from the fact that "Congress added that specific language there but not here," that "[w]e presume that it did so intentionally." *Id.* at 705. Accordingly, the Third Circuit held that 340B barred HRSA from requiring manufacturers to allow the use of any and all contract pharmacies. *Id.* at 703-04.

2. The Eighth Circuit's decision, however, reaches the opposite conclusion. It held that 340B's supposed "silence" about the provision of 340B-priced drugs to contract pharmacies left a gap that regulators were free to fill by requiring manufacturers to provide 340B-priced drugs to any and all contract pharmacies specified by a covered entity. App. 12a, 14a. In so holding, the Eighth Circuit decision rejects the very authority that the D.C. and Third Circuits held was *preserved* to manufacturers by Congress in imposing conditions—including as to the use of contract pharmacies—on the delivery of 340B-priced drugs, fundamentally altering the statutory scheme.

The ability of manufacturers to impose conditions on the sale of 340B-priced drugs is not only a natural incident of their authority to make "offers," but a crucial feature to the operation of 340B. As discussed, 340B represents a delicate balance between making manufacturers subsidize covered entities and making the system so burdensome that it disincentivized manufacturers from participating in it—and by extension Medicare and Medicaid. *Cf. Astra*, 563 U.S. at 120 (The "adjudication of rights under one program must proceed with an eye towards any implications for the other." (citation omitted)). Congress balanced 340B by ensuring it was a closed system with strict limitations on who can participate and benefit from manufacturers' subsidies. One such aspect is preserving manufacturers' ability to put reasonable conditions on the offer of 340B-priced drugs to keep the program circumscribed and guard against abuse. The Eighth Circuit's decision strikes at that crucial feature, upsetting the balance struck by Congress and frustrating 340B's operation. *Cf. Geier v. American Honda Motor Co.*, 529 U.S. 861, 878-79 (2000).

The conflict is underscored by the Eighth Circuit's conclusion that Arkansas is free to impose on manufacturers a requirement that the D.C. and Third Circuits held Congress barred the administering federal agency (HHS) itself from imposing. Allowing the States to impose requirements on manufacturers participating in a federal program that the administering federal agency cannot turns the Supremacy Clause on its head.

Moreover, the conflict reflected in these decisions directly implicates pricing specifically, not just delivery. There is no dispute that the manufacturers have been delivering the same drugs to contract pharmacies all along; what the statute requires, and the Eighth Circuit upheld, was not delivery, but *delivery at a specific price*. This conflicts directly with the D.C. and Third Circuits' holdings that manufacturers could *not* be required to offer, and deliver, 340B-priced drugs to any and all contract pharmacies. Although 340B requires manufacturers to "offer" their drugs at a certain price to covered entities, 42 U.S.C. § 256b(a)(1), manufacturers remain free to attach reasonable conditions on those "offers." If covered entities are unwilling to accept those offers, they may buy the same drugs *at the market price*. Act 1103 nevertheless forces manufacturers to provide 340B-priced drugs where a covered entity has rejected the only offer the manufacturer is required to make under federal law—directly impacting *pricing*.

In short, Arkansas is forcing manufacturers to provide 340B pricing in circumstances where federal courts have said they have no statutory obligation to provide the discounted price, *see supra* at 24-25—a direct conflict with federal law on a central aspect of

340B. *See, e.g., National Meat Ass'n v. Harris*, 565 U.S. 452, 463-64 (2012); *Engine Mfrs. Ass'n v. South Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 255 (2004). In any event, whether viewed as a regulation of pricing or delivery, requiring manufacturers to allow the use of an unlimited number of contract pharmacies directly conflicts with the statute's *preservation* of a manufacturer's ability to impose reasonable conditions on the offer of 340B-priced drugs, including as to contract pharmacy use.

B. The Eighth Circuit's Decision Conflicts With This Court's Precedent

The Eighth Circuit's decision also conflicts with this Court's decisions by upholding a state law that frustrates Congress's decision to centralize enforcement in the Federal Government.

1. In *Astra*, this Court made clear that the Federal Government alone controls 340B. There, covered entities asserted the right to bring private third-party-beneficiary claims against manufacturers for 340B overcharges under the federal contract between manufacturers and HHS that implements 340B. 563 U.S. at 117-18. This Court unanimously rejected such private actions as an alternative to the federal 340B enforcement scheme. As the Court explained, Congress "centralized enforcement" in the Federal Government over 340B. *Id.* at 119 (citation omitted). Recognizing a private right of action "could spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities," creating a substantial "risk of conflicting adjudications." *Id.* at 120. This would frustrate HHS's ability to maintain the "control rein" of 340B—"undermin[ing] the agency's efforts to

administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.*

Although *Astra* addressed whether covered entities could bring a claim as third-party beneficiaries, the concerns presented mirror those addressed in a typical preemption analysis. For example, in *Astra,* this Court emphasized the need for uniform, national enforcement of 340B in rejecting private enforcement actions. *Id.* And, in *NLRB v. Nash-Finch Co.*, this Court likewise concluded that the need for "uniform application" of a federal statute, there the National Labor Relations Act, preempted a state court's attempt to enjoin certain activity covered by the statute. 404 U.S. 138, 144-47 (1971) (citation omitted) (noting need for uniform standards and danger that state standards could produce conflict).

A centralized federal enforcement scheme is key to 340B. In *Astra,* the Court emphasized the need for HHS to "hold the control rein" over 340B. 563 U.S. at 120-21. Similarly, this Court has repeatedly found preemption where a state law would diminish federal control over a vital federal program. *See Arizona v. United States*, 567 U.S. 387, 401-02 (2012); *Buckman*, 531 U.S. at 350-51.[7]

The Eighth Circuit's decision allows Arkansas to immerse itself in the adjudication of federal questions that directly bear on the implementation of 340B—and the closely related Medicare and Medicaid programs. Act 1103 prohibits manufacturers from denying "340B drug pricing" to a contract pharmacy "that received drugs purchased under a 340B drug

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[7] Although PhRMA briefed the importance of *Astra* to the Eighth Circuit, the court failed to wrestle with *Astra*'s holding, citing it only for its description of 340B. *See* App. 5a-6a.

pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing." Ark. Code Ann. § 23-92-604(c)(2). In determining whether that requirement is met, the State—through AID—must assess, among other things, whether: (1) the covered entity qualifies; (2) the covered entity remains eligible to receive 340B-priced drugs; (3) the relationship between the covered entity and pharmacy is lawful; and (4) whether the drug is eligible for 340B pricing. But, ultimately, these are all questions of *federal* law. By creating its own enforcement mechanism, the Arkansas law thus will disrupt HHS's ability "to administer" 340B "on a uniform, nationwide basis." *Astra*, 563 U.S. at 120. This "risk of conflicting adjudications" was the exact problem identified in *Astra*, *id.*, a risk allowed to fester by the Eighth Circuit's decision.

Many States have enacted laws similar to Act 1103, and many more are considering doing so. *See supra* at 14-15. Under the Eighth Circuit's reasoning, every State could enact its own preferred obligations and enforcement scheme, creating a dizzying array of disparate enforcement obligations that would defeat the "centralized enforcement" mechanism established by Congress. *Astra*, 563 U.S. at 119 (citation omitted). In *Astra,* the threat to this centralized mechanism was private enforcement actions; here, it is state enforcement actions. But the impact on Congress's centralized enforcement scheme would be the same.

2. The Eighth Circuit's decision likewise conflicts with *Arizona*, which underscores that state laws—like Act 1103—that interfere with a centralized federal enforcement scheme are preempted.

In *Arizona*, the Court held that federal immigration law preempted Arizona's attempts to

impose its own obligations and enforcement scheme as to aliens present in the State. 567 U.S. at 400-07. One provision of the Arizona law—Section 3—made it a misdemeanor for aliens not to carry alien-registration documents. *Id.* at 400. Although not carrying these documents was already a misdemeanor under federal law, the Court held that federal law nevertheless preempted Section 3 because the "state framework of sanctions create[d] a conflict with the plan Congress put in place," as federal law allowed probation (whereas Arizona did not) and there was no possibility of a federal pardon for violations of Arizona law. *Id.* at 403.

Another provision of the Arizona law—Section 5(C)—made it a misdemeanor for aliens to seek or engage in unauthorized work in the State. *Id.* Federal law, on the other hand, penalized the *employer* who hired an unauthorized alien, not the alien. *Id.* at 404. The Court found that Arizona's enforcement scheme "would interfere with the careful balance struck by Congress with respect to unauthorized employment of aliens," as Congress had decided it was inappropriate to penalize "aliens who seek or engage in unauthorized employment." *Id.* at 406. Even though the state law would help "achieve one of the same goals as federal law—the deterrence of unlawful employment—it involve[d] a conflict in the method of enforcement." *Id.*

The conflict between Act 1103 and 340B is even more stark, because the Arkansas law not only strips manufacturers of authority preserved to them under 340B to impose conditions on the offer of 340B-priced drugs, but also penalizes them for imposing such conditions. Moreover, Act 1103 effectively assumes enforcement power over parts of 340B and layers

state penalties that differ from those provided by federal law on top of the federal penalty provisions. Just as in *Arizona*, Arkansas's attempt to layer its own requirements and penalties on top of the federal program must be, and is, preempted.

The disparate nature of remedies under state and federal law underscores the conflict. *Arizona*, 567 U.S. at 402-03. For example, if HHS finds a violation of 340B, it can order manufacturers to issue refunds for any overcharge and levy civil monetary penalties of up to $6,813 for knowing and intentional overcharges. 42 U.S.C. § 256b(d)(1)(B)(ii), (vi); 88 Fed. Reg. 69,531, 69,535 (Oct. 6, 2023). In Arkansas, however, AID can issue cease-and-desist orders, and levy additional penalties of up to $10,000 for *any* violation of Act 1103, whether or not it was knowing and intentional. Ark. Code Ann. § 23-66-210(a)(1). And in West Virginia, which recently enacted a similar law, the State can penalize a manufacturer $50,000 per violation, which is defined in terms of the smallest saleable unit of the drug. W. Va. Code § 60A-8-6a(a)(7), (c)(1)(A); 21 U.S.C. § 360eee(11)(A). Further, AID can now levy penalties even if the Federal Government decides not to pursue them. All of these disparities mirror the ones that this Court held required federal preemption of the state law at issue in *Arizona*. 567 U.S. at 402-03.[8]

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[8] The Eighth Circuit's decision also conflicts with the Fifth Circuit's decision in *Teltech Systems, Inc. v. Bryant*, 702 F.3d 232 (5th Cir. 2012), which follows *Arizona*'s teachings. *Teltech* addressed the preemptive effect of the federal Truth in Caller ID Act of 2009 (TCIA)—which prohibits the harmful misrepresentation of one's telephone number (called "spoofing")—on a Mississippi law that prohibited *both* harmful

The conflict between the Eighth Circuit's decision and this Court's precedent on whether, or when, a State's attempt to layer its own obligations and enforcement scheme on top of a centralized federal program and enforcement scheme violates the Supremacy Clause alone warrants certiorari.

C. The Eighth Circuit's Decision Is Manifestly Wrong

The Eighth Circuit's divergence from its sister circuits and this Court's precedent underscores that the Eighth Circuit's decision is simply wrong. First, because Congress in 340B *preserved* manufacturers' rights to impose conditions on the use of contract pharmacies when offering 340B-priced drugs, Arkansas's attempt to strip manufacturers of those rights poses a direct conflict with, and obstacle to, federal law and thus runs afoul of the Supremacy Clause. *See, e.g.*, *Gobeille*, 577 U.S. at 325-26; *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000); *Forest Park II v. Hadley*, 336 F.3d 724, 733-34 (8th Cir. 2003). Second, as explained, federal preemption principles prevent a State from layering its own enforcement scheme on top of a centralized federal enforcement scheme. *See Astra*, 563 U.S. at 120; *Arizona*, 567 U.S. at 402-03. And, third, the Arkansas law impermissibly intrudes on an area in

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and non-harmful spoofing. *Id.* at 237-38 (the TCIA punished spoofing with the intent to defraud, whereas the Mississippi law punished spoofing with the intent to merely deceive or mislead). Although the TCIA contained no express preemptive language, and consumer protection was an area of traditional state regulation, the Fifth Circuit held the TCIA preempted the Mississippi law under *Arizona*'s reasoning because the Mississippi law "upset[] Congress' considered regulatory choices." *Id.* at 239. The same is true as to Act 1103.

which Congress occupied the field—that is, the carefully circumscribed operation and enforcement of 340B. *See, e.g.*, *Arizona*, 567 U.S. at 400-03; *Hines v. Davidowitz*, 312 U.S. 52, 59-61, 72-74 (1941).[9]

The fact that the Eighth Circuit has decided an important federal question incorrectly—and in conflict with the decisions of other circuits and this Court—underscores the need for this Court's review.

III. This Case Presents An Ideal Vehicle To Resolve The Question Presented

This case presents a clean legal question that was squarely decided by the court of appeals below. As discussed, the Eighth Circuit's decision conflicts with the decisions of other circuits and this Court. And this Court's intervention is needed now. As noted, seven other States have already enacted equivalents of Act 1103, and twenty-two other States have or are considering such laws. *See supra* at 14-15. Suits like this one have been filed in many of those jurisdictions to decide the question presented. This litigation and the ensuing uncertainty and burdens placed on

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[9] The presumption against preemption changes none of this. The presumption against preemption does not apply where the state law implicates an area of "unique federal concern," *Boyle v. United Techs. Corp.*, 487 U.S. 500, 507-08 (1988), *i.e.*, where the state law targets a carefully calibrated federal program, as here. Regardless, the origins and validity of the doctrine are questionable at best. *See Bell v. Blue Cross & Blue Shield of Okla.*, 823 F.3d 1198, 1201 (8th Cir. 2016), *cert. denied*, 581 U.S. 938 (2017); *see also Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 544 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part) (detailing why the presumption against preemption is "an extraordinary and unprecedented principle of federal statutory construction"). In any event, the direct conflicts with federal law discussed above overcome any applicable presumption against preemption.

manufacturers will destabilize the program and risk the departure of 340B participants.

Act 1103 and similar laws risk making the national 340B program unworkable. By requiring States to interpret federal law to determine 340B-eligibility, these laws wrest questions of federal law away from federal authority. *See* 42 U.S.C. § 256b(d)(3)(A); *see also* 42 C.F.R. § 10.21(a)(1) (providing that ADR covers "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price"). The decentralization of decision-making will likely lead to divergent interpretations of 340B standards and manufacturers' obligations, disrupting the uniform administration and enforcement of 340B that *Astra* recognized as critical to its functioning. 563 U.S. at 120.

Moreover, delaying intervention presents a substantial risk of upsetting the careful balance Congress established among 340B, Medicare, and Medicaid. As explained, a manufacturer's 340B participation is a condition for its drugs to be eligible for federal payment under Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1), (5). Act 1103 and similar laws dramatically inflate drug manufacturers' costs of participating in 340B. As these costs rise, drug manufacturers could be required to shift costs, forego critical research, and—if the costs become too high—be forced to reconsider their participation in Medicare Part B and Medicaid.

The financial losses at stake—tens of billions of dollars and growing, all of which manufacturers likely will not be able to recover if the state statutes are

subsequently invalidated—are an additional reason to grant certiorari. As Justice Scalia explained, the "enormous" monetary consequences of "a question of federal statutory interpretation[] is a strong factor in deciding whether to grant certiorari." *Fidelity Fed. Bank & Trust v. Kehoe*, 547 U.S. 1051, 1051 (2006) (Scalia, J., joined by Alito, J., concurring in the denial of certiorari); *accord* Stephen M. Shapiro et al., *Supreme Court Practice* § 4.13 (11th ed. 2019). The huge financial consequences of the question presented—billions of dollars—thus alone weigh heavily in favor of certiorari.

Given the havoc that an alternative enforcement scheme imposed by the States like Arkansas will have on the now nearly $54 billion federal program, and covered entities, manufacturers, and patients that participate in or depend on the program, it is imperative that the Court grant certiorari now.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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July 31, 2024

APPENDIX

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UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff-Appellant,

v.

Alan MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department, Defendant - Appellee

Community Health Centers of Arkansas; Piggott Community Hospital, Intervenors - Appellees

American Hospital Association; Arkansas Hospital Association; 340B Health, Amici on Behalf of Appellee(s).

No. 22-3675

Submitted: September 20, 2023

Filed: March 12, 2024

[95 F.4th 1136]

Before SMITH, Chief Judge,[1] MELLOY and ERICKSON, Circuit Judges.

MELLOY, Circuit Judge.

Pharmaceutical Research and Manufacturers of America ("PhRMA"), an association representing pharmaceutical manufacturers, initially brought this

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[1] Judge Smith completed his term as chief judge of the circuit on March 10, 2024. *See* 28 U.S.C. § 45(a)(3)(A).

case against Arkansas Insurance Department Commissioner Alan McClain in his official capacity arguing that federal law impliedly preempts Arkansas Code § 23-92-604(c) ("Act 1103"). PhRMA argues that both the Section 340B Program and the Federal Food, Drug, and Cosmetic Act ("FDCA") preempt Act 1103 under theories of field, obstacle, and impossibility preemption. The district court[2] found that Act 1103 was not preempted by federal law under any theory. We affirm.

I

For three decades, many Arkansas health care providers have participated in the Section 340B Program, a drug pricing program established by Congress in 1992. 42 U.S.C. § 256b(a)(1). Section 340B incentivizes pharmaceutical manufacturers to provide qualified health care providers, referred to as "covered entities," with pricing discounts on certain drugs prescribed to individuals and families whose incomes fall below the federal poverty level. Since the beginning, covered entities have contracted with outside pharmacies, referred to as "contract pharmacies," for the distribution and dispensation of 340B drugs. This is in large part due to the fact that building or maintaining a pharmacy is cost-prohibitive for many covered entities. Additionally, the outsourcing of pharmacy services has allowed for drug dispensation closer to where low-income patients reside. Furthermore, in some states, like Arkansas, state law prohibits most nonprofit and

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[2] The Honorable Billy Roy Wilson, United States District Judge for the Eastern District of Arkansas.

government-funded providers from operating their own in-house pharmacies.

For 25 years, drug manufacturers represented by PhRMA distributed 340B drugs to covered entities' contract pharmacies. Then, in 2020, drug manufacturers began implementing distribution policies that limited or prohibited covered entities from contracting with outside pharmacies for the dispensation of 340B drugs to patients. This caused covered entities dependent on contract pharmacies to become unable to serve patients in need. The Arkansas General Assembly responded in 2021 by passing Act 1103, Ark. Code Ann. § 23-92-604(c), which applies to drug distribution agreements between manufacturers and covered entities in Arkansas. Act 1103 prohibits manufacturers from limiting covered entities' ability to contract with outside pharmacies.

After the passage of Act 1103, PhRMA brought this lawsuit against Commissioner McClain, the head of the agency charged with enforcing Act 1103. For purposes of this appeal, PhRMA takes issue with Ark. Code Ann. § 23-92-604(c), arguing that it is preempted by Section 340B and the FDCA and is therefore unconstitutional.[3] After PhRMA filed suit, Piggott Community Hospital and Community Health Centers of Arkansas (collectively, "Intervenors") intervened. Piggott Community Hospital is a 340B

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[3] PhRMA also argues that Act 1103 violates the Commerce Clause of the U.S. Constitution. The district court granted the parties' joint motion to stay proceedings on the Commerce Clause issue pending the outcome of the preemption issue. Accordingly, the Commerce Clause issue is not before us on appeal.

hospital that is owned and operated by the City of Piggott, Arkansas. Community Health Centers of Arkansas is a nonprofit comprised of eleven community health centers that all participate in the 340B Program. PhRMA and Intervenors filed cross-motions for summary judgment, which the district court granted in favor of Intervenors. PhRMA appeals the district court's decision. We affirm.

II

"Article VI of the Constitution provides that the laws of the United States 'shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.' " *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (citing Art. VI, cl. 2). It has long been established "that state law that conflicts with federal law is 'without effect.' " *Id.* (citation omitted); *see, e.g.*, *M'Culloch v. Maryland,* 17 U.S. (4 Wheat.) 316, 427, 4 L.Ed. 579 (1819). "Congress may . . . pre-empt, *i.e.*, invalidate, a state law through federal legislation." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376, 135 S.Ct. 1591, 191 L.Ed.2d 511 (2015). "But even where, as here, a statute does not refer expressly to pre-emption, Congress may implicitly pre-empt a state law, rule, or other state action." *Id.* Where preemption is alleged, " '[t]he purpose of Congress is the ultimate touchstone' of pre-emption analysis." *Cipollone*, 505 U.S. at 516, 112 S.Ct. 2608 (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504, 98 S.Ct. 1185, 55 L.Ed.2d 443 (1978)). Congress may impliedly preempt state law "either through 'field' pre-emption or 'conflict' preemption." *Oneok, Inc.*, 575 U.S. at 377, 135 S.Ct. 1591. Field preemption exists where "Congress has forbidden the State to take action in

the *field* that the federal statute pre-empts." *Id.* "By contrast, conflict pre-emption exists where 'compliance with both state and federal law is impossible,' or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Id.* (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989)) (internal quotation marks omitted). In either situation, federal law must prevail.

Notwithstanding the supremacy of federal law, "[c]onsideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.' " *Cipollone*, 505 U.S. at 516, 112 S.Ct. 2608 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). Indeed, there is a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 715, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985).

PhRMA argues that Section 340B impliedly preempts Act 1103 through field and obstacle preemption and that the FDCA preempts Act 1103 through impossibility preemption. "We review de novo the district court's resolution of cross-motions for summary judgment, 'viewing the evidence in the light most favorable to the nonmoving party and giving the nonmoving party the benefit of all reasonable inferences.' " *Principal Nat'l Life Ins. Co. v. Rothenberg*, 70 F.4th 1046, 1052 (8th Cir. 2023) (quoting *Dallas v. Am. Gen. Life & Accident Ins. Co.*,

709 F.3d 734, 736 (8th Cir. 2013)). We will affirm a district court's grant of summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A.

1.

PhRMA first argues that Section 340B preempts Act 1103 under theories of field and obstacle preemption. Congress established Section 340B of the Public Health Services Act as a pharmaceutical pricing program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113, 131 S.Ct. 1342, 179 L.Ed.2d 457 (2011); 42 U.S.C. § 256b. These health care providers "perform valuable services for low-income and rural communities but have to rely on limited federal funding for support," and the 340B Program was designed in part to support this work. *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738, 142 S.Ct. 1896, 213 L.Ed.2d 251 (2022). The 340B Program is administered by the Secretary of Health and Human Services ("HHS") and "superintended by the Health Resources and Services Administration" ("HRSA," an HHS agency), who help implement and enforce the prices that pharmaceutical manufacturers charge to covered entities. *Astra USA, Inc.*, 563 U.S. at 113, 131 S.Ct. 1342; 42 U.S.C. § 256b.

The 340B Program "has three basic parts: (1) a cap on drug makers' prices, (2) restrictions on covered entities, and (3) compliance mechanisms" for both covered entities and manufacturers. *Sanofi Aventis*

U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 699 (3d Cir. 2023). First, as a condition of participating in Medicaid, drug manufacturers must "opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement" with the Secretary of HHS. *Astra USA, Inc.*, 563 U.S. at 113, 131 S.Ct. 1342. The Pharmaceutical Pricing Agreement requires manufacturers to sell drugs to covered entities at a discounted "ceiling price." 42 U.S.C. § 256b(a)(1). The ceiling price is determined by a statutory formula. 42 U.S.C. §§ 256b(a)(2), 1396r-8(c). The second part of 340B mandates that discounted prices are only made available to covered entities. *Id.* § 256b(a). Covered entities are defined by statute to include fifteen different types of public and not-for-profit hospitals, community centers, and clinics that are "dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc.*, 563 U.S. at 115, 131 S.Ct. 1342; *see also* 42 U.S.C. § 256b(a)(4).

Finally, the 340B Program includes compliance mechanisms, penalties for noncompliance or abuse by manufacturers and covered entities, and a dispute resolution process through HHS. *See, e.g.*, *Astra USA, Inc.*, 563 U.S. at 115–16, 131 S.Ct. 1342; *Sanofi Aventis U.S. LLC*, 58 F.4th at 701–02. Manufacturers are required to report their 340B ceiling prices to the HRSA on a quarterly basis and are subject to auditing. 42 U.S.C. § 256b(a)(1), (a)(5)(C). Covered entities may only prescribe 340B discounted drugs to patients who qualify and may not request or receive duplicative 340B discounts and Medicaid rebates for the same drug. *Id.* § 256b(a)(5)(A)–(B). Additionally, covered entities may not engage in diversion of covered outpatient drugs through "resell[ing] or

otherwise transfer[ring] the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Both the Secretary of HHS and drug manufacturers are authorized to audit covered entities to ensure compliance with the diversion and duplicate rebate provisions. *Id.* § 256b(a)(5)(C). Drug manufacturers and covered entities that fail to comply "can be fined, and covered entities can be kicked out of the program." *Sanofi Aventis U.S. LLC*, 58 F.4th at 700. When payment, pricing, diversion, or discount disputes arise between manufacturers and covered entities, 340B mandates parties first go through HHS's dispute resolution process to resolve the issue. 42 U.S.C. § 256b(d)(3).

As the Third Circuit has observed, the 340B Program "is silent about delivery" and distribution of pharmaceuticals to patients. *Sanofi Aventis U.S. LLC*, 58 F.4th at 703. The pharmaceutical distribution chain is complex, and contract pharmacies are not the only third parties involved in getting 340B drugs from manufacturers to patients. Pharmaceutical manufacturers sell their drugs to wholesalers who then distribute and sell drugs to pharmacies or health care providers. Section 340B addresses drug wholesalers but does not mention pharmacies or the delivery of drugs by pharmacies to patients. Yet pharmacies are essential, and legally required, as part of the drug distribution chain. Thus, pharmacies have always been important participants in delivering 340B drugs to patients.

Although some covered entities have in-house pharmacies, many do not. Indeed, early in the 340B Program, HRSA observed that most covered entities relied on contract pharmacies, while only about four percent of such entities used in-house pharmacies.

Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). Therefore, since the 1990s, covered entities have contracted with outside pharmacies to handle the acquisition, distribution, and dispensation of 340B drugs.

When covered entities enter into agreements with contract pharmacies, these pharmacies do not become beneficiaries of the 340B Program. Rather, HRSA has clarified that "the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing" for patients. 61 Fed. Reg. at 43,550. "Covered entities using contract pharmacies . . . still order and pay for the drugs, but they [are] shipped directly to the pharmacies." *Sanofi Aventis U.S. LLC*, 58 F.4th at 700. Covered entities maintain legal title to the 340B drugs. 61 Fed. Reg. at 43,552. "The mechanism does not in any way extend this pricing to entities which do not meet program eligibility." *Id.* at 43,550. This includes contract pharmacies. Instead, 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.*

2.

In May 2021, the Arkansas General Assembly enacted Act 1103 in response to the growing practice among pharmaceutical companies of prohibiting or restricting covered entities from contracting with outside pharmacies. PhRMA argues that the following section of Act 1103 is preempted:

> (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.

Ark. Code Ann. § 23-92-604(c). Act 1103 defines "340B drug pricing" as "the program established under section 602 of the Veterans Health Care Act of 1992," referring to the 340B Program. *Id.* § 23-92-602(5). The Arkansas Insurance Division also promulgated a rule that defines "340B drug pricing" as "the acquisition and delivery of 340B-priced drugs as established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585." 003-22-123 Ark. Code R. § II(7) (West 2022). The first subsection of section 23-92-604(c) 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. The second subsection 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.

3.

PhRMA first argues that Act 1103 is unconstitutional because the 340B Program preempts the field. In cases where, as here, a statute does not

expressly preempt state law, it may nonetheless do so through field preemption. When a federal regulatory scheme occupies the field because of its pervasive nature, leaving no room for state action, field preemption applies. *Cipollone,* 505 U.S. at 516, 112 S.Ct. 2608. Field preemption also applies when Congress "intend[s] 'to foreclose any state regulation in the [regulated] *area*,' irrespective of whether state law is consistent or inconsistent with 'federal standards.' " *Oneok, Inc.*, 575 U.S. at 377, 135 S.Ct. 1591 (quoting *Arizona v. United States*, 567 U.S. 387, 401, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012)). Congress's intent to preempt a field "can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' " or a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona*, 567 U.S. at 399, 132 S.Ct. 2492 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). Neither inference is present here

First, the 340B Program is not "so pervasive . . . that Congress left no room for the States to supplement it." *Id.* Pharmacies have always been an essential part of the 340B Program. Yet, the text of 340B "is silent about delivery" of drugs to patients. *Sanofi Aventis U.S. LLC*, 58 F.4th at 703. This silence contrasts with 340B's provisions that directly address distribution by third-party wholesalers. *See, e.g.*, 42 U.S.C. § 256b(a)(8). Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field.

Furthermore, "practice of pharmacy is an area traditionally left to state regulation." *Pharm. Care*

Mgmt. Ass'n v. Wehbi, 18 F.4th 956, 972 (8th Cir. 2021). Indeed, 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.' " *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 940–41 (8th Cir. 2011) (quoting *Wyeth v. Levine*, 555 U.S. 555, 578–79, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009)). "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Id.* at 940 (citation omitted). We believe Congress was aware of the role of pharmacies and state pharmacy law in implementing 340B. Therefore, Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field.

PhRMA contends that 340B preempts the field because Congress intended to create a "closed system" with the statute. To support this argument, PhRMA first asserts that Act 1103 impermissibly interferes with 340B's "closed system" by adding pharmacies to the enumerated list of covered entities eligible to receive 340B pricing on drugs. This misconstrues what Act 1103 does. Pharmacies do not purchase 340B drugs, and they do not receive the 340B price discounts. Covered entities purchase and maintain title to the 340B-discounted drugs, while contract pharmacies dispense these drugs to covered entities' patients. *Sanofi Aventis U.S. LLC*, 58 F.4th at 700.

Second, PhRMA argues that Act 1103 creates its own oversight and enforcement scheme by

empowering a state agency to exact penalties on manufacturers who refuse to distribute to contract pharmacies. PhRMA argues this contravenes HHS's exclusive 340B jurisdiction. Again, PhRMA conflates the two statutes. Act 1103 ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies. Ark. Code Ann. § 23-92-604(c). The 340B Program, on the other hand, addresses discount pricing. Therefore, HHS has jurisdiction over different disputes: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs.

Pharmacy has traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted. *Pharm. Care Mgmt. Ass'n*, 18 F.4th at 972. For these reasons, we conclude that in enacting Section 340B, Congress did not intend to preempt the field.

4.

PhRMA next argues that Act 1103 is unconstitutional because of obstacle preemption. "Where state and federal law 'directly conflict,' state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011) (citation omitted). Obstacle preemption exists where state law "stands as an obstacle to the accomplishment and execution of the full purposes

and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000). What qualifies as "a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Id.* "If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power." *Id.* (citation omitted).

Act 1103 does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B. In arguing otherwise, PhRMA presents no evidence of an obstacle. Instead, PhRMA raises the same arguments it raised with field preemption. We reject these same arguments again here.

Act 1103 does not require manufacturers to provide 340B pricing discounts to contract pharmacies. Act 1103 does not set or enforce discount pricing. As such, the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle. Additionally, Act 1103's penalties are aimed at activity that falls outside the purview of 340B: Act 1103 incentivizes compliance through monetary penalties and equitable relief. Arkansas is simply deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements. There is no obstacle for pharmaceutical manufacturers to comply with both Act 1103 and Section 340B.

B.

PhRMA also argues that Act 1103 is unconstitutional because of impossibility preemption. PhRMA argues that as to certain highly regulated drugs, Act 1103's distribution requirement is at odds with the FDCA's Risk Evaluation and Mitigation Strategies ("REMS") Program. 23 U.S.C. § 355-1. The REMS Program is administered by the Food and Drug Administration ("FDA") and regulates high-risk pharmaceutical products to ensure their safe distribution and use. Through this statutory scheme, the FDA can attach a REMS requirement to ensure that a pharmaceutical's benefits outweigh the risk of harm if not properly distributed or dispensed. 21 U.S.C. § 355-1. REMS requirements can impose more restrictive methods of distribution or dispensation to ensure safety. Additionally, the REMS Program may require pharmacies to become certified to dispense REMS medication, and REMS may also limit which pharmacies qualify to receive and dispense REMS drugs. *Id.* § 355-1(e). As such, "[d]rug makers often comply by limiting distribution to a few pharmacies that are specially trained to educate and monitor patients." *Sanofi Aventis U.S. LLC*, 58 F.4th at 705.

Act 1103 does not make it impossible for drug manufacturers and wholesale distributors to comply with the REMS Program, and therefore the FDCA does not preempt Act 1103. Impossibility preemption exists when it is "impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc.*, 564 U.S. at 618, 131 S.Ct. 2567 (citation omitted). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620, 131 S.Ct. 2567. Impossibility preemption "arises

when 'compliance with both federal and state regulations is a physical impossibility.'" *Hillsborough Cnty., Fla.*, 471 U.S. at 713, 105 S.Ct. 2371 (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43, 83 S.Ct. 1210, 10 L.Ed.2d 248 (1963)).

Act 1103 does not force pharmaceutical manufacturers to violate REMS. Act 1103 prohibits drug manufacturers from denying 340B covered entities the ability to contract with third-party pharmacies for dispensation of 340B drugs. If a 340B drug is also subject to REMS safety requirements and the covered entity wants to contract with a pharmacy for dispensation, the covered entity bears the responsibility of contracting with a pharmacy that meets the REMS requirements. Providers, manufactures, and pharmacies are subject to many legal and regulatory requirements in the area of drug distribution. Just because a medication is subject to multiple legal requirements does not make it impossible to comply with Act 1103. PhRMA alleges no circumstance where a covered entity's contract pharmacy arrangement has made simultaneous compliance with state and federal law impossible. As such, the FDCA does not preempt Act 1103.

III.

For the foregoing reasons, Arkansas Act 1103 is not preempted by Section 340B or the FDCA's REMS Program. We affirm.

United States District Court,
E.D. Arkansas,
Central Division.

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff

v.

Alan MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department, Defendant

Community Health Centers of Arkansas; Piggott Community Hospital, Intervenors

Case No. 4:21-CV-864-BRW

Signed December 12, 2022

[645 F. Supp. 3d 890]

ORDER

BILLY ROY WILSON, UNITED STATES DISTRICT JUDGE

Pending are Plaintiff's Motion for Summary Judgment on Preemption (Doc. No. 24), Defendant Leslie Rutledge's Cross-Motion for Summary Judgment (Doc. No. 32), and Intervenors' Cross-Motion for Summary Judgment on Preemption (Doc. No. 35). The parties have responded and replied.[1] For the reasons set out below, Plaintiff's motion is DENIED. Intervenors' cross-motion is GRANTED. Defendant Leslie Rutledge's cross-motion is DENIED as MOOT.

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[1] Doc. Nos. 29, 38, 41, 45.

I. BACKGROUND[2]

Plaintiff claims Act 1103 enacted by the Arkansas General Assembly in 2021 is unconstitutional. Plaintiff represents several prescription drug manufacturing companies. Defendant Alan McClain is the Commissioner of the Arkansas Insurance Department, which is the agency charged with the implementation and enforcement of Act 1103.

Plaintiff named Leslie Rutledge in her official capacity as the Attorney General of Arkansas as a Defendant in this case.[3] On September 9, 2022, Ms. Rutledge filed a motion for summary judgment arguing that she was not a proper party to he lawsuit under Arkansas law.[4] On October 5, 2022, the parties filed a stipulation of dismissal where they agreed that Ms. Rutledge has no authority to enforce the relevant Arkansas law at issue, and requested that she be dismissed.[5] On that same day, I granted the dismissal.[6] Accordingly, Ms. Rutledge's Cross-Motion for Summary Judgment is DENIED as MOOT.

Intervenor Piggott Community Hospital ("PCH") is located in Piggott, Arkansas, and is designated under the Medicare program as a critical access hospital ("CAH"). PCH is owned and operated by the City of Piggott and participates in the 340B Program

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[2] Unless otherwise noted the Background information comes from the parties' Statements of Facts (Doc. Nos. 25, 31, 37, 38, 42).

[3] Doc. No. 1.

[4] Doc. No. 32.

[5] Doc. No. 39.

[6] Doc. No. 40.

based on its governmental ownership and CAH status.[7]

Intervenor Community Health Centers of Arkansas ("CHCA") is a non-profit organization comprised of eleven community health centers located in Arkansas. All of CHCA's members participate in the 340B Program by receiving funding under Section 330 of the Public Health Service Act ("PHSA").[8]

This case arises out of a dispute between drug manufacturers and the Arkansas Insurance Department ("AID") about the use of "contract pharmacies" as a part of the Federal 340B drug program. Plaintiff contends that these contract pharmacies "have found illegal ways to leverage the 340B discounts to their financial benefit, often without assisting the vulnerable patient populations that the 340B program was intended to help."[9]

Plaintiff contends that provisions found in Act 1103 inappropriately regulate and alter the Federal 340(B) Program, impose requirements that directly conflict the program, and regulate commercial transactions occurring entirely outside of Arkansas.[10] Plaintiff argues that Act 1103 is invalid under both the Supremacy and Commerce Clauses of the U.S. Constitution. Plaintiff seeks declaratory judgment and injunctive relief.[11]

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[7] 42 U.S.C. §§ 256b(a)(4)(N), 1395i–4(c)(2); 42 C.F.R. §§ 485.601–485.647.

[8] 42 U.S.C. §§ 254b, 256b(a)(4)(A), 1396d(*l*).

[9] Doc. No. 1, p. 2.

[10] *Id.*

[11] *Id.*

On September 29, 2021, Plaintiff filed its Complaint.[12] On August 9, 2022, the parties filed an joint motion to stay the proceedings on the commerce clause claim until the preemption claim has been resolved.[13] I granted the motion on that same day.[14] So, the only issue ripe for consideration at this point is preemption.

On August 8, 2022, Plaintiff filed its Motion for Summary Judgment on Claim I.[15] First, Plaintiff contends that the 340B Program is strictly a federal scheme that is not subject to state regulation. Second, Plaintiff argues that Act 1103 conflicts with the 340B Program by essentially adding "contract pharmacies" to the list of "covered entities" as defined in the statute. Third, Plaintiff asserts that Act 1103 conflicts with the enforcement authority granted to HHS and its agency the Health Resources and Services Administration ("HRSA") by establishing a separate enforcement scheme with additional penalties. Fourth, Plaintiff contends that Act 1103 conflicts with the Federal Food, Drug, and Cosmetic Act ("FDCA") "by mandating how federally regulated drugs may be distributed in Arkansas" without regard to federal safety standards.[16]

In response, Defendant and Intervenors seek a narrow interpretation of the provisions in Act 1103 and contend that even if I agree with Plaintiff's broad interpretation of Act 1103, a fact issue remains on the

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12 *Id.*

13 Doc. No. 27.

14 Doc. No. 28.

15 Doc. No. 24.

16 Doc. No. 26, p.13.

ownership status of the discounted drugs as they are distributed through the system.[17]

On September 9, 2022, Intervenors filed a Cross-Motion for Summary Judgment on Claim I.[18] Intervenors contend that the 340(B) Program only regulates drug pricing, and the disputed provisions in Act 1103 only regulate drug distribution in Arkansas, so no preemption exists. I agree.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate only when there is no genuine issue of material fact, so that the dispute may be decided on purely legal grounds.[19] The Supreme Court has established guidelines to assist trial courts in determining whether this standard has been met:

> The inquiry performed is the threshold inquiry of determining whether there is the need for a trial—whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.[20]

The Court of Appeals for the Eighth Circuit has cautioned that summary judgment is an extreme remedy that should only be granted when the movant has established a right to the judgment beyond

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17 Doc. Nos. 30, 35.

18 Doc. No. 35, 36.

19 *Holloway v. Lockhart*, 813 F.2d 874, 879 (8th Cir. 1987); Fed R. Civ. P. 56.

20 *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

controversy.[21] Nevertheless, summary judgment promotes judicial economy by preventing trial when no genuine issue of fact remains.[22] This court must view the facts in the light most favorable to the party opposing the motion.[23] The Eighth Circuit has also set out the burden of the parties in connection with a summary judgment motion:

> [T]he burden on the party moving for summary judgment is only to demonstrate, *i.e.*, "[to point] out to the District Court," that the record does not disclose a genuine dispute on a material fact. It is enough for the movant to bring up the fact that the record does not contain such an issue and to identify that part of the record which bears out his assertion. Once this is done, his burden is discharged, and, if the record in fact bears out the claim that no genuine dispute exists on any material fact, it is then the respondent's burden to set forth affirmative evidence, specific facts, showing that there is a genuine dispute on that issue. If the respondent fails to carry that burden, summary judgment should be granted.[24] Only disputes over facts that may affect the outcome

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[21] *Inland Oil & Transport Co. v. United States*, 600 F.2d 725, 727 (8th Cir. 1979).

[22] *Id.* at 728.

[23] *Id.* at 727-28.

[24] *Counts v. MK-Ferguson Co.*, 862 F.2d 1338, 1339 (8th Cir. 1988) (quoting *City of Mt. Pleasant v. Associated Elec. Coop.*, 838 F.2d 268, 273-74 (8th Cir. 1988) (citations omitted)).

of the suit under governing law will properly preclude the entry of summary judgment.[25]

III. DISCUSSION

A. 340(B) Drug Program

The 340B Drug Program, is a federal prescription drug discount plan established by Congress in 1992[26]. The Secretary of HHS administers the program. The 340(B) Program requires, as a condition of a manufacture's participation in Medicaid and Medicare Part B, that it sell its outpatient drugs at a discounted price to "covered entities," which are defined by statute to include 15 types of public and not-for-profit hospitals, community centers, and other federally funded clinics serving low-income patients.[27]

Specifically, all drug manufacturers participating in the 340B Program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[28] The 340B Program "ceiling prices," which are calculated according to a prescribed statutory formula,[29] are lower than the amounts other purchasers would pay. These drug pricing discounts are intended to "enable

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[25] *Anderson*, 477 U.S. at 248, 106 S.Ct. 2505.

[26] See Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (codified as amended at 42 U.S.C. § 256b).

[27] See Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), codified at § 340B Public Health Service Act, 42 U.S.C. § 256b (1992).

[28] 42 U.S.C. § 256b(a)(1).

[29] See *id.* § 256b(a)(1), (a)(4), (b)(1).

[covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[30]

To participate in the 340B Program, manufacturers are required to sign a contract with HHS known as the Pharmaceutical Pricing Agreement ("PPA"), which incorporates the statutory obligations of the 340B Program and expresses the manufacturers' agreement to abide by those obligations.[31] If, at some point, HHS determines that a drug manufacturer has failed to comply with its 340B Program obligations, the manufacturer's PPA can be terminated, which prevents the manufacturer from receiving coverage for its drugs under Medicare and Medicaid.[32]

Under the 340B Program, covered entities are prohibited from requesting "duplicate discounts or rebates," which means that covered entities may not request both a 340B Program discount and a Medicaid rebate for the same drug.[33] Covered entities are also prohibited from engaging in "diversion," which is defined by statute as the practice of "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity."[34]

B. Act 1103

Plaintiff's organization permitted 340B discounted drugs to be shipped to pharmacies under contract

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[30] H.R. Rep. No. 102-384, pt. 2 at 12 (1992) (conf. report).

[31] See 42 U.S.C. § 1396r-8(a)(1), (5).

[32] See *id.* § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–65, 413 (Dec. 12, 1996).

[33] 42 U.S.C. § 256b(a)(5)(A).

[34] *Id.* § 256b(a)(5)(B).

with covered entities and treated contract pharmacies the same as in-house pharmacies for over 25 years.[35] Beginning in July 2020, drug manufacturers began implementing policies that either eliminated or restricted distribution of 340B drugs delivered to contract pharmacies through bill-to-ship contract pharmacy arrangements.[36] To date, eighteen manufacturers have unilaterally imposed restrictions the ability of covered entities to access 340B drugs through contract pharmacy arrangements.[37] In May 2021, the Arkansas General Assembly enacted Act 1103 to protect contract pharmacy arrangements in Arkansas.

Plaintiff challenges two specific provisions found in Act 1103 enacted by the Arkansas General Assembly in 2021. The relevant provisions of the act provide:

> 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

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35 Doc. No. 37, p.6.

36 *Id.*

37 *Id.*

entity authorized to participate in 340B drug pricing.[38]

Additionally, the AID has promulgated Rule 123, 340B Drug Program Nondiscrimination Requirements which includes the same language found in Ark. Code Ann. § 23-92-604(c)[39] and defines "340B drug pricing" as "the acquisition and delivery of 340B-priced drugs as established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585."[40]

C. 340(B) Program Preemption

The federal preemption doctrine stems from the Constitution's Supremacy Clause, which states that laws of the United States made under the Constitution are the "supreme law of the land."[41] "[S]tate laws that interfere with, or are contrary to the laws of congress, made in pursuance of the constitution are invalid," or preempted.[42] "Whether a particular federal statute preempts state law depends upon congressional purpose."[43] In analyzing the issue of preemption, the Supreme Court is highly

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[38] Ark. Code Ann. § 23-92-604(c).

[39] Rule 123 340B Drug Program Nondiscrimination Requirements Part IV(9)(c)(1)-(2).

[40] *Id.* at Part II (7).

[41] U.S. Const. Art. VI, cl. 2.

[42] *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 604, 111 S.Ct. 2476, 115 L.Ed.2d 532 (1991).

[43] *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781, 791 (8th Cir. 2010).

deferential to state law in areas traditionally regulated by the states.[44]

The Eighth Circuit has stated that "there are three primary ways that federal law may preempt state law."[45] First, federal law may preempt state law where Congress has expressly stated that it intends to prohibit state regulation in a particular area.[46] Second, federal law may preempt state law where Congress has implicitly preempted state regulation by the "occupation of a field."[47] A field is occupied when the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."[48] Finally, even if Congress has not completely precluded the ability of states to regulate in a field, state regulations are preempted if they conflict with federal law.[49] Such a conflict exists "when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress."[50] To determine Congressional intent, courts "may consider

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[44] *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995).

[45] *N. Natural Gas Co. v. Iowa Utils. Bd.*, 377 F.3d 817, 821 (8th Cir. 2004).

[46] *Id.* (citing *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541, 121 S.Ct. 2404, 150 L.Ed.2d 532 (2001)).

[47] *Id.*

[48] *Id.* (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).

[49] *Id.* (citing *Silkwood v. Kerr–McGee Corp.*, 464 U.S. 238, 248, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984)).

[50] *Id.*

the statute itself and any regulations enacted pursuant to the statute's authority."[51] Plaintiff bears the burden of proving preemption.[52] The 340(B) Program contains no express preemption clause, so only implied preemption applies to this case.

1. Field Preemption

Even if a federal statute does not expressly preempt a state law, it may do so through field preemption "when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively."[53] The critical question is whether the "federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it."[54]

Plaintiff contends that the 340B Program is a solely federal scheme. Plaintiff cites *Astra USA, Inc. v. Santa Clara Cnty., Cal.*,[55] to support its position that "Congress intended to operate the 340B Program 'on a uniform, nationwide basis.' "[56]

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[51] *Aurora Dairy*, 621 F.3d at 792.

[52] *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 967 (8th Cir. 2021) (citing *Williams v. Nat'l Football League*, 582 F.3d 863, 880 (8th Cir. 2009)).

[53] *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995).

[54] *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (quotation omitted).

[55] 563 U.S. 110, 121, 131 S.Ct. 1342, 179 L.Ed.2d 457 (2011).

[56] Doc. No. 26, p. 26. 563 U.S. at 120, 131 S.Ct. 1342; see also id. at 113-14, 131 S.Ct. 1342 (rejecting attempt by covered entities to enforce 340B Program through suit against manufacturers alleging breach of contract).

In *Astra*, a collection of "covered entities" sued drug manufacturers for alleged overcharges on 340B Program-covered drugs.[57] Both sides "conceded that Congress authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling."[58] Unable to sue the drug companies directly under the 340B Program, the covered entities pursued their claims under a breach of contract theory as third-party beneficiaries of contracts between HHS and drug companies that create 340B Program discount-ceiling prices.[59]

The Supreme Court was not persuaded. The Court pointed to the fact that Congress had provided an alternative administrative process in which to resolve disputes under the 340B Program.[60] Specifically, Congress had responded to reports of inadequate 340B Program oversight and enforcement, by providing for the establishment of an ADR process within the agency.[61] "Congress thus opted to strengthen and formalize" the agency's enforcement "to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,' " with the agency's resolution of ADR complaints subject to review under the APA.[62]

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57 *Id.*

58 *Id.* at 113, 131 S.Ct. 1342.

59 *Id.*

60 *Id.* at 121, 131 S.Ct. 1342.

61 *Id.* at 121-22, 131 S.Ct. 1342 (citing 42 U.S.C. § 256b(d)).

62 *Id.*

I am not convinced that the Supreme Court's narrow holding concerning third-party lawsuits in *Astra* makes the 340B Program a solely federal scheme immune from any type of state regulation.

I note that the 340B Program is silent on what role (if any) contract pharmacies play in its discount drug scheme. Pharmacies are not mentioned anywhere in it—neither in 42 U.S.C. § 256b(a)(1), which contains the "sum total of the statute's language regarding manufacturers' obligations," nor in § 256b(a)(4), which defines "covered entity." As the district court in *AstraZeneca Pharms. LP v. Becerra* observed:

> When a statute does not include even a single reference to the pertinent word (e.g., "pharmacy"), it is highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous directive with respect to that word. Here, the absence of any reference to 'pharmacies' is a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.[63]

HHS stated in its 1996 Guidance that the 340B Program "is silent as to permissible drug distribution systems" and contains "many gaps."[64] Additionally, the practice of pharmacy is an area traditionally left to state regulation.[65]

Based on the record, Arkansas's covered entities have filled in this gap through contract pharmacy

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[63] 543 F. Supp. 3d 47, 59 (D. Del. 2021).

[64] 61 Fed. Reg. at 43,549.

[65] *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021).

arrangements. The 340B Program is not "so pervasive as to make reasonable the inference that Congress left no room for States" to protect their specific drug distribution systems.[66] This is not "a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws . . . ."[67] Accordingly, Act 1103 is not subject to field preemption under the 340(B) Program.

2. Impossibility Preemption

To establish impossibility preemption, a party must be unable to comply with both federal law and state law.[68] When determining whether impossibility preemption implies, a court must look to whether it is lawful under federal law to accomplish what the state law requires.[69] The 340B Program provides that "a covered entity shall not resell or otherwise transfer" drugs to any "person who is not a patient of the entity."[70] Plaintiff contends that this provision bars the distribution of 340B-discounted drugs by covered entities to anyone other than their patients, which Plaintiff contends Act 1103 requires. I disagree.

Under the "replenishment model," which is used in Arkansas, manufacturers ship prescription drugs

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66 *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947).

67 *Id.*

68 *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011); *Merck Sharp & Dohme Corp. v. Albrecht*, —— U.S. ——, 139 S.Ct. 1668, 1672, 203 L.Ed.2d 822 (2019).

69 See *id.*

70 42 U.S.C. § 256b(a)(5)(B).

to pharmacies for dispensing to all patients. At the time of dispensing, the pharmacies do not know whether the prescriptions were written by medical providers at covered entities and qualify for 340B discounts. After 340B eligibility is later determined (typically using an algorithm), the manufacturers process charge backs to account for the 340B Program drugs' discounted prices. The covered entities never physically possess the drugs.[71]

Plaintiff contends Act 1103 requires manufacturers to participate in diversion because the drugs are delivered to contract pharmacies, instead of the covered entities' patients.

However, to the extent that contract pharmacy arrangements can be characterized as transfers or resales to non-patients, Plaintiff's position is not a reasonable construction of the statute. The 340B Program's non-transfer/resale provision refers to situations where medications are given to individuals who are not receiving health care services from covered entities or are receiving services inconsistent with the type of services for which the covered entity qualified for 340B status.[72]

I note that it is beyond my purview to determine whether purchases made using the replenishment model constitute diversion as Congress explicitly required manufacturers to address diversion and duplicate-discounting concerns in the ADR process and to audit covered entities before availing

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[71] See *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 61 (D. Del. 2021).

[72] See *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 194 n. 50 (D.N.J. 2021).

themselves of the ADR process.[73] There can be no dispute that Congress mandated that any concerns regarding diversion be addressed first through ADR procedures, not in federal court. Accordingly, Act 1103 does not require illegal conduct under the 340(B) Program and is not preempted under the impossibility doctrine.

3. Obstacle Preemption

Obstacle preemption requires a more thorough analysis than impossibility preemption. The Supreme Court has previously said:

> What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects: For when the question is whether a Federal act overrides a state law, the entire scheme of the statute must of course be considered and that which needs must be implied is of no less force than that which is expressed. If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.[74]

Plaintiff argues that Act 1103 is preempted because it places contract pharmacies on the 340(B) Program's covered entities list and interferes with the

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[73] 42 U.S.C. § 256b(d)(3)(B)(iv).

[74] *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000) (internal citations and quotations omitted).

340B Program's enforcement mechanism, thereby undermining the purpose of the 340B Program. In response, Defendants contend that Act 1103 only applies to the distribution of the discounted drugs and the contracts between covered entities and pharmacies within the state, not pricing.

I agree with the Defendant and Intervenors. Even though the title of Act 1103 includes pricing in its name, the effects of the disputed provisions are limited to the distribution of and access to the discounted drugs. Plaintiff has provided no evidence that Act 1103 interferes with PPA agreements between covered entities and HHS, or, in effect, adds contract pharmacies to the covered entities list. The drug-ceiling price has already been set at the point Act 1103 becomes applicable to any specific drug shipment. Act 1103 has no bearing on setting the ceiling price. Further, the penalties that may be assessed for violations of Act 1103 relate to activities outside the scope of the 340(B) Program's enforcement procedures which are focused overcharging covered entities.[75] Accordingly, Act 1103 is not obstacle to the purpose and objective of the 340(B) Program.

D. FDCA Preemption

Plaintiff contends that Act 1103 is preempted by the FDCA's Risk Evaluation and Mitigation Strategies ("REMS") program. The REMS program was established in 2007 to ensure the safe use of potentially high-risk products that might otherwise not be approved for use.[76] The Food and Drug

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[75] *Id.* at 256b(a)(1), (a)(4), (b)(1).

[76] 21 U.S.C. § 355-1.

Administration ("FDA") can require a REMS when "necessary to ensure that the benefits of the drug outweigh the risks of the drug."[77] To evaluate a REMS program, the FDA must consider whether the REMS requirements are "unduly burdensome on patient access to the drug," whether they "minimize the burden on the health care delivery system," and whether the REMS program is "compatible with established distribution, procurement, and dispensing systems for drugs."[78] Under the statute, the FDA is permitted to require, that "pharmacies . . . that dispense [a] drug [covered by a REMS] are specially certified" or that a drug "be dispensed to patients only in certain health care settings."[79] A manufacturer who violates a REMS is subject to federal monetary penalties and potentially criminal liability.[80]

Plaintiff contends that Act 1103 requires manufacturers to provide contract pharmacies the 340(B) Program's discounted drugs regardless of whether the drug is subject to the REMS program. Plaintiff argues that manufacturers are forced to choose between either violating federal law or state law.

However, the FDCA does not include any statement preempting state laws governing

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77 *Id.* § 355-1(a).

78 *Id.* § 355-1(f)(2)(C), (D)(ii).

79 *Id.* § 355-1(f)(3)(B)–(C).

80 See *id.* § 352(y); *id.* § 355(p); *id.* § 333(f)(4); *id.* § 333(a).

distribution of prescription drugs.[81] Nothing in Act 1103 prevents manufacturers from limiting the pharmacies that may dispense drugs as required under a REMS. Act 1103 does not regulate drug safety. Again, Act 1103 prevents drug manufacturers from refusing to supply 340(B) Program discounted drugs ordered by covered entities solely because the covered entity has an arrangement with any number of contract pharmacies. Act 1103 and the FDCA regulate completely different subject matter and activities. Accordingly, the FDCA does not preempt Act 1103.

CONCLUSION

For the reasons set out above, Plaintiff's Motion for Summary Judgment on Claim I (Doc. No. 24) is DENIED. Intervenors' Cross-Motion for Summary Judgment on Claim I (Doc. No. 35) is GRANTED. Defendant Leslie Rutledge's Cross-Motion for Summary Judgment (Doc. No. 32) is DENIED as MOOT. The case will proceed to the Commerce Clause claim issue.

IT IS SO ORDERED this 12th day of December, 2022.

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[81] *Wyeth v. Levine*, 555 U.S. 555, 567, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 941 (8th Cir. 2011).

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 22-3675

Pharmaceutical Research and Manufacturers of America

Appellant

v.

Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department, et al.

Appellees

American Hospital Association, et al.

Amici on Behalf of Appellee(s)

Washington Legal Foundation and Kalderos, Inc.

Amici on Behalf of Appellant(s)

Appeal from U.S. District Court for the Eastern District of Arkansas – Central
(4:21-cv-00864-BRW)

[2024 WL 1919676]

ORDER

The petition for rehearing en banc is denied. The petition for rehearing by the panel is also denied.

Chief Judge Colloton, Judge Benton and Judge Kelly did not participate in the consideration or decision of this matter.

May 02, 2024

Order Entered at the Direction of the Court:
Acting Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Stephanie N. O'Bannon

42 U.S.C. § 256b

§ 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical

assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)]).

(B) An entity receiving a grant under section 256a[1] 1 of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II[1] of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

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1 See References in Text note below.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2)[1] of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share

adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)(iii)], or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i–4(c)(2)]), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(C)(i)], or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both

meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C. 1396r–8].

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act [42 U.S.C. 1396r–8(a)(5)(C)] shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this

subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs[2] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[2] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certifications of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a

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[2] So in original. Probably should be "subparagraph".

process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such

entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act [42 U.S.C. 1396a(a)(5)] of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions

(1) In general

In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C. 1396r–8(k)].

(2) Covered drug

In this section, the term "covered drug"—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act [42 U.S.C. 1396r–8(k)(2)]); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act [42 U.S.C. 1396r–8(k)(3)(A)], a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub. L. 111–152, title II, §2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health

and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which—

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that

knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by

which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).[1]

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[3] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to

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[3] So in original. Probably should be "subsection".

be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition.

Ark. Code Ann. §§ 23-92-601 to -606

23-92-601. Title.

This subchapter shall be known and may be cited as the "340B Drug Pricing Nondiscrimination Act".

23-92-602. Definitions.

As used in this subchapter:

(1) "Patient" means an individual seeking medical diagnosis and treatment;

(2) "Pharmacy" means the same as defined in § 17-92-101;

(3) "Provider" means a licensed pharmacist as defined in § 17-92-101;

(4)

(A) "Third party" means:

(i) A payor or the payor's intermediary; or

(ii) A pharmacy benefits manager.

(B) "Third party" does not include:

(i) The Arkansas Medicaid Program;

(ii) A risk-based provider organization as established under the Medicaid Provider-Led Organized Care Act, § 20-77-2701 et seq.; or

(iii) A self-insured governmental plan or a pharmacy benefits manager for a self-insured governmental plan; and

(5) "340B drug pricing" means the program established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.

23-92-603. Third-party requirements.

A third party shall:

(1) Inform a patient that the patient is not required to use a mail-order pharmacy;

(2) Obtain a signed waiver from a patient before allowing the use of a mail-order pharmacy;

(3) Make drug formulary and coverage decisions based on the third party's normal course of business;

(4) Allow a patient the freedom to use any pharmacy or any provider the patient chooses, whether or not the pharmacy participates in 340B drug pricing; and

(5) Eliminate discriminatory contracting as it relates to:

(A) Transferring the benefit of 340B drug-pricing savings from one (1) entity, including critical access hospitals, federally qualified health centers, other hospitals, or 340B drug-pricing participants and their underserved patients, to another entity, including without limitation pharmacy benefits managers, private insurers, and managed care organizations;

(B) Pricing that occurs when offering a lower reimbursement for a drug purchased under 340B drug pricing than for the same drug not purchased under 340B drug pricing;

(C) Refusal to cover drugs purchased under 340B drug pricing;

(D) Refusal to allow 340B drug-pricing pharmacies to participate in networks; and

(E) Charging more than fair market value or seeking profit sharing in exchange for services involving 340B drug pricing.

23-92-604. Third party and pharmaceutical manufacturer — Prohibitions.

(a) A third party shall not:

(1) Coerce a patient into using a mail-order pharmacy;

(2) Require a patient to use a mail-order pharmacy;

(3) Discriminate, lower the reimbursement, or impose any separate terms upon a pharmacy in any other third party contract on the basis that a pharmacy participates in 340B drug pricing;

(4) Require a pharmacy to reverse, resubmit, or clarify a 340B drug-pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing;

(5) Require a billing modifier to indicate that the drug or claim is a 340B drug-pricing claim unless the drug or claim is being billed to the fee-for-service Arkansas Medicaid Program;

(6) Modify a patient's copayment on the basis of a pharmacy's participation in 340B drug pricing;

(7) Exclude a pharmacy from a network on the basis of the pharmacy's participation in 340B drug pricing;

(8) Establish or set network adequacy requirements based on 340B drug pricing participation by a provider or a pharmacy; or

(9) Prohibit an entity authorized to participate in 340B drug pricing or a pharmacy under contract with an entity authorized to participate in 340B drug pricing from participating in the third party's provider network on the basis of participation in 340B drug pricing.

(b) A third party that is a pharmacy benefits manager shall not base the drug formulary or drug

coverage decisions upon the 340B drug-pricing status of a drug, including price or availability, or whether a dispensing pharmacy participates in 340B drug pricing.

(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.

23-92-605. Pharmacy claims.

All pharmacy claims processed by a pharmacy that participates in 340B drug pricing are final at the point of adjudication.

23-92-606. Rules.

The Insurance Commissioner shall promulgate rules to implement this subchapter.

RULE 123
340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS

[003-22-22 Ark. Code R. §§ I-VII]

I. AUTHORITY

This rule is issued pursuant to Ark. Code Ann. § 23-92-606 which mandates that the Insurance Commissioner ("Commissioner") shall a promulgate rule to implement the subchapter pertaining to the 340B Drug Pricing Nondiscrimation Act.

II. DEFINITIONS

As used in this Rule:

(1) "Arkansas-based community pharmacy" means a Pharmacy licensed and located in this State;

(2) "Covered entity" means an entity that meets the 340B Drug Pricing Program's eligibility requirements found at 42 U.S.C. § 256b(a)(4) to participate and is enrolled in the 340B Drug Pricing Program;

(3) "Patient" means an individual who has an established relationship with a covered entity and is

seeking medical diagnosis and treatment from the covered entity

(4) "Pharmacy" means the same as defined in § 17-92-101;

(5) "Provider" means a licensed pharmacist as defined in § 17-35 92-101;

(6)(A) "Third party" means:

(i) A payor or the payor's intermediary;

or

(ii) A pharmacy benefits manager.

(B) "Third party" does not include:

(i) The Arkansas Medicaid Program;

(ii) A risk-based provider organization as established under the Medicaid Provider-Led Organized Care Act, § 20-77-2701 et seq.; or

(iii) A self-insured governmental plan or a pharmacy benefits manager for a self-insured governmental plan; and

(7) "340B drug pricing" means the acquisition and delivery of 340B-priced drugs as established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.

III. THIRD PARTY REQUIREMENTS

A third party shall:

(1) Inform a patient that the patient is not required to use a mail-order pharmacy;

(2) Obtain a signed waiver from a patient before allowing the use of a mail-order pharmacy;

(3) Make drug formulary and coverage decisions based on the third party's normal course of business;

(4) Allow a patient the freedom to use any pharmacy or any provider the patient chooses, whether or not the pharmacy participates in 340B drug pricing; and

(5) Eliminate discriminatory contracting as it relates to:

(A) Transferring the benefit of 340B drug-pricing savings from one (1) entity, including critical access hospitals, federally qualified health centers, other hospitals, or 340B drug-pricing participants and their underserved patients, to another entity, including without limitation pharmacy benefits managers, private insurers, and managed care organizations;

(B) Pricing that occurs when offering a lower reimbursement for a drug purchased under 340B drug pricing than for the same drug not purchased under 340B drug pricing;

(C) Refusal to cover drugs purchased under 340B drug pricing;

(D) Refusal to allow 340B drug-pricing pharmacies to participate in networks; and

(E) Charging more than fair market value or seeking profit sharing in exchange for services involving 340B drug pricing.

IV. THIRD PARTY AND PHARMACEUTICAL MANUFACTURER-PROHIBITIONS

(a) A third party shall not:

(1) Coerce a patient into using a mail-order pharmacy;

(2) Require a patient to use a mail-order pharmacy;

(3) Discriminate, lower the reimbursement, or impose any separate terms upon a pharmacy in any other third party contract on the basis that a pharmacy participates in 340B drug pricing;

(4) Require a pharmacy to reverse, resubmit, or clarify a 340B drug-pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing;

(5) Require a billing modifier to indicate that the drug or claim is a 340B drug-pricing claim unless the drug or claim is being billed to the fee-for-service Arkansas Medicaid Program;

(6) Modify a patient's copayment on the basis of a pharmacy's participation in 340B drug pricing;

(7) Exclude a pharmacy from a network on the basis of the pharmacy's participation in 340B drug pricing;

(8) Establish or set network adequacy requirements based on 340B drug pricing participation by a provider or a pharmacy; or

(9) Prohibit an entity authorized to participate in 340B drug pricing or a pharmacy under contract with an entity authorized to participate in 340B drug pricing from participating in the third party's provider network on the basis of participation in 340B drug pricing.

(b) A third party that is a pharmacy benefits manager shall not base the drug formulary or drug coverage decisions upon the

340B drug-pricing status of a drug, including price or availability, or whether a dispensing pharmacy participates in 340B drug pricing.

(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.

The prohibitions in this subsection shall only apply to drug pricing contracts with or on behalf of a covered entity located and conducting business in Arkansas and is inapplicable to conduct occurring exclusively and entirely outside the boundaries of this State.

The prohibitions in this subsection shall also only apply to 340B drug pricing contract pharmacy arrangement transactions pertaining to a patient of a covered entity.

V. PHARMACY CLAIMS

All pharmacy claims processed by a pharmacy that participates in 340B drug pricing are final at the point of adjudication.

VI. PENALTIES

The penalties, actions or orders, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

VII. EFFECTIVE DATE

This Rule is effective after review and approval by the Arkansas Legislative Council, ten (10) days after filing of the approved Rule with the Arkansas Secretary of State.

_____

ALAN MCCLAIN
INSURANCE
COMMISSIONER

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DATE

SUMMARY

ARKANSAS INSURANCE DEPARTMENT
PROPOSED RULE 123

340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS

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To: Arkansas Legislative Council & Arkansas Bureau of Legislative Research

From: Booth Rand, Managing Attorney, Arkansas Insurance Department

CC: Alan McClain, Arkansas Insurance Commissioner; Jim Brader, General Counsel;

Date: May 25, 2022

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LEGISLATIVE AUTHORITY FOR RULE

This rule is issued pursuant to Ark. Code Ann. § 23-92-606 ("Act 1103 of 2021") which mandates that the Insurance Commissioner ("Commissioner") shall a promulgate rule to implement the subchapter pertaining to the 340B Drug Pricing Nondiscrimation Act ("Act 1103").

BACKGROUND AND PURPOSE OF RULE

The purpose of this Rule is to help reduce or remove federal commerce clause and preemption claims against Act 1103 of 2021 which have been raised in Federal District Court, by supplying new definitions not in the Act, and to add penalties for violations of the Act, not supplied in the Act.

EXPLANATION OF THE PROPOSED RULE

AID is re-noticing this earlier proposed Rule governing Act 1103 and the 340b drug program. A

brief background or explanation about why we are re-noticing this Rule is important.

On or about February 22, 2022, following approval by ADOC and the Governor's office allowing promulgation of the rule, the Department filed a proposed draft Rule, Rule 123 "340b Drug Program Nondiscrimation Requirements." Following filing of the proposed Rule at BLR/ALC, the Department held a hearing on the proposed draft rule on April 14, 2022. The Department received significant opposition to the proposed rule from the Arkansas Hospital Association and area hospitals, primarily on the proposed rule's requirements which (1) required arbitration of complaints with the Federal agency, HRSA, before applying state law enforcement, and (2) the Department limited jurisdiction of the Rule to 340b hospital covered entities which had a direct contract with the pharmaceutical manufacturers. The reason for the proposed limitations were due to concerns over federal pre-emption and federal commerce clause infringement claims derived from Act 1103 itself. The Department and the AG's Office are currently in litigation in federal court against PHARMA which has raised these concerns.

Following the hearing, AID met with the AG's office and intervenors and the hospital association related to the Department's proposed language. AID agreed to remove the arbitration and direct contracting limitations. AID also agreed to supply different definition language to help reduce the federal preemption and commerce clause claims raised against Act 1103.

We are re-notifying the public and re-filing this proposed Rule because we believe we may be making a material change to the earlier filed Rule. So out of

an abundance of caution we are filing this with BLR/ALC and going through rulemaking again.

The proposed re-notified Rule in this re-filing provides the following changes:

- We removed any arbitration requirement with HRSA before we begin state enforcement to help reduce hospital objections or concerns
- We removed the direct contracting language between pharmaceutical manufacturers and covered entity hospitals as to the application of Act 1103 to help reduce hospital objections or concerns
- We supplied a definition of "Arkansas-based community pharmacy" to mean a pharmacy licensed and located in this State to help reduce commerce clause infringement claims
- We supplied a definition of "340B drug pricing" to mean "acquisition and delivery of 340B-priced drugs" as established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585, to help reduce federal pre-emption claims by explaining we were not regulating "pricing" of the drugs
- We supplied a penalties and fines provision not supplied in Act 1103.

DRAFT
RULE 123
340B DRUG PROGRAM
NONDISCRIMINATION REQUIREMENTS

* * *

VIII. ENFORCEMENT POLICY

For complaints filed at the Arkansas Insurance Department ("Department") for alleged violations of Ark. Code Ann. Ark. Code Ann. § 23-92-604(c)(1) and Ark. Code Ann. § 23-92-604(c)(2), the complainant's covered entity must first exhaust all available federal arbitration and federal administrative rights for cancellation or limitation on contracting with outside pharmacies through United States Department of Health and Human Services ("HRSA") rules, and if HRSA determines, under the administrative dispute resolution process described in 42 U.S.C. § 256b(d)(3) and 42 C.F.R. §§ 10.20–24, that a drug manufacturer has improperly denied a pharmacy 340B drug pricing, or that a drug manufacturer has improperly prohibited 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; then, upon such violations, such actions may be reviewed to constitute an unfair and deceptive act or practice under Ark. Code Ann. §§ 23-66-209 and 23-66-210.

ALAN MCCLAIN
INSURANCE
COMMISSIONER

DATE