United States Court of Appeals
For the Eighth Circuit

No. 22-3675

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)

Appeal from United States District Court
for the Eastern District of Arkansas - Central

Submitted: September 20, 2023
Filed: March 12, 2024

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 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

[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).

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

states, like Arkansas, state law prohibits most nonprofit and 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 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.

[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.

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 (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 (1819). "Congress may . . . pre-empt, *i.e.*, invalidate, a state law through federal legislation." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (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 (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). Congress may impliedly preempt state law "either through 'field' pre-emption or 'conflict' pre-emption." *Oneok, Inc.*, 575 U.S. at 377. 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 (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 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (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 (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 (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 (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; 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. 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; *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; *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. 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 (quoting *Arizona v. United States*, 567 U.S. 387, 401 (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 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (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, "the 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

(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 (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 (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 (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. Impossibility preemption "arises when 'compliance with both federal and state regulations is a physical impossibility.'" *Hillsborough Cnty., Fla.*, 471 U.S.

at 713 (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (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.
