IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

ALAN MCCLAIN, *et al.*,

Defendants.

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

INTERVENOR-DEFENDANTS MEMORANDUM OF LAW IN SUPPORT OF THEIR CROSS MOTION FOR SUMMARY JUDGMENT ON CLAIM I (PREEMPTION) AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT ON CLAIM I (PREEMPTION)

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INTRODUCTION

Arkansas Act 1103 is not preempted by federal law. Ark. Code Ann. §§ 23-92-601–606. Plaintiff, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), mischaracterizes Act 1103, the federal 340B drug discount program at 42 U.S.C. § 256b, and contract pharmacy arrangements that permit Arkansas health care providers that participate in the 340B Program ("covered entities) to dispense drugs to their patients. Act 1103 and the 340B Program regulate different areas: Act 1103 governs drug distribution within the state of Arkansas, while the 340B Program governs drug pricing. The 340B Program has not occupied the field of drug distribution, which Congress has traditionally left to the states. Likewise, no conflict exists between Act 1103 and the 340B Program because Act 1103 does not add new participants to the 340B Program and does not impede federal oversight of 340B pricing. Act 1103 simply requires pharmaceutical manufacturers to permit Arkansas covered entities to dispense discounted drugs to their patients at community pharmacies. Act 1103 also does not conflict with federal Risk Evaluation and Mitigation Strategies ("REMS") because Act 1103 does not require manufacturers to ship to pharmacies not authorized under REMS.

Act 1103 regulates 340B drug *distribution* arrangements in two ways. First, the law prohibits a manufacturer from "denying [an Arkansas pharmacy] access" to drugs purchased by a covered entity. Ark. Code Ann. § 23-92-604(c)(1). Second, the law proscribes a manufacturer from restricting the acquisition and receipt of 340B-priced drugs purchased by a covered entity under a 340B contract pharmacy arrangement with an Arkansas pharmacy. *Id*. § 23-92-604(c)(2). Act 1103 does not regulate whether a manufacturer has overcharged a covered entity for drugs that have been purchased by the covered entity. Act 1103, therefore, does not intrude into the field of 340B drug pricing and purchasing.

Protecting distribution of 340B-priced drugs to Arkansas contract pharmacies is squarely within the ambit of Arkansas' police power to regulate the public health and safety of its citizens. Arkansas safety-net providers rely on contract pharmacy distribution arrangements to obtain 340B-priced drugs to be dispensed to their patients. Without contract pharmacies, many Arkansas safety-net healthcare providers would be unable to dispense 340B-priced drugs to their vulnerable patients to treat often life-threatening conditions. By preserving the right of Arkansas safety-net providers to dispense drugs to patients at community pharmacies, Act 1103 protects the public health and safety of Arkansans from the restrictive and detrimental distribution policies of drug manufacturers. Act 1103 is squarely within the authority of Arkansas to regulate drug distribution; it is not in conflict with federal law, and hence it is not preempted.

The federal 340B Program, in contrast, is a pricing program and does not regulate distribution. As a condition of having their products covered by Medicaid and Medicare Part B, pharmaceutical manufacturers agree to sell outpatient drugs to statutorily defined covered entities, which include community health centers, clinics that receive federal grants, and certain hospitals that treat large numbers of uninsured and under-insured patients. The 340B statute specifies the prices of drugs subject to discounts and the entities that may participate and says nothing about how drugs travel from manufacturers to patients, which is the subject of Act 1103. Several federal courts have affirmed that the 340B statute is silent on distribution. The Department of Health and Human Services has no authority to issue regulations governing 340B distribution. Indeed, Congress has traditionally left the regulation of drug distribution to the states, and Congress did the same in the 340B statute. Therefore, no conflict exists between Act 1103 and the 340B Program. Each operates in separate spheres, distribution and pricing.

Act 1103 also does not conflict with REMS. The REMS program is established at 21 U.S.C. § 355-1 to ensure the safe use of potentially risky pharmaceutical products. The statute addresses how certain REMS-regulated drugs are transported, stored, and administered. Specialty pharmacies can and do serve simultaneously as REMS-authorized participants and as covered entities' 340B contract pharmacies. If a pharmacy is not permitted to dispense a REMS drug, it would never receive REMS drugs. Act 1103 does not force a manufacturer to distribute REMS drugs to a pharmacy that is not permitted to dispense such drugs regardless of whether the pharmacy is a contract pharmacy.

Finally, a material fact remains in dispute that defeats PhRMA's motion for summary judgment. PhRMA fundamentally mischaracterizes contract pharmacies, which do not take title to 340B drugs. Ownership remains with the covered entity and is not transferred to the contract pharmacy as PhRMA asserts. Thus, Act 1103 does not add new participants to the 340B Program. This factual misstatement infects all of PhRMA's preemption arguments.

Accordingly, this Court should deny PhRMA's motion for summary judgment. Because nothing in the 340B statute precludes a state from regulating the distribution of 340B drugs, including protecting 340B contract pharmacy arrangements, and because Act 1103 does not conflict with the 340B Program or REMS, this Court should grant Intervenor-Defendants' motion for summary judgment.

BACKGROUND

I. The 340B Drug Pricing Program

The 340B Drug Pricing Program ("340B Program") is named for Section 340B of the Public Health Service Act ("PHSA"), which was enacted as part of the Veterans Health Care Act of 1992 ("VHCA") and requires drug manufacturers to offer discounts on covered outpatient

drugs to specified safety-net health care providers as a condition of the manufacturers' drugs being reimbursed by Medicaid and Medicare Part B.[1] 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1). Safety-net hospitals and clinics that participate in the 340B Program—referred to as "covered entities" in the 340B statute—provide health care and other critical services to the neediest individuals, regardless of their ability to pay. Covered entities must meet strict eligibility criteria specified in the 340B statute in order to enroll in the Program. *Id*. § 256b(a)(4). Each category of covered entity receives some form of federal assistance to treat the nation's most vulnerable patients. The 340B Program is administered by the Health Resources and Services Administration ("HRSA"), which is a subcomponent of the federal Department of Health and Human Services ("HHS").

The genesis of the 340B Program can be traced to 1990 when Congress established the Medicaid Drug Rebate Program ("MDRP") to combat rising drug costs to state Medicaid programs. *Id*. § 1396r-8. The MDRP requires pharmaceutical manufacturers to provide rebates to state Medicaid programs on outpatient drugs and biological products furnished to Medicaid beneficiaries.[2] For brand name drugs, those rebates were calculated based on the difference between a given drug's average price and its lowest price, or "best price," in the U.S. marketplace, subject to certain narrow exceptions and a minimum difference of at least 12.5 percent. *Id*. § 1396r-8(c)(1). Manufacturers responded to passage of the MDRP statute by raising their "best prices" on covered outpatient drugs for preferred customers, including large governmental purchasers like the Department of Veterans Affairs as well as non-profit safety-net

[1] Medicare Part B covers physician, hospital outpatient, and certain other non-hospital services. 42 U.S.C. § 1395k.
[2] "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins." *What Are "Biologics" Questions and Answers*, FDA (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

providers like federally qualified health centers ("FQHCs") and public hospitals. H.R. Rep. No. 102-384, pt. 2, at 9 (1992). Manufacturers "promptly cancelled discount contracts, terminated special-price practices, and raised the prices they charged" to safety-net providers. *Id*. at 10. Concerned about rising "[p]rices paid for outpatient drugs by the [Department of Veterans Affairs], and some Federally-funded clinics and public hospitals," Congress enacted the VHCA in order, among other things, "to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs" that they purchase. *Id*. at 7; Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943 (1992). Section 602 of the VHCA established the 340B Program, and Section 603 established a separate drug discount program for the four largest purchasers of drugs within the federal government, including the Department of Veterans Affairs.[3] Veterans Health Care Act of 1992 §§ 602-603.

The 340B Program makes drugs more affordable for covered entities and, by so doing, allows covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12. Covered entities provide significant levels of uncompensated care, and the discounts available through the 340B Program help relieve the financial burden that uncompensated care creates. Covered entities essentially lose less money on prescription drugs under the 340B Program for their uninsured and underinsured patients. And by mitigating these losses, they can be more generous with reducing or waiving patient copayments at the pharmacy counter or by providing other necessary services. The 340B Program also generates revenue for covered entities so that they are less dependent on taxpayer support. To the extent a covered entity patient has prescription drug coverage, the difference between the insurer's payment and the

[3] The three other largest federal purchasers are the Department of Defense, Public Health Service, and Coast Guard.

discounted price is income to the covered entity to supplement federal funds, thus allowing the covered entity to stretch its resources to treat more patients and to provide more services. *Id*. at 12.

II. 340B Contract Pharmacy Arrangements

Most illnesses and injuries cannot be adequately treated or managed without the patient taking one or more medications. That means a provider of health care—whether a doctor, clinic or hospital—must ensure that patients have access to a pharmacy to fill their prescriptions. For this reason, many providers own and operate their own pharmacies, referred to as in-house pharmacies. However, because the construction and management of a pharmacy is expensive and requires special expertise, many providers cannot afford to operate in-house pharmacies and instead must contract with independently-owned pharmacies to meet the pharmacy needs of their patients. Providers with large service areas also contract with independent pharmacies convenient and accessible to where the provider's patients reside. In addition, some medications require special storage and handling and can only be dispensed by a specialty pharmacy,[4] through a mail order program, or subject to a limited distribution network.[5]

Many 340B covered entities, including the Intervenor-Defendants, cannot fill prescriptions for their patients because they cannot afford to "expend precious resources to develop their own 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)

[4] A "[s]pecialty pharmacy focuses on high cost, high touch medication therapy for patients with complex disease states. Medications in specialty pharmacy range from oral to cutting edge injectable and biologic products. The disease states treated range from cancer, multiple sclerosis and rheumatoid arthritis to rare genetic conditions." *Specialty Pharmacies*, Am. Pharmacists Ass'n, https://www.pharmacist.com/Practice/Patient-Care-Services/Specialty.

[5] "Under a limited distribution network, a manufacturer contracts with one or a few specialty pharmacies to dispense high-maintenance medications. The specialty pharmacies are selected based on their expertise and ability to offer optimal patient outcomes." *Limited Distribution Drugs 101*, Clarivate (Sept. 27, 2019), https://clarivate.com/blog/limited-distribution-drugs-101/.

("1996 Guidance"). They rely instead on independent retail pharmacies to dispense drugs, typically oral medications, on their behalf.[6] These arrangements are established by contract between covered entities and pharmacies, so they are often called "contract pharmacy arrangements," and the pharmacies are generally referred to as "contract pharmacies."

Contract pharmacies are not permitted to purchase 340B drugs. Drugs dispensed by contract pharmacies are purchased by the covered entity using a "bill to/ship to" procedure—the drugs are purchased by, and billed to, the covered entity but shipped to the contract pharmacy.[7] After receiving the covered entity's 340B drugs, the contract pharmacy dispenses the drugs to the covered entity's patients, collects reimbursement for the drugs from both the patient and the patient's third party payer (if any), and remits the collected reimbursement to the covered entity. The covered entity, in turn, pays the pharmacy a fee for its dispensing and billing services.

Contract pharmacy arrangements are built on the well-established commercial practice of one party purchasing and taking title to a product and a second party taking possession of the product on the first party's behalf. The covered entity purchaser takes title, but not physical possession, of the drugs and arranges for shipment of the drugs, usually by a drug wholesaler, to the contract pharmacy, which then takes physical custody of the drugs and dispenses them to the covered entity's patients on the covered entity's behalf. Contract pharmacy distribution arrangements are commonly used within the U.S. drug distribution system and are not unique to

[6] "Retail pharmacy" means a pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that serves patients of a healthcare facility only, such as a provider's institutional pharmacy, which is also referred to as a "closed-door" pharmacy. In many states, providers may operate both retail and institutional pharmacies. *See, e.g.*, 42 U.S.C. § 1396r-8(k)(10); Ark. Code Ann. § 17-92-101(12) ("'Pharmacy' means the place licensed by the Arkansas State Board of Pharmacy in which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed or sold at retail."; Ark. Code Ann. § 17-92-602 ("'Hospital Pharmacy' means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use or benefit of patients in a hospital.")

[7] *See FAQs*, HRSA, https://www.hrsa.gov/opa/faqs ("What is a 'ship to bill to' arrangement?").

the 340B Program. *See, e.g.*, Fed. Trade Comm'n, University of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010)[8]; 134 Cong. Rec. H6971-02 (1988) (statement of Rep. Charlie Rose) ("[H]ealth centers often include onsite pharmacies, or agreements with community pharmacists to ensure that the medicines needed to treat or control these chronic conditions are available"); *Social Security and Welfare Proposals, Hearing Before the H. Comm. on Ways and Means*, 91st Cong. 2129 (1969) (statement of Jacob W. Miller, Chairman, Comm. Pub. Affs., Am. Pharm. Ass'n) (stating that "[as] I am sure you are aware, many health care facilities do not maintain their own onsite pharmaceutical services … [r]ather, they look to the community pharmacies to provide such service on a contract basis").

For approximately 26 years, every drug manufacturer participating in the 340B Program, including PhRMA's members, honored contract pharmacy arrangements and treated contract pharmacies the same as in-house pharmacies. That changed abruptly, however, beginning in July 2020, when one manufacturer after another either fully eliminated or significantly restricted distribution of 340B drugs ordered through bill to/ship to arrangements. *See, e.g.,* Sanofi, *Sanofi Policy* (Feb. 1, 2021), https://340besp.com/sanofi-policy-2021-02-02-09_18_19.pdf. As of the date of filing this brief, eighteen manufacturers have unilaterally imposed restrictions on contract pharmacy arrangements.[9] These restrictions have deprived covered entities of the revenue and savings that Congress intended for the 340B Program, which reduces the resources available to

[8] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

[9] The following drug companies have restricted 340B drug distribution and are members of Plaintiff: AbbVie, Amgen Inc. ("Amgen"), AstraZeneca Pharmaceuticals LP ("AstraZeneca"), Bausch Health, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), Bristol Myer Squibb ("BMS"), Eli Lilly and Company ("Lilly"), Exelixis, Gilead Sciences, Inc. ("Gilead"), GlaxoSmithKline ("GKS"), Johnson & Johnson ("J&J"), Merck and Company ("Merck"), Novartis Pharmaceuticals Corporation ("Novartis"), Novo Nordisk, Inc. ("Novo Nordisk"), Pfizer Inc. ("Pfizer"), Sanofi-Aventis US LLC ("Sanofi"), United Therapeutics Corporation ("United Therapeutics"), and UCB.

covered entities to meet the needs of their vulnerable patients, including the need for affordable and accessible prescription drugs.

III. The Importance of Contract Pharmacies in Arkansas

Arkansas has a history of supporting and protecting the two constituencies that advocated for passage of Act 1103—safety-net providers and independently owned retail pharmacies. Examples of Arkansas legislation benefiting safety-net providers include: a recent law directing funds to hospitals to prevent closures and a Medicaid expansion package with enhanced reimbursement through private insurance. Ark. Code Ann. § 23-61-1002 (stating that "it is the intent of the General Assembly for the Arkansas Health and Opportunity for Me Program to be a fiscally sustainable, cost-effective, and opportunity driven program that . . . [s]trengthens the financial stability of the critical access hospitals and other small, rural hospitals"); Act 1497, S.B. 1020, 89th Gen. Assemb., Reg. Sess. (Ark. 2013); Act 1498, S.B. 1143, 89th Gen. Assemb., Reg. Sess. (Ark. 2013). An even longer list of helpful legislation was passed for the benefit of independent pharmacists, including a 2017 pharmacy practice act, a 2018 pharmacy benefit manager ("PBM") licensure law, and several other pieces of legislation designed to protect against PBM predatory practices. Ark. Code Ann. § 17-92-101 *et seq.* (Pharmacy Practice Act); Ark. Code Ann. § 23-92-501 *et seq.* (Pharmacy Benefits Manager Licensure Act); Ark. Code Ann. § 23-79-1801, *et seq.* (requiring PBMs to disclose if the plan is self-funded or fully insured on benefit cards).

The Arkansas legislature's interest in supporting independent pharmacists is one of the reasons 340B contract pharmacies are so important in Arkansas. For example, under Arkansas Code Sections 17-92-605(d) and 17-92-607, non-profit, tax exempt, and governmentally funded hospitals are prohibited from holding a license as a retail pharmacy. That law was enacted in

large part to protect Arkansas community pharmacies from retail competition by hospital-based pharmacies. As a result, most of the 340B hospitals in Arkansas have no way to participate in the 340B Program for filling retail prescriptions except through contract pharmacies. FQHCs are not legally barred from owning their own retail pharmacies, but most of them dispense 340B drugs through contract pharmacies due to the cost and resource demands associated with establishing and operating an in-house pharmacy. The reliance of Arkansas covered entities on contract pharmacies generates much-needed business for Arkansas independent pharmacists who are fighting to protect their livelihoods against the increasing threats posed by PBMs, vertically-integrated insurance companies, and chain drug stores.

IV. Arkansas Act 1103

In May 2021, the Arkansas legislature passed Act 1103, which was titled the "340B Drug Pricing Nondiscrimination Act." Ark. Code Ann. §§ 23-92-601–606. Act 1103 prohibits discriminatory conduct against covered entities that have the practical effect of denying Arkansas covered entities the benefit of the 340B Program. Among those benefits is the right of covered entities and their contract pharmacy partners to enter into bill to/ship to arrangements for the acquisition and distribution of 340B drugs. The legislative history of Act 1103 makes clear that the Arkansas legislature understood the importance of contract pharmacies for both Arkansas safety-net providers and Arkansas independent pharmacists and that such arrangements needed protection from drug company restrictions. *To Establish the 340B Drug Pricing Nondiscrimination Act, Hearing on H.B. 1881 Before the Ark. House of Representatives*, 93d Gen. Assembly Regular Session (Ark. 2021) (statement of Rep. Michelle Gray) (stating that "[l]ast year one manufacturer . . . decided that they would no longer ship . . . medications to the contract pharmacy," that the manufacturer said that "[i]f Hospital does contract with a pharmacy

. . . we are no longer going to send medications there because we are trying to limit the amount of drugs that we send at a reduced price," and that Act 1103 is aimed to protect Arkansas "patients, our pharmacies, [and] our hospitals.").

Most of the provisions within Act 1103 offer protection from PBMs and other third-party payers. For example, Act 1103 prohibits a third party payer from discriminating, lowering reimbursement for, or imposing any "separate terms" on a pharmacy on the basis that the pharmacy is a contract pharmacy in the 340B Program. Ark. Code Ann. § 23-93-604(a)(3). Act 1103 also prevents any third-party payer from prohibiting a covered entity or contract pharmacy from participating in the third party's provider network on the basis of participation in the 340B Program. *Id.* § 23-93-604(a)(9). None of these payer-related provisions are being challenged by PhRMA.

PhRMA's lawsuit focuses exclusively on the two provisions in Act 1103 intended to protect the free use of contract pharmacy arrangements in distributing 340B drugs within the state of Arkansas: The relevant provisions state that 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.

Id. § 23-93-604(c). The first provision prohibits a drug manufacturer from interfering with contractual relationships between contract pharmacies and covered entities. *Id.* § 23-92-604(c)(1). The second provision prohibits a manufacturer from preventing a contract pharmacy from receiving 340B-priced drugs on behalf of a covered entity. *Id.* § 23-92-604(c)(2).

V. Preemption

The Supreme Court has repeatedly held that Congress's purpose is the "ultimate touchstone" in every preemption case. *See Wyeth v. Levine*, 555 U.S. 555, 565 (2009) ("the purpose of Congress is the ultimate touchstone in every pre-emption case") (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)); *Barnett Bank of Marion Cnty., N.A. v. Nelson*, 517 U.S. 25, 31 (1996) (explaining that where "explicit pre-emption language does not appear, or does not directly answer the question . . . courts must consider whether the federal statute's 'structure and purpose,' or nonspecific statutory language, nonetheless reveal a clear, but implicit, pre-emptive intent") (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). A state law may be preempted by a federal law either (1) through an express preemption clause, where Congress explicitly states that state law is preempted; or (2) through implied preemption, where a Court infers that a state law is preempted based on a federal law, including the federal law's text, structure, and Congress's intent. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

There are three forms of implied preemption: (1) field preemption, applicable when Congress has manifested an intention that the federal government occupy an entire field of regulation, *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 206 (1983) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); (2) impossibility preemption, applicable when it is physically impossible to comply with both federal and state laws, *Fla. Lime & Avocado Growers v. Paul*, 373 U.S. 132, 142-43 (1963); and (3) obstacle preemption, applicable when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

VI. Intervenor-Defendants

Piggott Community Hospital ("PCH") and the FQHC members of Community Health Centers of Arkansas ("CHCA") rely on the 340B Program to support their missions of caring for low-income and other vulnerable patients. But safety-net providers cannot effectively participate in the 340B Program for self-administered drugs in the absence of a retail pharmacy through which they may purchase and dispense such drugs. PCH is prohibited from owning a pharmacy, and most of CHCA's members cannot afford to establish their own pharmacies. For these reasons, PCH and CHCA's member health centers contract with independently-owned pharmacies to meet the pharmacy needs of their patients.

PCH is located in Piggott, Arkansas and is designated under the Medicare program as a critical access hospital ("CAH").[10] PCH is owned and operated by the City of Piggott and participates in the 340B Program based on its governmental ownership and CAH status. 42 U.S.C. §§ 256b(a)(4)(N), 1395i–4(c)(2); 42 C.F.R. §§ 485.601–485.647. As a requirement of its CAH designation, PCH is located in an area that serves residents who would otherwise be required to travel long distances to receive inpatient medical care. *See* 42 U.S.C. § 1395i–4(c)(2)(B)(i)(I); 42 C.F.R. § 485.610(c). As an Arkansas governmentally funded hospital, PCH is prohibited from owning an on-site retail pharmacy. *See* Ark. Code Ann. §§ 17-92-605(d), 17-92-607 (making it unlawful for any nonprofit, tax exempt, or governmentally funded hospital to acquire direct or indirect interest in, or otherwise hold directly or indirectly a pharmacy license for the retail sale of drugs). Therefore, PCH relies exclusively on independently-owned contract

[10] CAHs are small rural hospitals or health centers that receive favorable Medicare reimbursement to ensure their financial viability and hence access to health care in rural areas. *See* 42 C.F.R. §§ 485.601–485.647; *Critical Access Hospitals*, CMS (Dec. 1, 2021), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.

pharmacies to fill prescriptions with 340B drugs for its patients, many of whom are uninsured and low income.

CHCA is a non-profit membership organization comprised of eleven community health centers located in Arkansas that provide primary health services in over one-hundred-and-twenty service locations. CHCA members treat large numbers of uninsured and underinsured low-income Arkansans as a condition of community health care status. All of CHCA's members participate in the 340B Program by virtue of their receipt of FQHC funding under Section 330 of the PHSA. 42 U.S.C. §§ 254b, 256b(a)(4)(A), 1396d(l). Importantly, Section 330 requires health centers to offer "pharmaceutical services as may be appropriate" and to provide care regardless of a patient's ability to pay. 42 U.S.C. §§ 254b(b)(1)(A)(i)(I), 254b(k)3(G)(iii). The majority of CHCA's eleven health centers do not own their own pharmacies. Instead, they rely on outside, community-based retail pharmacies to order, receive, and dispense 340B self-administered medications on behalf of their patients.

STANDARD OF REVIEW

Summary judgment is granted if the evidence, viewed in the light most favorable to the nonmoving party, presents no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 246 (1986). The "substantive law will identify which facts are material" and "[d]isputes over facts that *might* affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248 (emphasis added). "[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial." *Id.* at 249.

ARGUMENT

Act 1103 does not intrude into the federal 340B scheme because the 340B statute governs pricing of drugs, and Act 1103 solely governs distribution of 340B-priced drugs to Arkansas pharmacies. The 340B statute establishes the 340B ceiling price and the entities eligible to purchase drugs at that price. 42 U.S.C. § 256b(a)(1), (4). The 340B statute does not regulate how 340B drugs are acquired and distributed, in large part because such matters are generally governed under state law. When enacting the 340B statute, Congress considered and rejected limitations on drug distribution, and Congress has been aware of 340B contract pharmacy arrangements for decades and has never addressed these distribution schemes in subsequent amendments to the statute. HHS, several federal courts, and PhRMA's own members have acknowledged that the 340B statute does not regulate drug distribution.

Act 1103 also does not create any direct conflicts with the 340B statute. Act 1103 does not add contract pharmacies as participants to the 340B Program, as PhRMA contends, because contract pharmacies do not take title to 340B drugs. Ownership remains with the covered entity, and the pharmacy is merely the mechanism for dispensing the covered entity's drugs to the covered entity's patients. Act 1103 also does not conflict with HHS's enforcement mechanisms, because both the ADR procedures and CMPs are focused on pricing, not distribution.

Neither does Act 1103 conflict with REMS. A pharmacy would not be permitted to contract with a covered entity to receive drugs that the pharmacy is not authorized to receive. Act 1103 does not require otherwise.

Finally, PhRMA's mischaracterization of contract pharmacies constitutes a disputed material fact that must defeat its motion for summary judgment. PhRMA's preemption arguments hinge on its assertion that contract pharmacies purchase 340B-discounted drugs. They do not. Title remains with the covered entity, as affirmed by federal guidance.

I. Act 1103 Is Not Preempted by Federal Law Because It Regulates Drug Distribution and Not 340B Drug Pricing and Purchasing

The 340B statute regulates the price at which drugs must be charged and who may receive those drugs, not how 340B-priced drugs are distributed. Act 1103 is not preempted because it regulates how 340B drugs are distributed, an area that Congress purposely left to the states. PhRMA's first argument is that the 340B Program is a "limited, unified Federal Program" that leaves no room for regulation by Arkansas or any other state which is essentially a field preemption argument. Pl. Br. at 18-22. PhRMA relies almost exclusively on selective quotes from a single case, *Astra USA, Inc. v. Santa Clara County*, that addresses the narrow issue of whether a covered entity has a private right of action against manufacturers for 340B overcharges. PhRMA's argument falls short of satisfying the test for field preemption, which requires that Congress manifest an intention that the federal government occupy an entire field of regulation. *Pac. Gas & Elec. Co.*, 461 U.S. at 206 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. at 230). The 340B statute is not "so pervasive as to make reasonable the inference that Congress left no room for States to supplement" drug distribution, which 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 on the same subject." *Rice*, 331 U.S. at 230.

A. The 340B Statute Regulates the Price of 340B Drugs and Who May Receive 340B Drugs, But Not How 340B Drugs Are Distributed

PhRMA's description of the 340B Program and the 340B statute focuses on the discounts that drug manufacturers provide under the 340B Program and that use of 340B drugs is limited to a covered entity's patients. Pl. Br. at 19. PhRMA fails to explain that Congress did not address the distribution of drugs in the 340B statute. *Id.* While PhRMA acknowledges that the 340B Program has a "limited scope and purpose," *id.* at 19, it inaccurately suggests that Congress intended the 340B statute to address both drug pricing *and* distribution.

1. The 340B Statute Does Not Regulate Drug Distribution

The reality is that the 340B statute governs the purchasing and pricing of 340B drugs and to whom 340B drugs may be sold and resold, but is completely silent on how 340B drugs make their way through the supply chain from manufacturer to patient. 42 U.S.C. § 256b(a)(1), (a)(4), (a)(5)(B). The statute regulates the beginning and end of a drug's journey from manufacturer to patient, but not the journey itself. The path that a drug travels from a drug company's manufacturing plant to the patient end user is long and circuitous. Prescription drugs may not legally be shipped directly from a manufacturer to a patient because they must be dispensed by a licensed pharmacy or health care provider pursuant to a valid prescription. 21 U.S.C. § 353(b)(1). Rarely do manufacturers ship prescription drugs directly to pharmacies and providers. Over 90 percent of prescription drugs in the U.S. are distributed by wholesalers on the manufacturers' behalf. *See, e.g.*, Terry Hisey et al., Healthcare Distrib. All. & Deloitte Consulting LLP, The Role of Distributors in the US Health Care Industry (2019).[11] And wholesalers are not mere custodians of the manufacturers' drugs. They actually purchase and take title to the drugs before reselling them to pharmacies and providers. *Id.* That means the drugs shipped by a manufacturer in response to an order placed by a pharmacy are not the same drugs delivered by the wholesaler on the manufacturer's behalf. They do not have to be the same because a prescription drug, identified by an 11 digit National Drug Code ("NDC"), is manufactured in such a precise and reproduceable manner that the medication represented by that NDC is treated in the commercial market as fungible. They share the same labeling, chemical composition, and route of administration but are otherwise different products.

[11] https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf.

The fungibility of prescription drugs in the U.S. makes it possible for wholesalers, rather than manufacturers, to be the primary suppliers of drugs, including 340B drugs. Yet, when Congress drafted and enacted the VHCA, it chose not to mention wholesalers in the 340B statute.[12] Nor is there mention of any other distribution mechanism found in the U.S. drug supply chain like relabeling, consigning, using central fill pharmacies or pharmacy warehouses, or entering into bill to/ship to contract pharmacy arrangements. When Congress enacted the 340B statute, it chose not to specify, or place limits on, the mechanisms available to covered entities for distribution of 340B drugs to patients. Thus, Act 1103 is not preempted because it does not "regulate[] conduct in a field that Congress intended the Federal Government to occupy exclusively." *English v. Gen. Elec. Co.,* 496 U.S. 72, 78–79 (1990).

Congress did not intend for HHS to control the distribution of drugs. Although HRSA issued guidelines addressing contract pharmacy arrangements, it acknowledged that those guidelines are not legally binding. Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020), https://340breport.com/your-340b-report-for-thursday-march-eae/. That is because Congress only conferred regulatory authority to HHS in three areas, none of which relate to contract pharmacies. *PhRMA v. Dep't of Health and Hum. Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) (holding HRSA has limited regulatory authority) (*PhRMA I*). HRSA, the agency that administers the 340B Program, lacks the statutory authority to regulate contract pharmacy arrangements or any other form of 340B distribution. Congress left the regulation of the

[12]The term "wholesaler" was added to the statute when Congress expanded the 340B program under the Affordable Care Act, but that provision simply gave HRSA the right to audit wholesalers on a selective basis "to ensure the integrity" of the program, not to control drug distribution. 42 U.S.C. § 256b(d)(1)(B)(v).

distribution of 340B-priced drugs to state laws and other federal laws.[13] 42 U.S.C. § 256b. Congress never expressed a "clear and manifest" intent to regulate the distribution of drugs at 340B prices. *Rice*, 331 U.S. at 230. Congress considered, but chose to refrain from, governing the field of 340B-priced drug distribution under the 340B *purchasing* statute in order to provide covered entities flexibility in how 340B drugs are distributed.

Similarly, PhRMA's argument that Congress intended that HHS control the 340B program is misplaced. Pl. Mot. at 18-21. As explained below in Section II.B, Congress required administrative dispute resolution procedures and the imposition of civil monetary penalties to address violations of mandated *pricing* requirements. ADR and CMPs do not address the distribution of 340B drugs prior to their administration to the patient.

PhRMA relies on cases that do not support federal preemption of Act 1103. Pl. Mot. at 22 (citing *US Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1327 (10th Cir. 2010) and *Nat'l Fed'n of the Blind v. United Airlines Inc.*, 813 F.3d 718, 734 (9th Cir. 2016)). In both of these cases, a federal agency had promulgated regulations that specifically governed the matter addressed in a state law. *US Airways, Inc.*, 627 F.3d at 1327-28 (State law governing "an airline's alcoholic beverage service" was field preempted because "the Federal Aviation administration ha[d] promulgated a federal regulation specifically addressing airlines' alcoholic beverage services"); *Nat'l Fed'n of the Blind*, 813 F.3d at 735 (State law was field preempted because a federal agency's regulation "informs airlines with striking precision about the attributes their accessible kiosks must have" and that "[i]n doing so, the new regulation speaks directly to the concerns raised by" Plaintiff's suit). In contrast, HHS has never issued regulations in the field of

[13] The original 340B statute only used the term "distribution" to refer to the 340B "prime vendor program under which covered entities *may* enter into contracts with prime vendors for the distribution of covered outpatient drugs." 42 U.S.C. § 256b(a)(8) (emphasis added). Rather than placing a limit on distribution, Congress created an additional distribution mechanism under the prime vendor program.

distribution of 340B-priced drugs or contract pharmacy distribution arrangements. Indeed, HHS has no power to do so. *Pharm I*, 43 F. Supp. 3d at 41.

2. When Enacting the 340B Statute, Congress Specifically Considered but Declined to Address Distribution of 340B Drugs

The legislative history of the 340B statute and precursor legislation demonstrates that Congress considered adding provisions to the 340B statute to address distribution of drugs, but opted not to do so. Eight months before enacting the 340B statute, the Senate considered a bill that, like the 340B statute, required drug manufacturers to provide discounts on drugs to safety-net providers and included several limits on distribution of those discounted drugs, including defining a covered entity as an entity capable of dispensing discounted drugs through "on-site pharmacy services." S. Rep. No. 102-259, at 2 (1992) (considering S. 1729, 102d Cong. (1992)). The draft legislation limited the dispensation of discounted drugs to on-site pharmacies that received the drugs either through wholesalers or directly from manufacturers as a "secondary means of drug distribution." *Id.* at 3, 9.

Congress rejected these distribution limitations. Congress heard testimony from several safety-net providers regarding the importance of contract pharmacy distribution arrangements. Jose Camacho, Executive Director of the Texas Association of Community Health Centers, testified to Congress on behalf of the National Association of Community Health Centers stating that federally mandated drug distribution requirements "would [not] be the most efficient distribution arrangement [for health centers] due to the … disruption of … distribution avenues" and that of 141 health centers surveyed, only 75 operated their own pharmacies."[14] *Bills to*

[14] The National Association of Community Health Centers ("NACHC") serves as the leading national advocacy organization in support of community-based health centers and the expansion of health care access for the medically underserved and uninsured. *About NACHC*, NACHC, https://www.nachc.org/about/about-nachc/ (last visited Sept. 8, 2022).

Amend the Public Health Service Act and the Social Security Act to Establish Limits on Certain Drug Prices, Hearing on H.R. 2890, H.R. 3405 and H.R. 5614 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 102d Cong. 77-82 (1992) (hereinafter referred to as "*Bills to Amend the Public Health Service Act*"). John Rector, Vice President of Government Affairs and General Counsel of the National Association of Retail Druggists, testified that nonprofit hospitals historically distributed drugs to third-party pharmacies and that "special contracts … [were] written for nonprofit sales, but the regular private drug distribution system [was] used to store and deliver the product." *Id.* at 285. Congress therefore understood that safety-net providers relied on contract pharmacy arrangements when it enacted the 340B statute.

Importantly, at the time that Congress adopted the 340B statute, it enacted a very similar statute requiring drug manufacturers to provide discounts to certain federal agencies that purchase drugs, such as the Veterans Administration. In contrast to the 340B statute, that statute addresses drug distribution. Congress contemporaneously established two drug purchasing programs under the VHCA—the 340B Program, codified at 42 U.S.C. § 256b, and the Federal Ceiling Price ("FCP") Program, codified at 38 U.S.C. § 8126, for the four largest purchasers of drugs within the federal government. Congress's express limitations on distribution in the FCP program demonstrates that it did not similarly intend the 340B statute to limit distribution. *See Director, OWCP v. Newport News Shipbuilding Co*., 514 U.S. 122 (1995) (comparing two similar statutes and interpreting an express standing provision in one statute as evidence that Congress did not intend the same concept to apply to another statute due to statutory silence).

To obtain drugs subject to FCP discounts, the federal agency must have "purchased [the drug] *under depot contracting systems* or [the drug must be] listed on the Federal Supply

Schedule." 38 U.S.C. § 8126(a)(2) (emphasis added). The term "depot" means a centralized commodity management system through which covered drugs are procured, including "a commercial entity operating under contract with such [federal] agency." 38 U.S.C. § 8126(h)(3)(A)(ii). If a federal agency that was otherwise entitled to a discount under the FCP Program made a purchase outside the statutorily-required drug distribution system, the agency "paid *the full retail price* for the drug." *Coal. for Common Sense in Gov't Procurement v. United States*, 707 F.3d 311, 312 (D.C. Cir. 2013). The agency is obligated to pay the retail price for the drug because "the Department did not procure the drug" under the statute's required distribution mechanisms, but "[i]nstead, the drug was distributed through commercial supply chains, and the … beneficiary purchased the drug from the retail pharmacy." *Id*. The statute governing the FCP Program, therefore, prohibits the purchase of discounted drugs through retail pharmacies. These prohibitions are noticeably absent from the 340B statute. Congress knew exactly how to govern distribution of discounted drugs, and chose only to regulate FCP drug distribution but not 340B drug distribution.

Congress chose not to wade into the complexities of drug distribution when drafting the 340B statute given the diversity and complexity of existing drug distribution arrangements among covered entities in this country. Congress relied instead on existing laws to regulate drug distribution. Congress's silence on drug distribution in the 340B statute was purposeful. Contract pharmacy arrangements are creatures of state law, namely, contract law and state agency law. 1996 Guidance, 61 Fed. Reg. at 43,550.

3. Congress Has Acquiesced to the Contract Pharmacy Distribution Model Because It Has Never Amended the 340B Statute to Address Drug Distribution

Congress amended the 340B statute in the 2010 Patient Protection and Affordable Care Act ("ACA"), and refrained from enacting any law to govern, much less expressly preempt, a

state law that regulates the distribution of 340B-priced drugs to contract pharmacies. Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18001). At enactment of the ACA, Congress was well aware of contract pharmacy distribution arrangements, state laws governing them, and HRSA's reliance on those laws. *See Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 181 (1988); *Director, OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 319–320 (1983). Rather than usurp from States their power to regulate distribution of 340B-priced drugs under contract pharmacy distribution arrangements, Congress chose to remain silent, thereby acquiescing to existing state laws related to distribution systems for 340B-priced drugs.

Thus, this Court should "recognize[] congressional acquiescence to administrative interpretations of a statute." *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 169 (2001). Here, Congress considered and rejected the "precise issue" now before the court. *Bob Jones Univ. v. United States*, 461 U.S. 574, 600 (1983); *see also CASA de Maryland, Inc. v. Trump*, 971 F.3d 220, 247 (4th Cir. 2020). In other words, "[i]t is well established that when Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the 'congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.'" *Commodity Futures Trading Comm'n v. Schor,* 478 U.S. 833, 853 (1986) (quoting *NLRB v. Bell Aerospace Co.,* 416 U.S. 267, 274-75 (1974)); *FDIC v. Philadelphia Gear Corp.*, 476 U.S. 426 (1986).

Courts have recognized congressional intent with respect to preemption when Congress amended a statute without making any changes that suggest that the federal law is intended to usurp the state's authority. *English*, 496 U.S. at 78–79 (analyzing amendments to federal act and

holding that state law claim did not fall within the preempted field despite "hav[ing] some effect on" decisions pertaining to federally regulated conduct); *Silkwood v. Kerr–McGee Corp*., 464 U.S. 238, 249-58 (1984) (rejecting both field and conflict preemption claims by analyzing legislative history and subsequent amendments to a federal act regulating radiation hazards); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 941 (8th Cir. 2011) (analyzing amendments to federal statute, recognizing traditional police power of states, and noting that the federal government has long regarded state law "as a complementary form of drug regulation" that "offers an additional, and important, layer of consumer protection"); *see also Farmers Educ. & Coop. Union of Am. v. WDAY, Inc*., 360 U.S. 525, 532 (1959) (acknowledging congressional acquiescence precepts in the context of preemption where a federal agency interpreted federal law to preempt state action and Congress had "since made significant additions" to a federal law "without amending it to depart from the [the federal agency's] view").

B. HHS, Federal Courts and Plaintiff's Own Members Have Recognized That the 340B Statute Does Not Regulate 340B Drug Distribution

There is wide consensus that the 340B statute does not regulate the distribution of 340B drugs. That conclusion was reached by HRSA, the agency within HHS charged with the administering the 340B Program; by the federal courts presiding over drug company lawsuits seeking to restrict contract pharmacies; and by several drug manufacturers themselves.

HRSA has long recognized that the 340B statute does not regulate 340B drug distribution and has relied on state laws to govern contract pharmacy distribution arrangements. The agency issued guidance in 1996 addressing contract pharmacy arrangements, observing that the use of contract pharmacies does not constitute "an unauthorized expansion of the [340B] program" because "[t]he statute is silent as to permissible drug *distribution* systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense

drugs itself."[15] 1996 Guidance,61 Fed. Reg. at 43,549 (emphasis added). HRSA emphasized that contract pharmacy distribution arrangements did not "create a new right but rather [was] simply recognizing an existing right that covered entities enjoy *under State law*." *Id.* at 43,550 (emphasis added). Moreover, HRSA stated that "the covered entity will adhere to all Federal, *State and local laws and requirements*" relating to contract pharmacy distribution arrangements. *Id*. at 43,551. HRSA specified that "if State X requires an entity to be licensed to purchase drugs and a covered entity subject to the laws of State X does not have a pharmacy license, it may not be able to purchase drugs"; "[h]owever, if State X permits a covered entity to use contract pharmacy services to purchase drugs on its behalf, the entity could presumably use this mechanism"; and "[t]o the extent the [1996] guidelines may be inconsistent with a State's distributor licensing requirements, this same reasoning would apply." *Id.* HRSA has thus recognized since 1996 that 340B contract pharmacy distribution arrangements were governed by state law and that participants of the 340B Program were subject to state law distribution requirements, such as Act 1103.

Several federal courts have also recognized that the 340B statute does not regulate the distribution of 340B-priced drugs. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 55 (D. Del. 2021) (recognizing that the 340B statute "refers to 'covered outpatient drugs … purchased by a covered entity' without any reference to the amount of such drugs purchased or the model by which the drugs are *distributed"*) (emphasis added); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs*., 570 F. Supp. 3d 129, 193 (D.N.J. 2021) ("§ 340B is silent

[15] The guidance also correctly stated that "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." 1996 Guidance,61 Fed. Reg. at 43,550.

as to permissible drug distribution systems") (internal citations and quotation marks omitted); *Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021) ("HRSA has long recognized that '[t]he [340B] statute is silent as to permissible drug distribution systems.'"); *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs*., No. 1:21-CV-00081, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021) ("the 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' delivery obligations").

Even PhRMA's members have emphasized that the 340B statute is silent on drug distribution, in contrast to its position here. AstraZeneca Pharmaceuticals LP stated that "Section 340B's silence on these issues [regarding contract pharmacy distribution arrangements] thus does not create any ambiguity to be interpreted" by HHS. Pl.'s Opening Br. in Support of its Second Mot. for Summary Judgment, *AstraZeneca Pharms. LP v. Becerra*, 2021 WL 9164718 (D. Del. July 23, 2021). Sanofi argued that "the 340B statute is silent as to permissible drug distribution systems." *See* Pl.'s Mot. to Dismiss, at 7, 22, 26, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, 570 F. Supp. 3d 129, No. 21-00806 (D.N.J. 2021).

C. Congress Has a Long History of Relying on State Laws to Regulate Drug Distribution

Preceding enactment of the 340B statute, a longstanding and complex framework of state laws governed how drugs were dispensed within the United States. Congress was aware of these state laws and intended for the 340B statute only to govern *purchasing* of drugs at 340B prices and the ultimate end users to whom 340B drugs may be dispensed or administered. *See Goodyear Atomic Corp.*, 486 U.S. at 181 (When Congress enacts legislation, it is presumed to know existing law that is pertinent to the legislation); *Director, OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 319–320 (1983) ("We may presume that our elected representatives, like

other citizens, know the law") (quoting *Cannon v. Univ. of Chicago*, 441 U.S. 677, 696–697 (1979) (internal quotations omitted)).

Contract pharmacy distribution arrangements existed as a matter of state law long before enactment of the 340B statute and were an integral component of the drug distribution systems for nonprofit healthcare providers. *See* Statement of Jacob W. Miller, *supra* at 8. Congress has long recognized the role of states in regulating the distribution of prescription drugs. *See, e.g.*, *Wyeth*, 555 U.S. at 578-79 (the United States Food and Drug Administration ("FDA") has long regarded state law "as a complementary form of drug regulation" that "offers an additional, and important, layer of consumer protection"); The Prescription Drug Marketing Act of 1987, 21 U.S.C. § 503 *et seq.* (requiring wholesalers to obtain licenses from *each state* in which the wholesaler operates); Drug Supply Chain Security Act of 2013, 21 U.S.C. § 353(e) (requiring wholesalers to be licensed by the State from which, and to which, the drug is distributed); *id.* § 360eee-2 (requiring the FDA to establish national standards for the state licensure of wholesalers to curb counterfeit drugs). The FDA approves new drugs as safe and effective but has limited authority to dictate how a pharmacy or provider may receive the drug. *See Am. Pharm. Ass'n v. Weinberger,* 377 F. Supp. 824 (D.D.C. 1974), *aff'd*, 530 F. 2d 1054 (D.C. Cir. 1976) (noting that the FDA lacks statutory authority to control post-approval distribution of methadone to certain pharmacies and providers).

States have traditionally shared authority with the federal government over the licensing and conduct of drug manufacturers and wholesale drug distributors. The federal government has long regarded state law "as a complementary form of drug regulation" that "offers an additional, and important, layer of consumer protection." *Lefaivre*, 636 F.3d at 941; *see Pharm. Care Mgmt. Ass'n v. Wehbi,* 18 F.4th 956, 972 (8th Cir. 2021) (indicating that HHS has a "general

position of deferring to States for regulating the practice of pharmacy") (citing Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4278 (Jan. 28, 2005)). For example, in all states within the United States Court of Appeals for the Eighth Circuit, wholesalers must meet specific application requirements and qualifications to satisfy necessary registration requirements. Ark. Code Ann. § 20-64-505; Ark. Code Ann. § 20-64-501 *et seq.* (grounds for pharmacies to receive and possess legend and controlled drugs); 070-00-08 Ark. Code R. § 2; Iowa Code Ann. § 657-17.3(155A); Minn. Stat. § 151.47; Minn. R. 6800.1400; Mo. Rev. Stat. § 338.333; Neb. Rev. Stat. § 71-7447; N.D. Admin. Code 61-10-01-05 to 61-10-01-06; S.D. Admin. R. 20:67:02. To allow the distribution of controlled substances, all seven states require that distributors be registered in their states and meet certain recordkeeping requirements. 070-00-08 Ark. Code R. § 2; Iowa Code Ann. §657-10.14(124); Minn. Stat. § 152.101; Mo. Rev. Stat. § 195.050; Neb. Rev. Stat. § 28-411, 414.03; N.D. Cent. Code § 19-03.1-20; S.D. Codified Laws § 34-20B-29, 39. Act 1103 is a perfect example of a state exercising its police power to support public health and simply complements existing laws in Arkansas regulating drug distribution.

D. Act 1103 Does Not Intrude on the Federal 340B Program Because It Regulates Distribution

Act 1103 does not intrude into the field regulated by the 340B Program because Act 1103 focuses exclusively on distribution—not purchasing—of 340B-priced drugs to Arkansas contract pharmacies. Congress does not cavalierly preempt state laws because States are independent sovereigns in the U.S. federal system. *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.,* 471 U.S. 707, 719 (1985). This presumption against federal preemption of a state statute designed to foster public health has special force when it appears, and the U.S. Secretary of Health and Human Services has not decided to the contrary, that the two governments are pursuing

"common purposes." *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003); *New York State Dept. of Soc. Servs. v. Dublino*, 413 U.S. 405, 421 (1973).

The 340B statute does not regulate a field in which the federal interest is so dominant that it will be assumed to preclude Act 1103 because Act 1103 does not regulate "the same conduct" regulated under the 340B statute. *See English,* 496 U.S. at 78–79; *Rice*, 331 U.S. at 230 (A federal law may preempt state law "where an Act of Congress touches a field in which the interest is so dominant that the federal system will be assumed to preclude enforcement of state laws *on the same subject*") (internal quotations omitted). Act 1103 is focused exclusively on distribution of 340B-priced drugs to Arkansas pharmacies, not the price at which those drugs are purchased by covered entities. The 340B statute governs the conditions under which drugs may be purchased at a discount. Act 1103 addresses a pharmacy's ability to receive those purchased drugs.

The legislative history of Act 1103 confirms that the law does not govern drug pricing and instead focuses on the shipment of drugs. *To Establish the 340B Drug Pricing Nondiscrimination Act*, *Hearing on H.B. 1881 Before the Ark. House of Representatives*, 93d Gen. Assembly Regular Session (Ark. 2021) (statement of Rep. Michelle Gray) (the [Arkansas] 340B Drug Pricing Nondiscrimination Act "is not price setting," and is intended to require manufacturers to "actually ship[] medications to the state of Arkansas"). Defendant AID confirmed that the law is intended to govern distribution of 340B-priced drugs in its Re-filed Proposed Rule by clarifying that "'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." Ark. Ins. Dep't, *Rule 123 340B Drug Program Nondiscrimination*

Requirements at 2 (May 26, 2022), https://insurance.arkansas.gov/uploads/pages/rule_123.pdf ("Re-filed Proposed Rule").

Act 1103 falls within Arkansas' police power to regulate drug distribution in the interest of public health and safety. *See Wyeth,* 555 U.S. at 565 ("[T]he historic police powers of the States [are] not to be superseded … unless that was the clear and manifest purpose of Congress."). Many Arkansas FQHCs, for example, do not receive sufficient federal funding to afford the cost of establishing a pharmacy and the increased overhead associated with maintaining the pharmacy's compliance with state and federal pharmacy law. These safety-net providers serve on the front lines of Arkansas' battle against poverty and health inequality, providing primary health care, discounted medications, support services, food, housing, and other crucial services to underprivileged Arkansans. Restricting access to 340B drugs at contract pharmacies may cause Arkansas covered entities to shut down or deny their patients discounts on their medications if the covered entity is otherwise unable to cover the cost of a high-priced drug.

Act 1103 is especially important in Arkansas in light of a unique state law prohibiting nonprofit, tax exempt, or governmentally funded hospitals from owning and operating their own in-house retail pharmacies.[16] Without the ability to dispense drugs through contract pharmacies, 340B hospitals in Arkansas would have no way of using the program to meet the retail pharmacy needs of their patients. Contract pharmacies pass through to covered entities the revenue they collect from dispensing 340B drugs. Therefore, contract pharmacies are a vital component of Arkansas' public health care system because they generate savings and revenue for uncompensated services and provide access to discounted medications to the covered entity's low-income patients. Arkansas-based contract pharmacies are not only critical to the ongoing

[16] Ark. Code Ann. § 17-92-607 (prohibiting Arkansas nonprofit, tax exempt, or governmentally funded hospitals from owning retail pharmacies).

operation of Arkansas safety-net providers, but they also serve as a vital component of Arkansas' public health system. Consistent with Arkansas' inherent power to maintain public health and safety, Act 1103 guarantees that these vital pharmacies may continue to receive 340B-priced medications for the betterment of Arkansas' underprivileged communities and public health care system.

Even if, *arguendo*, Act 1103 regulated conduct that overlapped with 340B drug purchasing, the federal interest in the 340B statute is "not so dominant" to preclude Act 1103's applicability respecting distribution of 340B-priced drugs to pharmacies. In *Hillsborough County v. Automated Medical Laboratories, Inc*., the Supreme Court reviewed whether local ordinances governing collection of blood plasma from paid donors was preempted by § 351 of the Public Health Service Act, under which the FDA had promulgated regulations establishing minimum standards for the collection of blood plasma. *Hillsborough Cnty.*, 471 U.S. at 721. The Court reasoned that the regulation of health and safety matters is primarily and historically a matter of local concern, and the FDA's National Blood Policy was not a sufficient indication of federal dominance to preempt the local ordinances. *Id.* at 719. Therefore, Arkansas' police power over public health concerns cannot be constrained absent a clear indication from Congress that such public health laws are to be preempted or that HRSA has exclusive authority to regulate the field of 340B-priced drug distributions. As noted above at Section I.A.2, Congress chose to exclude drug distribution from the 340B statute and HRSA's regulatory authority.

Finally, PhRMA's assertion that "Congress frequently assigns the States significant roles in administering [federal healthcare] programs" is beside the point. Pl. Mot. at 19. PhRMA cites the ACA, a health insurance regulatory program, and the Medicaid Drug Rebate Program, a federal reimbursement program, *id.*, none of which are remotely similar to the 340B Program.

PhRMA has not identified a single federal drug pricing statute or federal pricing statute that was both silent on distribution of goods and preempted state distribution laws. Intervenor-Defendants, by contrast, have pointed this Court to the NPIA, *Infra* at Section II.B, which is silent on permissible distribution systems, yet it is well-settled that those purchasers protected under the NPIA use contract pharmacy distribution arrangements under state law. It would be wholly inconsistent to find a "unitary enforcement" system of drug distribution under the 340B statute notwithstanding the statute's silence on distribution, while simultaneously ignoring contract pharmacy distribution arrangements under other federal statutes.

II. Act 1103 Does Not Conflict with the Purposes and Objectives of the 340B Statute Because Congress Refused to Regulate Drug Distribution Arrangements

This Court should also reject PhRMA's second preemption argument that Act 1103 conflicts with the 340B statute. Conflict preemption "occurs where either 'compliance with both state and federal law is impossible'" [impossibility preemption] or "the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' [obstacle preemption]." *Soo Line R.R. Co. v. Werner Enters.,* 825 F.3d 413, 420 (8th Cir. 2016) (quoting *Oneok, Inc. v. Learjet, Inc.,* 575 U.S. 373, 377 (2015)). State laws may be an obstacle to federal goals by interfering with a uniform system of federal regulation or imposing stricter requirements than Congress intended under federal law. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374-77 (2000); *see also Geier v. Am. Honda Motor Co*., 529 U.S. 861, 875 (2000). On the other hand, a state law does not create an obstacle to the Congressional objectives and purposes of a federal law when the state law regulates conduct that Congress intended to refrain from governing. *See Hines*, 312 U.S. at 67.

PhRMA has not reached the "high threshold [that] must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act." *Gade*, 505 U.S. at 110. The 340B

statute does not contain an express preemption clause, leaving Act 1103 to be assessed under implied preemption. An implied preemption analysis, however, does not justify a "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives," which "would undercut the principle that it is Congress rather than the courts that preempts state law." *Chamber of Commerce of the United States v. Whiting*, 563 U.S. 582, 607 (2011); *Gade,* 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in judgment); *see Silkwood*, 464 U.S. at 256. As explained in the previous section, Act 1103 does not create any obstacle to the field of federal regulation under the 340B statute because Act 1103 regulates conduct that Congress intentionally refrained from governing in the 340B statute, namely, the distribution of 340B drugs. *See Silkwood*, 464 U.S. at 238 (rejecting obstacle preemption claim against state law because the state law's "regulatory consequence was something that Congress was quite willing to accept" and it was "difficult to believe" that Congress would have removed state law recourse on regulated conduct); *Pac. Gas & Elec. Co.*, 461 U.S. at 211, 216 (rejecting obstacle preemption claim because Congress had amended federal law at issue and refused to preclude the "the dual regulation" provided under both federal and state laws and because the state legislature's "avowed" purpose of regulating a certain conduct did not interfere with the objectives of the federal law that regulated different conduct).

PhRMA asserts two other arguments in support of its allegation that Act 1103 is preempted by the 340B statute. It claims that Act 1103 adds contract pharmacies as a new "participant" to the 340B Program that Congress never intended and that Act 1103 co-opts federal enforcement authority to police manufacturers' compliance with the 340B statute's mandate that they offer 340B-priced drugs for purchase by covered entities. Pl. Mot. at 22-31. Neither argument has merit. Participation in the 340B Program is reserved for covered entities,

not contract pharmacies, and nothing in Act 1103 confers covered entity status to contract pharmacies. The 340B administrative dispute resolution ("ADR") process is the sole mechanism for adjudicating covered entity complaints of being overcharged, but Act 1103 has a different purpose, namely, to protect the right of Arkansas covered entities and pharmacies to dispense drugs through bill to/ship to contract pharmacy arrangements.

A. Act 1103 Does Not Add Contract Pharmacies as a New "Participant" to the 340B Program

PhRMA is incorrect that contract "pharmacies . . . purchase drugs at the 340B price" to replenish the drugs dispensed to covered entity patients. Pl. Mot. at 9; Pl. Statement of Material Facts ¶¶ 27, 28. Act 1103 does not expand the 340B Program to enable contract pharmacies to "participate" in the 340B Program in conflict with the purposes of the 340B statute, as PhRMA contends. *See, e.g.*, Pl. Mot. at 3; ECF No. 1 ¶¶ 66-104 (seeking an order declaring that Act 1103 does not require PhRMA's members to offer price discounts under the 340B Program to contract pharmacies in Arkansas).

PhRMA significantly misrepresents how 340B contract pharmacy arrangements operate. Contract pharmacies do not purchase or take title to 340B drugs. Decl. of Krista M. Pedley, ¶¶ 7, 8, 9, ECF No. 24-1, Ex. 1-E (former OPA Director, Rear Admiral Krista Pedley stating that contract pharmacies do not purchase 340B drugs and that covered entities purchase 340B drugs) ("Pedley Decl."); Decl. of Dr. Lanita S. White, Chief Executive Officer of Community Health Centers of Arkansas ¶ 8, ECF No. 17, Ex. 1 ("CHCA Decl.") (CHCA's "community health centers purchase and take title to the 340B medications, but the drugs are shipped to and dispensed by contract pharmacies."). Rather, the contract pharmacy obtains possession of the drugs on behalf of the covered entity to dispense the drugs to the covered entity's patients. *Id*. It is a well-recognized precept of the 340B Program that only covered entities may purchase 340B

drugs from wholesalers and manufacturers. Pedley Decl. ¶¶ 7, 8, 9; CHCA Decl. ¶ 8. Moreover, only covered entities may establish 340B accounts with wholesale distributors. Pedley Decl. ¶ 9; CHCA Decl. ¶ 8. Indeed, PhRMA's own exhibit—from Rear Admiral Krista Pedley—states that covered entities, not contract pharmacies, purchase 340B drugs. Pedley Decl. ¶¶ 7, 8, 9.

The 340B statute requires drug manufacturers to enter into a pharmaceutical pricing agreement ("PPA") that requires "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." 42 U.S.C. § 256b(a)(1) (emphasis added). This mandate does not require covered entities to take physical possession of 340B drugs, nor does it govern the distribution channels or delivery location of the 340B-priced drug. The statute merely says that covered entities may purchase drugs at a statutorily determined price.

In 1992, as now, the meaning of the term "purchase" was "to obtain (as merchandise) by paying money or its equivalent." *Purchase,* Webster's Third New International Dictionary Unabridged (1992); *see also Purchase*, Black's Law Dictionary (11th ed. 2019) (the "act or instance of buying" or the "acquisition of an interest . . . by sale, discount, negotiation, mortgage, pledge, lien, issue, reissue, gift, or any other voluntary transaction."). The term did not, and does not, require a purchaser to obtain physical possession of a good. In contrast, distribution is a concept that is entirely focused on possession and delivery of the drug. *See* 21 U.S.C. § 802(11) ("The term 'distribute' means to deliver (other than by administering or dispensing)" a drug). The prevailing understanding of the term "purchase" in 1992 when Congress enacted Section 340B was to obtain title by paying a price, rather than obtain possession.[17]

[17] *See also* U.C.C. § 2-106(1) ("A 'sale' consists in the passing of title from the seller to the buyer for a price."). This definition does not require a buyer to obtain physical possession.

Because contract pharmacies do not purchase 340B drugs, Act 1103 does not expand the scope of the 340B statute by adding contract pharmacies as new participants. *Supra* at Section II.A; *see Eli Lilly & Co.*, 2021 WL 5039566, at *3 ("The 1996 Guidance therefore explicitly provided that permitting the use of contract pharmacies does not constitute an unauthorized expansion of the 340B Program because '[t]he statute is silent as to permissible drug distribution systems,' and contains 'no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself.'"); 1996 Guidance, 61 Fed. Reg. at 43,549. *Contra* Pl. Mot. at 4, 18, 22-25. "Participation" in the 340B Program, which confers the right to purchase 340B drugs, but not distribute 340B drugs, is reserved for covered entities and nothing in Act 1103 elevates the status of contract pharmacies to covered entities or authorizes them to purchase 340B drugs. *Contra* Pl. Mot. at 23-25. While Congress enumerated the entities that may purchase 340B-priced drugs, it chose to remain silent on the entities authorized to possess and dispense those drugs throughout the distribution pathway, including pharmacies that may receive 340B-priced drugs under contract pharmacy distribution arrangements. 42 U.S.C. § 256b(a)(1), (4); *supra* Sections I, II.B.; *Bills to Amend the Public Health Service Act*.

This Court should reject PhRMA's obstacle preemption claim because Act 1103's "regulatory consequence was something that Congress was quite willing to accept." *Silkwood*, 464 U.S. at 256; *see Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021) (HHS has a "general position of deferring to States for regulating the practice of pharmacy") (citing *Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4,194, 4,278 (Jan. 28, 2005)). As discussed above, instead of placing limitations on how covered entities obtain or dispense 340B drugs by requiring that they obtain them through wholesaler distributors and dispense them at on-site pharmacies, Congress was "quite willing" to rely on state regulation of bill to/ship to contract

pharmacy arrangements for the entire 340B federal statutory scheme to function. *Supra* Section II. Indeed, Congress was well aware at enactment of the 340B statute that only five percent of covered entities maintained in-house pharmacies. 1996 Guidance,61 Fed. Reg. at 43,550. With this knowledge, Congress chose to allow covered entities to obtain 340B drugs through existing distribution channels rather than confining covered entities to a mandatory distribution system. *See supra* Section I.C.

PhRMA's claim that Act 1103 inserts a new participant into the 340B Program is particularly absurd because its members rely on wholesalers to sell 340B drugs. In a bill to/ship to arrangement, the contract pharmacy only takes possession of 340B drugs, not ownership. In a wholesaler arrangement, the wholesaler takes both ownership and possession of the drugs from the manufacturer. If PhRMA were correct that the Arkansas legislature added contract pharmacies as new 340B "participants" in Act 1103, then manufacturers have also inserted wholesalers as new and unintended participants in the 340B Program. Of course, neither is true because both wholesalers and contract pharmacies distribute 340B drugs, as Congress intended, and neither participates as a covered entity in the 340B Program.

PhRMA's conflict preemption claim, if upheld, would yield other absurd results for its drug company members and should also be rejected for that reason. *See Nixon v. Missouri Mun. League*, 541 U.S. 125, 128 (2004); *United States v. Am. Trucking Ass'ns, Inc.*, 310 U.S. 534, 543 (1940) (courts will not interpret statutes in a way that leads to absurd results). If the 340B statute required purchasers to take both title and possession of 340B drugs, all manufacturers would be culpable of selling 340B drugs to ineligible purchasers because they rely almost exclusively on wholesaler arrangements to deliver drugs for most 340B transactions. The sales to wholesalers, in contrast to covered entities, would be included in the manufacturer's Medicaid rebate and

340B discount calculations, essentially exposing the manufacturer to a financial penalty. Over 90 percent of prescription drugs in the U.S. are distributed by wholesalers on manufacturers' behalf. *See, e.g.,* Terry Hisey et al., Healthcare Distrib. All. & Deloitte Consulting LLP, The Role of Distributors in the US Health Care Industry (2019).[18] While the number of 340B contract pharmacy arrangements may be growing, the percentage of 340B transactions involving bill to/ship to arrangements comprises well below the 90 percent distributed by wholesalers. Another absurd consequence is that the reselling of 340B drugs to covered entity patients would not allow for family members or other authorized agents to pick up drugs from the 340B pharmacy on the patients' behalf. Pharmacies would have to dispense 340B drugs directly to the patient. Surely Congress could not have intended such a result.

PhRMA also misconstrues the 340B statute's diversion prohibition. Pl. Mot. at 24. PhRMA states that the 340B statute limits the availability of 340B-discounted drugs to covered entities and their patients. *Id.* However, the 340B diversion prohibition is focused on the end-user of the 340B-priced drugs—the patient. The diversion prohibition in no way precludes entities involved in the distribution pathway to possess 340B-priced drugs. If it did, the wholesaler distribution system, through which 90 percent of drugs are delivered, would be contrary to the 340B statute. PhRMA's interpretation would force manufacturers to sell directly to covered entities which would be difficult, if not impossible, for either party to implement, and the court should not impose an interpretation of the 340B statute that leads to absurd results. *See Nixon*, 541 U.S. at 138; *Am. Trucking Ass'ns*, 310 U.S. at 543. Unsurprisingly, no federal agency or court has ever ruled that use of contract pharmacies constitutes diversion. *See, e.g.*, *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-CV-00081, 2021 WL

[18] https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf.

5039566, at *20 (S.D. Ind. Oct. 29, 2021) (rejecting drug manufacturer's assertions that "sales of 340B drugs to covered entities using contract pharmacy arrangements [are not] 'purchases by' covered entities," that contract pharmacies purchase drugs, and that use of a "replenishment model" at contract pharmacies constitutes diversion). And until 2020, PhRMA's members all recognized and did not interfere with contract pharmacy arrangements.

The legislative history, structure, and context of the 340B statute demonstrates a manifest interest by Congress to provide covered entities with flexibility on the use of a distribution system for 340B-priced drugs. Accordingly, Act 1103 does not create an obstacle to Congress' objectives, but rather, it facilitates Congress's intent that 340B covered entities do not have to purchase discounted drugs directly from manufacturers and can use preexisting distribution channels, including wholesalers and contract pharmacies.

B. Congress Established the ADR Process and CMPs to Address Overcharge and Diversion Claims, Not the Legitimacy of Contract Pharmacy Arrangements

PhRMA's other conflict preemption argument is equally meritless. PhRMA asserts that Act 1103 intrudes into HRSA's authority under the 340B statute to uniformly resolve "claims by covered entities that they have been overcharged for drugs purchased" from manufacturers or HHS's authority to issue civil monetary penalties ("CMPs") against "any manufacturer . . . that knowingly and intentionally charges a covered entity a price for purchase" above 340B prices. Pl. Mot. at 20-21, 26-31. The statutory language creating the ADR process and investing HHS with authority to impose CMPs actually undermines PhRMA's contention that Act 1103 somehow usurps those federal enforcement powers. 42 U.S.C. § 256b(d)(1)(B)(vi), (d)(3)(A). Congress was careful to use the terms "for drugs purchased" and "purchased by" covered entities in the portions of the 340B statute relied on by PhRMA. *Id*. § 256b(d)(3)(A). As previously

discussed, the purchasing of 340B drugs is separate from how 340B drugs are distributed and Act 1103 addresses only the latter. PhRMA concedes that "Congress . . . vested unitary authority in HHS to ensure *compliance* with the Program's requirements via resolution of disputes *between participants*." Pl. Mot. at 20 (emphasis added). And as discussed above, contract pharmacies and other parties involved in distribution supply chain are not "participants" in the 340B Program. *See supra* Section II.A. Congress simply never endeavored to regulate comprehensively or create a unitary dispute resolution system addressing distribution of 340B-priced drugs.

This Court should not infer broad obstacle preemption if there is no evidence of congressional intent to promote uniform federal regulation of conduct governed by state law. *See, e.g.*, *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 146–47 (the intent to obstacle preempt state law under obstacle preemption will not lightly be implied from an ambiguous statute); *Florida State Conf. of NAACP v. Browning,* 522 F.3d 1153, 1162 (11th Cir. 2008) (rejecting obstacle preemption claim against state voter identification law in light of federal voter identification statute where, reading the federal statute as a whole, congressional intent for federalization of voter identification standards and comprehensive federal regulation of voter registration was not apparent); *Harris v. Great Dane Trailers, Inc.*, 234 F.3d 398, 402 (8th Cir. 2000) ("Only when federal regulators determine that uniformity is needed to promote the predominant legislative purpose of [the conduct regulated by the federal law] will uniformity itself justify broad conflict preemption."); *Buzzard v. Roadrunner Trucking, Inc.*, 966 F.2d 777, 783 (3d Cir. 1992) (rejecting preemption of state tort common law claim related to federally regulated conduct of manufacturer because the state law remedy "[would] not take away the

flexibility established by the federal scheme, and it [would] not have the effect of prohibiting an option granted by Congress or the [federal agency]" to the manufacturer).

Moreover, Act 1103 is not preempted because, as discussed *supra*, clear evidence exists that Congress disclaimed interest in regulating the conduct governed by the state law. *See Silkwood*, 464 U.S. at 256; *Pac. Gas & Electric Co.*, 461 U.S. at 204; *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 487-88 (2008) (rejecting obstacle preemption claim and "find[ing] it too hard to conclude that a statute expressly geared to protecting 'water,' 'shorelines,' and 'natural resources' was intended to eliminate *sub silentio* oil companies" common law duties to refrain from injuring the bodies and livelihoods of private individuals); *see also Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 352 (2001).

The 340B statute does not, and was never intended to, govern contract pharmacy arrangements. Nor does it regulate manufacturers' relationships with pharmacies, or their interactions with other entities involved in distribution of 340B-priced drugs. *See supra* Section II.A.1. The 340B statute confines both HHS and Office of Inspector General ("OIG") enforcement authority to the purchasing transactions between manufacturers and covered entities. It does not extend to transactions outside those two entities. As discussed *supra* Section I.A.2, Congress disclaimed interest in regulating distribution of 340B-priced drugs, and HHS's enforcement authority under the 340B statute does not regulate that conduct.

Act 1103 has a completely different purpose from the 340B statute. It does not set the 340B ceiling price; it does not provide covered entities with a remedy for manufacturers overcharging them for drugs they purchase; it does not govern what entities may purchase 340B-priced drugs; and it does not authorize new purchasers of 340B drugs. Rather, it was enacted to protect contract pharmacy arrangements, a longstanding distribution mechanism for

preferentially-priced drugs under state law. *Supra* Background Section III, IV. This right existed for safety-net healthcare providers decades prior to enactment of the 340B statute, has long been recognized by HRSA, and was ratified by Congress through legislative acquiescence in 2003 and 2010. *Supra* Section I.A.2, I.D.

PhRMA strongly implies that contract pharmacy arrangements are unique to the 340B Program, but they are not. They existed well before the 340B Program was established and are commonly used for non-340B drugs. In 2010, the Federal Trade Commission ("FTC") confirmed the longstanding right of certain non-profit organizations to contract under state law with for-profit retail pharmacies to dispense drugs discounted under the Robinson-Patman Antidiscrimination Act ("Robinson-Patman Act") and the Non-Profit Institutions Act ("NPIA").[19] 15 U.S.C. §§ 13–13b; Fed. Trade Comm'n, University of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010).[20] The FTC reviewed and approved the same bill to/ship contract pharmacy model used in the 340B Program with only one difference—the drugs were subject to discounts obtained under the NPIA, not the 340B statute. *Id.* Notably, both the 340B statute and NPIA provide for the purchase, and restrict the resale, of discounted drugs by non-profit healthcare entities. 15 U.S.C. §§ 13-13c; 42 U.S.C. § 256b(a)(5)(B).

As shown by AID's implementing Re-filed Proposed Rule, Act 1103 focuses on protecting the "acquisition and delivery" of 340B-priced drugs by Arkansas pharmacies, not the drugs' purchase price. Re-filed Proposed Rule at 2. Act 1103 is therefore focused on distribution and prohibits a manufacturer from engaging in any conduct that encumbers

[19] Congress enacted the Robinson-Patman Act to deter price discrimination against small businesses in the sale of fungible products, including drugs. 15 U.S.C. §§ 13–13b. The NPIA creates an exception to the Robinson-Patman Act for sales to certain non-profit entities "for their own use." 15 U.S.C. § 13c.
[20] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

distribution of 340B drugs among Arkansas covered entities and pharmacies. *Supra* Background Section IV; *To Establish the 340B Drug Pricing Nondiscrimination Act*, *Hearing on H.B. 1881 Before the Ark. House of Representatives*, 93d Gen. Assembly Regular Session (Ark. 2021) (statement of Rep. Michelle Gray) (the [Arkansas] 340B Drug Pricing Nondiscrimination Act "is not price setting," and it is intended to require manufacturers to "actually ship[] medications to the state of Arkansas"); Re-filed Proposed Rule at 2.

PhRMA's members, having argued in other forums that HHS and OIG lack authority to initiate enforcement actions against their restrictive contract pharmacy policies, cannot now suddenly do an about-face and assert that HHS has exclusive enforcement authority over every aspect of the 340B Program, including distribution of 340B-priced drugs.

The Arkansas General Assembly realized that, to combat the growing trend of manufacturers interfering with the distribution of 340B-priced drugs to contract pharmacies, a state law remedy was needed outside the scope of the 340B statute. Re-Filed Proposed Rule at 2 (clarifying that "'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"); *To Establish the 340B Drug Pricing Nondiscrimination Act*, *Hearing on H.B. 1881 Before the Ark. House of Representatives*, 93d Gen. Assembly Regular Session (Ark. 2021) (statement of Rep. Michelle Gray) (establishing that the General Assembly of Arkansas' purpose for Act 1103 was to allow "our patients [and our] hospitals" to continue receiving 340B drugs, that the [Arkansas] 340B Drug Pricing Nondiscrimination Act "is not price setting," and that Act 1103 is intended to require manufacturers to "actually ship[] medications to the state of Arkansas"). This form of state regulation is precisely what Congress contemplated when it consistently refrained from regulating, or giving HHS the authority to regulate, 340B drug distribution.

C. PhRMA Relies on Caselaw That Supports Defendant-Intervenors' Position

PhRMA relies on *Buckman Co. v. Plaintiffs' Legal Committee* for the proposition that state tort law claims are preempted when a federal agency had an enforcement mechanism at its disposal. Pl. Br. at 26-27. PhRMA's reliance on this case is misplaced because the facts that supported the outcome in that care are completely different than the facts in this case. *Buckman Co. v. Plaintiff's Legal Comm*., 531 U.S. 341 (2001). In *Buckman Co.*, plaintiffs asserted a state-law, fraud-on-the-agency tort claim that a medical device manufacturer made false representations to the FDA to obtain approval to market its device. *Id.* The federal process under which the manufacturer sought approval, governed by section 510(k) of the Food, Drug and Cosmetic Act, requires medical device manufacturers to submit information supporting approval. The *Buckman Co.* Court analyzed the federal approval process at § 510(k) and reasoned that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied," the "petitioner's dealings with the FDA were prompted by the [the federal law]," and "the very subject matter of petitioner's statements [challenged by Plaintiff] were dictated by that [federal] statute's provisions." *Buckman Co.,* 531 U.S. at 347-48. The Court stated that "in contrast to situations implicating federalism concerns and the historic primacy of state regulation of matters of health and safety . . . no presumption against pre-emption" was available in the case. *Id*. (internal quotations and citations omitted).

Those facts are starkly dissimilar to this case. First, regulation of contract pharmacy distribution arrangements under state-law police-powers precedes enactment of the 340B statute. These state-regulated distribution arrangements were commonplace for nonprofit providers *decades* prior to enactment of the 340B statute.[21] *Supra* Section I.C. In contrast, the Court

[21] *Social Security and Welfare Proposals, Hearing Before the H. Comm. on Ways and Means*, 91st Cong. 2129

determined that the claims in *Buckman Co.*, which the court described as "[p]olicing fraud against federal agencies" were not "a field which the States have traditionally occupied." *Buckman Co.*, 531 U.S. at 347-48 (quoting *Rice*, 331 U.S. at 230). And neither Congress, HHS, nor the FTC has ever stepped in to usurp a state's police power to regulate contract pharmacy distribution arrangements for discounted drugs. *Id.* Act 1103 is entitled to a presumption against preemption from HHS's 340B enforcement rules according to PhRMA's supporting caselaw. *Buckman Co.,* 531 U.S. at 347-48.

Second, unlike the activities at issue in *Buckman Co.*, Act 1103's distribution protections neither arise from the 340B statute's protections allowing covered entities to purchase 340B drugs nor are they "dictated by that [federal] statute's provisions." *Id.* While the 340B statute governs overcharges on purchases between manufacturers and covered entities, Act 1103 carefully prescribes protections for pharmacies to maintain their continued role in possessing and furnishing 340B-priced drugs to vulnerable Arkansas patients. Unlike *Buckman Co.,* Act 1103's protections, regulating drug distribution and manufacturers' interactions with distribution-chain participants, therefore falls outside the federal agency's regulatory authority. The holding in *Buckman Co*., therefore, has no precedential value in this case.

PhRMA's reliance on *Astra USA, Inc. v. Santa Clara County* is misplaced for very similar reasons. In *Astra,* the Court analyzed whether covered entities maintained a private right of action as third-party beneficiaries of PPAs between manufacturers and HHS. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). Importantly, those PPAs are strictly based on the text of the 340B statute, limiting the focus of the *Astra* dispute to *covered entity purchases*.

(1969) (statement of Jacob W. Miller, Chairman, Comm. Pub. Affs., Am. Pharm. Ass'n) (stating to Congress that "[as] I am sure you are aware, many health care facilities do not maintain their own onsite pharmaceutical services. Rather, they look to the community pharmacies to provide such service on a contract basis.").

Astra, 563 U.S. at 113 ("They [the PPAs] are uniform agreements that recite the responsibilities §340B imposes, respectively, on drug manufacturers and the Secretary of HHS.").

Astra in no way addressed distribution of 340B-priced drugs, nor did it analyze the primacy of state laws regulating contract pharmacy distribution arrangements. Rather, the case was focused on a much different issue—whether HHS's enforcement authority under the ADR process was the proper adjudicatory framework to remedy "covered entities complaining of 'overcharges'" on purchases of 340B drugs under the statute. *Id.* at 122. The *Astra* decision does not suggest that HHS's authority extends outside the 340B statute to drug distribution. *Astra*, 563 U.S. at 114. ("Congress placed the Secretary (acting through her designate, HRSA) in control of §340B's drug-price prescriptions."). Rather, *Astra* elucidates very clear strictures on HHS's limited enforcement role over 340B-drug purchasing, rather than the distribution of 340B-priced drugs.

III. Act 1103 Does Not Conflict with the Purposes and Objectives of the Food and Drug Administration Amendments Act

PhRMA alleges that Act 1103 directly conflicts with the FDCA's Risk Evaluation and Mitigation Strategies ("REMS") requirements and that it is impossible to comply with both the REMS requirements and Act 1103. No actual conflict exists, however, between Act 1103 and the FDCA REMS requirements or any other sections of the FDCA.

Courts have interpreted the physical impossibility standard as a high burden and that the "possibility of impossibility [is] not enough." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 n.8 (2011). Anything short of explicitly conflicting commands to act one way and also act the opposite way is insufficient to satisfy that burden. *See Wyeth,* 555 U.S. at 571-73, 581; *Barnett Bank*, 517 U.S. at 31. Congress did not intend state laws that govern drug distribution to be preempted by the FDCA to the extent they vary in even the slightest degree. *Wyeth*, 555 U.S. at

571. The statute, congressional intent, and the practical effect of the REMS requirements all demonstrate that a manufacturer can comply with both REMS and Act 1103.[22]

The REMS program was created in 2007 under the Food and Drug Administration Amendments Act as a way to ensure the safe use of otherwise high-risk drugs. 21 U.S.C. § 355-1. The FDA imposes REMS requirements if "necessary to ensure that the benefits of the drug outweigh the risks of the drug." *Id*. § 355-1(a); *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary*, FDA (Apr. 2019). REMS components may include requirements for those who prescribe, dispense, or use the drug, such as medication guides, patient package inserts, or a communication plan for health care providers. 21 U.S.C. § 355-1(e). As stated on the FDA website, "[c]ertain REMS may also require pharmacies or other healthcare settings to become certified to dispense the REMS medication."[23]

It is completely appropriate for a pharmacy to serve simultaneously as a REMS-authorized participant and as a covered entity's 340B contract pharmacy. And if the pharmacy is not permitted to dispense a REMS drug, it would not receive the REMS drugs at all. The issue of whether the pharmacy is entitled to receive 340B drugs never arises and, as a result, Act 1103 is not implicated.

If Congress thought a state might pose "an obstacle to its objectives [under the FDCA], it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Wyeth*, 555 U.S. at 574. However, Congress did not do so. *Id*. at 567 (noting that Congress declined to enact an express preemption provision for prescription drugs under the FDCA); *Lefaivre*, 636 F.3d at 941. In fact, the FDCA requires the FDA to consider whether the

[22] PhRMA cites no case addressing the preemptive effect of the REMS program.
[23] *Roles of Different Participants in REMS*, FDA (Mar. 24, 2020), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems.

REMS requirements are not "unduly burdensome on patient access to the drug" and also "minimize the burden on the health care delivery system," and the REMS must "be compatible with established distribution, procurement, and dispensing systems for drugs." 21 U.S.C. §§ 355-1(f)(2)(C), (D)(ii). Act 1103 is a complementary drug distribution statute that requires manufacturers to ship 340B drugs that are subject to the REMS statute to those contract pharmacies that are authorized to handle and dispense REMS drugs. Thus, the REMS requirements are intended to be compatible with state drug distribution laws, such as Act 1103. Act 1103 does not conflict with the purpose of REMS to ensure access to safe and effective medication.

PhRMA misses the point by arguing that limitations imposed by a REMS plan require manufacturers to distribute 340B drugs in accordance with relevant REMS requirements and that manufacturers would not be permitted to provide the drug to contract pharmacies that do not qualify under the REMS. Pl. Mot. at 31-32; *see also* 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,312 (Aug. 28, 2015). The pertinent question for preemption is whether enforcement of Act 1103 would result in violation of one or more of the restrictions. The answer is clearly no.

A REMS plan often limits which drugs may be purchased by covered entities and which pharmacies are authorized to dispense those drugs. Nothing in Act 1103 forces a manufacturer to distribute REMS drugs outside of REMS requirements, whether or not that pharmacy is a contract pharmacy. For example, Bristol Myers Squibb manufactures three drugs that are subject to REMS due to the serious risk that the drugs pose to patients if precautions are not taken. *Commitment to Safety and Patients: Risk Evaluation and Mitigation Strategies (REMS)*, Bristol

Myers Squibb, (July 2022).[24] If a REMS program restricts the pharmacies that can dispense a drug, a wholesaler will only ship the drug to those pharmacies and covered entities would have to have a contract pharmacy arrangement with one of those pharmacies in order for 340B-priced drugs to be shipped to that pharmacy. If the covered entity does not have a bill to/ship to arrangement with an authorized pharmacy, Act 1103 would not be implicated.

Act 1103 does not make it impossible for drug manufacturers to comply with the FDCA because Act 1103 does not prohibit the manufacturer from complying with REMS requirements. Furthermore, Act 1103 does not determine under what conditions a drug can be used safely and effectively, which is within the FDA's regulatory authority. PhRMA's allegation that its members must choose to comply with either the FDCA's REMS requirements or Act 1103 should be rejected.

IV. PhRMA's Motion Should Be Denied Because a Material Issue of Fact Remains in Dispute

Finally, this Court should deny PhRMA's motion because a material issue of fact remains in dispute in this case. PhRMA's motion hinges on its allegation that contract "pharmacies . . . purchase drugs at the 340B price" to replenish the drugs dispensed to covered entity patients. Pl. Mot. at 9; Pl. Statement of Material Facts ¶¶ 27, 28. PhRMA significantly misrepresents how 340B contract pharmacy distribution arrangements operate. Contract pharmacies do not *purchase* or take title to 340B drugs distributed under the 340B Program. Pedley Decl. ¶¶ 7, 8, 9 (former OPA Director, Rear Admiral Krista Pedley stating that contract pharmacies do not purchase 340B drugs and that covered entities purchase 340B drugs); CHCA Decl. ¶ 8 (CHCA's "community health centers purchase and take title to the 340B medications, but the drugs are shipped to and dispensed by contract pharmacies."). This disputed fact is material to whether

[24] https://www.bms.com/patient-and-caregivers/risk-evaluation-and-migration-strategies-rems.html.

Act 1103, which prohibits manufacturers from encumbering access to 340B priced drugs for Arkansas pharmacies, would impliedly conflict with Congress's objectives for the 340B Program, which entitles only covered entities to *purchase* those drugs. Pl. Mot. at 24; 42 U.S.C. § 256b(a)(1), (4).

PhRMA alleges that "pharmacies . . . purchase drugs at the 340B price" and, therefore, Act 1103 would "conflict with Congress' purposes and objectives" that only covered entities purchase 340B drugs. Pl. Mot. at 9, 23-24; Pl. Statement of Material Facts ¶¶ 27, 28. Based on this faulty factual allegation, PhRMA contends that Act 1103 expands the 340B Program to enable any contract pharmacy to "participate" in the 340B Program in conflict with the purposes of the 340B statute. *See, e.g.*, Pl. Mot. at 3; ECF No. 1 ¶¶ 66-104 (seeking an order declaring that Act 1103 does not require PhRMA's members to offer price discounts under the 340B Program to contract pharmacies in Arkansas).

However, contract pharmacies do not purchase 340B drugs. Pedley Decl. ¶¶ 7, 8, 9; CHCA Decl. ¶ 8. Rather, the contract pharmacy obtains possession of the drugs on behalf of the covered entity to dispense the drugs to the covered entity's patients. *Id.*; CHCA Decl. ¶ 8. It is a well-recognized precept of the 340B Program that only covered entities purchase 340B drugs from wholesalers and manufacturers. Pedley Decl. ¶¶ 7, 8, 9; CHCA Decl. ¶ 8. Moreover, only covered entities may establish 340B accounts with wholesale distributors. *See id.*; CHCA Decl. ¶ 8. Indeed, PhRMA's own exhibit—from Rear Admiral Krista Pedley—states that covered entities, not contract pharmacies, purchase 340B drugs. Pedley Decl. ¶¶ 7, 8, 9.

PhRMA's assertion not only defeats its Motion by leaving in dispute an issue of material fact, it undermines the core of PhRMA's preemption arguments. Without evidence that 340B drugs are purchased by contract pharmacies, PhRMA fails to demonstrate that Act 1103 invades

the conduct regulated by the 340B purchasing statute. This Court should, therefore, deny PhRMA's motion for summary judgment as a matter of law.

CONCLUSION

For the foregoing reasons, Act 1103 is not preempted by federal law, and the court should grant Intervenor-Defendant's motion for summary judgment and deny PhRMA's motion for summary judgment.

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Respectfully submitted,

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