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

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA — **PLAINTIFF**

V. — **Case No. 4:21-CV-864-BRW**

ALAN MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department — **DEFENDANT**

COMMUNITY HEALTH CENTERS OF ARKANSAS; PIGGOTT COMMUNITY HOSPITAL — **INTERVENORS**

ORDER

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

I. BACKGROUND[2]

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

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

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

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

Intervenor Piggott Community Hospital ("PCH") is located in Piggott, Arkansas, and is designated under the Medicare program as a critical access hospital ("CAH"). PCH is owned and operated by the City of Piggott and participates in the 340B Program based on its governmental ownership and CAH status.[7]

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

This case arises out of a dispute between drug manufacturers and the Arkansas Insurance Department ("AID") about the use of "contract pharmacies" as a part of the Federal 340B drug program. Plaintiff contends that these contract pharmacies "have found illegal ways to leverage

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[3]Doc. No.1

[4]Doc. No. 32.

[5]Doc. No. 39.

[6]Doc. No. 40.

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

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

the 340B discounts to their financial benefit, often without assisting the vulnerable patient populations that the 340B program was intended to help."[9]

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

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

On August 8, 2022, Plaintiff filed its Motion for Summary Judgment on Claim I.[15] First, Plaintiff contends that the 340B Program is strictly a federal scheme that is not subject to state regulation. Second, Plaintiff argues that Act 1103 conflicts with the 340B Program by essentially adding "contract pharmacies" to the list of "covered entities" as defined in the statute. Third, Plaintiff asserts that Act 1103 conflicts with the enforcement authority granted to HHS and its agency the Health Resources and Services Administration ("HRSA") by establishing a

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

[10]*Id.*

[11]*Id.*

[12]*Id.*

[13]Doc. No.27.

[14]Doc. No 28.

[15]Doc. No. 24.

separate enforcement scheme with additional penalties. Fourth, Plaintiff contends that Act 1103 conflicts with the Federal Food, Drug, and Cosmetic Act ("FDCA") "by mandating how federally regulated drugs may be distributed in Arkansas" without regard to federal safety standards.[16]

In response, Defendant and Intervenors seek a narrow interpretation of the provisions in Act 1103 and contend that even if I agree with Plaintiff's broad interpretation of Act 1103, a fact issue remains on the ownership status of the discounted drugs as they are distributed through the system.[17]

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

II. SUMMARY JUDGMENT STANDARD

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

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

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[16]Doc. No. 26, p. 13.

[17]Doc. Nos. 30, 35.

[18]Doc. Nos. 35, 36.

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

[20]*Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

The Court of Appeals for the Eighth Circuit has cautioned that summary judgment is an extreme remedy that should only be granted when the movant has established a right to the judgment beyond controversy.[21] Nevertheless, summary judgment promotes judicial economy by preventing trial when no genuine issue of fact remains.[22] This court must view the facts in the light most favorable to the party opposing the motion.[23] The Eighth Circuit has also set out the burden of the parties in connection with a summary judgment motion:

> [T]he burden on the party moving for summary judgment is only to demonstrate, *i.e.*,"[to point] out to the District Court," that the record does not disclose a genuine dispute on a material fact. It is enough for the movant to bring up the fact that the record does not contain such an issue and to identify that part of the record which bears out his assertion. Once this is done, his burden is discharged, and, if the record in fact bears out the claim that no genuine dispute exists on any material fact, it is then the respondent's burden to set forth affirmative evidence, specific facts, showing that there is a genuine dispute on that issue. If the respondent fails to carry that burden, summary judgment should be granted.[24] Only disputes over facts that may affect the outcome of the suit under governing law will properly preclude the entry of summary judgment.[25]

III. DISCUSSION

A. 340(B) Drug Program

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

[22] *Id.* at 728.

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

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

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

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

Specifically, all drug manufacturers participating in the 340B Program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[28] The 340B Program "ceiling prices," which are calculated according to a prescribed statutory formula,[29] are lower than the amounts other purchasers would pay. These drug pricing discounts are intended to "enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[30]

To participate in the 340B Program, manufacturers are required to sign a contract with HHS known as the Pharmaceutical Pricing Agreement ("PPA"), which incorporates the statutory obligations of the 340B Program and expresses the manufacturers' agreement to abide by those obligations.[31] If, at some point, HHS determines that a drug manufacturer has failed to comply

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

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

[28]42 U.S.C. § 256b(a)(1).

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

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

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

with its 340B Program obligations, the manufacturer's PPA can be terminated, which prevents the manufacturer from receiving coverage for its drugs under Medicare and Medicaid.[32]

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

B. Act 1103

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

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

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

[33]42 U.S.C. § 256b(a)(5)(A).

[34]*Id.* § 256b(a)(5)(B).

[35]Doc. No. 37, p. 6.

[36]*Id.*

[37]*Id.*

> A pharmaceutical manufacturer shall not:
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> (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
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> (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.[38]

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

C. 340(B) Program Preemption

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

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[38]Ark. Code Ann. § 23-92-604(c).

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

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

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

[42]*Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 604 (1991).

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

preemption, the Supreme Court is highly deferential to state law in areas traditionally regulated by the states.[44]

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

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[44]*N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995).

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

[46]*Id.* (citing *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001)).

[47]*Id.*

[48]*Id.* (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

[49]*Id.* (citing *Silkwood v. Kerr–McGee Corp.*, 464 U.S. 238, 248 (1984)).

[50]*Id.*

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

1. Field Preemption

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

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

In *Astra*, a collection of "covered entities" sued drug manufacturers for alleged overcharges on 340B Program-covered drugs.[57] Both sides "conceded that Congress authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling."[58] Unable to sue the drug companies directly under the

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

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

[53] *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

[54] *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517 (1992) (quotation omitted).

[55] 563 U.S. 110, 121(2011).

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

[57] *Id.*

[58] *Id.* at 113.

340B Program, the covered entities pursued their claims under a breach of contract theory as third-party beneficiaries of contracts between HHS and drug companies that create 340B Program discount-ceiling prices.[59]

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

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

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

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[59] *Id.*

[60] *Id.* at 121

[61] *Id.* at 121-22 (citing 42 U.S.C. § 256b(d)).

[62] *Id.*

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

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

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

2. Impossibility Preemption

To establish impossibility preemption, a party must be unable to comply with both federal law and state law.[68] When determining whether impossibility preemption implies, a court must look to whether it is lawful under federal law to accomplish what the state law requires.[69]

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

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

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

[66]*Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

[67]*Id.*

[68]*PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668, 1672 (2019).

[69]See *id.*

The 340B Program provides that "a covered entity shall not resell or otherwise transfer" drugs to any "person who is not a patient of the entity."[70] Plaintiff contends that this provision bars the distribution of 340B-discounted drugs by covered entities to anyone other than their patients, which Plaintiff contends Act 1103 requires. I disagree.

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

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

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

I note that it is beyond my purview to determine whether purchases made using the replenishment model constitute diversion as Congress explicitly required manufacturers to

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[70]42 U.S.C. § 256b(a)(5)(B).

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

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

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

3. Obstacle Preemption

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

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

Plaintiff argues that Act 1103 is preempted because it places contract pharmacies on the 340(B) Program's covered entities list and interferes with the 340B Program's enforcement mechanism, thereby undermining the purpose of the 340B Program. In response, Defendants contend that Act 1103 only applies to the distribution of the discounted drugs and the contracts between covered entities and pharmacies within the state, not pricing.

I agree with the Defendant and Intervenors. Even though the title of Act 1103 includes pricing in its name, the effects of the disputed provisions are limited to the distribution of and access to the discounted drugs. Plaintiff has provided no evidence that Act 1103 interferes with

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[73] 42 U.S.C. § 256b(d)(3)(B)(iv).

[74] *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000) (internal citations and quotations omitted).

PPA agreements between covered entities and HHS, or, in effect, adds contract pharmacies to the covered entities list. The drug-ceiling price has already been set at the point Act 1103 becomes applicable to any specific drug shipment. Act 1103 has no bearing on setting the ceiling price. Further, the penalties that may be assessed for violations of Act 1103 relate to activities outside the scope of the 340(B) Program's enforcement procedures which are focused overcharging covered entities.[75] Accordingly, Act 1103 is not obstacle to the purpose and objective of the 340(B) Program.

D. FDCA Preemption

Plaintiff contends that Act1103 is preempted by the FDCA's Risk Evaluation and Mitigation Strategies ("REMS") program. The REMS program was established in 2007 to ensure the safe use of potentially high-risk products that might otherwise not be approved for use.[76] The Food and Drug Administration ("FDA") can require a REMS when "necessary to ensure that the benefits of the drug outweigh the risks of the drug."[77] To evaluate a REMS program, the FDA must consider whether the REMS requirements are "unduly burdensome on patient access to the drug," whether they "minimize the burden on the health care delivery system," and whether the REMS program is "compatible with established distribution, procurement, and dispensing systems for drugs."[78] Under the statute, the FDA is permitted to require, that "pharmacies . . . that dispense [a] drug [covered by a REMS] are specially certified" or that a drug "be dispensed

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

[76] 21 U.S.C. § 355-1.

[77] *Id.* § 355-1(a).

[78] *Id.* § 355-1(f)(2)(C), (D)(ii).

to patients only in certain health care settings."[79] A manufacturer who violates a REMS is subject to federal monetary penalties and potentially criminal liability.[80]

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

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

Act 1103 is not preempted by either the 340(B) Program or the FDCA. The parties are directed to submit an agreed proposed briefing schedule on the remaining commerce clause claim within five days of the date of this Order. The January 3, 2023 trial date is continued, and will be reset by a revised scheduling to be entered at a future date.

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[79] *Id.* § 355-1(f)(3)(B)–(C).

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

[81] *Wyeth v. Levine*, 555 U.S. 555, 567 (2009); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 941 (8th Cir. 2011).

CONCLUSION

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

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

BILLY ROY WILSON

UNITED STATES DISTRICT JUDGE