UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF OKLAHOMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, v. GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma, and the OKLAHOMA INSURANCE DEPARTMENT, Defendants.	)	Case No. CIV-19-977-J

ORDER

Before the Court are the parties' cross motions for summary judgment [Doc. Nos. 96 and 97] .[1] The motions have been fully briefed. Based upon the parties' submissions, the Court makes its determination.[2]

I. Background

In simple terms, health insurance plans design pharmacy benefits by determining, among other factors, what drugs are covered, where beneficiaries can obtain these drugs using their plan benefits, and any cost-sharing the plan member will be required to pay for the covered drug. The vast majority of health insurance plans providing drug benefits use a pharmacy benefit manager (PBM) to act as an intermediary in ensuring beneficiaries can use their drug benefits to obtain

[1] In its motion, Plaintiff Pharmaceutical Care Management Association (PCMA) requests oral argument. Having reviewed the parties' submissions, the Court determines that oral argument is not necessary and denies PCMA's request.

[2] PCMA has also filed a *Daubert* motion to exclude the expert testimony of Debra Billingsley [Doc. No. 99]. Because the Court has not relied on Ms. Billingsley's testimony in ruling on the parties' cross motions for summary judgment, the Court concludes that no ruling on PCMA's *Daubert* motion is necessary.

prescriptions. PBMs create pharmacy networks and then contract with pharmacies in those networks to provide prescriptions to beneficiaries. When a pharmacy dispenses the prescription, it then files a claim with the PBM. The PBM processes that claim and notifies the pharmacy how much the plan will pay and how much the beneficiary must pay. Afterwards, the PBM reimburses the pharmacy according to the contract between the PBM and the pharmacy. The contract between the PBM and the pharmacy determines the reimbursement rate, not the insurance plan. The PBM then bills the insurance plan according to its contract with the insurance plan, and the insurance plan pays the prescription benefit to the PBM.

Several states, including Oklahoma, have sought to regulate PBMs. In 2019, the Oklahoma Legislature passed the Oklahoma's Patient's Right to Pharmacy Choice Act (Act), Okla. Stat. tit. 36, § 6958, *et seq.* To compliment the Act, the Oklahoma Insurance Department enacted various regulations.

PCMA is the national trade association for PBMs, representing sixteen PBMs. In this case, PCMA challenges the Act and the related regulations.[3] Specifically, PCMA alleges the Employment Retirement Income Security Act (ERISA) and Medicare Part D preempt the Act and related regulations and claims that the regulations were adopted in violation of the Oklahoma Administrative Procedures Act (OAPA). On July 9, 2020, the Court granted in part and denied in part PCMA's motion for preliminary injunction and enjoined enforcement of Okla. Stat. tit. 36, §§ 6961(A),(D) and Okla. Admin. Code 365:25-29-7.1(a)(3). PCMA and Defendants now each move for judgment as a matter of law.

[3] PCMA brings this litigation on behalf of its members.

II. Analysis

A. ERISA preemption

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA. 29 U.S.C. § 1144(a). "[A] state law relates to an ERISA plan if it has a connection with or reference to such a plan." *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 479 (2020) (internal quotations and citation omitted).[4] Regarding "connection with" preemption, laws that require providers to structure benefit plans in certain ways or bind plan administrators to specific rules for beneficiary status are preempted. *See id.* at 480. Further, "[a] state law may also be subject to pre-emption if acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage." *Id.* (internal quotations and citation omitted). However, "not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan." *Id.* "[S]tate rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage" are not preempted. *Id.*

PCMA asserts the Act impermissibly dictates the design of ERISA plans by regulating the nature and scope of the plan's provider network and the programs an employee benefit plan may adopt to ensure network quality and integrity. Specifically, PCMA contends the Act's Any Willing Provider Provision, Okla. Stat. tit. 36, § 6962(B)(4); Retail-Only Pharmacy Access Standards, Okla. Stat. tit. 36, § 6961(A),(B); Affiliated Pharmacy Prohibition, Okla. Stat. tit. 36, § 6961(C); Probation-Based Pharmacy Limitation Prohibition, Okla. Stat. tit. 36, § 6962(B)(5); Network

[4] PCMA contends the Act only implicates "connection with" preemption. The Court will thus limit its analysis to "connection with" preemption.

Provider Restriction Prohibition, Okla. Stat. tit. 36, § 6963(D); Cost Sharing Discount Provision, Okla. Stat. tit. 36, § 6963(E); and Promotional Materials Provision; Okla. Stat. tit. 36, § 6961(D),[5] dictate network composition, cost-sharing differentials, and communications with beneficiaries and thereby directly affect the benefits a plan offers to plan members. PCMA contends that as a result these provisions have an impermissible connection with ERISA plans and are thereby preempted.

Upon review of the specific language of these provisions, the Court concludes that they do not have a "connection with" an ERISA plan. The Any Willing Provider Provision applies only to preferred network participation status of pharmacies that are already in the plan's pharmacy network and does not require a plan to accept any willing pharmacy into its pharmacy network. The Retail-Only Pharmacy Access Standards and Cost Sharing Discount Provision do not prohibit using mail-order pharmacies; the use of these pharmacies just does not count toward meeting the access standards, and the plan cannot restrict an individual's choice of an in-network pharmacy. The Affiliated Pharmacy Prohibition does not prohibit including affiliated pharmacies in the plan pharmacy network; the plan is just prohibited from requiring patients to use the affiliated pharmacies. The Probation-Based Pharmacy Limitation Prohibition addresses a pharmacy's contract, which is with the PBM and not the plan. The Network Provider Restriction Prohibition relates to pharmacies that are in-network providers and thus leaves the plan with options as to the composition of its in-network providers. While these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices.

[5] The Court will use the names given to these provisions by PCMA in its briefing.

Regarding the Promotional Materials Provision, PCMA asserts the Act impermissibly prohibits plans from communicating their benefit design to beneficiaries by not allowing them to mention certain pharmacies without mentioning all pharmacies. The Act's Promotional Materials Provision, however, does not regulate benefit design disclosures to beneficiaries but regulates how PBMs can advertise its providers. This provision therefore does not relate to a central matter of plan administration nor undermine the uniform regulation of ERISA plans.

PCMA also asserts the Post-Sale Price Reduction Prohibition, Okla. Stat. tit. 36, § 6962(B)(6), and the Affiliated Pharmacy Price Match, Okla. Stat. tit. 36, § 6962(B)(3), impermissibly dictate the design of ERISA plans by regulating the programs an employee benefit plan may adopt to ensure network quality and integrity. While the Post-Sale Price Reduction Prohibition and the Affiliated Pharmacy Price Match will have some effect on the way PBMs pay and/or reimburse pharmacies, these provisions do not impermissibly dictate the design of ERISA plans by forcing the plans into making a specific choice.

Finally, PCMA contends the Act's Health Insurer Monitoring Requirement, Okla. Stat. tit. 36, § 6963(A),(B), is preempted by ERISA. Defendants assert PCMA lacks standing to challenge this provision because it imposes obligations exclusively upon a health insurer,[6] and PCMA is made up exclusively of PBMs and does not contain any health insurers. PCMA asserts it has standing because complying with the insurers' monitoring activities required by this provision causes harm to PBMs by creating an administrative burden on them. An administrative burden can constitute an injury in fact for standing purposes. *See Okla. ex rel. Pruitt v. Sebelius*, No. CIV-11-30-RAW, 2013 WL 4052610 at *8 (E.D. Okla. Aug. 12, 2013). However, PCMA only makes

[6] Under the Act, a "health insurer" is a separate and distinct entity from a PBM. *See* Okla. Stat. tit. 36, § 6960(1),(3).

a conclusory allegation of administrative burden in relation to the Health Insurer Monitoring Requirement. Having reviewed the parties' submissions, the Court finds that PCMA has not made a sufficient showing of injury and that PCMA lacks standing to raise an ERISA challenge to this provision.

Accordingly, the Court concludes the Act is not preempted by ERISA and Defendants are, therefore, entitled to summary judgment as to this claim.

B. Medicare Part D Preemption[7]

Medicare Part D incorporates the express preemption provision contained in Medicare Part C. *See* 42 U.S.C. § 1395w-112(g). Part C's preemption provision provides:

> The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.

42 U.S.C. § 1395w-26(b)(3). The Tenth Circuit has not addressed the scope of Medicare Part D, but other appellate courts have found preemption where "(1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established 'standards' in the area regulated by state law; and (2) the state law acts 'with respect to those standards.'" *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018);[8] *see also Do Sung Uhm v. Humana*, 620 F.3d 1134, 1148 n.20, 1157-58 (9th Cir. 2010). The standards need not conflict for preemption to occur. *Rutledge*, 891 F.3d at 1113.

[7] Defendants concede the Promotional Materials Provision and the Cost Sharing Discount Provision are preempted by Medicare Part D. *See* Defendants' Response to Plaintiff's Motion for Summary Judgment [Doc. No. 100] at 2, n.2.

[8] In *Rutledge*, the Supreme Court did not review the Eighth Circuit's holding that the Arkansas statute was preempted by Medicare Part D.

PCMA contends CMS has already established detailed standards regulating a Part D's sponsor's pharmacy networks. PCMA therefore asserts Medicare Part D preempts the Retail-Only Pharmacy Access Standards, Any Willing Provider Provision, Affiliated Pharmacy Prohibition, and Network Provider Restriction Prohibition. The Court will address each of these standards.

First, Part D has standards for convenient access to network pharmacies, and these standards contain geographic restrictions for pharmacy networks. The Retail-Only Pharmacy Access Standards contain similar geographic restrictions on retail pharmacies in a PBM's network. Because CMS has established standards regarding convenient access to network pharmacies and the Retail-Only Pharmacy Access Standards act with respect to those standards, the Court concludes the Retail-Only Pharmacy Access Standards are preempted by Medicare Part D.

Second, while Part D has an any willing provider standard in relation to a plan's standard network, the Any Willing Provider Provision in the Act relates to the preferred network rather than the standard network. As such, the Any Willing Provider Provision does not act "with respect to" the Part D any willing provider standard and is not preempted by Medicare Part D.

Third, PCMA asserts that Part D's Preferred Pharmacy Network Standard, 42 C.F.R. § 423.120(a)(9), expressly permits the use of preferred pharmacy networks, and the Act's Affiliated Pharmacy Prohibition and Network Provider Restriction are preempted because they set additional requirements for when a Part D sponsor may limit a beneficiary's choice of pharmacy. Part D's Preferred Pharmacy Network Standard simply provides that a Part D plan may include a preferred pharmacy network but does not regulate or provide any standards as to how such preferred pharmacy networks must be structured or managed. Because there are no standards to act "with respect to", the Affiliated Pharmacy Prohibition and Network Provider Restriction are not preempted by Medicare Part D.

Fourth, PCMA asserts the Service Fee Prohibition, Okla. Stat. tit. 36, § 6962(B)(2), Affiliated Pharmacy Price Match, and Post-Sale Price Reduction Prohibition are preempted. PCMA contends these provisions regulate a Part D sponsor's payment of claims that are in addition to, and in conflict with, the market-based model Congress sought to create in establishing the Part D program and create state specific standards for retroactive claims adjustments where exclusive federal regulation already exists. Medicare Part D prohibits interference with the negotiations between Part D Sponsors and pharmacies and prohibits any requirement of a particular formulary or price structure for the reimbursement of covered part D drugs. *See* 42 U.S.C. § 1395w-111(i). "[This] statute prohibits both federal and state interference in negotiations between Part D sponsors and pharmacies . . . ." *Rutledge*, 891 F.3d at 1113. Further, Medicare Part D defines "negotiated prices" in part as prices "The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug." 42 C.F.R. § 423.100. Additionally, Part D provides that a plan "must comply with all administrative processes and requirements established by CMS . . . for . . . (3) Retroactive claims adjustment, ..." 42 C.F.R. § 423.464(a). Because the Service Fee Prohibition, Affiliated Pharmacy Price Match, and Post-Sale Price Reduction Prohibition act with respect to Medicare Part D standards for negotiated prices and negotiations with pharmacies, the Court concludes these provisions are preempted by Medicare Part D.

Fifth, PCMA asserts the Probation-Based Pharmacy Limitation Prohibition and Termination Payment Requirement, Okla. Stat. tit. 36, § 6962(B)(7), impermissibly infringe upon Medicare Part D's quality assurance standards and thus are preempted by Medicare Part D. The quality assurance standards set forth in Part D provide, in pertinent part: "A Part D sponsor must

have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use" and then sets forth certain measures that should be used. 42 C.F.R. § 423.153(c). Neither the Probation-Based Pharmacy Limitation Prohibition nor the Termination Payment Requirement act with respect to Medicare Part D's quality assurance standards and thus are not preempted.

Finally, PCMA asserts the Health Insurer Monitoring Requirement and the Contract Approval Rule, Okla. Admin. Code 365:25-29-9(c)(1), are preempted by Medicare Part D. As set forth above, PCMA has not made a sufficient showing of injury in relation to the Health Insurer Monitoring Requirement, and the Court concludes that PCMA lacks standing to raise a Medicare Part D challenge to this provision. PCMA, however, has made a sufficient showing of injury in relation to the Contract Approval Rule to have standing to challenge the rule.[9]

PCMA contends the Contract Approval Rule adds new monitoring requirements for Part D sponsors on top of those already created by the federal government. The Contract Approval Rule requires every insurer that uses the services of a PBM to approve all contracts used by the PBM and its retail pharmacy network to ensure compliance with the Act. Medicare Part D sets forth specific items that must be contained in the contract between the Part D plan sponsor and the PBM or other similar entity. Since the contracts at issue in the Contract Approval Rule and the Medicare Part D standards are different types of contracts, the Court concludes the Contract Approval Rule does not act with respect to the Medicare Part D standards and therefore is not preempted.[10]

[9] Under the Contract Approval Rule, PBMs are required to submit each contract used by the PBM and its pharmacy network for approval, thereby creating a sufficient administrative burden to constitute an injury for standing purposes.

[10] However, as set forth below, the Court concludes the Contract Approval Rule is not valid.

C. OAPA Claims

1. Supplemental jurisdiction

Defendants assert this Court does not have supplemental jurisdiction over PCMA's OAPA claims. 28 U.S.C. § 1367 provides, in pertinent part:

> in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

28 U.S.C. § 1367(a). When the state and federal claims "derive from a common nucleus of operative fact" such that the relationship between the claims permits the conclusion that the entire action comprises one constitutional case, the state claims are within a court's supplemental jurisdiction. *See City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 164-65 (1997). PCMA's federal preemption claims and state OAPA claims all derive from a common nucleus of operative facts and comprise one constitutional case. This Court, accordingly, has supplemental jurisdiction over PCMA's OAPA claims.

Defendants further assert that even if this Court has supplemental jurisdiction, the Court should decline to exercise it. Section 1367(c) provides:

> The district courts may decline to exercise supplemental jurisdiction over a claim under subsection (a) if –
>
> (1) the claim raises a novel or complex issue of State law,
>
> (2) the claim substantially predominates over the claim or claims over which the district court has original jurisdiction,
>
> (3) the district court has dismissed all claims over which it has original jurisdiction, or
>
> (4) in exceptional circumstances, there are other compelling reasons for declining jurisdiction.

28 U.S.C. § 1367(c). None of these bases is applicable in this case. While Defendants contend there is an independently compelling reason for declining jurisdiction, the Court, upon reviewing

the facts of this case, finds no compelling reason. The Court will, therefore, address PCMA's OAPA claims.

2. Merits

PCMA contends that certain Oklahoma administrative regulations were adopted in violation of the OAPA. Oklahoma allows challenges to administrative regulations under Okla. Stat. tit. 75, § 306(A). When a regulation is challenged, the agency which promulgated the regulation bears the burden of showing:

> 1. that the agency possessed the authority to promulgate the rule;
> 2. that the rule is consistent with any statute authorizing or controlling its issuance and does not exceed statutory authority;
> 3. that the rule is not violative of any other applicable statute or the Constitution; and
> 4. that the laws and administrative rules relating to the adoption, review and promulgation of such rules were faithfully followed.

Okla. Stat. tit. 75, § 306(C).

PCMA asserts the Promotional Materials Rule, Okla. Admin. Code 365:25-29-7.1(a)(3), is inconsistent with the Promotional Materials Provision because it leaves out a significant qualifying clause: "participating in the preferred and nonpreferred pharmacy and health networks." *Compare* Okla. Stat. tit. 36, § 6961(D) *with* Okla. Admin. Code 365:25-29-7.1(a)(3). Defendants do not deny the language is different in the statute and the regulation but urge the Court to deviate from a literal reading that would lead to an absurd result even if the language is unambiguous. The Court declines to deviate because the plain language of the regulation places a burden on PBMs that is inconsistent with the Act and does more than the Act allows. Accordingly, the Court concludes the Promotional Materials Rule is not valid.

PCMA also asserts the Contract Approval Rule is inconsistent with the Health Insurer Monitoring Requirement because the rule appears to require each health insurer that contracts with

a PBM to approve every contract a PBM enters into while the Act requires health insurers merely to "monitor" the activities of those with which they contract and ensure that the requirements of the Act are met. While a duty to approve contracts to ensure compliance with the Act could fall within the definition of monitor, the monitoring required under the Health Insurer Monitoring Requirement does not necessarily have to include approving all contractual documents utilized by the PBMs. Defendants contend the Contract Approval Rule provides an efficient means to administer the Health Insurer Monitoring Requirement. Defendants' cursory efficiency argument, however, does not satisfy their burden to show that the Contract Approval Rule does not exceed the statutory authority of the Act. Accordingly, the Court concludes the Contract Approval Rule is not valid.

Finally, PCMA asserts the Specialty Drugs Rule, Okla. Admin. Code 365:25-29-7.1(a)(2),[11] arbitrarily applies the Act to specialty drugs despite great differences between specialty and regular drugs and despite the Affiliated Pharmacy Prohibition that specifically explicates the distinction. Defendants contend there is no distinction between regular and specialty drugs in the Act and the Specialty Drugs Rule is consistent with the Act. Having reviewed the Act, the Court finds the Affiliated Pharmacy Prohibition does not create or imply a difference between specialty and standard drugs and the Act does in fact contemplate all prescription drugs regardless of whether they are specialty or not. Accordingly, the Court concludes the Specialty Drugs Rule is valid.

[11] The Specialty Drugs Rule provides: "The act draws no distinction between regular or specialty drugs, both being prescription medications, therefore, specialty drugs fall within the contemplation of the act."

III. Conclusion

For the reasons set forth above, the Court GRANTS IN PART and DENIES IN PART PCMA's Motion for Summary Judgment [Doc. No. 97] and Defendants' Motion for Summary Judgment [Doc. No. 96] as follows:

(A) The Court GRANTS PCMA's Motion for Summary Judgment as to its Medicare Part D preemption claim with respect to the Act's Promotional Materials Provision, Cost Sharing Discount Provision, Retail-Only Pharmacy Access Standards, Service Fee Prohibition, Affiliated Pharmacy Price Match, and Post-Sale Price Reduction Prohibition and as to its OAPA claim with respect to the Promotional Materials Rule and Contract Approval Rule and DENIES the remainder of PCMA's Motion for Summary Judgment, and

(B) The Court GRANTS Defendants' Motion for Summary Judgment as to PCMA's ERISA preemption claim; PCMA's Medicare Part D preemption claim with respect to the Act's Any Willing Provider Provision, Affiliated Pharmacy Prohibition, Network Provider Restriction, Probation-Based Pharmacy Limitation Prohibition, Termination Payment Requirement, and Contract Approval Rule; and PCMA's OAPA claim with respect to the Specialty Drugs Rule and DENIES the remainder of Defendants' Motion for Summary Judgment.

IT IS SO ORDERED this 4th day of April, 2022.

BERNARD M. JONES
UNITED STATES DISTRICT JUDGE