

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

PHARMACEUTICAL CARE MANAGEMENT
ASSOCIATION,

Plaintiff,

v.

No. CIV-19-977-J

GLEN MULREADY, in his official capacity as
Insurance Commissioner of Oklahoma, and

OKLAHOMA INSURANCE DEPARTMENT,

Defendants.

DEFENDANTS' RESPONSE OPPOSING
PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Community pharmacies are an integral part of Oklahoma’s health care system. These brick-and-mortar retailers and their pharmacists improve the lives of Oklahomans every day by dispensing critical medications and providing medical services. *See* Ex. A, Decl. of Justin Wilson, D.Pharm., ¶¶ 9-10, 33; Ex. B, Decl. of Debra Billingsley, ¶ 52. Their efforts have been invaluable during the ongoing viral pandemic; they have spearheaded home delivery to protect the vulnerable—often free of charge—risked their health to dispense medication, and even implemented COVID-19 testing. Ex. A, Wilson ¶ 30; Ex. B, Billingsley ¶ 53.

But the viability of Oklahoma’s pharmacies, especially independent and rural pharmacies, has been severely undermined in recent times. This is due in large part to multi-billion-dollar entities known as pharmacy benefit managers (PBMs), the middlemen of the pharmaceutical world. PBMs wield enormous market power and have increasingly been self-dealing, restricting patient choice, shrinking reimbursements to pharmacies, and over-loading pharmacies with fees, all while avoiding transparency and accountability. *See* Ex. A, Wilson ¶¶ 12-28; Ex. B, Billingsley ¶¶ 18-33; Ex. C, Decl. of Ronald White, ¶¶ 16-20, 23.

Numerous States, with outcry in their communities about these abuses, have begun regulating PBMs. Indeed, in a recent Supreme Court filing, a remarkable **45 States** (including Oklahoma) jointly detailed “PBM business practices [that] have caused widespread harm,” and the “array of measures” States have passed to regulate PBMs and “protect access to affordable prescription drugs.” Brief for Calif. et al., *Rutledge v. PCMA*, 2020 WL 1372774, *5, *14 (March 2, 2020). The Oklahoma Legislature added to this nationwide regulatory consensus by passing—unanimously—the Patient’s Right to Pharmacy Choice Act. *See* 36 O.S. §§ 6958 *et*

seq.; Doc. 1-2. This Act contains a number of important regulations that increase PBM transparency, protect access to affordable prescription drugs, rein in anti-competitive practices, and protect pharmacies and patients from ongoing harms.

Last fall, Plaintiff Pharmaceutical Care Management Association (PCMA) sued, claiming the Pharmacy Choice Act is preempted by the Employee Retirement Income Security Act, 29 U.S.C. §§ 1001 *et seq.* (ERISA) and Medicare Part D. *See* Doc. 1. PCMA, a national PBM trade association, has now moved for a preliminary injunction. But PCMA has not met the criteria for such an injunction. Taking a scattershot approach, PCMA makes conclusory statements about preemption but fails to show with detailed and well-supported argument that it has a likelihood of success on its numerous preemption challenges. Moreover, PCMA ignores that PBMs in Oklahoma will still have to change their practices to comply with the Act for the multitude of health plans that are not covered by ERISA or Part D. So PCMA's "irreparable harm" will come to fruition, regardless of this lawsuit. On the flip side, the Act passed because pharmacies and patients in Oklahoma are suffering and clamoring for relief. *See* Ex. A, Wilson ¶¶ 12-34; Ex. B, Billingsley ¶ 55; Ex. C, White ¶¶ 18-23. The public interest, in other words, counsels strongly against injunction.

In the end, this Court should decline to enjoin the Act, which as a traditional State health and safety law is entitled to a presumption that it is "not to be superseded" by federal law "unless that was the clear and manifest purpose of Congress." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins.*, 514 U.S. 645, 654-55 (1995); *Gobeille v. Liberty Mut. Ins.*, 136 S. Ct. 936, 946 (2016) (presumption gives way only in "fundamental area of ERISA regulation"). To hold otherwise would render PBMs virtually untouchable.

BACKGROUND

A. Community Pharmacies: Vital Resources for Oklahomans

The traditional pharmacy model involves “community” or “retail” pharmacies; *i.e.*, physical establishments that serve a community. Ex. A, Wilson ¶ 9. Rural, urban, and suburban, such pharmacies perform many key functions: they dispense vital medications, answer difficult questions, resolve drug therapy problems, and ensure patients have the best possible health outcomes. *See* Ex. A, Wilson Decl. ¶¶ 9-10, 33; Ex. B, Billingsley ¶ 52.

Community pharmacy practice can be further divided into “independent” pharmacies, which are privately owned, and regional or national “chain” pharmacies, among others. Ex. A, Wilson ¶ 9. Independent pharmacies represent over one-third (35 percent) of community pharmacies nationwide. 2019 Nat’l Comm. Pharm. Ass’n (NCPA) Digest, NCPA, at 9, <http://www.ncpa.co/pdf/digest/2019/2019-digest.pdf>. This ratio is higher in Oklahoma, which as of 2018 had 409 independent pharmacies compared to 393 other types of community pharmacies (*i.e.*, 51/49 percent). *Id.* at 11. These independent pharmacies “play an important role in caring for the nation’s roughly 47 million,” and are particularly critical for “providing vital services to very rural areas.” *Id.* at 12-13; *see also* Ex. B, Billingsley ¶ 52. Indeed, around “74 percent of independent pharmacies are serving areas with a population less than 50,000.” 2019 NCPA Digest at 12-13; *see also* Ex. A, Wilson ¶ 2.

But independent pharmacies have floundered in the past several years. Nationwide, in 2018, the “number of [pharmacy] startups was smaller than closings,” independent pharmacies dispensed fewer prescriptions than 2017, and gross margins as a percentage of sales decreased. 2019 NCPA Digest at 5-6. One number, however, has gone up: the “cost of dispensing for

the average independent pharmacy.” *Id.* at 12. In Oklahoma, there were 49 fewer independent pharmacies in 2018 than in 2015—a decline of over 10 percent. *Compare* 2019 NCPA Digest at 10, *with* 2016 NCPA Digest, NCPA, at 10, <http://www.ncpa.co/pdf/digest/2016/2016-ncpa-digest-spon-cardinal.pdf>. Much of this decline can be placed at the feet of pharmacy benefit managers (PBMs).

B. PBMs: Courting Controversy and Creating Conflicts of Interest

The pharmaceutical system is notoriously complex. Health plans, in particular, are caught between physicians, hospitals, pharmacies, and drug manufacturers. Ex. A, Wilson ¶ 11. This pinch led, about half a century ago, to the creation and development of PBMs, which were meant to be the “go-between for the health plans, the pharmacies, and the manufacturers, serving as the negotiators and claims processors.” Ex. A, Wilson ¶ 11; *see also* Ex. C, White ¶¶ 10-12. PBMs are the middlemen in the process, in other words, negotiating and facilitating on all sides in an intricate web of relationships. Ex. B, Billingsley ¶¶ 12-17; *see also* 59 O.S. § 357 (defining “[p]harmacy benefits management” for Oklahoma law); *PCMA v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005) (describing role of PBMs).

At least at first, PBMs were not particularly powerful. In 1981, for instance, around 5 percent of a typical pharmacy’s business was paid directly by a PBM or health plan. Ex. C, White ¶ 12. Fast-forward 40 years and that number “has skyrocketed to 95%.” *Id.* (emphasis added). This explosion of influence occurred mostly during decades where PBMs operated with little direct regulation or oversight. *See* Ex. A, Wilson ¶ 12. During that same time, they expanded their practice, buying and operating retail and mail-order pharmacies themselves. Ex. A, Wilson ¶ 12. Now, PBMs wield enormous power that dwarfs that of major chains, to

say nothing of independents. *Id.* ¶¶ 12-14; Ex. B, Billingsley ¶¶ 18-20 (noting that Walgreens once lost \$4 *billion* disputing with a PBM); Ex. C., White ¶¶ 12-13, 20. Moreover, just three PBMs control 85% of the market. Ex. B, Billingsley ¶ 18.

PBMs have increasingly embraced controversial practices. *See* Ex. A, Wilson ¶¶ 12-28, 31-34 (testimony of pharmacist and former Okla. Pharm. Bd. president); Ex. B, Billingsley ¶¶ 21-34 (testimony of executive director of Okla. Pharm. Ass'n (OPhA)); Ex. C., White ¶¶ 12-20, 23 (testimony of pharmacist, former PBM auditor, and current Insurance Dep't Director of PBM Reg. Compliance). In sum, PBMs have used their market power to pay pharmacies unsustainably low reimbursements; push patients from community pharmacies and toward pharmacies owned by PBMs; harm pharmacists who the State is trying to rehabilitate; and charge exorbitant and retroactive fees. *Id.* These practices are making the pharmacy business borderline unviable, especially for independents. Ex. A, Wilson ¶ 22; Ex. B, Billingsley ¶ 55. Pharmacies have almost no bargaining or negotiating power in regard to PBMs. Ex. A, Wilson ¶¶ 14, 31-32; Ex. B, Billingsley ¶¶ 19-20; Ex. C, White ¶¶ 13, 20. Because they control the networks, PBMs can cut off a pharmacy's access to patients. So if pharmacies want to stay in business, they must accept lopsided terms.

Recently, the White House Council of Economic Advisors found that PBMs “exercise undue market power against manufacturers and against health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves.” CEA, White Paper, Reforming Biopharmaceutical Pricing at Home and Aboard (February 2018). These types of abuses have led to rising prescription costs and the closure of independent pharmacies—particularly in rural areas—and less access to necessary treatments. U.S. Dep't

of Health & Human Servs., OIG, *Fraud and Abuse*, 84 Fed. Reg. 2,340, 2,340-41 (Feb. 6, 2019); *see also* Linette Lopez, *What CVS is Doing to Mom-and-Pop Pharmacies in the U.S. Will Make Your Blood Boil*, BUSINESS INSIDER (Mar. 30, 2018), <https://tinyurl.com/vqph452>. Lower reimbursements to pharmacies aren't translating to lower costs for consumers—just higher profits for PBMs. That is to say, patients are suffering too, not just pharmacies. *See, e.g.*, Ex. C, White ¶ 23.

C. States Push Back: A Nationwide Consensus to Regulate PBMs

These PBM abuses have not gone unnoticed. Contrary to PCMA's portrayal of Oklahoma as a rogue State, PI Mem. 12-13, pharmacists and patients have protested these practices in *many* States. Those States have responded with PBM laws and regulations. *See* Ex. B, Billingsley ¶ 35; Brief for Calif., *Rutledge*, 2020 WL 1372774 at *14-21 (cataloguing variety of State approaches to PBM regulation). Many of these have gone unchallenged—including Oklahoma laws PCMA inexplicably ignores despite its broad preemption logic. *See* 59 O.S. §§ 357-360 (regulating PBM licensure, transparency, and rate calculation).

Other laws have been challenged by PCMA recently and upheld in federal district courts. *See PCMA v. Tufte*, 326 F. Supp. 3d 873 (D.N.D. 2018) (granting summary judgment to State against PCMA's ERISA and Part D challenges); *PCMA v. Rutledge*, 240 F. Supp. 3d 951 (E.D. Ark. 2017) (similar). And even when the Eighth Circuit reversed the Arkansas court, *Rutledge*, 891 F.3d 1109 (8th Cir. 2018), the United States urged the Supreme Court to reverse the Eighth Circuit, Brief for United States as Amicus Curiae, *Rutledge v. PCMA*, 2019 WL 6609430 (Dec. 4, 2019), and the Supreme Court granted certiorari, 140 S. Ct. 812 (2020).

Although the *Rutledge* briefing has finished, the Supreme Court’s argument and decision were unfortunately postponed to next term due to the COVID-19 outbreak. In any event, the United States and nearly every individual State have joined together in opposing PCMA’s position in that case. *See, e.g.*, Brief for Calif., *Rutledge*, 2020 WL 1372774. To put it bluntly, rare is the day when the United States, California, Texas, New York, and Oklahoma all agree on *anything*, much less a critical legal and factual issue. But that is how bad things have gotten with PBMs, and how dire the situation is for pharmacies and patients.

D. Oklahoma Takes Bipartisan Action: The Pharmacy Choice Act

In 2019, in response to Oklahomans’ vocal exasperation at those abuses,¹ the Oklahoma Legislature enacted the Pharmacy Choice Act in a unanimous, bipartisan basis. *See* Ex. D, House. & Senate Votes, HB 2632. The Act contains numerous provisions that (1) protect patient access and choice, (2) require PBM transparency, and, (3) rein in anti-competitive practices. Defendants do not quibble with most of Plaintiff’s summary labels for, and descriptions of, these provisions. The Act speaks for itself, though, and where it differs from Plaintiff’s description the Act obviously controls.

Nor do Defendants have space to explain the purpose and effect of every challenged provision, although Defendants’ witnesses provide more detail. *See* Ex. A, Wilson ¶¶ 14-28; Ex. B, Billingsley ¶¶ 35-43; Ex. C, White ¶¶ 12-23. Justin Wilson, for example, explains with numbers from his pharmacies how “PBMs have drastically decreased reimbursements to

¹ When the Act was being deliberated, for example, Rep. Regina Goodwin (D-Tulsa) stated: “[M]y pharmacist there in Tulsa, Oklahoma has really been ringing the phone saying he needs this, he’s independent . . . it’s this kind of legislation that helps the little guy” *See* Audio/Video, Okla. House 1st Reg. Sess., 57th Legis., Day 22, March 11, at 3:57:20 PM, *available at* <https://www.okhouse.gov/Video/Default.aspx>.

pharmacies they don't own." Ex. A, Wilson ¶¶ 20-24. Wilson testifies this problem would be addressed by the Act's barring PBMs from reimbursing a pharmacy "an amount less than the amount that the PBM reimburses" its own pharmacy for the same covered services." *Id.* ¶ 24 (quoting 36 O.S. § 6962(B)(3)). Similarly, Debra Billingsley testifies that PBMs have been charging pharmacies retroactive fees, Ex. B, Billingsley ¶¶ 29-30, 50-51, a practice that will be curtailed by the Act's barring PBMs from charging "a pharmacist or pharmacy a fee related to the adjudication of a claim." 36 O.S. § 6962(B)(2). Finally, Ronald White testifies about pharmacies being excluded from preferred networks, which has led to patients complaining about being forced to avoid their local pharmacy. Ex. C, White ¶¶ 19, 22-23. This is addressed by several provisions of the Act, including the provision prohibiting PBMs from denying a pharmacy preferred network status if it "is willing to accept the terms and conditions that the PBM has established for other pharmacies." 36 O.S. § 6962(B)(4).

E. Subsequently: COVID-19, Delayed Review, and Further Abuse

Given the byzantine nature of the case, the State initially agreed to stay enforcement of certain parts of the Act against PCMA and its members, temporarily, but without waiving any argument in defense of the law. Doc. 19. In return, Plaintiff agreed not to seek a preliminary injunction. *Id.* Shortly after, the U.S. Supreme Court granted certiorari in *Rutledge*. 140 S. Ct. 812 (2020). Expecting a quick adjudication by the Supreme Court, the parties jointly moved, and this Court agreed, to hold the case in abeyance. Doc. 25 & 26.

But conditions changed. Not only did COVID-19 cause the Supreme Court to postpone hearing *Rutledge*, but it further strained Oklahoma pharmacists when their services are needed most. Ex. B, Billingsley ¶ 53. And, critically, PBMs ramped up their abusive

practices. *See* Ex. A, Wilson ¶¶ 31-32; Ex. B, Billingsley ¶¶ 54-55; Ex. C, White Decl. ¶ 23. While the Act has been on hold, Wilson has “been seeing proposed contracts and contractual revisions coming from PBMs out there that are egregiously awful for us. I’ve never seen anything like it. ... [T]he system is truly, truly broken.” Ex. A, Wilson ¶ 32. As such, “there are pharmacies that will not survive the year if the State is prevented from enforcing [the Act].” Ex. B, Billingsley ¶ 55. The Insurance Department has received over **100 complaints** in the last month alone, most of them regarding patients being forced to use preferred or mail-order pharmacies instead of local stores. Ex. C, White ¶ 23.

As a result, Defendants moved to lift the stay and withdraw from the non-enforcement stipulation. Doc. 27. Plaintiff did not oppose this motion, and the Court agreed to lift the stay and proceed. Doc. 30. Plaintiff thereafter filed to preliminarily enjoin the Act, and enforcement has been delayed pending this Court’s resolution of that motion. For the following reasons, PCMA’s motion should be denied and enforcement should proceed.

ARGUMENT

I. PCMA Does Not Have Standing to Challenge the Provisions of the Pharmacy Choice Act that Regulate Health Insurers But Not PBMs.

At the outset, a federal court must assure itself of standing. That inquiry is claim-specific. Thus, though PCMA may have standing to assert some claims, this does not necessarily give rise to standing for the rest. *See Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996); *Rosen v. Tn. Comm’r of Fin. and Admin.*, 288 F.3d 918, 928 (6th Cir. 2002) (“[S]tanding is a claim-by-claim issue.”). Here, PCMA does not have standing on all of its claims.

PCMA’s brief refers in passing to the “Act’s ‘Health Insurer Obligations.’” PI Mem. 7 (citing 36 O.S. § 6963(A), (B)). Separately, the complaint purports to challenge other

provisions of the Act that regulate only health insurers. *See* Compl. ¶ 27(d) (citing 36 O.S. § 6964(A)). PCMA does not have standing to challenge these provisions, which impose obligations exclusively upon a “health insurer.” The Act defines a “health insurer” to include “any corporation, association, benefit society, exchange, partnership or individual licensed by the Oklahoma Insurance Code.” 36 O.S. § 6960(1). A PBM, in contrast, is a distinct entity that provides “pharmacy benefits management” for health insurers and other entities. *Id.* § 6960(3). PCMA is made up exclusively of PBMs. *See* PI Mem. 2. As a result, PCMA lacks standing to vindicate the rights of health insurers. PCMA has also failed to argue why these provisions are preempted. After referring to the Health Insurer Obligations in its background, *see* PI Mem. 7, PCMA does not mention them further. This challenge fails.

II. PCMA is Not Entitled to a Preliminary Injunction.

Preliminary injunctive relief is an “extraordinary and drastic remedy.” *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008). “[T]he right to relief must be clear and unequivocal.” *Schrier v. Univ. Of Colo.*, 427 F.3d 1253, 1258 (10th Cir. 2005). To obtain a preliminary injunction, PCMA must show that it is entitled to such relief based on four factors: (1) a substantial likelihood that PCMA will prevail on the merits; (2) PCMA’s members will suffer irreparable harm unless the injunction issues; (3) the harm to PCMA’s members outweighs the harm to Oklahoma; and (4) issuing an injunction would be in the public interest. *See id.* PCMA has failed to meet its burden with respect to each of these factors.

A. PCMA Has Not Shown a Substantial Likelihood of Merits Success.

PCMA cannot show a substantial likelihood of success on the merits of its claims. *See Munaf*, 553 U.S. at 690-91. For starters, PCMA devotes little more than a sentence or two to

each separate legal challenge—cursory and conclusory arguments plainly inadequate to warrant the extraordinary relief of enjoining a democratically-enacted law. *See Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 679 (10th Cir. 1998) (“Arguments inadequately briefed in the opening brief are waived”); *PCMA v. Tufto*, 297 F. Supp. 3d 964, 986-87 (D.N.D. 2017) (denying PCMA’s motion for an injunction with respect to its Part D claims because PCMA offered only “a one-sentence legal conclusion supporting its position” for each claim).

1. The ERISA Claims are Contrary to Supreme Court Precedent.

The Pharmacy Choice Act aims to improve (1) **transparency**—36 § 6961(D), § 6962(C)(3), and § 6964(A); (2) **access**—§ 6961(A), § 6962(B)(4)-(5), and § 6963(D)-(E), and (3) **affordability**—§ 6961(C) and § 6962(B)(2)-(3), (6)-(7), primarily through regulation and oversight of PBMs. The Act regulates the rates at which PBMs reimburse pharmacies, the relationship between PBMs and pharmacies, and the services PBMs provide.

ERISA was never intended to thwart States’ attempts to regulate PBMs. ERISA regulates certain employer-sponsored pension and welfare benefit plans, but it “does not guarantee substantive benefits.” *Gobeille*, 136 S. Ct. at 943. “The statute, instead, seeks to make the benefits promised by an employer more secure by mandating certain oversight systems and other standard procedures.” *Id.* To be sure, ERISA preempts “any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.” 29 U.S.C. § 1144(a). But the “relate to” language, though facially broad, does **not** modify “the starting presumption that Congress does not intend to supplant state law.” *Travelers*, 514 U.S. at 654-55. “A law relates to a covered employee benefit plan ... if it [1] has a connection with or [2] reference to such plan.” *Cal. Div. of Labor Standards Enft v. Dillingham Constr.*, 519 U.S. 316, 324 (1997)

(cleaned up). PCMA focuses exclusively on the “connection with” prong. PI Mem. 11-13. A State law has an “impermissible connection with ERISA plans” only if it “governs a central matter of plan administration or interferes with national uniform plan administration.” *Gobeille*, 136 S. Ct. at 943 (citation omitted) (cleaned up).

Because the provisions of the Act would affect only PBMs’ business model—and not ERISA plan administration—they do not have an impermissible connection with ERISA plans. State laws have such an impermissible connection if they mandate certain benefits, *Shaw v. Delta Air Lines*, 463 U.S. 85, 97 (1983), dictate who is eligible for coverage, *Egelhoff v. Egelhoff*, 532 U.S. 141, 147-48 (2001), “eliminate[] [a] method for calculating pension benefits,” *Alessi v. Raybestos-Manhattan*, 451 U.S. 504, 524 (1981), or “prohibit[] plans from being structured in a manner requiring reimbursement in the event of recovery from a third party,” *FMC Corp. v. Holliday*, 498 U.S. 52, 60 (1990). These laws give rise to preemption because they mandate *internal* “employee benefit structures or their administration.” *Travelers*, 514 U.S. at 658. The Pharmacy Choice Act does none of these things.

On the other hand, ERISA does not preempt State laws regulating the *external* providers who supply the goods and services that a health plan’s beneficiaries ultimately consume. State laws that regulate a plan’s relationship with external providers may permissibly “alter[] the incentives, but ... not dictate the choices, facing ERISA plans.” *Dillingham*, 519 U.S. at 334. Likewise, State laws that regulate the services of providers might have an “indirect influence” on ERISA plans, but they generally “do[] not bind plan administrators to any particular choice” and therefore do not “function as a regulation of an ERISA plan itself.” *Travelers*, 514 U.S. at 659-60. If that were not the case, ERISA would preempt State laws

regulating everything from “medical-care quality standards” and “hospital workplace” conditions to “hospital rates.” *Dillingham*, 519 U.S. at 328-29.

For that reason, in *Travelers* the Supreme Court held that “ERISA was not meant to pre-empt basic rate regulation.” 514 U.S. at 667 n.6. As the Supreme Court recognized, rate regulations do “not bind plan administrators to any particular choice.” *Id.* at 659. And they do not “preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one.” *Id.* at 660. Instead, they “simply bear[] on the costs of benefits and the relative costs of competing insurance to provide them.” *Id.* That is true here. The “Claims Processing Provisions” do not dictate choices on ERISA health plans. Far from it, they merely regulate the amounts that PBMs pay pharmacies for dispensing prescription drugs, the reimbursements that PBMs provide to pharmacies, and the fees that they charge. *See* 36 O.S. § 6962(B)(2)-(3), (6)-(7). They are basic rate regulations.

Similarly, the “Network Restrictions” simply regulate the quality of the pharmacy networks that PBMs sell to ERISA and non-ERISA plans alike. They do not mandate any aspect of a network that a plan might elect to make available directly to its beneficiaries. Many of these provisions are designed to protect against PBM abuse and self-dealing. *See supra* 4-8. Again, ERISA does not preclude States from enacting laws that regulate third parties that happen to sell their services to ERISA plans. If it did, ERISA would preempt the regulation of not only PBMs, but also lawyers, accountants, doctors, and pharmacists.

Contrary to PCMA’s contention, *Gobeille* does not establish that ERISA preempts all PBM-regulating laws. *See* PI Mem. 12. *Gobeille* involved a Vermont law that *compelled* plans and third-party administrators to “report detailed information about claims and plan members” to

further a State-run healthcare database. 136 S. Ct. at 945-46. The Supreme Court deemed this law preempted because it exposed plans to potentially divergent obligations related to reporting and disclosure, “a central aspect of plan administration.” *Id.*

Unlike the Vermont law in *Gobeille*, the Pharmacy Choice Act does not impose concrete mandates regarding a “central matter of plan administration.” *Id.* Rather, it regulates the rates that PBMs reimburse pharmacies for dispensing drugs and the quality of the networks that PBMs sell to plans. And the Act’s provisions do not impose conflicting obligations. The effect on PBMs’ profits that might indirectly affect a health plan is not enough to trigger ERISA preemption. The Supreme Court has made clear that “[a]ny state ... law[] that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is preempted.” *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 816 (1997). To hold otherwise would be to declare that PBMs are unable to be regulated at all, given that everything they do indirectly affects health plans in some way.

Likewise, the “Any Willing Provider” provision simply prohibits PBMs from discriminating against willing providers. *See* 36 O.S. § 6962(B)(4). It does not place mandates on health insurers, nor does it regulate the terms and conditions that PBMs set for a provider—PBMs can place the bar as high as they want. This falls short of an impermissible connection. PCMA seeks to resurrect the overbroad ERISA-preemption view the Supreme Court laid to rest in *Travelers*, in which the Court said “[i]f ‘relate to’ were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course.” 514 U.S. at 655. That is a result “no sensible person could have

intended.” *Dillingham*, 519 U.S. at 335-36 (Scalia, J., with Ginsburg, J., concurring).²

2. All but One of PCMA’s Claims Fail under Medicare Part D Because It Has Not Shown Impermissible Overlap between the Part D Standard and the Contested Provision of Oklahoma Law.

Medicare Part D is a public-private partnership through which private companies sponsor Medicare-funded prescription drug benefits, subject to Part D regulations. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Part D borrows its preemption clause from Part C. *See* 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g). Thus, the preemption clause governing Part D 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 [Part D plans] which are offered by [Part D sponsors] under this part.” 42 U.S.C. § 1395w-26(b)(3) (Part C preemption); *id.* § 1395w-112(g) (Part D incorporating by reference Part C preemption). So, simply put, PCMA must show that the provisions of the Act that it challenges regulate “with respect to” a “standard[] established under” Part D.

² Even if PCMA’s view is correct, the challenged provisions would still fall within ERISA’s savings clause for state insurance laws. *See* 29 U.S.C. § 1144(b)(2)(A). This clause “does not require that a state law regulate ‘insurance *companies*’ ... to be saved from pre-emption; it need only be a ‘law ... which regulates *insurance*.’” *Ky. Ass’n of Health Plans v. Miller*, 538 U.S. 329, 336 n. 1 (2003). Oklahoma’s Act is codified in Title 36, which houses state *insurance* laws, and is executed by the State Insurance Department. *See* 36 O.S. § 6965. Additionally, to be saved, “the law must substantially affect the risk pooling arrangement between the insurer and the insured.” *Miller*, 538 U.S. at 342. The Supreme Court has held that “any willing provider” provision satisfies the pooling-risk prong: “[b]y expanding the number of providers from whom an insured may receive health services,” the law substantially affects “the type of risk pooling arrangements that insurers may offer.” *Id.* at 338-39. Here, the Claims Processing and Network Restrictions also expand the services and the number of pharmacies that may dispense benefits. Thus, they regulate insurance and are saved.

PCMA alludes to an even broader rule, but settles upon the standard discussed above. PI Mem. 14-15. And for good reason. Every court to address Medicare Part D preemption has required an overlapping federal standard. *See Rutledge*, 891 F.3d at 1113 (Part D preempts State laws “when (1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established ‘standards’ in the area regulated by the state law; and (2) the state law acts ‘with respect to’ those standards.”); *Do Sung Uhm v. Humana*, 620 F.3d 1134, 1148 n.20, 1157-58 (9th Cir. 2010) (preempting consumer protection claim involving marketing materials because CMS had on-point standards); *accord Meek-Horton v. Trover Sols.*, 915 F. Supp. 2d 486, 490-91 (S.D.N.Y. 2013); *Pacificare of Nev. v. Rogers*, 127 Nev. 799, 805-806 (2011).³

PCMA’s haphazard approach lands on a single provision that actually acts with respect to a Part D standard: 36 O.S. § 6961(A). Section 423.120(a) of Title 42 of the Code of Federal Regulations sets accessibility standards by requiring a certain number of network participants within a type of community such as rural or urban. And the Oklahoma law does the same. So the laws do overlap.⁴ Thus, Part D preempts this provision—but only as-applied to Part D plans. As a practical matter, the Part D plans must still comply with identical provisions pursuant to federal law. However, PCMA fails to show any other overlap between a Part D standard and the remaining State-law provisions it challenges:

³ CMS is the federal agency charged with administering Part D, and it has consistently required overlapping federal standards for preemption. Thus, “although the Congress included broad preemption rules . . . we d[o] not believe that the Congress intended for each and every State requirement applying to [Part D plans] to become null and void.” CMS, *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4,194, 4,319 (Jan. 28, 2005).

⁴ The provisions do not overlap as to preferred networks, however, because the Part D standard does not act with respect to preferred networks. *See* 42 C.F.R. § 423.120(a).

- 42 C.F.R. § 423.120(a)(9) does not overlap with 36 O.S. §§ 6961, 6962(B)(4)-(5), or 6963(E). The federal standard permits a Part D plan to “reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy.” The Act does not address when a Part D plan may reduce copayments or coinsurance for preferred pharmacies. It instead addresses access to and composition of PBM pharmacy networks and prevents PBMs from forcing beneficiaries to use affiliated pharmacies.
- 42 C.F.R. § 423.120(a)(8) does not overlap with 36 O.S. § 6962(B)(4). The Oklahoma provision prohibits a PBM from denying a pharmacy preferred status if that pharmacy meets the PBM’s requirements for that status. The federal standard only prohibits a Part D sponsor from denying a pharmacy entry into its network if that pharmacy meets *Part D standards*. These are completely separate inquiries.
- 42 U.S.C. § 1395w-102(d) does not overlap with 36 O.S. § 6962(B)(3) or (B)(6). The Part D standard ensures consumers have access to negotiated prices for drugs by imposing requirements on a Part D plan sponsor or Medicare Advantage (MA) organization. Oklahoma’s laws do not block access to negotiated prices. They (1) prohibit a PBM from reimbursing pharmacies that it owns more than other pharmacies and (2) address when a PBM can retroactively deny or reduce reimbursement during claim adjudication.
- 42 C.F.R. § 423.153(c) does not overlap with any of the provisions that PCMA challenges. Indeed, it is unclear what PCMA is arguing here. Oklahoma law does not address any topic covered by 42 C.F.R. § 423.153(c). Nor does any provision of state law interfere with Part D sponsors’ duty to assert compliance with state law on the part of their network providers.

Indeed, how could a federal requirement to assert compliance with state pharmacy law possibly mean a specific state pharmacy law is invalid?

- 42 U.S.C. § 1395w-111(i) does not overlap with 36 O.S. § 6962(B)(2). Oklahoma law prohibits PBMs from charging fees to pharmacies for the submission of a claim, enrollment in a pharmacy network, or development of a claims processing service. In contrast, the federal standard addresses the *Secretary of Health and Human Services'* responsibility to preserve competition, including the Secretary's abstention from negotiations between drug manufacturers, pharmacies, and Part D plan sponsors. None of these items concern fees charged for claim adjudication.
- 42 C.F.R. § 423.505(i)(5) does not overlap with 36 O.S. § 6963(A)-(B) and OAC § 365:25-29-9(c)(1). The federal standard governs contracts entered between Part D sponsors and CMS requiring the sponsors to “retain[] the right to approve, suspend, or terminate” a delegation of “selection of its prescription drug providers to another organization.” In contrast, the Act sets forth a health insurer's responsibility to ensure compliance with the Pharmacy Choice Act. To that end, the Insurance Department rule requires an insurer to approve contracts between a PBM and any retail pharmacy network providers beforehand. In sum, the federal standard addresses contracts between a Part D plan sponsor and a third party, whereas the Oklahoma law addresses contracts between a PBM and different third parties. These, again, are separate topics.
- 42 C.F.R. § 423.2262 does not overlap with 36 O.S. § 6961(D). The Oklahoma law requires a PBM to list all pharmacies, hospitals, and providers in the PBM's network on material such as mail and ID cards—if any are mentioned at all. The federal standard, in contrast,

addresses only the marketing material or enrollment form of a Part D plan.

3. PCMA's Oklahoma APA Claims are Unfounded.

If this Court elects to exercise supplemental jurisdiction, PCMA asserts that three administrative rules—the Promotional Materials Rule, the Contract Approval Rule, and the Specialty Drugs Rule—violate the Oklahoma Administrative Procedure Act (APA). PCMA claims that they are inconsistent with or exceed statutory authority. That is incorrect.

Contrary to PCMA's intimations, in Oklahoma, “[s]tatutory construction by agencies charged with the law’s enforcement is given persuasive effect especially when made shortly after the statute’s enactment.” *Cox v. State*, 87 P. 3d 607, 616 (Okla. 2004). Rules “are presumed to be valid until declared otherwise by a district court of this state or the Supreme Court.” 75 O.S. § 306(C). Moreover, an “agency has, by implication and in addition to the powers expressly given by ... statute, such powers as are necessary for the due and efficient exercise of the powers expressly granted, or such as may be fairly implied” *Okla. Pub. Employees Ass’n v. Okla. Dep’t of Cent. Servs.*, 55 P.3d 1072, 1084 (Okla. 2002).

PCMA first claims that the Promotional Materials Rule is inconsistent with the statute. The statute says “[PBMs] shall not in any manner on any material ... include the name of any pharmacy, hospital or other providers unless it specifically lists all pharmacies, hospitals and providers *participating in the preferred and nonpreferred pharmacy and health networks.*” 36 O.S. § 6961(D) (emphasis added). PCMA says this rule is inconsistent because it does not contain this italicized language. But read in context the law and rule are the same. Properly understood, the rule of course refers only to these network participants, even if it doesn’t explicitly say so. PBMs, obviously, do not need to list every healthcare provider in existence.

Next, the Contract Approval Rule sets forth an efficient means to make sure that insurers “monitor” and “ensur[e]” the compliance of each contract covered under this section meets the requirements of the Act—which PCMA acknowledges they must do. PI Mem. 18. Under the Act, an insurer must “monitor” each contract and “ensur[e]” that it is in compliance. Thus, if an insurer finds a contract not in compliance, it must have some recourse. Rather than allowing noncompliant contracts to be entered into, the regulation requires approval beforehand without having to go back and undo a noncompliant contract and thus provides for the efficient administration of the Act.

Finally, PCMA asserts that the Specialty Drugs Rule is inconsistent with the Act. The rule says “[t]he act draws no distinction between regular or specialty drugs.” OAC § 365:25-29-7.1(a)(2). PCMA asserts that a single mention of specialty drugs in 36 O.S. § 6961(C) “draw[s] [a] distinction” creating an inconsistency. PI Mem. 18. But PCMA offers no further explanation on this point. A closer look shows that, far from drawing a distinction, the provision makes explicit *the lack thereof* in the Act’s prohibition on PBMs forcing patients to use pharmacies owned by the PBM. 36 O.S. § 6961(C). There is no APA violation here.

B. PCMA Has Not Shown Its Members Will Suffer Irreparable Harm.

Irreparable harm is “not an easy burden to fulfill.” *Greater Yellowstone Coalition v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003). The moving party bears the burden to show that the harm is “both certain and great,” and not “merely serious or substantial.” *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1250 (10th Cir. 2001); *see also RoDa Drilling Co., v. Siegal*, 552 F.3d 1203, 1210 (10th Cir. 2009) (“[p]urely speculative harm will not suffice”).

PCMA's vague, unquantified assertions do not satisfy this exacting standard. Moreover, PCMA overstates the alleged harm to its members in two striking ways.

First, even if PCMA were to prevail on its principal claims—all of which involve ERISA and Part D—PCMA's members *still would have to comply with the challenged State laws* as they apply to plans that are not covered by ERISA or Medicare Part D. That is because where a State law is preempted by ERISA, that law is invalidated only “insofar” as it “relates to” an ERISA plan, 29 U.S.C. § 1144(a), and where a State law is preempted by Medicare Part D, it is superseded solely “with respect to [Part D] plans,” 42 U.S.C. § 1395w-26(b)(3). Thus, PCMA's members will continue to bear the alleged burden and expense of complying with the laws for a substantial volume of their business in Oklahoma even in the absence of injunctive relief. *See* Ex. C, White ¶ 27; *cf.* 2019 NCPA Digest at 19 (Part D covers just 37% of prescriptions filled in the average community pharmacy).

This deflates PCMA's claims of irreparable harm—for direct costs and administrative expenses—because PCMA's preemption claims go only to a subset of the total plans that its members service. Thus, even though PCMA's members may bear some added costs to comply with the Act, they may only rightly invoke the harm as it relates to ERISA and Medicare Part D plans. For this reason and more, the District of North Dakota denied PCMA an injunction when it challenged a slew of North Dakota laws. *See Tuftte*, 297 F. Supp. 3d at 982-83 (“Neither does PCMA address how complying with the State's bills as they relate to non-ERISA and non-Medicare Part D plans might mitigate any financial burdens.”).

Additionally, some provisions of the Act mirror Medicare Part D. For example, the pharmacy access standards in 36 O.S. § 6961(A) and 42 C.F.R. § 423.120(a) are identical. Thus,

these requirements already exist for Part D plans. The State law merely extends these network requirements to other types of plans, which would occur even in the event of a preliminary injunction. Moreover, the business model of PBMs is premised on offering a unique slate of options to customers that is constantly modified, and the notion that there are substantial administrative costs in shifting operations is not supported by the record.

Second, PCMA's claims of administrative uniformity simply do not comport with reality. More than forty States have enacted PBM regulations, and only a small handful are enjoined—all within the Eighth Circuit, whose preemption approach is under review by the Supreme Court. In every other State and in circuit, PBMs are required to comply. *See* Ex. B, Billingsley ¶¶ 42, 50; Ex. C, White ¶ 26. This includes states with provisions similar to those Oklahoma has enacted. *Compare, e.g.*, 36 O.S. § 6962(B)(4), *with* Haw. Rev. Stat. § 431R-2 (similar “Any Willing Provider” provisions). Indeed, “[c]ompared to the enactments of other States, the Pharmacy Choice Act’s regulation of retroactive modifications to reimbursements, limitations on certain fees, and prohibition on discriminatory reimbursement practices represents a *modest* approach to provide some measure of financial protection against predatory PBM business practices.” Ex. B, Billingsley ¶ 50 (emphasis added). This cripples PCMA’s suggestion that Oklahoma is an extreme outlier.

The harm must be certain—unsupported intimations will not suffice. But, much as in *Tufte*, where the court denied an injunction, “PCMA does not offer any predictions or figures to demonstrate what its view of what a ‘significant’ financial burden might mean.” 297 F.Supp.3d at 983. And the scope of harm is further reduced where the record does not support concrete plans to engage in conduct regulated by the Oklahoma law.

Furthermore, PCMA has not identified any special harm associated with responding to COVID-19. PCMA’s claim that its members “are at the front lines of responding to COVID-19” is as inflated as its cost and disruption claims. PI Mem. 22. PBMs are by definition *middlemen*, not front-line workers. If anyone impacted by the Oklahoma law is on the “front lines” of the pandemic it is pharmacists, who are face-to-face with Oklahoma patients every day, and who the State is seeking to protect from PBM abuses through enforcement of the Act. *See* Ex. A, Wilson ¶¶ 29-30, Ex. B, Billingsley ¶¶ 53-54. PCMA’s members are among the largest and most profitable companies in the country. When this is over, they will be fine. At minimum PCMA has not shown that its injuries are “certain and great.” *Dominion Video Satellite v. Echostar Satellite*, 356 F.3d 1256, 1262 (10th Cir. 2004).

C. The Irreparable Harm that the State Will Suffer and the Public Interest Both Favor Denying the Motion for a Preliminary Injunction.

Oklahoma and Oklahomans will be irreparably harmed if the Court enjoins Defendants from enforcing the challenged law and regulations. The State has a sovereign right to see that its laws are enforced. Indeed, “[a]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.” *Maryland v. King*, 133 S. Ct. 1, 3 (2012) (Roberts, C.J., in chambers) (quoting *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977)); *see also* *Planned Parenthood v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013) (“When a statute is enjoined, the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws.”).

PCMA’s only retort is that the State has no interest in enforcing an unconstitutional law, *see* PI Mem. 23, but that assumes PCMA will prevail on the merits. As explained above, PCMA has failed to show a substantial likelihood of success on the merits of its claims. And

because Oklahoma’s laws regulate in areas of traditional State concern, they are entitled to a presumption against preemption. *Travelers*, 514 U.S. at 661 (explaining that “nothing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern”); *accord* 42 U.S.C. § 1395 (declaring that nothing in the Medicare Act shall be construed to allow the federal government to regulate “the practice of medicine or the manner in which medical services are provided”); *accord Med. Soc’y of N.Y. v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992) (“The regulation of public health and the cost of medical care [as] virtual paradigms of matters traditionally within the police powers of the state.”).

But it is more than that. Defendants’ interests are inextricably intertwined with the public interest. And the balance of the relative harms weighs decidedly against an injunction. Whatever profits PBMs siphon from the market with an injunction will be offset by decreases for other market participants. For example, if a PBM loses profits because it is unable to direct patients to its own pharmacies and instead that patient chooses its community pharmacist, the revenue loss by PBM is offset by the revenue increase to the community pharmacist. At most, in other words, the balance of harm is neutral.

Although a neutral balance is enough to deny a preliminary injunction, it is not a mere offset that is occurring here. As discussed above, the Oklahoma Legislature enacted this bill to curb serial abuses by PBMs that are threatening the solvency of the State’s community pharmacies, restricting Oklahomans’ access to quality medicine, depriving patients of important medical information, and driving up drug prices. *See supra* 4-8.

PCMA's members are middlemen that have profited immensely at the expense of patients, plans, and pharmacies. They are fully capable of adjusting their business models to deal with the Act, much as they are doing in the numerous other states that regulate PBMs. Moreover, PCMA's claim that it will not be able to keep costs low for patients is "questionable," according to White, a former PBM auditor. Ex. C, White ¶ 24; *cf. Rowe*, 429 F.3d at 298 (citation omitted) ("[W]hether and how a PBM actually saves an individual benefits provider customer money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider.").

In sum, it is not in the public interest to enjoin the State from enforcing the Pharmacy Choice Act. To the contrary, the Oklahoma Legislature concluded *unanimously* that the public interest was being undermined by PBMs, which were causing harm to Oklahoma's healthcare system and its residents. Let this be clear: every single representative of the people of Oklahoma who voted on this bill—Republican and Democrat, urban and rural—agreed that enforcing the Act is in the public interest. And although the State agreed to a temporary stay of enforcement, that stipulation did not include *any* concession on harm. Doc. 19. Fulfilling the adage that no good deed goes unpunished, PCMA cynically seeks to wield the State's comity as a sword against it. And even if some prior pause of enforcement was tolerable, the State sought to withdraw from the stipulation in part because it was receiving reports of increasing abuses. Doc. 27; *see supra* 8-9. In the view of the State's and its elected officials, this misconduct necessitated immediate enforcement of the Act.

CONCLUSION

PCMA's motion for a preliminary injunction should be denied.

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