No. 22-6074

IN THE
UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

Pharmaceutical Care Management Association,

Appellant,

vs.

Glen Mulready et al.,

Appellees.

ON APPEAL FROM UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF OKLAHOMA

BRIEF OF AMICI CURIAE STATES OF MINNESOTA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, HAWAII, IDAHO, ILLINOIS, INDIANA, KANSAS, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MISSISSIPPI, NEBRASKA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VIRGINIA, WASHINGTON, AND THE DISTRICT OF COLUMBIA, IN SUPPORT OF APPELLEES AND AFFIRMANCE

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STATEMENT UNDER FED. R. APP. P. 29(A)(4)(D)

The States of Minnesota, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, and the District of Columbia, submit this brief as amici curiae to support the appellees. The states have an interest in preserving states' authority to regulate companies doing business in their states, protecting their residents' access to healthcare, and curbing abusive business practices. To advance these interests, nearly all states regulate pharmacy benefit managers. Appellant's sweeping approach to ERISA and Medicare preemption would severely impede states' abilities to protect their residents and potentially upend licensing and regulatory structures in nearly every state.

The states file this brief under Fed. R. App. P. 29(a)(2), which permits a state to file an amicus brief without the parties' consent or leave of the Court.

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States have an inherent interest in ensuring their residents can afford their lives. Consumers across America struggle to afford healthcare. A principal cause of their plight is the increasing, unsustainable cost of prescription drugs. States have sought to address these concerns in myriad ways, more recently by regulating a source of these increasing costs: pharmacy benefit managers (PBMs). PBMs are not health plans. They are intermediaries in the prescription-drug insurance market, a segment of the healthcare industry that has grown exponentially, largely without regulation and to the detriment of consumers. States have enacted laws to curb some of the worst abuses in the PBM industry and to protect consumers, independent pharmacies, and states.

Because regulation cuts into their profits and provides accountability, PBMs naturally resist these laws. Appellant Pharmaceutical Care Management Association (PCMA), a national trade association, has filed multiple lawsuits claiming ERISA or Medicare preempts various states' regulations. PCMA advocates for nearly boundless ERISA and Medicare preemption. Because this position is meritless, the Court should affirm the district court.

ARGUMENT

PCMA claims ERISA and Medicare broadly preempt state PBM regulations. ERISA preemption applies only to laws that require employer health plans to structure benefit plans in specific ways, such as by requiring specific benefits or

rules to determine beneficiary status. *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 480 (2020). Medicare preempts state laws only if a Medicare "standard" exists that particularly addresses the subject of state regulation. 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g) (2018).

While the regulations that PCMA challenges on appeal may seem narrow, PCMA's approach to preemption is not. For the Court to appreciate more fully the potential impact of this case, this brief addresses more broadly some of the types of conduct by PBMs that have created the need for state regulation. As PBMs have gained a foothold in the healthcare industry, they have impeded consumers' access to affordable medications. In short, PBMs are not the consumer-friendly entities that PCMA portrays. Because the challenged Oklahoma laws do not dictate plan benefits or conflict with a Medicare standard, they are not preempted.

I. REGULATING PBMS PROTECTS CONSUMERS AND CURBS ABUSES BY A MULTI-BILLION-DOLLAR INDUSTRY.

Prescription drugs are an inescapable and increasingly prevalent facet of modern healthcare. Between 2015 and 2018, 48.6% of Americans took a prescription drug in the preceding thirty days.[1] Prescription drug use is higher among Americans over age 65, with 88.5% having taken a prescription drug in the last thirty days.[2] In

[1] Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Health, United States,* Table 39 (2019), https://perma.cc/54DK-3BTG.
[2] *Id.*

2020, annual American prescription-drug spending grew to $348.4 billion.[3] Healthcare spending is projected to continue increasing.[4]

While early PBMs in the 1970s played a limited role in the healthcare system, their role steadily expanded over the past fifty years to control nearly every aspect of health plans' pharmacy benefits.[5] How a medication gets to a consumer is relatively straightforward: manufacturer → distributor → pharmacy → consumer. But how that medication is paid for and which pharmacies a consumer can use are anything but simple, in large part due to PBMs. PBMs implement complicated processes and requirements that maximize PBM profits at the expense of pharmacies and patients. As PBMs have grown increasingly larger and more concentrated, they hold ever more leverage over pharmacies. (Appellant's App. 107-08, ¶¶ 19-21.)

PBMs thrived behind the scenes, exploiting the lack of transparency PBMs designed into the system.[6] This enabled PBMs to interweave a web within the healthcare industry, imposing self-serving protections that reduced reimbursement rates to pharmacies, maximized rebates to PBMs, and imposed various confidentiality requirements to hide their business practices. For example, before

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[3] U.S. Dep't of Health & Human Servs., *National Health Expenditure Fact Sheet* (2020), https://perma.cc/JVN8-H5XL.
[4] *Id.*
[5] Oversight Hearing of the S. Comm. on Bus., Professions & Econ. Dev., *Pharmacy Benefit Managers 101* 2 (Cal. Mar. 20, 2017), https://perma.cc/D4SL-PBB6.
[6] Stephen Barlas, *Employers and Drugstores Press for PBM Transparency*, 40 Pharmacy & Therapeutics 206-08 (2015), https://perma.cc/G8RX-TP54.

states began regulating, basic information like the amount PBMs reimbursed pharmacies for dispensing medications was often confidential.[7] PBMs thrived in this opaque space so much that the most recent estimate of the PBM market's annual gross profits is $28 billion.[8] Coupled with PBMs' limitation of consumers' pharmacy choices, PBMs created a captive market that demanded regulation to safeguard the public's financial and physical health.

A. State Regulation Is Necessary Because PBMs Harm Pharmacies and Consumers.

PBMs have exploited decades of lax or non-existent regulation to become a massive part of the prescription-medication industry. Because PBMs are essentially middlemen, their profits depend on reaping large fees and rebates while spending as little as possible to reimburse pharmacies for medications. This drives down reimbursement rates and increases consumers' drug prices, all while operating largely without oversight or accountability. State regulation is necessary to curb PBM practices that harm pharmacies and consumers.

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[7] *Id.*

[8] PBM Accountability Project, *Understanding the Evolving Business Model and Revenue of Pharmacy Benefit Managers* 4 (2021), https://perma.cc/V4EB-88LX.

1. PBMs harm pharmacies by lowering reimbursement rates and favoring certain pharmacies.

Local pharmacies are critical in providing healthcare to rural communities, and pharmacy closures have been particularly detrimental.[9] From 2003 to 2018, approximately 16% of independently owned rural pharmacies closed.[10] Even in major metropolitan areas, between 2007 and 2015, pharmacies were less likely to open and more likely to close in neighborhoods with majority Black or Hispanic/Latinx residents.[11] This trend in pharmacy closures spans the rural-urban divide and is traceable to PBMs. PBMs' historically unregulated business model harmed pharmacies in two principal ways: by using PBMs' superior bargaining position to drive down reimbursements to pharmacies and by steering business—typically on favorable terms—to pharmacies affiliated with the PBM.

First, PBMs' reimbursement rates and practices harm independent pharmacies. PBMs profit from the "spread" between the amount they charge health

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[9] Abiodun Salako et al., RUPRI Ctr. for Rural Health Pol'y Analysis, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018* (2018), https://perma.cc/9XKN-7TU2.

[10] *Id.*

[11] Jenny S. Guadamuz et al., *Fewer Pharmacies in Black and Hispanic/Latino Neighborhoods Compared with White or Diverse Neighborhoods, 2007-15,* 40 Health Affairs 802, 805 (2021).

plans for a drug and the amount they reimburse pharmacies.[12] The less the PBM reimburses the pharmacy, the higher the "spread" and the higher the PBM profit.

Low reimbursements are a major financial concern for independent pharmacies.[13] Minnesota has seen more pharmacies close in the last decade than any state.[14] Local pharmacies must work with PBMs, which have outsized bargaining power that continues to consolidate.[15] Three of the largest U.S. companies, and all major insurers, now own or operate PBMs.[16] All but the largest retail pharmacies receive only "take it or leave it" offers from PBMs.[17] This bargaining disparity invariably results in independent pharmacies effectively having no choice but to accept financially detrimental terms.

Second, PBMs steer business away from independent pharmacies and toward PBM-owned or -affiliated pharmacies. In addition to limiting consumers' choice and creating potential conflicts of interest, this reduces non-affiliated pharmacies'

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[12] Elizabeth Seeley & Aaron Kesselheim, Commonwealth Fund, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead* (2019), https://perma.cc/4Q36-B5YE.
[13] Abiodun Salako et al., *Financial Issues Challenging Sustainability of Rural Pharmacies*, 2 Am. J. Med. Research 147, 153 (2017).
[14] Sarah D. Kerr, *Pharmacist's View: Independent Pharmacies Threatened by Middlemen*, Duluth News Trib., Apr. 26, 2021, https://perma.cc/NN4C-2DSG.
[15] *Id.*; Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 36 (2007).
[16] *Fortune 500–2020*, Fortune Mag. (2020), https://perma.cc/2CKZ-VQ93; Bruce Japsen, *Express Scripts Boosts Cigna as Employers Stick with Larger Insurer*, Forbes Mag. (Aug. 1, 2019), https://perma.cc/C2W3-7JC2.
[17] Garrett & Garis, *supra* note 15, at 46.

business. Again, a lack of regulation perpetuates the problems. For example, when Ohio pharmacists reported conflicts of interests with PBMs requiring customers to obtain prescriptions from PBM-owned pharmacies, the state auditor could not fully investigate because PBM data were inaccessible.[18] PBMs also divert prescriptions to their own pharmacies by "prescription trolling": after local pharmacists work with patients, insurers, and doctors to obtain prior authorization for expensive medications, PBMs can divert prescriptions to their own mail-order pharmacies.[19] While the PBM provides advantageous terms to affiliated pharmacies, independent pharmacies are forced to accept terms that are likely to put them out of business. This is often done behind the veil of contractual gag clauses preventing pharmacies from providing information to consumers and thereby shielding PBMs' business practices from sight. State regulation in this space is critical because pharmacy closures resulting from PBMS' business practices reduce access to medical care for state residents and impair public health.

[18] Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* 1, 13 (Aug. 16, 2018), https://perma.cc/V29P-DRA3.

[19] Hearing on HF 728 Before the H. Commerce Comm., 2019 Leg., 91st Sess. at 1:52:25 (Minn. 2019) (statement of Randy Schindelar), http://ww2.house.leg.state.mn.us/audio/mp3ls91/com022719.mp3.

2. PBMs' historically unregulated business practices harm consumers by driving up drug costs.

PBMs contribute to the crisis of increasing medical costs nationwide. While medical spending has increased by approximately 17% since 2014, prescription-medication list prices have increased 33%.[20] One-third of consumers have skipped filling prescriptions and 10% have rationed their medications.[21] Rising medication costs directly affect the most vulnerable Americans' ability to afford their lives and access medications.

One contributing factor to rising drug costs is PBMs demanding increasingly large rebates from drug manufacturers. One study found a nearly equal correlation between increases in PBM rebates and list prices.[22] PBM market consolidation is leading manufacturers to offer increasingly attractive rebates: with three PBMs controlling an estimated 80-90% of the market, if one PBM excludes a drug then the manufacturer loses access to a relatively large market share.[23] This market control

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[20] Tori Marsh, Good RX, *Prices for Prescription Drugs Rise Faster Than Prices for Any Other Medical Good or Service* (Sept. 17, 2020), https://perma.cc/L2LR-C643.
[21] *Id.*
[22] Neeraj Sood et al., USC Leonard D. Schaeffer Ctr. for Health Pol'y & Econ., *The Association Between Drug Rebates and List Prices* (Feb. 11, 2020), https://perma.cc/L7GA-SA86.
[23] *Id.*; Appellant's App. 107-08, 149; *see also Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Finance*, 116th Cong. (2019) (statement of John M. Prince, CEO, OptumRX) (recounting a PBM demanding manufacturers provide two years' notice before lowering list prices).

results in PBMs securing favorable terms from manufacturers and pharmacies and contributes to higher prices for prescription medications.

Another way PBMs enrich themselves at the expense of consumers and independent pharmacies is through "claw backs." Gag clauses often prohibit pharmacists from telling consumers a medication's actual cost. Sometimes, the cash costs are less than consumers' copays. PBMs nonetheless require pharmacies to collect the copay from the unwitting consumer. The PBM can then later claw back from the pharmacy the difference between the copay and the actual cost, keeping the difference.[24] For example, a pharmacist collected a $35 copay for an allergy spray, only to have the PBM claw back $30.[25] The consumer would have been better off paying the $5 cash price for the medication, but a PBM gag clause precluded the pharmacist from telling the consumer.[26] These types of practices also affect local pharmacies when the pharmacy's reimbursement is below the acquisition cost. And claw backs inject uncertainty because PBMs can claw back money long after the pharmacy dispenses the prescription.[27]

The damage to pharmacies and consumers can be seen in the recent surge in "cash-only" pharmacies. By opting out the insurance system (and thereby PBMs),

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[24] Julie Appleby, *Filling a Prescription? You Might Be Better Off Paying Cash*, CNN, June 23, 2016, https://perma.cc/M242-ADQL.
[25] *Id.*
[26] *Id.*
[27] Schindelar testimony, *supra* note 19, at 1:53:54.

such pharmacies profit by selling (usually generic) drugs for just above cost.[28] This scenario may potentially save the patient substantial money, but it requires patients to forgo already paid for insurance benefits. That these cash-only pharmacies exist highlights the harms that PBMs cause to consumers and independent pharmacies.

While the sources of rising drug costs are complex, they should not be beyond the states' traditional police power of protecting the public. States have done the work to identify and regulate problematic facets of the PBM industry that have developed over years, and states play a critically important role in this sphere.

B. State PBM Regulation Protects the Public from Anti-Competitive and Abusive Practices.

In response to these concerning trends, nearly all states now regulate PBMs.[29] Between 2017 and 2021, states enacted over 100 laws to address how PBMs contribute to higher drug costs.[30] In August 2022, 135 bills involving PBM legislation were pending in thirty-four states.[31] Relevant types of PBM regulations

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[28] Adiel Kaplan, Kenzi Abou-Sabe, & Vicky Nguyen, NBC News, *Frustrated Pharmacists are Opting Out of the Insurance System, Saving Some Customers Hundreds of Dollars a Month* (Aug. 19, 2022), https://perma.cc/HC8Y-24GD.

[29] Nat'l Conference of State Legislatures, *State Policy Options and Pharmacy Benefit Managers* (Mar. 23, 2022), https://perma.cc/VF7T-6ESZ.

[30] Sarah Lanford & Jennifer Reck, Nat'l Acad. State Health Pol'y, *Legislative Approaches to Curbing Drug Costs Targeted at PBMs: 2017-2021* (June 14, 2021), https://perma.cc/8D57-DBLL

[31] Nat'l Acad. State Health Pol'y, *2022 State Legislative Action to Lower Pharmaceutical Costs* (Pharmacy Benefit Mgr Topic Selected) (Aug. 23, 2022), https://perma.cc/2MCC-LDE7.

for this appeal include: (1) Network-adequacy requirements; (2) pharmacy-participation regulations; and (3) conflict-of-interest regulations.[32] State regulation in these and other areas limits the harms discussed above.

1. Network-adequacy regulations

Network-adequacy regulations aim to ensure that all consumers have access to the pharmacy services they need. These regulations typically limit the distance between consumers' homes and the nearest network pharmacy or prohibit PBMs from requiring use of mail-order pharmacies.[33] Oklahoma requires a certain percentage of enrollees live within a certain distance of a retail pharmacy. Okla. Stat. tit. 36, § 6961 (2022). Oklahoma also precludes PBMs from using mail-order pharmacies to circumvent the distance requirements. *Id*. Over half of states have some type of network-adequacy regulation.[34] As noted above, the closure of rural

[32] Other types of state regulations are not discussed here because they are less pertinent to the Oklahoma laws before the Court. For example, some states require registration or licensure. *E.g.*, Minn. Stat. § 62W.03. Additionally, while the amici do not necessarily agree with the district court's conclusions that Medicare preempts certain other provisions of the Oklahoma law, those provisions are not on appeal.

[33] *E.g.*, Ark. Code Ann. § 23-92-505 (2021); Cal. Code Regs. tit. 28, § 1300.51H(iv (2022); Del. Code Ann. tit. 18, § 3362A (2021); Ga. Code Ann. § 33-64-10 (2021); Haw. Rev. Stat. § 431R-3 (2022); Me. Stat. tit. 24-A, § 4349 (2020); Minn. Stat. § 62W.05, subd. 1 (2022); Mont. Code Ann. § 33-2-2409 (2022); N.M. Stat. Ann. § 59A-61-5(H) (2022); 27 R.I. Gen. Laws § 27-29.1-2 (2022); W. Va. Code Ann. § 33-51-8(d) (2022).

[34] Nat'l Conference of State Legislatures, *supra* note 29.

and neighborhood pharmacies is a serious issue, especially where consumers are left without access to a pharmacy, negatively affecting health outcomes.

2. Pharmacy participation

A corollary of network-adequacy requirements are state regulations prohibiting discrimination against non-affiliated pharmacies. Many states require PBMs to allow otherwise qualified pharmacies to participate equally in their networks—including preferred networks—and prohibit PBMs from reimbursing their own affiliated pharmacies on preferential terms.[35] These regulations curtail the ability of PBM-affiliated pharmacies to unfairly compete with independent pharmacies through self-dealing. These regulations also improve network adequacy and coverage while protecting consumer choice. As previously noted, local pharmacies not only dispense medications but serve as a critical source of healthcare information, especially in rural areas.

[35] *E.g.*, Ala. Code § 27-45A-10 (2021); Colo. Rev. Stat. § 10-16-122 (2021); Del. Code Ann. tit. 18, § 3362A; Haw. Rev. Stat. § 431R-2 (2022); Ind. Code § 27-1-24.5-19 (2021); La. Stat. Ann. § 40:2870 (2022); Md. Code Ann., Ins. § 15-1628 (2022); Minn. Stat. § 62W.06 (2022); N.J. Stat. Ann. § 17B:26-2.1i (2021); N.C. Gen. Stat. § 58-51-37 (2021); N.D. Cent. Code § 19-02.1-16.2 (2021); 27 R.I. Gen. Laws § 27-29.1-3 (2022); S.C. Code Ann. § 38-71-147; Tex. Ins. Code § 1369.555(a) (2022); Vt. Stat. Ann. tit. 8, § 4089j (2022); Va. Code Ann. § 38.2-3467 (2022); W. Va. Code Ann. § 33-51-8(d); Wis. Stat. Ann. § 632.865 (2022).

3. Conflicts of interest

Absent legislation, courts have generally held that PBMs owe no fiduciary duty to plan sponsors or participants except in limited circumstances. *E.g.*, *In re Express Scripts, Inc. PBM Litig.*, No. 4:05-MD-01672, 2008 WL 2952787, at *3 (E.D. Mo. July 30, 2008) (unpublished). The lack of a fiduciary duty prevents plan participants from even litigating whether PBMs' contracts with drug manufacturers enrich PBMs to plans' detriment. *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 667, 692 (M.D. Tenn. 2007).

States have properly taken the lead on preventing unfair practices, self-dealing, and conflicts of interest. Examples of regulation in this area include: imposing a duty of good faith and fair dealing on PBMs;[36] prohibiting conflicts of interest or requiring PBMs to disclose conflicts of interest.[37] Particularly relevant here are patient-steering prohibitions. Patient steering occurs when PBMs push consumers to fill prescriptions at PBM-related pharmacies instead of local or unaffiliated pharmacies. A significant percentage of independent community

[36] *E.g.*, Iowa Code § 510B.4(1) (2022); S.D. Codified Laws § 58-29E-3 (2022) *see also* Cal. Bus. & Prof. Code § 4441(c) (2022); La. Stat. Ann. § 40:2864(A) (2022); Minn. Stat. § 62W.04(a) (2022); Nev. Rev. Stat. § 683A.178(1) (2021).

[37] *E.g.*, Cal. Bus. & Prof. Code § 4441(d); D.C. Code § 48- 832.01(b)(1)(C) (2022); 305 Ill. Comp. Stat. 5/5-36(d) (2022); Iowa Code § 510B.4(2) (2022); Minn. Stat. § 62W.04(b) (2022); Nev. Rev. Stat. § 683A.178(2); N.D. Cent. Code § 19-02.1-16.2(3); 27 R.I. Gen. Laws § 27-29.1-7 (2022); Vt. Stat. Ann. tit. 18, § 9472(c)(2) (2022).

pharmacists report that PBM steering has caused patients to transfer prescriptions to another pharmacy.[38] To combat this practice, states have enacted regulations to prevent steering, usually by preventing discounts, requirements, or incentives for a patient to use a PBM-affiliated pharmacy. Minnesota, for example, prohibits PBMs from penalizing, requiring, or financially incentivizing an enrollee's use of a pharmacy in which the PBM has an ownership interest. Minn. Stat. § 62W.07(b).[39] Oklahoma's conflict-of-interest regulation was similarly crafted to address this problem. (Appellant's App. 149-50, ¶¶ 20-23.)

II. ERISA DOES NOT PREEMPT STATE LAWS GOVERNING TRANSACTIONS BETWEEN PBMS AND PHARMACIES.

To protect consumers and address industry abuses, nearly every state regulates PBMs. To protect PBMs' profits, PCMA claims that ERISA broadly preempts these laws because they supposedly dictate plan benefits. The Court should reject this argument. As long recognized and recently reaffirmed by the Supreme Court,

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[38] Nat'l Comm. Pharmacists Ass'n, *Patient Steering a Massive Problem for Community Pharmacists, New Survey Shows* (Sept. 17, 2020) https://perma.cc/QE5Q-2BYA (reflecting 79% of responding pharmacy owners and managers reported having steering-caused transfers in preceding six months).

[39] Other states have patient-steering regulations that apply in varying circumstances: *E.g.*, Ala. Code § 27-45A-8 (2021); Ga. Code Ann. § 33-64-11, -12 (2021); La. Stat. Ann. § 40:2870 (2020); Md. Code Ann., Ins. § 15–1611.1 (2022); Miss. Code Ann. § 73-21-161 (2021); N.C. Gen. Stat. § 58-51-37 (2021); N.D. Cent. Code § 19-02.1-16.2; Or. Rev. Stat. § 735.536 (2021); S.C. Code Ann. § 38-71-2230; Tenn. Code Ann. § 56-7-3120 (2022); Tex. Ins. Code § 1369.554(a) (2022); Vt. Stat. Ann. tit. 8, § 4089j; Va. Code Ann. § 38.2-4312.1 (2021); W. Va. Code Ann. § 33-51-11 (2022).

ERISA preempts only laws affecting the "who" and "what" of benefits. *Rutledge*, 141 S. Ct. at 480 (recognizing primary concern is state laws that "determine[e] beneficiary status" or require "specific benefits"). The challenged Oklahoma laws regulate PBM-*pharmacy* relationships, not PBM-*beneficiary* or plan-beneficiary relationships. Okla. Stat. tit. 36, §§ 6961(A)-(B), 6962(B)(4)-(5), 6963(E) (2021). Because Oklahoma's laws do not regulate benefits plans, ERISA does not preempt them.

A. ERISA Preempts Only State Laws Affecting Who Receives Benefits and Which Benefits They Receive.

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) (2018). Congress "unequivocally" did not intend to "modify the starting presumption that Congress does not intend to supplant state law." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813 (1997). State laws "relate to" an ERISA plan if they have a "connection with" or "reference to" a plan. *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 656 (1995). PCMA contends only that Oklahoma's laws implicate "connection with" preemption. (Appellant's Br. 22-23.)

When reviewing a state law for ERISA preemption, the Supreme Court focuses on the ERISA preemption clause's central concern: the ability of plan administrators to determine benefits by looking at plan documents rather than fifty

states' laws. *Egelhoff v. Egelhoff*, 532 U.S. 141, 148-49 (2001); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 98-99 (1983). A "connection" for ERISA purposes must be more than a potential, incidental impact. For example, the Court rejected an ERISA-preemption challenge to a state law that required hospitals to collect surcharges from patients who did not have insurance from a particular insurer. *Travelers*, 514 U.S. at 649. The Court recognized that providers would pass these costs on to the entities paying for the insurance, i.e., ERISA plans. *Id.* at 659. Nevertheless, the statute did not "bind plan administrators to any particular choice and thus function as a regulation of the ERISA plan itself." *Id.* Such indirect influences do not preclude a uniform interstate benefit package that trigger ERISA concerns. *Id.* at 660.

In contrast, the Court struck down a state's automatic revocation of spousal beneficiary designations upon divorce. *Egelhoff*, 532 U.S. at 143. Other state regulations that could implicate ERISA preemption are laws that conflict with ERISA's reporting, disclosure, and bookkeeping requirements regarding benefits because they are central to uniform systems of plan administration. *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 323 (2016).

In *Rutledge*, the Court reaffirmed that ERISA does not preempt regulations that merely "alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." 141 S. Ct. at 480. The Court rejected PCMA's arguments that federal law preempted state regulation of pharmacy

reimbursement rates. The Court held that mandating PBM pricing methodologies does not "require plans to provide any particular *benefit* to any particular *beneficiary* in any particular way." *Id.* at 482 (emphases added). In short, the Court reiterated that ERISA preemption is concerned with the *who* and the *what* of benefits. Applying *Rutledge*, another circuit has held that ERISA does not preempt state laws affecting who PBMs include in their networks. *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 968 (8th Cir. 2021).

B. Oklahoma's Laws Do Not Affect the Who or What of Beneficiaries' Benefits.

Despite *Rutledge*, PCMA argues that Oklahoma's (and essentially all states') PBM regulations are preempted. PCMA is wrong; because none of Oklahoma's statutes alter substantive coverage, they are not preempted.

1. PBMs Are Not Benefit Plans Subject to ERISA Preemption.

Foundational to PCMA's preemption argument is its premise that PBMs stand in the shoes of benefit plans, such that if a state regulates a PBM's network design, then the state is regulating a plan. But this equivalence is unfounded. PBMs are distinct entities from the plans they serve and ERISA does not preempt states from regulating the networks PBMs choose to offer.

PBMs, on their own, have no connection with ERISA plans. For example, ERISA is inapplicable to PBM services provided to private-purchase insurance plans because there is no ERISA "connection." *Travelers*, 514 U.S. at 656. But PCMA

contends that upon contracting with benefit plans, PBMs are free to create networks that violate state consumer protections. This position has no basis in law. Indeed, carried to its logical conclusion, PCMA's argument would mean that if, for example, an employer offered a health plan and that health plan contracted with specific hospitals, those hospitals would be exempt from state licensing laws regulating medical facilities.

PCMA essentially asks the Court to hold PBMs are plans. Indeed, before the district court it went as far as arguing that *Gobeille* established the interchangeability of third parties and plans. (Appellant's App. 654-57.) In *Gobeille*, the lower court held that a benefit plan had standing to argue ERISA preempted a state regulation imposing requirements on a third-party administrator. *Liberty Mut. Ins. Co. v. Donegan*, 746 F.3d 497, 502 (2d Cir. 2014). That holding was not at issue on appeal; the Court assumed without further discussion that the lower court was correct. *Gobeille*, 577 U.S. at 319. It did not, as PCMA has claimed, conclusively hold that PBMs stand in the shoes of benefit plans. (Appellant's App. 654.)

Moreover, PCMA's conflicting positions between this case and other cases show that PCMA really seeks to avoid accountability. In past cases, for example PCMA and PBMs have argued that PBMs do not have, and states cannot impose, fiduciary duties to plans. *See, e.g.*, *Pharm. Care Mgmt. Ass'n v. Dist. of Columbia*, 613 F.3d 179, 185 (D.C. Cir. 2010) (accepting argument); *Pharm. Care Mgmt. Ass'n*

v. Rowe, 429 F.3d 294, 300-05 (1st Cir. 2005) (rejecting argument); *see also Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463, 466 (7th Cir. 2007) (holding that PBM was not a fiduciary); *In re EpiPen Direct Purchaser Litig.*, No. 20-CV-0827, 2021 WL 147166, at *17 (D. Minn. Jan. 15, 2021) (unpublished) (noting PBMs' argument that they have no fiduciary duty to their clients). While the states dispute this (which is not at issue here and is particularly dubious post-*Rutledge*), PBMs essentially seek to avoid being beholden to anyone; on the one hand PCMA argues that PBMs have no fiduciary duties, but on the other it argues that PBMs are so closely related to plans that states cannot regulate. The Court should reject these inconsistent positions.

2. Oklahoma's Laws Do Not Force Plans to Make Particular Plan-Design Choices.

That PBMs are not plans is fatal to PCMA's ERISA challenges. But even if the Court reaches the merits of each challenged law, none is preempted by ERISA.

PCMA challenges four Oklahoma laws, three of which address pharmacy networks: First, PBMs' networks must include sufficient pharmacies so covered individuals can fill prescriptions reasonably close to their homes. Okla. Stat. tit. 36, § 6961(A)-(B) (2021). Second, PBMs must give a network pharmacy preferred-participation status if the pharmacy meets the PBM's conditions for that status. *Id.* § 6962(4) (2021). And third, PBMs cannot exclude pharmacies from a network solely because a pharmacy's employee is on probationary status with the state's

licensing board. *Id.* § 6962(5) (2021). None of these laws affects who a plan covers or what benefits a plan provides. PBMs can set their standards, but then simply must adhere to them and permit pharmacies that meet those standards to participate.

Fourth, PCMA challenges Oklahoma's prohibition on PBMs incentivizing use of particular in-network pharmacies. *Id.* § 6963(E) (2021). This prohibition is akin to the cost regulation upheld in *Rutledge*. PCMA claims such incentives reduce PBMs' costs. (Appellant's Br. 10-11.) But "ERISA does not pre-empt state regulations that merely increase costs or alter incentives for ERISA plans." *Rutledge*, 141 S. Ct. at 480. This is precisely what section 6963(E) does. It prohibits a tool that PBMs use to engage in self-dealing, i.e., steering (by driving enrollees to PBM-affiliated pharmacies), under the guise of cost savings. But it does not alter the who or what of benefits, and ERISA does not preempt it.

C. Oklahoma's Laws Do Not Govern Central Matters of Plan Administration.

Finally, PCMA argues in the alternative that even if none of these provisions affect substantive plan benefits, they affect central matters of plan administration. (Appellant's Br. 40-42.) PCMA creates a distinction without a difference by essentially recasting as plan-administration arguments its arguments that Oklahoma's laws affect substantive benefits. Although in rare circumstances laws can impact matters of plan administration without impacting substantive benefits, this is not such a case.

As recognized in *Rutledge*, whether a law "governs a central matter of plan administration" is typically shorthand for whether a regulation affects substantive plan benefits. *Rutledge*, 141 S. Ct. at 480. Examples of regulations that govern central matters of plan administration include those requiring payment of specific benefits, binding plans to specific rules for determining who gets benefits, or otherwise requiring plans to adopt particular *substantive* coverage. *Id.* In other words, whether a state law governs a central matter of plan administration usually is not a separate inquiry from whether the state law affects substantive coverage.

In rare circumstances, state laws that did not alter substantive benefits have been preempted under a plan-administration analysis. For example, in *Gobeille*, the Court held that ERISA preempted a requirement to report healthcare information because ERISA already had extensive reporting and recordkeeping requirements. *Gobeille*, 577 U.S. at 321. Generally, however, even when the Court concludes that state law is preempted because it governs a central matter of plan administration, the state law addresses substantive benefits. *E.g.*, *Egelhoff*, 532 U.S. 147-48; *see also Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722, 730 (8th Cir. 2017) (defining plan administration as determining claimants' eligibility, calculating benefits, making disbursements, monitoring funds for paying benefits, and keeping appropriate records).

The case PCMA cites, *Egelhoff*, proves this point. PCMA argues that its plan-administration arguments are distinct from its substantive-benefits arguments. (Appellant's Br. 41-42.) But *Egelhoff* was about *who* received substantive benefits. In that case, state law automatically altered a beneficiary designation upon divorce, notwithstanding that the ERISA plan provided the ex-spouse remained a beneficiary. *Egelhoff*, 532 U.S. at 147-48. The Court's preemption analysis centered on the ERISA requirement to administer plans consistent with plan documents and the direct conflict between the state law and the plan documents regarding beneficiary status. *Id.* at 150.

Because *Egelhoff* does not support PCMA and its plan-administration arguments merely repackage its prior arguments that Oklahoma's laws allegedly impact substantive benefits, its arguments fail for the same reasons: first, PBMs are not plans; and second, even taking Oklahoma's laws individually, none alters plans' benefits, they only alter PBMs' decisions.

III. NO MEDICARE STANDARD PREEMPTS OKLAHOMA'S PREFERRED-PARTICIPATION REQUIREMENT.

Medicare does not preempt Oklahoma's preferred-participation requirement because there is no Medicare standard addressing the issue. This Court should reject PCMA's overbroad interpretation of Medicare preemption provision. Properly construed, Medicare does not stymie states from promoting competition by requiring

PBMs to give its network pharmacies equal opportunity to be in its preferred network.

A. Medicare Preemption Requires a Medicare Standard Specifically Addressing the Issue Subject to State Regulation.

Medicare's preemption clause states, "[t]he 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 [prescription-drug] plans." 42 U.S.C. § 1395w-26(b)(3) (Medicare Part C preemption provision); *see also id.* § 1395w-112(g) (adopting Part C's preemption provision for Part D prescription-drug plans). Preemption occurs only if a state law either (1) regulates the same subject matter as a Medicare Part D standard, or (2) otherwise frustrates the purpose of a standard. *Wehbi*, 18 F.4th at 972. Thus, for preemption to occur, there must be an existing standard on the specific topic subject to state regulation. This interpretation of Medicare's preemption clause has been accepted by other courts. *See, e.g.*, *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018); *Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148-49 (9th Cir. 2010).

Contrary to Medicare's plain language, PCMA advocates for a broad preemption standard and aims to eradicate states' traditional police powers. First, PCMA suggests that Medicare preempts virtually all state regulation of PBM-pharmacy contracts. (Appellant's Br. 45-48.) It notes that Medicare requires "reasonable and relevant terms and conditions of participation" and further requires

plans to permit any pharmacy that meets a plan's terms and conditions to participate. 42 U.S.C. § 1395w-104(b)(1)(A) (2018); 42 C.F.R. § 423.505(b)(18) (2020). But the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering Medicare, has rejected this position. For example, when state laws prohibited PBMs from requiring additional credentials to be a network pharmacy, CMS endorsed those laws as "a reasonably consistent minimum practice." *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*, 83 Fed. Reg. 16,440, 16,598 (Apr. 16, 2018). If CMS's standards preempted such laws, CMS would have said so. Instead, CMS recognized that the any-willing-pharmacy standard does not generally preempt state laws regulating pharmacy inclusion. Otherwise, even regulatory-floor laws would be preempted. Moreover, in the same rulemaking, CMS expressed concerns that PBM's restrictive accreditation requirements could potentially cut pharmacies out of most of the prescription-drug market. *Id.*

PCMA's broad view of Medicare preemption also belies the historic balance between Medicare and adjacent state regulations. *Cf. Med. Soc'y of State of N.Y. v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992) (recognizing that regulating public health and medical-care costs "are virtual paradigms of matters traditionally within the police powers of the state"). Indeed, states sometimes lead the way, with federal laws

eventually catching up. For example, Congress amended Medicare in 1997 to require marketing-material review. Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 285-86. Before 1997, some states had laws to prevent fraudulent solicitations, deceptive advertising, and misrepresentations in the enrollment process. *See, e.g.*, *Solorzano v. Superior Court*, 13 Cal. Rptr. 2d 161, 167-70 (Cal. Ct. App. 1992). While the federal law then preempted conflicting state laws in this area, states were the leaders. *E.g.*, *Uhm*, 620 F.3d at 1157. Here, the lack of CMS standards necessarily means that PCMA's preemption claims fail. Although CMS could theoretically promulgate standards that may, in some circumstances, preempt states' PBM regulations, unless CMS does so, states are free to continue protecting their consumers by prohibiting unscrupulous actions.

Finally, PCMA supports its broad view of preemption by arguing that Medicare prohibits states from "interfering" in PBM-pharmacy negotiations, citing the Eighth Circuit's decision in *Pharmaceutical Care Management Ass'n v. Rutledge*, 891 F.3d 1109. (Appellant's Br. 51-52.) But although *Rutledge* accurately articulates the test for Medicare standard preemption, its analysis of the separate "interference" section of Medicare is unpersuasive. In that case, the court stated—without any substantive analysis—that Medicare prohibits "state interference in negotiations between Part D sponsors and pharmacies." *Id.* (citing 42 U.S.C. § 1395w-111(i) (2018)). But that conclusion has no basis in the cited text; instead,

the statute prohibits only the Secretary of Health and Human Services from interfering in negotiations or requiring particular formularies or price structures, not states. 42 U.S.C. § 1395w-111(i). Moreover, even if that section applied to the states, it applies only to "negotiations or disputes involving payment related contractual terms." 83 Fed. Reg. at 16,590. It does not apply to regulations that "promote competition," "increas[e] the transparency of prices," or "minimiz[e] barriers to entry." *Id.* As discussed below, Oklahoma's preferred-participation statute squarely falls into these categories.

B. No Medicare Standard Overlaps with Oklahoma's Preferred-Participation Statute.

Oklahoma prohibits PBMs from denying network pharmacies preferred-participation status if they meet the PBM's conditions for that status. Okla. Stat. tit. 36, § 6962(4). The law does not set or alter the conditions that PBMs establish for preferred networks; it requires only that PBMs admit pharmacies into the preferred network if the pharmacy agrees to the PBM's conditions. No Medicare standard overlaps with that prohibition. As a result, Medicare does not preempt Oklahoma's statute.

PCMA alleges that two Medicare standards combine to overlap with Oklahoma's statute, one that requires plan sponsors to allow any willing pharmacy into its network if the pharmacy meets the sponsor's requirements, 42 C.F.R. § 423.505(b)(18) (2021), and one that allows sponsors to reduce

copayments or coinsurance for drugs obtained through a preferred pharmacy. *Id.* § 423.120(a)(9) (2021). Neither standard overlaps with the preferred-participation statute. As the district court recognized, the first standard addresses joining a sponsor's general network; the preferred-participation statute does not address or affect initial network access. (Appellant's Add. 66.) The second standard authorizes preferred pharmacies to exist by allowing copayment reductions for prescriptions filled at such pharmacies. The Oklahoma statute does not alter that authorization.

Without a relevant standard to cite, PCMA attempts to create a piecemeal standard, taking pieces of the two standards it discusses and attempting to merge them into a third, new standard: that sponsors must allow any willing pharmacy into its preferred pharmacy network. No Medicare standard requires (or otherwise addresses) this practice.[40] Here, the lack of CMS standards necessarily means that PCMA's preemption claim fails. While CMS could theoretically promulgate standards that could preempt states' preferred-participation regulations, it has not, and states are free to continue protecting their consumers by prohibiting anticompetitive actions.

[40] Indeed, in making this argument, PCMA attempts to have its cake and eat it, too. On the one hand, PCMA claims the combined Medicare standards preempt state regulation, but on the other hand PBMs' current practice is to exclude some pharmacies from its preferred networks for Medicare plans, presumably on the basis that no Medicare standard prohibits it from doing so.

CONCLUSION

PBMs' market abuses have caused numerous harms, which states are attempting to curtail by placing reasonable restrictions on PBM-pharmacy contracts that increase transparency, discourage rent-seeking behavior, and reduce self-dealing. State laws to this effect do not alter substantive coverage of ERISA plans, and therefore they are not preempted. Similarly, no Medicare standard overlaps to preempt states from requiring PBMs to give pharmacies preferred-participation status if they meet the PBM's requirements. Accordingly, the Court should reject PCMA's broad approach to preemption and affirm the district court.

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WITH FED. R. APP. P. 32

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(4)(G) and (5) because this brief contains 6,407 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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s/Angela Behrens
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The undersigned, on behalf of the party filing and serving this brief, certifies that the brief has been scanned for viruses with the most-recent version of Cylance, a commercial-virus scanning program, and is virus-free. This brief also complies with privacy-redaction requirements of 10th Cir. R. 25.5.

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CERTIFICATE OF SERVICE

I certify that I caused this document to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system on October 18, 2022. All participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

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