No. 22-6074

IN THE

United States Court of Appeals for the Tenth Circuit

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff-Appellant,

– v. –

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

Defendants-Appellees.

On Appeal From a Final Judgment of the United States District Court for the Western District of Oklahoma (Jones, J.), No. 5:19-cv-977

BRIEF OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC., AMERICAN PHARMACIES, INC., AND OKLAHOMA PHARMACISTS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

Robert T. Smith
Howard R. Rubin
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW – Suite 200
Washington, DC 20007-5118
202-625-3500

Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT

Consistent with Rule 26.1 of the Federal Rules of Appellate Procedure and Rule 26.1 of the Local Rules of the Tenth Circuit, *amici curiae* state that the National Community Pharmacists Association, the American Pharmacists Association, the National Association of Chain Drug Stores, Inc., American Pharmacies, Inc., and the Oklahoma Pharmacists Association each has no parent company, and no publicly traded company owns ten percent or more of any of *amici*'s stock.

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GLOSSARY

CMS:	Centers for Medicare and Medicaid Services
ERISA:	Employee Retirement Income Security Act of 1974
FTC:	Federal Trade Commission
HMO:	Health maintenance organization
Medicare Part D:	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
PBM:	Pharmacy benefit manager

STATEMENT OF INTEREST OF *AMICI CURIAE*[*]

Amici curiae are four trade associations that represent the interests of pharmacists and pharmacy owners, and a cooperative of independent pharmacies. This litigation involves a challenge to the Patient's Right to Pharmacy Choice Act, an Oklahoma law that, like the laws of nearly all States, regulates how pharmacy benefit managers (PBMs) transact business with patients and pharmacies. Because PBMs have affected all aspects of pharmacy care, and Oklahoma's law seeks to regulate certain business practices of PBMs that have harmed pharmacies and their patients, *amici* have a strong interest in the outcome of this case.

The National Community Pharmacists Association (NCPA) represents the interests of the owners, managers, and employees of more than 19,000 independent community pharmacies across the United States. NCPA's members employ over 239,000 individuals on a full or part-time basis and dispense roughly 40% of the nation's retail prescriptions.

[*] All parties consent to the filing of this brief. No counsel for any party authored this brief in whole or in part. No person or entity—other than *amici curiae* and their counsel—made a monetary contribution specifically for the preparation or submission of this brief.

The American Pharmacists Association (APhA) is the voice for pharmacists, advancing the profession of pharmacy. APhA delivers invaluable leadership and support to pharmacists across all practice settings, including its nearly 50,000 member pharmacists, scientists, students, and technicians.

The National Association of Chain Drug Stores, Inc. (NACDS) is comprised of over 80 chain-pharmacy companies, including national companies and regional chains with a minimum of four stores. There are over 40,000 retail chain pharmacies in the United States, employing nearly 3 million people, including 155,000 pharmacists who fill over 3 billion prescriptions annually.

American Pharmacies, Inc. is a cooperative of independent pharmacies serving the professional, economic, and advocacy needs of its members. It represents the interests of more than 600 member pharmacies in 36 States, including Oklahoma.

The Oklahoma Pharmacists Association (OPhA) is a State-level association representing the interests of pharmacists in Oklahoma. OPhA includes more than 500 pharmacist members located in over 130 cities across Oklahoma who are directly affected by the challenged legislation.

ARGUMENT

This appeal involves a challenge to the Patient's Right to Pharmacy Choice Act, an Oklahoma law that regulates PBMs. In the district court, the Pharmaceutical Care Management Association (PCMA)—a trade association representing PBMs—claimed the Employee Retirement Income Security Act of 1974 (ERISA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Part D) preempt more than a dozen provisions of Oklahoma's law. PCMA Br. 15-16 & n.9. On appeal, however, PCMA narrowed its claims to just four provisions, which regulate the composition and quality of the pharmacy networks that PBMs sell to health plans. *Id.*

As the above implies, a PBM is *not* a health plan, and it is not a plan "sponsor" or "administrator," either. Yet a careful reader might not know this from the briefs of PCMA and its *amicus*. They refer repeatedly to "plans" and "plan administrators," implying that PBMs are subject to robust regulation under ERISA and Medicare Part D. That is simply not the case.

As explained below, States have compelling reasons to regulate PBMs. PBMs are not subject to any meaningful form of federal regulation, and they have engaged in conduct that harms plans, patients, and pharmacies. Laws

like Oklahoma's—and the laws of dozens of other States—are aimed at this conduct.

In challenging Oklahoma's law, PCMA pins its hopes on a theory of preemption that the Supreme Court has twice rejected as "'unsettling'"—that federal law preempts State law in areas the federal government does not regulate. *Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A.*, 519 U.S. 316, 330 (1997) (quoting *N.Y. Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 665 (1995)). The Court has emphasized that ERISA does not displace generally applicable State laws in "those areas where ERISA has nothing to say." *Id.* And Congress, in its wisdom, enacted a similar standard to govern preemption under Medicare Part D, which displaces State laws only where they overlap with specific Part D standards. 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g).

More relevant here, the Supreme Court has held that ERISA does not preempt State laws that regulate third parties that happen to sell goods or services to ERISA plans. In *Rutledge v. PCMA*, for example, the Court rejected a challenge to an Arkansas law that regulated the relationship between PBMs and pharmacies—in part because the State's law "does not directly regulate health benefit plans at all, ERISA or otherwise," and it therefore

"does not require *plans* to provide any particular benefit to any particular beneficiary in any particular way." 141 S.Ct. 474, 481-82 (2020) (emphasis added). And in *Travelers*, the Court explained that State laws that regulate only insurers—which, like PBMs, sell services to ERISA plans—do not come within the reach of ERISA's preemption clause: "'laws that regulate only the insurer, or the way in which it may sell insurance, do not "relate to" benefit plans'" in "'the first instance.'" 514 U.S. at 663 (quoting *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 741 (1985)).

That is dispositive of PCMA's ERISA claims. Like the Arkansas law in *Rutledge*, Oklahoma's PBM law regulates downstream from any benefits determination—that is, by regulating the pharmacy networks that *PBMs sell* to benefit plans, Oklahoma does not require *ERISA plans* to provide any particular benefit to any particular beneficiary in any particular way.

Nor is a contrary result compelled by an older line of cases, invoked by PCMA and its *amicus*, discussing State any-willing-provider laws. Each of those cases is distinguishable, and each was decided before *Rutledge*.

Finally, every court to address the issue has held that Medicare Part D's preemption clause supersedes State laws only when they "regulate the same subject matter" as a Part D standard. *PCMA v. Wehbi*, 18 F.4th 956, 971

(8th Cir. 2021) (citing authorities). In *Wehbi*, for instance, the Eighth Circuit held that because no Part D standard regulates the accreditation standards that PBMs impose on network pharmacies, States are free to regulate this aspect of a PBM's pharmacy networks. *Id.* at 972-73, 975.

On appeal here, PCMA has narrowed its claims under Medicare Part D, focusing on a single sub-provision of Oklahoma law. PCMA Br. 20, 48-55. That sub-provision requires PBMs to allow any pharmacy to participate in a PBM's preferred network "if the [pharmacy] is willing to accept the terms and conditions that the PBM has established for other [pharmacies] as a condition of preferred network participation status." 36 Okla. Stat. § 6962(B)(4).

And yet, PCMA concedes no Part D standard governs access to preferred-pharmacy networks. PCMA Br. 52-53. That alone defeats PCMA's argument under Medicare Part D.

The District Court did not err in rejecting PCMA's far-reaching claims of preemption. This Court should affirm.

I. Oklahoma has compelling reasons to regulate PBMs.

States have faced a crisis of access to pharmacy care within their borders. Over the last 15 years, the business practices of PBMs have caused

more than 1,200 pharmacies to close their doors—and this has been hardest felt in rural communities, including in Oklahoma. Abiodun Salako et al., *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, at 1, 5, RUPRI Center for Rural Health Policy Analysis (July 2018).[1] In the meantime, the cost of prescription drugs has skyrocketed.

According to numerous independent studies, PBMs are the chief culprits of this crisis of care. As explained below, PBMs are not subject to meaningful federal regulation. And PBMs have engaged in business practices that have negatively affected the safe and efficient delivery of prescription drugs.

In response, nearly all States have enacted laws regulating PBMs. The Oklahoma law at issue here, the Pharmacy Choice Act, addresses a subset of the business practices of PBMs that have inhibited safe, cost-effective, and convenient access to pharmacy care. These provisions operate in a space unoccupied by federal law.

[1] https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

A. The federal government generally does not regulate PBMs.

Through ERISA and Medicare Part D, the federal government regulates two species of benefit plans. ERISA regulates certain private-employer and union-sponsored benefit plans. 29 U.S.C. § 1003. Medicare Part D, in contrast, is a public-private partnership through which private companies sponsor Medicare-funded prescription drug benefits for Americans aged 65 and older, and individuals with certain disabilities. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

Notably, PBMs are *not* benefit plans. Rather, benefit plans hire PBMs as service providers that sell plans access to prescription drugs. *Rutledge*, 141 S.Ct. at 478. PBMs deliver this access by contracting separately with pharmacies to create networks through which plan beneficiaries can fill their prescriptions. *Id.*

Because of their unique status, PBMs are not subject to regulation under ERISA. And PBMs are not subject to meaningful regulation under Medicare Part D, either.

1. ERISA does not regulate PBMs.

PBMs are not "fiduciaries" under ERISA. As a general matter, a person must exercise "discretionary authority," "control," or "responsibility" over the management or administration of a plan or its assets to qualify as an ERISA "fiduciary." 29 U.S.C. § 1002(21)(A). PBMs do none of these things.

PCMA concedes that its members are *not* ERISA fiduciaries—because that status is incompatible with the business model of PBMs. PCMA App'x, Vol. 1, at 110, 176-77, 181-91; Vol. 2, at 200-01, 228-31; Vol. 3, at 648. And federal appellate courts are unanimous in holding that PBMs are not ERISA fiduciaries, because they do not exercise discretion or control over the administration of ERISA plans.[2]

Because PBMs do not qualify as ERISA fiduciaries, they cannot qualify as plan "administrators" either. An "administrator" is a specifically designated fiduciary under ERISA. 29 U.S.C. § 1002(16)(A). As the

[2] *Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463, 473 (7th Cir. 2007) (holding that PBMs are not ERISA fiduciaries); *PCMA v. Rowe*, 429 F.3d 294, 300-01 (1st Cir. 2005) (same), *cert. denied*, 547 U.S. 1179 (2006); *accord In re Express Scripts/Anthem ERISA Litig.*, 285 F.Supp.3d 655, 680 (S.D.N.Y. 2018), *aff'd*, 837 F.App'x 44 (2d Cir. 2020), *cert. denied*, 142 S.Ct. 2867 (2022); *Bickley v. Caremark Rx, Inc.*, 361 F.Supp.2d 1317, 1332 (N.D. Ala. 2004), *aff'd*, 461 F.3d 1325 (11th Cir. 2006).

Department of Labor has made plain, "a plan administrator . . . must, [by] the very nature of his position, have 'discretionary authority or discretionary responsibility in the administration' of the plan." 29 C.F.R. § 2509.75-8(D-3) (citation omitted).

Thus, although PCMA and its *amicus* refer repeatedly throughout their briefs to "plans" and "plan administrators," PBMs are neither. Instead, PBMs are third-party service providers that may perform only "ministerial functions" on behalf of a plan. *Id.* § 2509.75-8(D-2). Or put differently, because of their status as non-fiduciaries, PBMs "have no power to make any decisions as to plan policy, interpretations, practices or procedures." *Id.*

Critically, ERISA does not regulate the business practices of third-party providers that, like PBMs, sell goods and services to ERISA plans—which makes sense. Otherwise, as Oklahoma notes, ERISA would displace States laws regulating everything from doctors, accountants, and lawyers, to hospitals and insurers. Okla. Br. 22.

"[S]ervice providers" become "liable" under ERISA only "when they cross the line from advisor to fiduciary." *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993). In *Pegram v. Herdich*, for example, the Supreme Court held that an HMO-employed physician who cared for an ERISA beneficiary was

not liable under ERISA because he was not a fiduciary, but a State may hold such a doctor liable through a malpractice action. 530 U.S. 211, 231, 236 (2000). Similarly, in *Rutledge*, which involved an ERISA challenge to an Arkansas law that regulates PBMs, the Court emphasized that "state law" governs the goods and services that plans, as market participants, purchase for their beneficiaries. 141 S.Ct. at 482.[3]

2. Medicare Part D largely regulates "plan sponsors," not PBMs.

Medicare Part D focuses on the regulation of plan "sponsor[s]," not PBMs. *E.g.*, 42 U.S.C. § 1395w-112(a). Under Part D, a plan sponsor must be "organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage." 42 U.S.C. § 1395w-112(a)(1). But PBMs have "not historically achieved" this status, which

[3] The Third Circuit has held that a non-fiduciary may be liable under ERISA if it violates ERISA while acting as an agent of an ERISA plan. *Kollman v. Hewitt Assocs., LLC*, 487 F.3d 139, 148 (3d Cir. 2007). But in that situation, the agent is held accountable for actions it has taken on behalf of its principal, an ERISA fiduciary, in violation of ERISA. *Id.*; *cf. Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 317, 323 (2016) (holding that ERISA preempted a State law that compelled a third-party "administrator" to disclose "detailed information about claims and plan members" on behalf of an ERISA plan). A PBM, in contrast, does not act as an agent of an ERISA fiduciary in the "administration of its own business as a PBM." *Moeckel v. Caremark, Inc.*, 622 F.Supp.2d 663, 677 (M.D. Tenn. 2007); *supra* note 2.

would subject them to regulation as insurers. *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4,194, 4,509 (Jan. 28, 2005).

Thus, when the Centers for Medicare and Medicaid Services (CMS) first promulgated regulations implementing the Part D program, it clarified that "[n]othing in this rule directly regulates PBMs, positively or negatively, or directly encourages or discourages their use over alternative methods of managing drug benefits." *Id.* at 4,510. Instead, like Congress, CMS has focused on regulating plan sponsors.

Since Medicare Part D was first implemented, Congress and CMS have added only a handful of standards that regulate PBMs—and only to the extent PBMs are serving Part D plans. For example, after the growth of PBM services, Congress added a provision requiring PBMs to make certain disclosures to Part D plan sponsors, 42 U.S.C. § 1320b-23, which CMS then implemented through amendments to 42 C.F.R. § 423.514(d), *Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes*, 77 Fed. Reg. 22,072, 22,171 (Apr. 12, 2012).

Thus, "the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of

its contract with CMS." 42 C.F.R. § 423.505(*i*)(1). And plans must do so regardless of whether they hire a PBM to assist them. *Cf.* 70 Fed. Reg. at 4,510 (stating that CMS is agnostic on whether plans hire PBMs); Okla. Br. 14 (explaining that nothing requires plans to hire PBMs).

B. PBMs have engaged in business practices that harm plans, patients, and pharmacies.

The business model of PBMs involves maximizing the difference between what they charge plans and what they pay pharmacies for access to prescription drugs. This incentivizes PBMs to engage in business practices that can harm plans, patients, and pharmacies. In the absence of regulation, PBMs have done just that.

On the plan side, PBMs have exploited undisclosed conflicts of interest, which have resulted in actions that are harmful to the plans and patients that PBMs purport to serve. *E.g.*, Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 Yale Law & Pol'y Rev. 360 (2020). For example, PBMs have used their market power to demand hidden rebates from pharmaceutical manufacturers in order to place drugs on the PBMs' lists of approved medications. *Id.* at 361-62. This has led some PBMs to favor more-

expensive drugs, because the hidden rebates generate greater profits for PBMs, even though those drugs are more costly to plans and patients. *Id.* Relatedly, pharmaceutical manufacturers have claimed PBMs have punished them for lowering drug costs, because it means less room for PBMs to demand hidden rebates from manufacturers. *Id.* at 362. For these and other reasons, the First Circuit recognized that "'[w]hether and how a PBM actually saves an individual benefits [plan] money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits [plan].'" *Rowe*, 429 F.3d at 298 (citation omitted).

To maintain pricing secrecy, PBMs typically include gag clauses in their contracts with pharmacies, prohibiting pharmacists from disclosing to patients and plans the amount the PBM reimbursed the pharmacy for dispensing a drug. This, in turn, can have real financial consequences for patients. For example, a PBM may charge the patient a copay (*e.g.*, $20) that exceeds the amount the pharmacy would otherwise charge for the drug if the patient declined to use insurance (*e.g.*, $8). In this situation, pharmacists can save patients money, but gag clauses prevent pharmacists from alerting patients of this fact. PCMA App'x, Vol. 1, at 110-11; Robert Pear, *Why Your*

Pharmacist Can't Tell You That $20 Prescription Could Cost Only $8, N.Y. Times, Feb. 24, 2018.[4]

Separately, PBMs have preyed on pharmacies, causing hundreds to close their doors. Because the three largest PBMs control approximately 85% of the market for beneficiaries with prescription-drug coverage, PCMA App'x, Vol. 1, at 107; Vol. 2, at 315, pharmacies have limited bargaining power when negotiating with PBMs. Refusing to accept a PBM's contract could mean the inability to serve the majority of patients in a pharmacy's community. As a result, PBM-pharmacy contracts generally grant PBMs unilateral authority to dictate the amount of reimbursement paid to pharmacies, allowing PBMs to reimburse pharmacies less than any pharmacy can purchase drugs at wholesale. *Rutledge*, 141 S.Ct. at 478-79. In addition, PBMs require pharmacies to dispense prescriptions regardless of the amount the pharmacy is reimbursed, PCMA App'x, Vol. 1, at 108; assess fees months after claims are processed, *id.* at 111; and impose a variety of other restrictions on the practice of pharmacy, *id.* at 110-12.

[4] https://www.nytimes.com/2018/02/24/us/politics/pharmacybenefit-managers-gag-clauses.html.

PBMs also have leveraged their market power to capture a share of the retail pharmacy market. Darrel Rowland, *Specialty drugs: The new arena for pharmacy benefit manager profits?*, Columbus Dispatch, Apr. 24, 2019.[5] PBMs have accomplished this by prohibiting their network pharmacies from distributing "specialty drugs," which are typically higher-cost drugs that require special handling, and by simultaneously expanding the designation of "specialty drugs" to include non-specialty medications that have been on the market for a long time. *Id.* PBMs then require patients to obtain those drugs through mail-order pharmacies owned by the PBMs. *Id.*

CMS has expressed concern that PBMs are using pharmacy contracts "in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies." *Medicare Program; Contract Year 2019 Policy and Technical Changes*, 82 Fed. Reg. 56,336, 56,410 (Nov. 28, 2017). Many of these PBM-imposed restrictions have nothing to do with patient health. *Id.*

The Federal Trade Commission is also investigating, among other things, whether PBMs use "unfair audits of independent pharmacies" and other excuses, like the placement of a single pharmacist on probation, to

[5] https://www.dispatch.com/news/20190423/specialty-drugsnew-arena-for-pharmacy-benefit-manager-profits.

remove pharmacies from their networks. *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*, June 7, 2022[6]; PCMA App'x, Vol. 1, at 153-54. PBMs then steer the patients of these excluded pharmacies to PBM-affiliated pharmacies.

These practices negatively affect patients by requiring them to go through mail-order pharmacies for medications that should be available at their corner drugstore. And these practices can lead to negative health consequences—whether because patients do not receive refills in a timely fashion or because the medication is spoiled by temperature extremes. Adiel Kaplan et al., *Millions of Americans receive drugs by mail. But are they safe?*, NBC News (Dec. 8, 2020).[7]

The net result is decreased access to retail pharmacies, which, for many Americans, are their most accessible form of healthcare. An independent study found that abusive PBM business practices drove more than 16% of independent rural pharmacies out of business. Salako, *supra*, at 1. And that

[6] https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

[7] https://www.nbcnews.com/specials/millions-of-americans-receive-drugs-by-mail-but-are-they-safe/.

same study found that from 2003 to 2018, PBM-business practices caused 26 zip codes in Oklahoma to lose their only pharmacy. *Id.* at 5; Okla. Br. 5 (citing evidence that PBMs forced the closure of 10% of Oklahoma's independent pharmacies in just three years).

C. Oklahoma's PBM law addresses a subset of abusive PBM conduct.

Through the passage of the Pharmacy Choice Act, the Oklahoma Legislature addressed a subset of abusive PBM business practices. As relevant to PCMA's appeal, the Act:

- regulates the quality of the pharmacy networks in Oklahoma that PBMs sell to plans and insurers, and ensures that those networks have a sufficient number of physical locations from which patients can receive their medication, 36 Okla. Stat. § 6961(A)-(B);
- requires PBMs to allow any pharmacy to participate in the PBM's preferred network "if the [pharmacy] is willing to accept the terms and conditions that the PBM has established for other [pharmacies] as a condition of preferred network participation status," *id.* § 6962(B)(4);
- dictates that PBMs may not "[d]eny, limit or terminate a [pharmacy's] contracts" because a pharmacist employed by the pharmacy is on "probation status" with "the State Board of Pharmacy," *id.* § 6962(B)(5); and
- provides that PBMs "shall not require or incentivize" the use of a particular pharmacy—particularly PBM-owned pharmacies—using "discounts in cost-sharing," *id.* § 6963(E).

PCMA challenges all four of these provisions under ERISA, and it challenges the last of these provisions under Medicare Part D. PCMA Br. 25-30, 48-52.

II. ERISA does not preempt Oklahoma's PBM law.

ERISA regulates the "administration of benefit plans" for certain private-employer and union-sponsored plans. *Travelers*, 514 U.S. at 651. It does so by imposing upon ERISA plans "reporting and disclosure mandates, participation and vesting requirements, funding standards, and fiduciary responsibilities for plan administrators." *Id.* (citations omitted). As noted above, PBMs are neither plans nor plan "administrators," and they are not fiduciaries either.

ERISA also includes a preemption clause, 29 U.S.C. § 1144(a). As a gloss on ERISA's text, the Supreme Court has held that ERISA preempts State laws that have a "connection with" or "reference to" ERISA plans. *Rutledge*, 141 S.Ct. at 479.

Only "connection with" preemption is at issue here. PCMA Br. 22-23. A state law has a "connection with" ERISA plans when it "'governs a central matter of plan administration or interferes with nationally uniform plan administration.'" *Rutledge*, 141 S.Ct. at 480 (citation omitted).

"Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan." *Id.* For that reason, the Supreme Court has held that ERISA is "primarily concerned" with preempting State laws that require employers to "structure benefit plans in particular ways," such as by requiring employers to offer "specific benefits or by binding plan administrators to specific rules for determining beneficiary status." *Id.* (citations omitted).

As explained below, ERISA does not preempt the Pharmacy Choice Act. Oklahoma's law regulates in an area unoccupied by ERISA—the quality of the goods and services that third parties happen to sell to ERISA plans. Laws like Oklahoma's regulate downstream from any benefits determination—that is, they do not affect who is eligible for coverage or which drugs are covered.

A. States may regulate the practices of third-party service providers to ERISA plans—even if those regulations indirectly affect ERISA plans.

The Supreme Court has held repeatedly that ERISA does not preempt State laws regulating the standards that apply to third parties who sell goods and services to ERISA plans. Instead, State law governs this relationship.

In *Travelers*, for example, the Court made clear that State laws that regulate only insurers—a common service provider to ERISA plans—do not raise any preemption concerns under ERISA: "'laws that regulate only the insurer, or the way in which it may sell insurance,'" do not "relate to" ERISA plans "'in the first instance.'" 514 U.S. at 663-64.[8]

More recently, in *Rutledge*, the Court emphasized that an Arkansas law that regulates only PBMs—another service provider to ERISA plans—"does not directly regulate health benefit plans at all, ERISA or otherwise." 141 S.Ct. at 481. Just as importantly, the Court held that regulating the relationship between PBMs and pharmacies "does not require *plans* to provide any particular benefit to any particular beneficiary in any particular way." *Id.* at 482 (emphasis added).

[8] In contrast, the Supreme Court has followed a traditional ERISA preemption analysis when State laws regulate "employers" or "benefit plans," such as by requiring "employers" to provide "specific benefits," *Rutledge*, 141 S.Ct. at 480 (citing *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983) (State law that dictated the benefits "employers" must provide through their benefit plans)), or by binding benefit plans "to specific rules for determining beneficiary status," *id.* (citing *Egelhoff v. Egelhoff*, 532 U.S. 141, 144, 146-50 (2001) (State law that applied to an "'employee benefit plan'" and regulated its administration)).

PCMA and its *amicus* attempt to distinguish *Rutledge* on the ground that it involved a State law that regulates only the amounts that PBMs reimburse pharmacies. PCMA Br. 25; Br. of *Amicus Curiae* Ass'n of Fed. Health Orgs. (AFHO) 5. But that's not accurate. In addition to challenging Arkansas's regulation of costs, PCMA challenged provisions of Arkansas law that dictate the "process" and "substantive standard" that PBMs apply in adjudicating appeals by pharmacies, compel PBMs to reverse and rebill claims, and authorize pharmacies to decline to dispense medications to beneficiaries. *Rutledge*, 141 S.Ct. at 481-83. The Supreme Court held that ERISA does not preempt these provisions, either. *Id.*

Oklahoma's PBM law is not meaningfully different from the Arkansas law in *Rutledge*. Oklahoma, like Arkansas, regulates PBMs, not plans or plan administrators. 36 Okla. Stat. §§ 6961(A)-(B), 6962(B)(4), 6962(B)(5), and 6963(E) (regulating only "Pharmacy benefit managers" and, in the case of § 6963(E), PBMs and "health insurer[s]"). True, Oklahoma's law, like Arkansas's, limits the services "a plan might prefer that PBMs" are permitted to offer. *Rutledge*, 141 S.Ct. at 482. But by regulating the pharmacy networks that *PBMs sell* to plans, Oklahoma, like Arkansas, "does not require *plans* to provide any particular benefit to any particular beneficiary

in any particular way." *Id.* (emphasis added). In short, as the federal government explained, a State PBM law "regulates PBM administration, not ERISA plan administration." U.S. *Amicus* Br. 15, *Rutledge v. PCMA*, No. 18-540 (U.S. Dec. 4, 2019), 2019 WL 6609430.

The district court therefore held correctly that Oklahoma's PBM law "may alter the incentives and limit some of the options that an ERISA plan can use" when purchasing services from PBMs. PCMA App'x, Vol. 3, at 737. But Oklahoma's law does not "force[ ] ERISA plans to make any specific choices" about which benefits to offer or who is eligible for coverage. *Id.*

PCMA suggests the regulation of PBMs amounts to the regulation of ERISA plans because it "would be a practical impossibility for the vast majority of health plans to manage pharmacy benefits without a PBM," citing *PCMA v. District of Columbia*, 613 F.3d 179, 183 (D.C. Cir. 2010). PCMA Br. 6. To be sure, the D.C. Circuit held that State laws that regulate PBMs "function as a regulation of an ERISA plan itself." *District of Columbia*, 613 F.3d at 188; *Wehbi*, 18 F.4th at 966-67 (quoting the same).

But *PCMA v. District of Columbia* was decided before *Rutledge*, which emphasized that State PBM laws do "not directly regulate health benefit plans at all, ERISA or otherwise." 141 S.Ct. at 481. And the D.C. Circuit did

not take into account the portion of *Travelers* holding that the regulation of only a third-party service provider, like a PBM, does not give rise to ERISA preemption "'in the first instance.'" 514 U.S. at 663-64. For this reason, in *Rowe*, the First Circuit reached a result opposite the D.C. Circuit's, holding that a Maine law that regulated PBMs did "'not restrict the freedom of employee benefit plans to administer or structure their plans in Maine precisely as they would elsewhere.'" 429 F.3d at 301 (citation omitted). And the federal government has criticized the approach taken by the D.C. Circuit for conflating the regulation of PBMs with ERISA plans. U.S. *Amicus* Br. 18, *Rutledge*, No. 18-540 (U.S. Dec. 4, 2019).

PCMA's *amicus* takes a different tack, arguing that Oklahoma's law might apply to plans that administer their own pharmacy benefits. AFHO *Amicus* Br. 7-8. But there is no merit to this argument, either.

To start, PCMA has not made this argument—and for good reason. PCMA represents only PBMs and therefore does not have standing to assert claims on behalf of health plans—ERISA or otherwise. PCMA Br. 3.

In any event, under Oklahoma law, a PBM is an entity distinct from a "health insurer" or "third-party payor"; a PBM provides "pharmacy benefits management" services to these entities. 36 Okla. Stat. § 6960(1), (4). Other

provisions of the Act reinforce that a PBM is limited to an "entity that provides pharmacy benefits management services under a contract with" a "health plan" or insurer. *Id.* § 6962(C)(1)(b). And although the Act has been in force for nearly three years, PCMA's *amicus* cites no evidence Oklahoma has enforced it against an ERISA plan administering its own pharmacy benefits.

On top of that, Oklahoma's definition of a PBM is not meaningfully different from the Arkansas law in *Rutledge*, which defines a PBM to mean "an entity that administers or manages a pharmacy benefits plan or program." Ark. Code § 17-92-507(a)(7). Although PCMA argued in *Rutledge* that Arkansas's definition could capture plans that administer their own pharmacy benefits, regulating "the plan itself," Resp. Br. 46-47, *Rutledge v. PCMA*, No. 18-540 (U.S. Mar. 25, 2020), 2020 WL 1478581, the Supreme Court disagreed, holding that Arkansas's law "does not directly regulate health benefit plans at all, ERISA or otherwise." *Rutledge*, 141 S.Ct. at 481. And because Arkansas's law applies only to PBMs, it did not dictate plan benefits or coverage. *Id.* at 482.

The same outcome is compelled here. ERISA does not preempt Oklahoma's PBM law.

B. The Supreme Court considered and rejected all of PCMA's arguments here.

PCMA suggests ERISA preempts any State law that could be said to bear on provider networks because it affects "the design and structure of the prescription drug benefit itself." PCMA Br. 1. But courts have wisely refused to measure ERISA preemption in these terms—otherwise, there would be no end to ERISA's preemptive reach.

In *Rutledge*, for example, the Supreme Court rejected PCMA's challenge to Arkansas's decline-to-dispense provision. 141 S.Ct. at 482. That provision authorizes a pharmacy to decline to dispense a drug if a PBM is going to reimburse the pharmacy less than the pharmacy's cost to acquire the drug. Ark. Code § 17-92-507(e). PCMA argued this provision "effectively denies plan beneficiaries their benefits." *Rutledge*, 141 S.Ct. at 482. But the Court held the law did not regulate "plan design" in any impermissible way, and it emphasized that "state-law mechanisms" govern the relationship between PBMs and pharmacies. *Id.*

Similarly, in *Wehbi*, the Eighth Circuit rejected PCMA's challenge to a North Dakota law that regulates the accreditation requirements that PBMs impose on pharmacies as a condition of participating in a PBM's pharmacy

network. 18 F.4th at 968. In that case, like here, PCMA argued the law impermissibly regulated "benefit design" by limiting the range of choices plans can make in their interactions with PBMs and pharmacies. PCMA Replacement Br. 22-27, 31, *PCMA v. Wehbi*, No. 18-2926 (8th Cir. May 11, 2021), 2021 WL 2022000. But the Eighth Circuit held that ERISA does not preempt these PBM-network provisions, emphasizing that they "do not 'requir[e] payment of specific benefits' or 'bind[] plan administrators to specific rules for determining beneficiary status.'" *Wehbi*, 18 F.4th at 968 (quoting *Rutledge*, 141 S.Ct. at 480).

PCMA's countervailing argument is meritless. According to PCMA, allowing States to dictate the quality and safety standards applicable to PBM pharmacy networks would alter "pharmacy benefits by curtailing and eliminating certain widely-employed plan structures." PCMA Br. 25. But the same reasoning would hold that ERISA allows plans to offer benefits in a form the States deem unsafe. To save costs, for example, an ERISA plan might wish to utilize the services of unlicensed healthcare professionals. Yet nothing in ERISA empowers benefit plans to override generally applicable State health and safety standards.

Moreover, accepting PCMA's argument would mean ERISA preempts a host of State laws regulating service providers to ERISA plans. The Supreme Court, however, has recognized repeatedly that ERISA does not preempt such laws, including State laws regulating "medical-care quality standards," *Dillingham*, 519 U.S. at 329, and "general health care regulation," *Travelers*, 514 U.S. at 661. A State law that regulates the quality of the networks that PBMs sell to health plans is no different.

PCMA and its *amicus* also argue that, culminating in *Kentucky Association of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003), the Supreme Court and various courts of appeal held that State any-willing-provider laws have an impermissible "connection with" ERISA plans. PCMA Br. 38-39; AFHO *Amicus* Br. 16-17. They are mistaken.

To start, PCMA misstates *Miller*'s holding. According to PCMA, the Supreme Court held that "state laws that restrict a plan's ability to design a limited network have an impermissible 'connection with' ERISA." PCMA Br. 38. But that's not what *Miller* held. In *Miller*, the Sixth Circuit held that ERISA preempted Kentucky's any-willing-provider law—in large part because that law treated some ERISA plans differently than non-ERISA plans and therefore made a forbidden "reference to" ERISA plans. *Ky. Ass'n*

of Health Plans, Inc. v. Nichols, 227 F.3d 352, 358-61 (6th Cir. 2000). (PCMA does not claim Oklahoma's law discriminates among ERISA plans, and it pursues only "connection with" preemption here. PCMA Br. 22-23.) Critically, in *Miller*, although the Sixth Circuit held that ERISA preempted Kentucky's any-willing-provider law, "[n]either party sought review of that holding in [the Supreme] Court." Reply Br. 2, *Ky. Ass'n of Health Plans, Inc. v. Miller*, No. 00-1471 (U.S. Dec. 9, 2002), 2002 WL 31789695. Instead, the parties disputed whether—and the Supreme Court decided only that—Kentucky's law was saved from preemption under ERISA's insurance-savings clause, 29 U.S.C. § 1144(b)(2)(A). *Miller*, 538 U.S. at 334-42.

PCMA suggests the Supreme Court was required to decide whether ERISA preempted Kentucky's law before addressing the savings clause, PCMA Br. 39, but that's not right. ERISA preemption is not jurisdictional, and the Supreme Court has therefore skipped directly to a savings-clause analysis when that was the only issue disputed. *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 367 (1999) (skipping directly to the savings clause because the "parties agree" ERISA otherwise preempted the State law at issue); *Miller*, 538 U.S. at 334-42 (same). Simply put, the Supreme Court has

never addressed whether ERISA preempts State any-willing-provider laws in the first instance.

Nor do the other cases cited by PCMA and its *amicus* establish that Oklahoma's network provisions are preempted. Three of those cases found preemption principally because the State law made a forbidden "reference to" ERISA plans—a claim that PCMA does not raise here. *Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr., Inc.*, 154 F.3d 812, 822-26 (8th Cir. 1998); *CIGNA Healthplan of La., Inc. v. Louisiana ex rel. Ieyoub*, 82 F.3d 642, 647-48 (5th Cir. 1996); *see Tex. Pharmacy Ass'n v. Prudential Ins. Co. of Am.*, 105 F.3d 1035, 1037 (5th Cir. 1997) (noting that the parties conceded the State law at issue was preempted under *CIGNA*). And the fourth case engaged in only a superficial analysis of "connection with" preemption and was decided before *Rutledge* and *Travelers*. *Stuart Circle Hosp. Corp. v. Aetna Health Mgmt.*, 995 F.2d 500, 502 (4th Cir. 1993).

In any event, it is impossible to square PCMA's cases with *Rutledge*, which, as noted above, held that ERISA does not preempt State laws regulating the "process" and "substantive standards" that PBMs use to reimburse pharmacies. 141 S.Ct. at 480-82. That is little different than a State law that requires a PBM to allow pharmacies to access its pharmacy

networks if the pharmacy is willing to accept the PBM's terms and conditions.

If anything, a State any-willing-provider law is *less onerous* than the law in *Rutledge*. Arkansas dictated the amount PBMs reimburse pharmacies. *Id.* Here, in contrast, PBMs are free to reimburse preferred-network pharmacies at any amount they choose, and they are free to impose whatever terms and conditions they desire on their preferred-network pharmacies. Thus, contrary to PCMA's blanket assertion (PCMA Br. 8-9), PBMs can still adopt terms and conditions that require preferred pharmacies to achieve certain quality metrics, and that encourage pharmacies financially to satisfy those metrics.

III. Medicare Part D does not preempt Oklahoma's preferred-network provision, which operates in a space unregulated by the federal government.

Medicare Part D includes a preemption clause, which it borrows from Part C. That clause provides that "[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 [Part D plans] which are offered by [Part D sponsors] under this part." 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g).

Every court to consider Medicare Part D's preemption clause has held that preemption requires the existence of a Part D standard "regulat[ing] the same subject matter" as the State law at issue. *Wehbi*, 18 F.4th at 971-72 (citing authorities). That approach also maintains fidelity with the views of CMS, which has explained that preemption "operates only when CMS actually creates standards in the areas regulated." 70 Fed. Reg. at 4,320. A broader standard cannot be justified by "principles of Federalism or the statute." *Id.*

Contrary to PCMA's suggestions (PCMA Br. 4, 20, 50), Medicare Part D does not preempt the "field" of PBM regulation. As noted above, few Part D standards apply to PBMs in the first place, and CMS has recognized that States play an important role in regulating PBMs. *E.g.*, *Medicare Program; Contract Year 2019 Policy and Technical Changes*, 83 Fed. Reg. 16,440, 16,598 (Apr. 16, 2018) (stating that CMS did not deem problematic State laws that regulate PBM-imposed pharmacy accreditation standards).

Thus, in *Wehbi* the Eighth Circuit held that Medicare Part D does not preempt a State law regulating the accreditation requirements that PBMs impose on pharmacies to participate in their networks. 18 F.4th at 972-73. The court emphasized that CMS has left the standards of network participation to the States. *Id.* at 972 (citing 70 Fed. Reg. 4,278). And after

reviewing many of the same statutory provisions and regulations that PCMA cites here, PCMA Br. 48-49, the court held that Congress and CMS intended to "leave to the states the specifics of what plans and PBMs may or may not demand of pharmacies," *Wehbi*, 18 F.4th at 973.

PCMA does not acknowledge *Wehbi*—a case it litigated and lost—let alone discuss that decision. And PCMA otherwise concedes no Part D standard governs the requirements for participation in a PBM's preferred-pharmacy network. PCMA Br. 52-53. That defeats PCMA's lone claim of Part D preemption.

CONCLUSION

The district court's judgment should be affirmed.

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Respectfully submitted,

/s/ Robert T. Smith
Robert T. Smith
Howard R. Rubin
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW – Suite 200
Washington, DC 20007
202-625-3500
robert.smith1@katten.com
howard.rubin@katten.com

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g)(1) of the Federal Rules of Appellate Procedure, I hereby certify that this brief is in compliance with the type form and volume requirements. Specifically, the Brief of *Amici Curiae* is proportionately spaced; uses a Roman-style, serif typeface (Book Antiqua) of 14-point; and contains 6,497 words, exclusive of the material not counted under Rule 32(f) of the Federal Rules of Appellate Procedure.

/s/ Robert T. Smith
Robert T. Smith
Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2022, I electronically transmitted a copy of the foregoing Brief of *Amici Curiae* to the Clerk of the Court using the Electronic Case Filing (ECF) system for filing. Service will be accomplished electronically through the ECF system to all registered participants.

/s/ Robert T. Smith
Robert T. Smith
Counsel for Amici Curiae