No. 22-6074

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 DEPARTMENT OF INSURANCE,

Defendants-Appellees.

On appeal from the
United States District Court for the Western District of Oklahoma
Case No. 5:19-cv-977-J

BRIEF *AMICUS CURIAE* OF THE ERISA INDUSTRY COMMITTEE, AMERICAN BENEFITS COUNCIL, NATIONAL LABOR ALLIANCE OF HEALTH CARE COALITIONS, SELF-INSURANCE INSTITUTE OF AMERICA, AND PACIFIC HEALTH COALITION SUPPORTING PLAINTIFF AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Amici are The ERISA Industry Committee, American Benefits Council, National Labor Alliance of Health Care Coalitions, Self-Insurance Institute of America, Inc., and Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition.

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a)(4)(A), undersigned counsel certifies that each *amicus* is a non-profit advocacy organization, and none has a parent corporation or issues stock.

/s/ *Michael B. Kimberly*

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GLOSSARY

Council	*Amicus* the American Benefits Council
ERIC	*Amicus* The ERISA Industry Committee
ERISA	Employee Retirement Income Security Act of 1974
NLA	*Amicus* National Labor Alliance of Health Care Coalitions
PHC	*Amicus* Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition
SIIA	*Amicus* Self-Insurance Institute of America, Inc.

INTRODUCTION & INTERESTS OF THE *AMICI CURIAE**

This appeal presents the question whether certain provisions of Oklahoma law that govern the design of provider networks for ERISA-covered prescription drug benefits are preempted by ERISA's express preemption clause. *See* 29 U.S.C. § 1144(a). They plainly are.

The Employee Retirement Income Security Act of 1974 (ERISA) contains a broad and express preemption provision, which Congress intended to establish a "uniform regulatory regime over employee benefit plans." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 208 (2004). Congress sought to ensure that "employee benefit plan regulation would be 'exclusively a federal concern'" (*id.*), because otherwise "[r]equiring ERISA administrators to master the relevant laws of 50 States . . . would undermine the congressional goal of minimiz[ing] the administrative and financial burden[s] on plan administrators—burdens ultimately borne by the beneficiaries" (*Gobeille v. Liberty Mutual Insurance Co.*, 577 U.S. 312, 321 (2016) (quotation marks omitted)).

ERISA preemption doctrine has evolved substantially over the past fifty years, but one rule has remained constant: Employers and labor organizations

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* Pursuant to Rule 29(a)(4)(E), *amici* state that no party's counsel authored this brief in part or in whole, and no party or party's counsel or individual other than *amici* contributed financially to the preparation or submission of this brief.

that elect to provide (that is, "sponsor") ERISA-covered benefit plans may decide what benefits to offer and on what terms to offer them. *See Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 833 (2003). Simply put, states may not dictate the scope or design of ERISA-covered benefits. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983). Thus, laws that prohibit plan sponsors "from structuring their employee benefit plans in a [particular] manner" are strictly off limits. *Id.* at 97.

That simple rule resolves the ERISA-preemption aspect of this case. Generally speaking, a voluntary healthcare benefit has three elements: (1) the services or items that are covered, (2) the "in network" providers from whom covered services or items may be obtained, and (3) the terms for participant contributions to the plan, including premiums, copays, coinsurance, and deductibles. Employers and labor organizations designing healthcare benefits must make considered judgments concerning each of these elements—an adjustment to one often entails an adjustment to the others. For example, a plan sponsor might choose to offer a limited network of providers coupled with a lower premium, a broad network of providers coupled with a higher premium, or a hybrid "preferred provider network" option that gives participants different levels of copays depending on which in-network providers they see.

Whatever the plan sponsor's decision, the importance of the provider-network design to an ERISA-governed plan's overall benefit design cannot be overstated. One of the first things any employee considers when selecting among plans during open enrollment—and when selecting among providers after obtaining coverage from her employer or labor organization—is which doctors, hospitals, and pharmacies are "in network."

The importance of provider-network design to the overall shape of the benefit is not an accident of chance. ERISA plans have successfully use network design to control healthcare costs over the past fifty years in no small part because states have (until the decision below) been forbidden from regulating in this area. This freedom has led to better and more cost-effective health benefits for employees. Without ERISA's preemption provision, states—looking always to protect local economic interests—would create a patchwork of variable network-design regulations that would make a uniform and administrable provider network virtually impossible for multistate employers or labor organizations.

The proof of the pudding is in the eating. The provisions challenged in this appeal (1) eliminate mail-service-only networks (including specialty networks) by requiring pharmacy networks to meet certain geographic restrictions; (2) require inclusion of any willing pharmacy into a plan's preferred network;

(3) prohibit use of cost-sharing discounts to incentivize use of particular pharmacies; and (4) forbid terminating a pharmacy's contract based on whether one of its pharmacists is on probation with the State Board of Pharmacy. In letter and effect, the Act prohibits prescription drug benefit plans from using preferred networks and mail-service networks, which are critical design features of many—indeed most—prescription drug benefits.

The decision below upholding Oklahoma's law cannot be squared with basic ERISA preemption principles. A prescription drug benefit is integral to almost any healthcare benefits package. Employees have come to expect such coverage, and allowing unchecked state regulation of prescription-drug benefit design imperils employers' and labor organizations' ability to continue voluntarily offering these benefits. None of this is conjecture. Already, many multistate employers and labor organizations have begun adjusting the core structures of their ERISA-covered plans to account for the unique requirements of Oklahoma law, reducing prescription-drug benefits for Oklahoma residents and driving up the cost. If the Court were to affirm and give the green-light to further state regulation of network design, countless other states would follow suit, and the situation would quickly spiral out of control.

Amici are five non-governmental organizations whose missions include ensuring that ERISA's protection of uniform benefit design is respected to

support employers' and labor organizations' ability to offer employee benefits. Congress included an exceptionally broad preemption clause for the sake of employees who depend on their employers to offer generous benefits. That is not possible without uniform federal regulation.

The ERISA Industry Committee (ERIC) is a national nonprofit organization exclusively representing large employers throughout the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every sector of the economy, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans for millions of active and retired workers, as well as their families.

The American Benefits Council (the Council) is a Washington D.C.-based employee benefits public policy organization. The Council advocates for employers dedicated to the achievement of best-in-class solutions that protect and encourage the health and financial well-being of their workers, retirees, and families. Council members include over 220 of the world's largest corporations and collectively either directly sponsor or administer health and retirement benefits for virtually all Americans covered by employer-sponsored plans.

The Self-Insurance Institute of America, Inc. (SIIA) is a national trade association of self-insured employers and industry participants, including third-

party administrators, captive managers, and excess insurance carriers. SIIA serves as a critical resource for self-insured benefits and reinsurance risk. With leading member companies providing healthcare for self-insured employers and their workforces, SIIA advocates on the federal and state level for policies that promote, protect, and advance the administration, design, and implementation of self-insured coverage.

The Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition (PHC) is a not-for-profit that represents 49 member-plans including Taft-Hartley funds, governmental health plans, public sector health benefits trust funds, and single employer plans. PHC's members cover groups that range anywhere from 100 to more than 29,000 employees, with PHC's members collectively covering approximately 300,000 employees and dependents across the country.

The National Labor Alliance of Health Care Coalitions (NLA) is the largest alliance of labor union trusts (primarily Taft-Hartley funds) and labor management coalitions. NLA's members purchase a wide variety of health services and work together to increase the value of the benefits they offer. NLA's members together serve more than 6 million covered individuals throughout the United States and Eastern Canada.

Confirming that ERISA preempts states' attempt to regulate provider-network design is a matter of enormous practical importance to *amici* and their members—and, ultimately, to the millions of employees covered by ERISA-governed plans. To be sure, certain aspects of the pharmacy benefit manager (PBM) business model are at odds with the interests of many plan sponsors. At the same time, PBMs play an essential role in helping most ERISA-covered plans to design and administer their prescription drug benefits. And this is a case about health plan benefit design, not PBMs as such. Given "the centrality of pension and welfare plans in the national economy, and their importance to the financial security of the Nation's work force" (*Boggs v. Boggs*, 520 U.S. 833, 839 (1997)), protection of uniform plan design and administration is critical to the interests of employers, labor unions, and their plans' participants and beneficiaries.

ARGUMENT

I. ERISA PREEMPTS THE CHALLENGED LAWS

Settled ERISA preemption principles place state regulation of ERISA plans' benefit design squarely out of bounds. Because the challenged provisions of the Oklahoma law at issue in this appeal intrude directly into an employer's design of its pharmacy-provider network, they are preempted according to these well-settled principles.

A. ERISA preempts state laws that "relate to" covered benefit plans, including state laws that directly regulate plan design

1. ERISA was intended to "encourag[e] the formation of employee benefit plans." *Aetna Health*, 542 U.S. at 208. Congress thus set out to ensure that "administrative costs" of running benefit plans would not "unduly discourage" their formation in the first place. *Conkright v. Frommert*, 559 U.S. 506, 517 (2010). To that end, ERISA seeks to "assur[e] a predictable set of liabilities, under uniform standards of primary conduct and a uniform regime of ultimate remedial orders and awards when a violation has occurred." *Id.*

ERISA's preemption provision is central to those objectives. Congress recognized that "[r]equiring ERISA administrators to master the relevant laws of 50 States" would undermine Congress's purpose of "'minimiz[ing] the administrative and financial burden[s]' on plan administrators—burdens ultimately borne by the beneficiaries." *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 149-150 (2001); *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9-11 (1987). A "principal goal[]" of the statute is "to enable employers 'to establish a uniform administrative scheme,'" with "'standard procedures to guide processing of claims and disbursement of benefits.'" *Egelhoff*, 532 U.S. at 148. But that uniformity is "impossible" if plans may be "subject to different legal obligations in different States." *Id.*

ERISA therefore preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA. 29 U.S.C. § 1144(a). This provision secures the value of employee benefits "'by eliminating the threat of conflicting and inconsistent State and local regulation.'" *Shaw*, 463 U.S. at 99. The Supreme Court has characterized ERISA's preemption provision as "broad" and "comprehensive." *Gobeille*, 577 U.S. at 319-320.

The advantage of uniform regulation is well known. "An employer that makes a commitment systematically to pay certain benefits undertakes a host of obligations, such as determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements." *Fort Halifax*, 482 U.S. at 9. Already "task[ed] [with] coordinating complex administrative activities," "[a] patchwork scheme of regulation would introduce considerable inefficiencies in benefit program operation, which might lead those employers with existing plans to reduce benefits, and those without such plans to refrain from adopting them." *Id.* at 11. That is, the greater the increase in administrative burden, the lower the likely benefits levels for employees over time. In addition, by allowing employers and labor organizations to structure their plans on a uniform multistate basis,

ERISA ensures that employee benefits are offered equitably to employees nationwide—that employees in Nebraska receive the same health coverage as their counterparts in Massachusetts.

2. Consistent with these principles, ERISA does not dictate the shape or substance of the benefits that a plan sponsor chooses to offer, leaving decisions about the extent and design of benefits to each employer. *Shaw*, 463 U.S. at 97. It is "private parties, not the Government, [who] control the level of benefits." *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 511 (1981). While federal law sets some minimum standards for employer-sponsored health plans (*e.g.*, 29 U.S.C. § 1181 (limiting preexisting-condition exclusions), *id.* § 1185 (minimum standards for post-natal care), 29 C.F.R. § 2590.715-2714 (dependent coverage)), ERISA is primarily concerned with ensuring that any benefits offered are readily understood by and reliably provided to employees.

Against this background, the Supreme Court has made clear that ERISA preempts any state law that "bind[s] plan administrators to [a] particular choice" concerning the substance of plan benefits. *Rutledge v. PCMA*, 141 S. Ct. 474, 480 (2020). Regulations of this sort "prohibit[] employers from structuring their employee benefit plans in a [particular] manner" and thus impermissibly relate to ERISA-governed plans. *Shaw*, 463 U.S. at 97. Where the effect of a state "statute [is] to force the employer either to structure all its

benefits payments in accordance with [one state's] law, or to adopt different payment formulae for employees inside and outside the State," ERISA preempts it. *Fort Halifax*, 482 U.S. at 10.

B. The provider network is a crucial component of an employer-sponsored health plan's benefit design.

An employer or labor organization that offers health benefits must make several judgments when designing the benefit. Components of a healthcare benefit include (1) what services and items are covered, including surgical procedures, fertility services, specialty drugs, and so on; (2) the providers from whom covered services or items may be procured, including doctors, hospitals, and pharmacies; and (3) cost-sharing provisions, including premiums, deductibles, coinsurance, and copayment amounts. *See* 29 C.F.R. §§ 2520.102-3(j)(2), 2590.715-2715(a)(2)(i). Most relevant here is the second—the plan's design of its provider network—which often substantially impacts the other two.

1. Nearly every ERISA-covered health benefit plan uses a provider network as an element of its benefit design. Of the more than 54% of Americans with employer-sponsored healthcare coverage,[1] less than 1% of participants

[1] *See* Katherine Keisler-Starkley & Lisa N. Bunch, *Health Insurance Coverage in the United States: 2021*, U.S. Census Bureau 4, 6 (Sept. 2022), perma.cc/-GR3Q-8LH5.

covered by employer-sponsored plans have a benefit design that does not use a provider network.[2] Since the 1990s, plan sponsors have steadily increased their reliance on provider networks to structure their health benefit plans, shifting from 73% with a "conventional" no-network model to less than 1% today.[3] The importance of the provider network to the plan's benefit design is now self-evident; indeed, plans are defined and distinguished by the overarching structure of the provider network they use.[4]

Plan sponsors choose whether to offer a plan in which *only* in-network services are covered (like an exclusive provider organization or health maintenance organization) or a plan in which participants pay less to use in-network providers and more to use out-of-network providers (like a preferred provider organization).[5] Within these basic structures, employers and labor organizations have discretion to determine whether to offer a more expansive

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[2] *See* Kaiser Family Found., *Employer Health Benefits* 9, 71 (2021), perma.cc/-499S-SDDC; *see also* Bonita Briscoe, *Understanding Health Plan Types: What's in a Name?*, Bureau of Labor Statistics (Jan. 2015), perma.cc/AEY3-N557.

[3] *See* Kaiser Family Found., *supra*, at 71.

[4] *See* Kaiser Family Found., *supra*, at 71; Briscoe, *supra*; *How to Pick a Health Insurance Plan*, Healthcare.gov (as of Apr. 1, 2023), perma.cc/JTR7-K8QP (listing "exclusive provider organizations," "health maintenance organizations," "point of service" plans, and "preferred provider organizations" as "plan types you'll find in the Marketplace").

[5] *See* Briscoe, *supra*; Kaiser Family Found., *supra*, at 68.

network, typically at a higher cost, or a narrower network, typically at a lower cost. These network choices inform additional plan choices, like differentiated cost-sharing levels between in-network and out-of-network providers, and participant premiums.[6]

Because of the centrality of network design to the overall design, plan participants not only assess whether a service is eligible for coverage and what their copay or deductible is, but also determine in advance whether their preferred doctor or hospital is in-network. That is, everyone understands that the design and structure of the provider network is a foundational element of overall benefit design.

Federal law concerning plan disclosures confirms that network design is integral to the benefit itself. It requires plan sponsors to communicate to covered employees in plain language the design of the benefits they get, including the structure and scope of the provider network. *See* 29 C.F.R. § 2520.102-3 (setting content for the "summary plan description"); *id.* § 2590.715-2715(a) (setting content for the "summary of benefits and coverage").

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[6] *See* Daniel Polsky & Bingxiao Wu, *Provider Networks and Health Plan Premium Variation*, 56 Health Serv. Res. 16-24 (2021), perma.cc/686Q-43S2 (finding that "a one standard deviation increase in physician network breadth was linked to a premium increase of 2.8 percent or $101 per year").

For example, the *summary plan description*—a key document that every plan administrator must provide to participants—requires describing "the plan's requirements respecting eligibility for participation and for benefits," including for health plans, a description of the "provisions governing the use of network providers, the composition of the provider network, and whether, and under what circumstances, coverage is provided for out-of-network services." 29 C.F.R. § 2520.102-3(j)(2)(3).

Likewise, a federally-required *summary of benefits and coverage* or SBC requires plan sponsors to give plan participants a way to obtain "a list of network providers" for the plan. 29 C.F.R. § 2590.715-2715(a)(2)(i)(K); *see also* U.S. Department of Labor, *Summary of Benefits and Coverage Template* (Oct. 31, 2022), perma.cc/5TEP-N9K3 (template requiring employers to answer for participants: "Will you pay less if you use a network provider?").

Federal benefits standards recognize this too. For example, one federal rule governing ERISA-governed health plans requires parity between a plan's design for medical benefits and its design for mental health benefits, specifically referring to provider networks as an element of the benefits for which parity requirements must be satisfied. *See* 29 C.F.R. § 2590.712(c)(2)(ii)(A), (c)(4)(ii)(C)-(D).

2. As with networks of doctors or hospitals to provide medical services, plan sponsors use pharmacy networks to provide prescription-drug coverage for plan participants. Constructing a pharmacy network that meets participant needs and helps control costs requires judgment about how best to balance scope of coverage, provider access, and cost-efficiency on a multistate basis. Carefully considered network design is, moreover, essential to achieving the goals of lowering employees' and the health plan's prescription drug costs while at the same time increasing patient safety and adherence.

Pharmacy networks generally. Sponsors of ERISA-covered plans that offer prescription drug benefits, typically working with PBMs, develop networks of pharmacies to determine where plan participants can fill their prescriptions. Pharmacies compete for inclusion in plan networks because it attracts a steady stream of business from plan participants and gives pharmacies access to instant, point-of-sale reimbursements processes. *See* Fed. Trade Comm'n, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* 4-5 (Aug. 2005), perma.cc/4F6K-USVC. For their parts, plan sponsors and participants benefit from lower negotiated reimbursement rates and improved service that comes with in-network pharmacy relationships. Thus, provider networks benefit plan sponsors, employees, and pharmacies.

Plan sponsors can (and typically do) offer a range of plans with different network options. Some plans use expansive pharmacy networks that include virtually all pharmacies willing to provide discounts to the plan. Other plans use significantly narrower pharmacy networks through which they can achieve deeper discounts, offering participants a narrower benefit at a lower cost, and with greater quality control. Still other plans use a tiered network, which includes both "preferred" in-network pharmacies and regular in-network pharmacies. Preferred pharmacies offer more favorable discounts in exchange for preferred status and thus higher patient volume. Beneficiaries then pay smaller copays or lower coinsurance at preferred pharmacies, while still enjoying the option of using a wide range of other pharmacies at somewhat higher cost-sharing levels if they choose.

Mail-service pharmacies. ERISA-plan sponsors often include mail-service pharmacies in their benefit package. A mail-service pharmacy provides participants a convenient way to access medications and promotes better adherence to the prescribed medication therapy by eliminating barriers to access. *E.g.*, Elena V. Fernandez et al., *Examination of the Link Between Medication Adherence and Use of Mail-Order Pharmacies in Chronic Disease States*, 22 J. Manag. Care Spec. Pharm. 1247-1259 (2016), perma.cc/2RM2-KP7C.

Mail-service pharmacies are especially important for individuals with limited transportation or health conditions that restrict their mobility. The flexibility to receive prescriptions by mail was critical to many during the global pandemic, in particular, given that simply picking up a prescription at a pharmacy presented a substantial health risk in its own right. And many employees simply appreciate the convenience of 90-day supplies of prescriptions arriving to their door, and without needing to make more frequent trips during business hours to a retail pharmacy.

Mail-service pharmacies also help employers fulfill the most fundamental goal for their health-benefit plans: improving their employees' health. Researchers have found statistically significant improvements in compliance for patients receiving medications for a variety of chronic afflictions, including hypertension, high cholesterol, and diabetes, from mail-service drug delivery. Fernandez, *supra*, at 1254. As an effect of the increased convenience, participants better adhere to the medication regimes, improving overall outcomes and reducing the need for more serious interventions. Further, because they are able to fill prescriptions on a larger scale, mail-service pharmacies can also implement computer-controlled quality processes, robotic dispensing, and advanced workflow practices that dispense prescriptions with greater accuracy and reduce medication errors.

For the same reason, mail-service pharmacies produce substantial plan savings through discounts made possible by their scale. *See* Centers for Medicare & Medicaid Services, *Part D Claims Analysis: Negotiated Pricing General Mail Order and Retail Pharmacies* (Dec. 2013), perma.cc/ZY46-9CZL.

Specialty pharmacies. ERISA plan sponsors also frequently include specialty pharmacy networks in their benefit packages. Specialty pharmacies dispense and manage drug regimens for rare or particularly complex chronic health problems, like cancer, multiple sclerosis, HIV, or rheumatoid arthritis. These medications typically entail unique patient education protocols, require prior authorization or other approvals, need special handling, storage, or administration, and are unusually expensive. Because specialty pharmacies have specialized credentials to manage such complicated drug regimens safely and effectively, they have been shown to dramatically improve patient outcomes and reduce the costs of managing these conditions.[7]

The judgments exercised in designing multi-pronged prescription-drug provider networks are similar in kind to the judgments a plan makes when designing networks for other medical services and products. Employers and

[7] *E.g.*, Jun Tang et al., *Effects of Specialty Pharmacy Care on Health Outcomes in Multiple Sclerosis*, 9 Am. Health & Drug Benefits 420 (2016); Suzanne J. Tschida et al., *Outcomes of a Specialty Pharmacy Program for Oral Oncology Medications*, 4 Am. J. Pharmacy Benefits 165, 170 (2012).

labor organizations carefully balance the breadth, quality, accessibility, and cost of the network alongside their judgments of which services and products are covered. The structure and scope of a plan's provider networks is integral to the overall design of the prescription drug or other health benefit it offers.

C. The challenged provisions are preempted according to these principles.

1. Given the centrality of network design to overall benefit design, settled ERISA preemption principles compel preemption of state laws that interfere with a plan's network design, as do the challenged provisions here. Indeed, although the question has gone unaddressed by this court, the Fourth, Fifth, and Sixth Circuits all have concluded that ERISA preempts state laws (like Oklahoma's) regulating a plan's provider network.

In *Stuart Circle Hospital Corp. v. Aetna Health Management*, 995 F.2d 500 (4th Cir. 1993), the Fourth Circuit held a state law requiring plans to allow into their networks any and every provider willing to meet the terms for network participation—a so-called any-willing-provider law—"restricts the ability of an insurance company to limit the choice of providers" included in its network, which "otherwise would confine the participants of an employee benefit health plan to those preferred by the insurer." *Id.* at 502. Because Virginia's any-willing-provider law dictated benefit design—that is, because it

regulated "the structure" of provider networks (*id.* at 501-502)—it "relate[d] to employee benefit plans" and was preempted by ERISA (*id.* at 502).

In *CIGNA Healthplan of Louisiana v. Louisiana ex rel. Ieyoub*, 82 F.3d 642 (5th Cir. 1996), the Fifth Circuit considered a similar any-willing-provider law, which likewise mandated that "[n]o licensed provider . . . who agrees to the terms and conditions of the preferred provider contract shall be denied the right to become a preferred provider." *Id.* at 645. The court there explained that "ERISA plans that choose to offer coverage" using preferred provider networks "are limited by the [Louisiana] statute to using [networks] of a certain structure—i.e., a structure that includes every willing, licensed provider." *Id.* at 648. Reasoning that "ERISA preempts 'state laws that mandat[e] employee benefit structures'" in that way, the court concluded that the any-willing-provider law at issue there had a connection with ERISA-covered benefit plans and was preempted. *Id.* at 647-648.

Finally, in *Kentucky Association of Health Plans v. Nichols*, 227 F.3d 352 (6th Cir. 2000), *aff'd* 538 U.S. 329 (2003), the Sixth Circuit considered Kentucky's any-willing-provider law. Observing that "state laws that mandate employee benefit structures are preempted," the court expressly agreed with the Fourth and Fifth Circuits and held that an any-willing-provider law, by dictating

benefit design, is "'connected with' ERISA covered plans" and thus preempted. 227 F.3d at 362-363.

This basic rule was most recently confirmed by *Rutledge*. The Court there reiterated that ERISA is "primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways," thus "ensuring that plans do not have to tailor substantive benefits to the particularities of multiple jurisdictions." 141 S. Ct. at 480. Laws that constrain benefit design, that "require plans to provide any particular benefit to any particular beneficiary in any particular way," are off the table. *Id.* at 482.

2. The provisions challenged in this appeal directly regulate the design of provider networks for ERISA-covered prescription drug benefits and fall squarely within the heartland of ERISA preemption.

The challenged provisions of Oklahoma law:

- Require plans to allow any willing pharmacy to participate in the plan's preferred network (Okla. Stat. tit. 36, § 6926(B)(4) (the any-willing-provider requirement));
- Require plans to design their standard and preferred networks to include retail pharmacies within certain geographic distances from beneficiaries and without counting mail-service pharmacies (*id.* § 6961(A)-(B) (the retail-access requirement));
- Limit plans from excluding pharmacies from their networks if they employ pharmacists on probation (*id.* § 6962(B)(5) (the pharmacist-on-probation requirement)); and

- Bar plans from providing cost-sharing discounts to employees for using particular pharmacies (*id.* § 6963(E) (cost-sharing-discount prohibition)).

The effect of these provisions, individually and collectively, is to require ERISA plan sponsors to structure their provider networks in Oklahoma-specific ways. They must allow every pharmacy into their preferred network and include pharmacies with checkered sanctions histories and questionable service quality. And they must include certain numbers of retail pharmacies in their networks, effectively eliminating plan sponsors' ability to offer mail-service pharmacy benefits at lower-cost-sharing for medications for chronic conditions. In addition to all that, Oklahoma layered on the cost-sharing-discount prohibition, effectively outlawing the use of preferred pharmacy networks altogether because, without better cost-sharing, there's no effective difference between a preferred and non-preferred pharmacy for participants. Because the challenged provisions all concern benefit design, they are preempted under long-standing ERISA-preemption precedent.

3. Oklahoma's emphasis on *Rutledge* to defend these laws is misplaced. *Rutledge* concerned an Arkansas law that "requires PBMs to reimburse pharmacies for prescription drugs at a rate equal to or higher than the pharmacy's acquisition cost." 141 S. Ct. at 481. The Court there held that a law of that sort "is merely a form of cost regulation" that requires plans or their PBMs to pay

higher amounts for prescription drugs. *Id.* ERISA, the Court explained, "does not pre-empt state rate regulations that merely increase costs" for plans but do not "dictate plan choices" concerning benefit design. *Id.* at 480-481.

This case involves regulations of an entirely different kind. The challenged provisions are no mere regulation of an ERISA plan's reimbursement rates. Nor is this case about indirect economic effects on plans. By directly dictating provider-network design, Oklahoma law "specifically mandates that certain benefits available to ERISA plans must be constructed in a particular manner." *CIGNA Healthplan*, 82 F.3d at 649. Laws like this do "not merely raise the cost of the implicated benefits; [they instead] delineate[] their very structure." *Id.* Rather than merely having to pay more to network providers for covered drugs (as in *Rutledge*), under Oklahoma's laws, ERISA plans have to design their benefit package to include *more providers*.

It makes no difference for ERISA preemption purposes that the law regulates third-party PBMs serving ERISA plans, either. As a starting point, the laws at issue here regulate plans directly: They apply regardless of whether a plan's prescription drug benefits are managed by a third-party PBM or the plan sponsor administers the prescription-drug benefit itself. *See* Okla. Stat. tit. 36, § 6960(3) (defining PBM to encompass any person that manages pharmacy benefits, including plans themselves). But it would not matter either way,

because a state can no more interfere with benefit design or plan administration carried out through a plan's agent than with design or administration carried out by the plan itself. The Supreme Court has held so expressly. In *Gobeille*, it held state-law obligations imposed on third-party administrators for reporting to the State were preempted; and, in *Rutledge*, it declined to adopt the view that states are free to regulate employee benefit plans so long as the state imposes the obligation only on a third-party administrator like a PBM.

This point is not subject to reasonable dispute. "It is of no moment that [a state] intrudes indirectly . . . rather than directly" upon the workings of ERISA-covered benefits. *Alessi*, 451 U.S. at 525. The question, instead, is whether the law "connects with" employee benefit plans—and here, Oklahoma's regulations of network design undoubtedly do. *See Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724, 739 (1985) (mandated-benefits law "relate[d] to" ERISA plans even though it applied only to insurers selling group-health policies); *CIGNA Healthplan*, 82 F.3d at 650 (statute preempted "insofar as it relates to third party administrators and health care plans that provide services to ERISA-qualified benefit plans").

The point is taken home by the practical operation of the Oklahoma laws here at issue. Employers and labor organizations that sponsor ERISA plans already have had to change their benefit design, which would be true regardless

of whether or not they were employing third-party PBMs. Okla. Stat. tit. 36, § 6960(3). Some plans have eliminated mail-service pharmacy benefits for Oklahoma residents entirely; others have amended their summary plan descriptions to include Oklahoma-specific caveats and exceptions. This interstate disuniformity is working against *plan sponsors* and is precisely what ERISA preemption forbids. *Fort Halifax*, 482 U.S. at 10.

II. PREEMPTION OF STATE REGULATION OF NETWORK DESIGN IS A MATTER OF TREMENDOUS PRACTICAL IMPORTANCE

The practical importance of ERISA preemption in this context is mind-spinning. More than half of all Americans, and nearly 63% of working-age adults, obtain their health insurance coverage through plans sponsored by private employers. Employers are thus the principal source of health benefits in the United States. To provide those benefits, employers and labor organizations more often than not sponsor employee health benefit plans governed by ERISA.

As the Supreme Court has recognized time and again, ERISA preemption is essential to ensuring that employers and labor organizations can continue to offer generous health benefits to their employees. ERISA's preemption provision reflects Congress's concern that conflicting state requirements "would introduce considerable inefficiencies in benefit program operation, which might lead those employers with existing plans to reduce benefits, and

those without such plans to refrain from adopting them." *Fort Halifax*, 482 U.S. at 11. Regulations like Oklahoma's impose precisely those burdens by making the administration of benefits more costly and less efficient—reducing the value of benefits to plan beneficiaries. If state regulation of provider-network design is not categorically preempted by ERISA, states could conceivably attempt to regulate networks of any kind in any way they like. Multistate employers will thus be forced to design state-specific benefit plans that accommodate every state's geographically-limited protectionist network regulations or risk state enforcement actions to clarify and enforce their preemption rights.

This is not conjecture. Oklahoma's insurance commissioner is already taking enforcement actions against at least one PBM based on plans having changed their benefits offerings, like reducing mail-service benefits, in response to the new strictures of Oklahoma law. *See* Notice of Hearing & Order to Show Cause, *State of Oklahoma v. Caremark, LLC*, No. 22-637 (filed Mar. 31, 2023), perma.cc/UXJ3-Q4V2.

Several other states in recent years have also considered or enacted laws like Oklahoma's that intrusively regulate provider networks. For example:

- the Tennessee legislature recently enacted legislation (Tenn. Pub. Ch. No. 1070 (2022)) that requires allowing any willing provider into a plan's network or preferred network and provided specifically that "this part applies to plans governed by the Employee Retirement Income Security Act of 1974 (ERISA)" (*id.* §§ 6, 7).

- the Washington legislature recently considered legislation (SB 5213 (2023)) that restricts the use of "nonresident" pharmacies,
- the Massachusetts legislature is currently considering legislation (HB 1215) that sets geographic-access rules that exclude mail-service pharmacies and that restricts the use of preferred pharmacy networks,
- the Virginia legislature recently considered legislation (HB 2491 (2023), SB 1338 (2023)) that would specifically require ERISA-governed plans to comply with Virginia's preexisting PBM act, including its network adequacy and any-willing-provider rules (*see* Va. Code § 38.2-3467).

While most states are not taking such steps, it takes only one or two of these laws to frustrate the purpose of uniform plan design. The increased administrative expenses necessary to tailor networks state-by-state are certain to be substantial, and they will hurt participants first and foremost. As of 2020—before states began invoking *Rutledge* as a license to regulate ERISA-governed pharmacy benefits—an estimated 4.2 cents of every premium dollar went toward administrative expenses. *See* Am.'s Health Ins. Plans, *Where Does Your Health Care Dollar Go?* (2022), perma.cc/XC8R-PYZM. By inviting 50 states to impose their own varying requirements for provider networks, sponsors' administrative expenses will increase many times over. As Congress understood when it enacted ERISA, that increased burden will be borne predominantly by plan participants, who will see commensurate reductions in benefits or increased premium and cost-sharing obligations.

Of course, PBMs sometimes engage in business practices that *amici* do not support. But regulating those practices does not require trammeling ERISA preemption. States like Oklahoma have ample regulatory tools at their disposal—consumer protection laws, unfair trade practices laws, and antitrust laws—that can be used effectively to curb any bad acts. It is not necessary to intrude on areas of exclusive federal regulation under ERISA to accomplish that goal.

Despite Oklahoma's contrary suggestion, *Rutledge* did not jettison longstanding ERISA preemption precedent, nor did it declare open season for states to regulate provider networks. Reversal is essential to unwind the harms that are already accruing to plan participants and that will inevitably snowball if other states adopt laws similar to Oklahoma's. ERISA preemption was specifically intended to forbid local protectionist interests from ruining employers' and labor organizations' ability to offer nationwide employee-benefit plans. This Court's reminder to states on this score is imperative.

CONCLUSION

The Court should reverse the judgment below.

Dated: April 10, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), undersigned counsel for *amici* certifies that this brief:

(i) complies with the type-volume limitation of Rule 29(a)(5) because it contains 5,814 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word and is set in Century Supra in 14 points.

Dated: April 10, 2023 /s/ *Michael B. Kimberly*

CERTIFICATE OF DIGITAL SUBMISSION

Pursuant to 10th Circuit Rule 25, I hereby certify that with respect to the foregoing brief: (i) all required privacy redactions have been made in accordance with 10th Circuit Rule 25.5; and (ii) if filing of hardcopies is required, this ECF submission is an exact copy of those documents.

Dated: April 10, 2023 /s/ *Michael B. Kimberly*

CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2023, I electronically filed the foregoing brief with the Clerk of this Court using the CM/ECF system and thereby accomplished electronic service on participants in this case.

Dated: April 10, 2023 /s/ *Michael B. Kimberly*