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 the United States District Court
for the District of Oklahoma
[5:19-cv-977-J (Judge Bernard M. Jones)]

BRIEF FOR AMICUS CURIAE THE UNITED STATES IN SUPPORT OF NEITHER PARTY URGING AFFIRMANCE IN PART AND REVERSAL IN PART

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GLOSSARY

AWP	Any Willing Provider
CMS	Centers for Medicare & Medicaid Services
ERISA	Employee Retirement Income Security Act of 1974
HMO	Health Maintenance Organization
PBM	Pharmacy Benefit Manager
PCMA	Pharmaceutical Care Management Association

INTEREST OF THE UNITED STATES

The United States respectfully submits this brief in response to this Court's invitation to set forth its views as to whether provisions of Oklahoma's Patient's Right to Pharmacy Choice Act, Okla. Stat. tit. 36, § 6958 *et seq.*, are preempted by the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 *et seq.*, and/or Medicare Part D. In the view of the United States, ERISA does not preempt the Probation-Based Pharmacy Limitation provision in any respect. ERISA does preempt the Any Willing Provider (AWP) provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition to the limited extent that those provisions apply directly to ERISA plans themselves, but does not preempt application of those provisions to third-party pharmacy benefit managers (PBMs). Finally, the Medicare statute preempts the AWP provision as applied directly or indirectly to Medicare Part D plans because that provision is inconsistent with standards that the Centers for Medicare & Medicaid Services (CMS) issued to govern pharmacy networks for Part D plans.

STATEMENT OF THE CASE

A. ERISA

With specified exceptions, ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of [Title 29]." 29 U.S.C. § 1144(a). The "employee benefit plan" described

in Section 1003(a) includes one that is "established or maintained" by an "employer" that is "engaged in commerce or in any industry or activity affecting commerce." *Id.* § 1003(a). In particular, it includes an "employee welfare benefit plan" established or maintained by an employer for the purpose of providing "medical" benefits "through the purchase of insurance or otherwise." *Id.* § 1002(1). Sponsors of ERISA-governed health-benefit plans often retain PBMs to administer their plan's prescription drug benefits, including by providing a network of pharmacies at which plan participants can obtain drugs at favorable rates and processing prescription drug claims. *See* Advisory Council on Emp. Welfare & Pension Benefit Plans, *PBM Compensation and Fee Disclosure* (2014), https://perma.cc/5T7A-SATY.

In construing ERISA's express preemption provision, the Supreme Court has said that the provision's broad "relates to" language cannot extend "to the furthest stretch of its indeterminacy," because such an interpretation would preempt practically all state laws, as any law could "relate to" ERISA plans in some manner. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995). Instead, a state law impermissibly "relates to" an ERISA plan if it either has a "connection with," or makes "reference to," such a plan. *Id.* A state law has an impermissible "connection with" ERISA plans if it "governs a central matter of plan administration," thereby "interfer[ing] with nationally uniform plan administration." *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 320 (2016); *Travelers*, 514 U.S. at 656-57. A state law makes impermissible "reference to" a plan if it acts

"immediately and exclusively" upon ERISA plans or if the existence of ERISA plans is "essential to the law's operation." *California Div. of Labor Standards Enf't v. Dillingham Const., N.A., Inc.*, 519 U.S. 316, 325 (1997).

However, ERISA's preemption provision contains a savings clause, 29 U.S.C. § 1144(b)(2)(A), that "reclaims [to the States] a substantial amount of ground" that the preemption provision's broad "relates to" language otherwise would take away. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 364 (2002). The savings clause provides that "nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities." 29 U.S.C. § 1144(b)(2)(A). By saving state laws that "regulate[] insurance," the savings clause "leaves room for complementary or dual federal and state regulation." *John Hancock Mut. Life Ins. Co. v. Harris*, 510 U.S. 87, 99 (1993).

The Supreme Court has articulated a two-part test to determine whether a law is saved as an insurance regulation even if it "relates to" ERISA plans in the first instance. *See Kentucky Ass'n of Health Plans v. Miller*, 538 U.S. 329 (2003). First, the state law must "be specifically directed toward entities engaged in insurance." *Id.* at 342. This "does not require that a state law regulate 'insurance companies' or even 'the business of insurance' to be saved from preemption; it need only be a 'law . . . which regulates insurance.'" *Id.* at 336 n.1 (emphases omitted). Second, the state law must "substantially affect the risk pooling arrangement between the insurer and the insured." *Id.* at 342.

While ERISA's savings clause carves out large exceptions from the broad reach of ERISA preemption, the so-called "deemer clause" in turn limits the scope of the savings clause. It provides that an employee benefit plan shall not be "deemed to be an insurance company . . . or to be engaged in the business of insurance . . . for purposes of any law of any State purporting to regulate insurance companies." 29 U.S.C. § 1144(b)(2)(B). "In this fashion Congress satisfied its goal of reserving to the states regulation of the business of insurance and protecting ERISA plans themselves from being subjected to state and local regulation." *Fuller v. Norton*, 86 F.3d 1016, 1024 (10th Cir. 1996). As a result, a state law may be generally saved from preemption as a law regulating insurance but remain preempted to the extent it seeks to regulate ERISA plans directly.

B. Medicare Part D

The Medicare program, which Congress established through Title XVIII of the Social Security Act, provides federally subsidized health insurance for persons who are 65 or older or who have a disability. In 2003, Congress amended the statute to add a prescription drug benefit, known as Medicare Part D. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, tit. I, 117 Stat. 2066, 2071-2176. Under Part D, private health insurance companies, called plan sponsors, enter into contracts with CMS to offer prescription drug plans to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-112.

Part D plan sponsors frequently contract with PBMs to manage pharmacy benefits on their behalf, including by negotiating contracts with pharmacies and constructing pharmacy networks. U.S. Gov't Accountability Office, GAO-19-498, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* 2 (2019), https://perma.cc/9Z99-RCSW (reporting that as of 2016, Part D sponsors used PBMs to provide 74% of drug benefit management services). Part D plans and their PBMs often construct networks of "preferred" and "nonpreferred" pharmacies. *See* Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4254 (Jan. 28, 2005) (final rule). "Preferred" pharmacies are network pharmacies that offer prescription drugs to Part D enrollees at lower levels of cost-sharing than non-preferred in-network pharmacies, meaning that beneficiaries have lower out-of-pocket costs when they fill their prescriptions there. 42 C.F.R. § 423.100 (defining network pharmacy, preferred pharmacy, and non-preferred pharmacy).

The Part D statute and its implementing regulations address the pharmacy networks established by or on behalf of Part D plans. The statute provides that "[a] prescription drug plan shall permit the participation" in its network "of any pharmacy that meets the terms and conditions under the plan." 42 U.S.C. § 1395w-104(b)(1)(A). CMS's implementing regulations impose an "any willing pharmacy" requirement, mandating that plans allow any pharmacy to participate in their standard networks if the pharmacy is willing to accept the same terms and conditions as other pharmacies.

See 42 C.F.R. § 423.505(b)(18) (requiring that Part D plans have a "standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy"); *id.* § 423.120(a)(8) (providing that, in "establishing its contracted pharmacy network," a Part D sponsor offering qualified prescription drug coverage "[m]ust contract with any pharmacy that meets the Part D sponsor's standard terms and conditions"). In establishing that requirement, CMS considered but expressly declined to require that Part D plans allow any willing pharmacy to participate in their networks as a "preferred" pharmacy. *See* 70 Fed. Reg. at 4254.

The 2003 Medicare amendments also modified a pre-existing preemption provision contained in Part C (governing Medicare benefits for services provided through health management organizations) and made that amended provision apply "in the same manner" to the new Part D. *See* Pub. L. 108-173, § 232(a), 117 Stat. at 2208 (amending 42 U.S.C. § 1395w-26(b)(3)); 42 U.S.C. § 1395w-112(g) (incorporating 42 U.S.C. § 1395w-26(b)(3)). As amended, the preemption provision reads:

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

42 U.S.C. § 1395w-26(b)(3). The Medicare Part D statute thus provides that CMS-established standards relating to Part D supersede state laws or regulations (other than

state licensing laws or laws relating to plan solvency) "with respect to" a prescription drug plan offered by a Part D sponsor.

C. Provisions of Oklahoma Law at Issue on Appeal

In 2019, Oklahoma enacted the Patient's Right to Pharmacy Choice Act, Okla. Stat. tit. 36, § 6958 *et seq.*, to regulate the practices of PBMs. Four provisions of that law are at issue in this appeal.

Three of the provisions involve the structure or composition of PBMs' pharmacy networks. First, the Retail-Only Pharmacy Access Standards require that PBMs design their pharmacy networks so that a certain percentage of covered individuals live within a set geographical distance from at least one brick-and-mortar pharmacy within the network. Okla. Stat. tit. 36, § 6961(A)-(B). Second, the Probation-Based Pharmacy Limitation Prohibition makes it unlawful for PBMs to deny, limit, or terminate a contract with a pharmacy because a pharmacist employed with the pharmacy is on "probation status with the State Board of Pharmacy." *Id.* § 6962(B)(5). Lastly, the AWP provision requires PBMs to admit to their preferred networks any pharmacy that "is willing to accept the terms and conditions that the PBM has established for other providers as a condition of preferred network participation status." *Id.* § 6962(B)(4).

The fourth provision, the Cost-Sharing Discount Prohibition, concerns the cost-sharing rules applicable to prescription drug benefits. It prohibits PBMs and health insurers from requiring, or incentivizing the use of, "any discounts in cost-

sharing or a reduction in copay or the number of copays to individuals to receive prescription drugs from an individual's choice of in-network pharmacy." Okla. Stat. tit. 36, § 6963(E).

For purposes of the challenged provisions, the Act defines "pharmacy benefits manager" as a "person that performs pharmacy benefits management" and "any other person acting" for them. Okla. Stat. tit. 36, § 6960(4).

D. Prior Proceedings

Pharmaceutical Care Management Association (PCMA), a trade association representing PBMs, challenged several provisions of the Oklahoma law as preempted by ERISA and Medicare Part D, including the four provisions at issue in this appeal. The district court granted summary judgment partially in favor of PCMA and partially in favor of Oklahoma.

The district court held that ERISA did not preempt any of the provisions at issue in this appeal because "[w]hile these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices." Op. 4, Aplt.App. Vol. 3, at 737.

As to Medicare Part D, the district court held that the AWP provision is not preempted. The court acknowledged that "Part D has an any willing provider standard in relation to a plan's standard network" but reasoned that Oklahoma's provision "relates to the preferred network rather than the standard network." Op. 7, Aplt.App. Vol. 3, at 740. The court concluded that the AWP provision "does not act

'with respect to' the Part D any willing provider standard and is not preempted by Medicare Part D." *Id.*[1]

ARGUMENT

I. ERISA Does Not Preempt the Probation-Based Pharmacy Limitation Prohibition and Preempts the Other Three Challenged Provisions Only as Applied Directly to ERISA Plans

ERISA does not preempt the Oklahoma law's Probation-Based Pharmacy Limitation Prohibition because that provision neither makes "reference to" nor has a "connection with" ERISA plans, and thus does not "relate to" ERISA plans within the meaning of statute's preemption provision. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983); 29 U.S.C. § 1144(a). While the other three challenged provisions do have a "connection with" ERISA plans, those provisions are saved from preemption under ERISA's insurance savings clause except to the extent they apply to ERISA plans that directly engage in covered conduct.

A. ERISA Does Not Preempt the Probation-Based Pharmacy Limitation Prohibition

A state law impermissibly "relates to" an ERISA plan under the statute's express preemption provision if the law either makes "reference to" or has a "connection with" an ERISA plan. *Shaw*, 463 U.S. at 96-97. PCMA does not contend that the Probation-Based Pharmacy Limitation Prohibition makes "reference to"

[1] The district court addressed whether certain other provisions were preempted by Medicare Part D, Op. 6-9, Aplt.App. Vol. 3, at 739-42, but the only Part D preemption challenge in this appeal involves the AWP provision.

ERISA plans, and as explained below, that prohibition also does not have an impermissible "connection with" ERISA plans.

A state law has a "connection with" ERISA plans if it "governs a central matter of plan administration," thereby "interfer[ing] with nationally uniform plan administration." *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 319 (2016). Laws that "require providers to structure benefit plans in particular ways" impermissibly intrude on plan administration and preclude national uniformity, and thus come within the scope of ERISA's express preemption provision. *Rutledge v. PCMA*, 141 S. Ct. 474, 480 (2020). In contrast, laws "that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage" are not preempted. *Id.*

The Probation-Based Pharmacy Limitation Prohibition is not subject to preemption under those standards. While that prohibition eliminates one possible basis for excluding a pharmacy from a PBM's network (*i.e.*, a pharmacist's probation status), it does not mandate the inclusion of any pharmacy or class of pharmacies. Any impact it may have on pharmacy-benefit design is accordingly *de minimis* at most, and the prohibition does not "require providers to structure benefit plans in particular ways." *Rutledge*, 141 S. Ct. at 480.

That conclusion aligns with the Eighth Circuit's decision in *PCMA v. Wehbi,* 18 F.4th 956 (8th Cir. 2021), which held that ERISA did not preempt a similar North Dakota provision prohibiting PBMs from requiring pharmacies, as a condition of

network participation, to satisfy accreditation standards inconsistent with those imposed by North Dakota law. The Eighth Circuit explained that the provision regulates a "non-central" matter of plan administration and found that any "modest disuniformity" it causes "does not warrant preemption." *Id.* at 968; *cf. Rutledge*, 141 S. Ct. at 480 ("[N]ot every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan."). PCMA identifies no sound basis for reaching a contrary result here.

B. ERISA Preempts the Any Willing Provider Provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition Only as Applied Directly to ERISA Plans

Unlike the Probation-Based Pharmacy Limitation Prohibition, the AWP provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition do have a "connection with" ERISA plans, and thus "relate to" ERISA plans within the meaning of the statute's express preemption provision, *Shaw*, 463 U.S. at 97, because they impose requirements on plan structure and benefit design and thereby impair national uniformity. Those provisions are nevertheless saved from preemption under ERISA's insurance savings clause, except to the extent they apply to ERISA plans that directly engage in covered conduct themselves.

1. The Any Willing Provider Provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition "Relate to" ERISA Plans

a. The AWP, Retail-Only, and Cost-Sharing provisions have a connection with ERISA plans because they "require providers to structure benefit plans in particular ways" that are central to plan administration. *Rutledge*, 141 S. Ct. at 480.

The AWP provision and Retail-Only Pharmacy Access Standards affirmatively dictate the scope of a plan's pharmacy network. The AWP provision mandates the inclusion in preferred pharmacy networks of all pharmacies willing to abide by the terms for preferred network participation. Okla. Stat. tit. 36, § 6962(B)(4). And under the Retail-Only Pharmacy Access Standards, pharmacy networks must include a sufficient number of brick-and-mortar pharmacies proximately located to covered individuals. *Id.* § 6961(A)-(B).

The Cost-Sharing Discount Prohibition is similarly prescriptive. That provision requires that cost-sharing and copayment rules be the same as between retail and mail-order pharmacies. Okla. Stat. tit. 36, § 6963(E). It therefore precludes plans from offering differential cost-sharing terms to participants based on their choice of provider. *See* Okla. Br. 30.

Those types of choices about pharmacy-network composition and cost-sharing terms go to core aspects of plan structure and benefit design, as they directly regulate the terms of participants' coverage—*i.e.*, where and under what cost-sharing terms participants can obtain covered prescription drugs. Indeed, their centrality to plan

structure and benefit design is reflected in ERISA itself. For example, in 2020, Congress amended ERISA to require agency guidance on how group health plans and issuers can ensure that certain plan features comply with ERISA's mental health parity requirements, specifically naming "network admission standards" and factors relating to "network adequacy" as among those plan features. *See* 29 U.S.C. § 1185a(a)(7)(C)(ii). And ERISA has long recognized that a plan's cost-sharing rules are also a core feature of plan design. *See, e.g.*, *id.* § 1185a(a)(3)(A) (prohibiting plans from imposing "separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits").

Moreover, by affirmatively dictating the scope of a plan's pharmacy network and the cost-sharing requirements to which participants may be subject, these three challenged provisions also interfere with "nationally uniform plan administration." *Rutledge*, 141 S. Ct. at 480. For example, due to the AWP and Retail-Only provisions, a plan sponsor seeking to populate its pharmacy network exclusively with mail-order pharmacies would be prohibited from doing so in Oklahoma. And a plan seeking to encourage the use of mail-order pharmacies through lower copayments or cost-sharing requirements would be constrained from doing that, too, in Oklahoma.

For those reasons, it is unsurprising that four other courts of appeals, confronted with AWP laws similar to the Oklahoma provision challenged here, have concluded that those provisions "relate to" ERISA plans for purposes of ERISA's preemption provision. 29 U.S.C. § 1144(a); *see Kentucky Ass'n of Health Plans, Inc. v.*

Nichols, 227 F.3d 352, 361-63 (6th Cir. 2000) (Kentucky AWP law preempted but saved by insurance savings clause), *aff'd*, 538 U.S. 329 (2003); *CIGNA Healthplan of La., Inc. v. State of Louisiana*, 82 F.3d 642 (5th Cir. 1996) (Louisiana AWP law preempted and not saved); *Prudential Ins. Co. of Am. v. National Park Med. Ctr., Inc.*, 154 F.3d 812 (8th Cir. 1998) (Arkansas AWP law preempted and not saved); *Stuart Circle Hosp. Corp. v. Aetna Health Mgmt.*, 995 F.2d 500 (4th Cir. 1993) (Virginia AWP law preempted but saved).

b. The contrary arguments offered by the district court and Oklahoma lack merit.

The district court reasoned that the challenged provisions lack a "'connection with'" ERISA plans because they do not "force[] ERISA plans to make any specific choices." Op. 4, Aplt.App. Vol. 3, at 737. Oklahoma similarly emphasizes that the provisions do not dictate "specific choices" for plans. *See* Okla. Br. 27, 29. But neither the Supreme Court nor this Court have ever held that state laws have a "connection with" ERISA plans only if they foreclose plans from taking any approach save one. Where, as here, a state law materially and directly forecloses central benefit-design choices that would otherwise be available to a plan, the law has the relevant "connection with" ERISA plans even if plans retain some residual flexibility. *See, e.g.*, *New York Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 668 (1995) (recognizing that a state law may be preempted where it "effectively restricts [an ERISA plan's] choice of insurers"); *FMC Corp. v. Holliday*, 498 U.S. 52, 60

(1990) (holding that a state law had a "connection with" ERISA plans because it "prohibit[ed] plans from being structured in a manner requiring reimbursement in the event of recovery from a third party").

The district court and Oklahoma are likewise incorrect in asserting that the AWP provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition just "alter the incentives" for ERISA plans in a manner comparable to the laws upheld in *Rutledge* and *Travelers*. Op. 4, Aplt.App. Vol. 3, at 737; *see* Okla. Br. 26-29. The Arkansas law at issue in *Rutledge* merely regulated the rates at which PBMs must reimburse pharmacies. *See Rutledge*, 141 S. Ct. at 481 (explaining that Arkansas's law "affects plans only insofar as PBMs may pass along higher pharmacy rates to plans with which they contract"). And the law in *Travelers* imposed hospital surcharges on treatments provided to patients covered by certain insurers, and thus "simply b[ore] on the *costs* of benefits and the relative *costs* of competing insurance to provide them." *Travelers*, 514 U.S. at 660 (emphases added). In short, both laws affected the costs paid by plans, not plan structure or benefit design in the first instance. *See Rutledge*, 141 S. Ct. at 481 ("Like the New York surcharge law in *Travelers*, Act 900 is merely a form of cost regulation."). In contrast, the AWP provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition are specifically directed to core aspects of plan structure and benefit design. *See supra* pp. 12-14.

Finally, Oklahoma incorrectly argues that the Act does not implicate ERISA because it directly regulates only PBMs, not ERISA plans. Okla. Br. 21-24. To start,

that argument appears to be at odds with the plain text of the Act itself. The Act defines "pharmacy benefits manager" in functional terms as a "person that performs pharmacy benefits management" and "any other person acting" for them. Okla. Stat. tit. 36, § 6960(4). Thus, if an ERISA plan sought to construct its own pharmacy network without relying on a third-party PBM, it appears that the Act would be directly applicable to the plan's conduct. But even if the Act were construed to regulate only third-party PBMs, that would not eliminate the "connection with" ERISA plans discussed above. The Act applies to a PBM to the extent that the PBM is managing prescription drug benefits for a health insurer or self-funded plan (among other entities). *See id.* § 6961. And "[b]ecause PBMs manage benefits on behalf of plans, a regulation of PBMs 'function[s] as a regulation of an ERISA plan itself,'" *Wehbi*, 18 F.4th at 966 (quoting *PCMA v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010)), at least to the extent the regulation governs a central matter of plan administration.[2] For that reason, the Eighth Circuit recently rejected an argument that

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[2] Whether ERISA plans are the direct object of a state law may be relevant to whether the law makes impermissible "reference to" ERISA plans, as that analysis focuses on whether the law "acts immediately and exclusively upon ERISA plans." *See California Div. of Labor Standards Enf't v. Dillingham Const., N.A., Inc.*, 519 U.S. 316, 325 (1997). But it is not dispositive to the analysis of whether a law has a "connection with" ERISA plans, as that analysis focuses on "the nature of *the effect* of the state law on ERISA plans." *Id.* (emphasis added). A regulation directed toward PBMs may have the requisite "connection with" ERISA plans if, as here, its effect is to significantly constrain core choices about plan structure and benefit design.

state-law provisions automatically "escape preemption to the extent that they regulate PBMs rather than plans." *Id.* at 966-67. This Court should do the same.

2. The Any Willing Provider Provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition Are Saved from Preemption Except as Applied Directly to ERISA Plans

While the AWP provision, Retail-Only Pharmacy Access Standards, and Cost-Sharing Discount Prohibition "relate to" ERISA plans within the meaning of ERISA's express preemption provision, their application to third-party PBMs escapes preemption because of ERISA's insurance savings clause, 29 U.S.C. § 1144(b)(2)(A). Under the so-called "deemer clause," *id.* § 1144(b)(2)(B), however, the provisions remain preempted to the extent that they apply to ERISA plans that directly engage in covered conduct.[3]

a. A state law "regulates insurance," 29 U.S.C. § 1144(b)(2)(A), and is therefore saved from preemption under ERISA's insurance savings clause, if it (1) is "specifically directed toward entities engaged in insurance," and (2) "substantially affects the risk pooling arrangement between the insurer and the insured." *Kentucky Ass'n of Health Plans v. Miller*, 538 U.S. 329, 342 (2003). The AWP, Retail-Only, and Cost-Sharing provisions satisfy both parts of that test.

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[3] The parties dispute whether Oklahoma adequately preserved an argument that the savings clause applies. *See* PCMA Br. 39 n.14; Okla. Br. 35 n.7. The United States takes no position on that question, and provides its views on the savings clause and deemer clause because they are necessary to comprehensively address the issues raised in this Court's order inviting the filing of this brief.

Those three provisions are not merely "laws of general application that" only incidentally "have some bearing on insurers." *Miller*, 538 U.S. at 334. As Oklahoma points out, "the Act is codified in Title 36, which houses state insurance laws, and is executed by the State Insurance Department." Okla. Br. 35 n.7. And as discussed, the AWP, Retail-Only, and Cost-Sharing provisions address core features of insurance coverage—namely, network composition and cost-sharing rules. *See supra* pp. 12-14. That is sufficient to establish that the provisions are "'specifically directed toward' the insurance industry" and therefore satisfy the first prong of *Miller*'s test. *Miller*, 538 U.S. at 334 (citation omitted). Indeed, *Miller* itself found that the insurance savings clause covered similar Kentucky AWP provisions. *Id.* at 331-32.

It makes no difference that the provisions here may be enforced against third-party PBMs, not just insurers themselves. The AWP provisions in *Miller* likewise applied to some "[health maintenance organizations (HMOs)] that do not act as insurers but instead provide only administrative services to self-insured [ERISA health] plans." 538 U.S. at 336 n.1. The Supreme Court determined that the fact that "these noninsuring HMOs [are] administering self-insured plans . . . suffices to bring them within the activity of insurance" for purposes of the insurance savings clause. *Id.* So too here: When a third-party PBM structures a pharmacy network or designs a cost-sharing benefit for its insurer client, it is sufficiently engaged in the "activity of insurance" to come within the insurance savings clause's scope. *Id.* Moreover, the Act explicitly makes insurers "responsible for monitoring all activities carried out by, or on

behalf of, the health insurer under the [Act]." Okla. Stat. tit. 36, § 6963(A), (B). This further supports the conclusion that the Oklahoma laws aim to regulate "insurance practices" and the entities that carry out those practices, whether they are insurance companies in the traditional sense or PBMs.

The second part of the *Miller* test requires that a state law "substantially affect the risk pooling arrangement between the insurer and the insured." 538 U.S. at 342. The Supreme Court held that Kentucky's AWP laws in *Miller* satisfied this test because, "[b]y expanding the number of providers from whom an insured may receive health services, AWP laws alter the scope of permissible bargains between insurers and insureds in a manner similar to . . . mandated benefit laws." *Id.* at 338-39. Oklahoma's AWP law is no different from Kentucky's AWP laws, save for the fact that the regulated networks are pharmacy providers as opposed to medical providers. The Court's holding in *Miller* that AWP laws in general substantially affect risk pooling arrangements thus applies with equal force to the Oklahoma AWP provision.

The Court's logic in *Miller* also supports the conclusion that the two remaining provisions affect risk-pooling arrangements. The Retail-Only provision regulates network composition in a similar fashion to the AWP provision by increasing the number of retail pharmacies that must be included in a pharmacy network, thereby "expanding the number of providers from whom an insured may receive" services. 538 U.S. at 338. The Cost-Sharing provision also "alter[s] the scope of permissible bargains between insurers and insureds," *id.* at 338-39, by prohibiting insurers and

PBMs from offering more favorable cost-sharing terms (*e.g.*, lower copays) to insureds in exchange for filling their prescriptions at certain pharmacies (*e.g.*, mail-order pharmacies instead of retail pharmacies). To the extent that Oklahoma insureds may prefer arrangements with lower cost-sharing for prescriptions filled through mail-order pharmacies as opposed to retail pharmacies, Oklahoma prohibits that trade off. *Cf. id.* at 339 ("No longer may Kentucky insureds seek insurance from a closed network of health-care providers in exchange for a lower premium.").

b. Even if a law regulating insurance is saved from preemption, there is a "specified exception to the saving clause . . . found in § 514(b)(2)(B), the so-called 'deemer clause.'" *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 733 (1985). The deemer clause provides that an employee benefit plan shall not be "deemed" to be in the business of insurance for purposes of a state law purporting to regulate insurance companies and insurance contracts. 29 U.S.C. § 1144(b)(2)(B). In practical effect, the clause means that state insurance laws are not saved to the extent they "are applied directly to benefit plans." *Metropolitan Life*, 471 U.S. at 741; *see Fuller v. Norton*, 86 F.3d 1016, 1024 (10th Cir. 1996) ("[T]he deemer clause . . . insures that states will not treat ERISA plans as 'persons' subject to state laws enumerated in the savings clause."). In *FMC Corp. v. Holliday*, for example, the Supreme Court explained that where an ERISA plan contracts for an insurance policy with a third-party insurer, the insurer is not "relieved from state insurance regulation" by the deemer clause, and the plan is consequently "subject to indirect state insurance regulation." 498 U.S. at 61.

But if the plan opts to "self-fund" rather than obtaining an insurance policy through a third party, the deemer clause exempts the plan's own conduct "from state [insurance] regulation insofar as that regulation 'relates to' the plans." *Id.*

Applying that framework here, the AWP, Retail-Only, and Cost-Sharing provisions are saved from preemption, and are thus enforceable, as applied to PBMs and other third-party entities with which ERISA plans contract.[4] But to the extent an ERISA plan itself were to engage directly in conduct covered by the Act—such as by denying preferred pharmacy status to a willing provider or providing cost sharing discounts to individuals when they receive prescription drugs from certain in-network

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[4] To the extent that the Eighth Circuit suggested a broader application of the deemer clause in *Prudential Insurance Co. of America v. National Park Medical Center, Inc.*, 413 F.3d 897 (8th Cir. 2005), its analysis is incorrect. There, the Eighth Circuit invoked the deemer clause in concluding that ERISA preempted indirect regulation of self-funded plans through the regulation of the insurance companies with which they contract for access to provider networks. *See id.* at 912-13. As explained, however, *FMC Corp.* indicates that the deemer clause does not foreclose States from applying their insurance laws to third parties with which plans contract, even where that results in indirect regulation of ERISA plans. *See* 498 U.S. at 61. In concluding otherwise, the Eighth Circuit characterized the Supreme Court's subsequent decision in *Rush Prudential HMO, Inc., v. Moran*, 536 U.S. 355 (2002), as extending the deemer clause to laws that are "*indirectly* applied to self-funded plans." *Prudential Ins.*, 413 F.3d at 912-13 (emphasis added) (citing *Rush Prudential*, 536 U.S. at 371-72 n.6). But the "indirectly" modifier does not appear in the Supreme Court's decision—the Eighth Circuit added it on its own, without explanation, even though the statement in *Rush Prudential* is best read (particularly in light of its citation to *FMC Corp.*) as being limited to instances in which the insurance law is "applied to self-funded plans" *directly*. *Rush Prudential*, 536 U.S. at 372 n.6.

pharmacies—the deemer clause would shield the plan from direct state regulation, and enforcement of the provisions against the plan would be preempted.[5]

II. The Medicare Statute Expressly Preempts the Oklahoma Law's Any Willing Provider Provision as Applied to Part D Plans

Separately, the Medicare statute preempts the Act's AWP provision as applied directly or indirectly to Medicare Part D plans because that provision is inconsistent with CMS-issued standards.

A. The Medicare statute and its implementing regulations establish standards that govern pharmacy networks for Part D plans. The statute provides that "[a] prescription drug plan shall permit the participation" in its pharmacy network "of any pharmacy that meets the terms and conditions under the plan." 42 U.S.C. § 1395w-104(b)(1)(A). CMS's implementing regulations, in turn, establish an "any willing pharmacy" requirement. That requirement mandates that a plan include in its *standard* network any pharmacy that is willing to meet the plan's standard terms and conditions. *See* 42 C.F.R. § 423.505(b)(18); *id.* § 423.120(a)(8).

In issuing those implementing regulations, CMS considered but expressly declined to require plans to allow any willing pharmacy to participate in their networks as a "preferred" pharmacy. *See* 70 Fed. Reg. at 4254. CMS recognized that several commenters supported such a requirement. *See id.* CMS nevertheless rejected the

[5] Determining when a plan's own conduct directly implicates the Act would involve fact-specific questions that the present appeal provides no occasion for the Court to resolve.

proposal, citing a need to account for a separate statutory provision that authorizes Part D plans "to reduce cost-sharing differentially for network pharmacies." *Id.*; *see* 42 U.S.C. § 1395w-104(b)(1)(B). This differential cost-sharing allowance results in "preferred" pharmacies offering prescription drugs to Part D enrollees at lower levels of cost-sharing than non-preferred pharmacies. *See* 42 C.F.R. § 423.120(a)(9) ("A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy."); *id.* § 423.100 (defining "preferred pharmacy" as "a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy"). CMS concluded that its any willing pharmacy requirement—which mandates pharmacy access to standard, but not preferred, networks—"strikes an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs." 70 Fed. Reg. at 4254.

Oklahoma's AWP provision is inconsistent with those CMS-issued standards and the deliberate decision CMS made to require access only to standard networks because it requires PBMs to permit any willing pharmacy to participate in a drug plan's "preferred" network. The state-law requirement is thus preempted under the terms of the Medicare Part D express preemption provision, which provides that

federal standards "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 offered by Part D plan sponsors. 42 U.S.C. § 1395w-26(b)(3); *see id.* § 1395w-112(g); *cf. Crosby v. National Foreign Trade Council*, 530 U.S. 363, 380 (2000) (finding conflict between state law and federal statute because the statute was "drawn not only to bar what [it] prohibit[s] but to allow what [it] permit[s]"); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (finding preempted a state law that "would have stood 'as an obstacle to the accomplishment and execution of' the important means-related federal objectives" reflected in federal regulations addressing an overlapping issue).[6]

B. The district court acknowledged that "Part D has an any willing provider standard in relation to a plan's standard network." Op. 7, Aplt.App. Vol. 3, at 740. The court nonetheless concluded that Oklahoma's AWP provision is not preempted because it "relates to the preferred network rather than the standard network." *Id.*

That reasoning overlooks the fact that CMS, in implementing the Part D statute, considered and rejected proposals to extend its any willing pharmacy requirement to include access to "preferred" networks. CMS subsequently confirmed

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[6] Because Oklahoma's AWP provision is inconsistent with a CMS-issued standard, it is unnecessary to decide whether the provision is preempted under a broader preemption theory, and we do not address that question here. *See Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1150 (9th Cir. 2010) (declining to address "precise degree to which the 2003 [Medicare] amendment[s] expanded the preemption provision" because the state law at issue was "inconsistent" with federal standards).

that it would need to engage in additional analysis before extending this federal requirement to preferred networks. *See* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29,886-88 (May 23, 2014). Oklahoma's AWP provision thus interferes with CMS's policy choice not to require access to preferred networks, notwithstanding Congress's explicit instruction that federal standards "shall supersede" inconsistent state laws. 42 U.S.C. § 1395w-26(b)(3); *see id.* § 1395w-112(g).

In addition to defending the district court's reasoning, Oklahoma argues that the state-law AWP provision should not be preempted because it regulates only PBMs, which are intermediaries and not themselves Part D plan sponsors. *See* Okla. Br. 47-48. Federal law makes clear, however, that PBMs stand in the shoes of Part D sponsors and create pharmacy networks to provide drugs to enrollees in those sponsors' prescription drug plans. *See Wehbi*, 18 F.4th at 966 (explaining that regulation of PBMs functions as regulation of plans "[b]ecause PBMs manage benefits on behalf of plans"). Indeed, CMS's regulations specify that the Part D sponsor "maintains ultimate responsibility for . . . complying with all terms and conditions of its contract with CMS," regardless of that sponsor's relationships with other entities. 42 C.F.R. § 423.505(i).

Moreover, the Part D preemption provision does not require a state law to directly regulate Part D plan sponsors in order to be preempted. Instead, it provides

that "standards established under [Part D] shall supersede any State" standards "with respect to" prescription drug plans "which are offered by [Part D sponsors] under this part." 42 U.S.C. § 1395w-26(b)(3); *see id.* § 1395w-112(g); *see also Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1157-58 (9th Cir. 2010) (explaining that the Part D preemption provision's " language about [plan] sponsors modifies or describes what a [prescription drug plan] is—it does not shift the locus of preemption from the prescription drug plan to the sponsor"). The Act's AWP provision establishes a rule governing the pharmacy networks that PBMs can establish for the prescription drug plans offered by Part D sponsors. Because that rule is inconsistent with CMS-issued standards, it is preempted.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed in part and reversed in part.

Respectfully submitted,

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This brief complies with the type-volume limit of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 6,492 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system.

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