

FILED
United States Court of Appeals
Tenth Circuit

PUBLISH

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

August 15, 2023

Christopher M. Wolpert
Clerk of Court

PHARMACEUTICAL CARE
MANAGEMENT ASSOCIATION,

Plaintiff - Appellant,

v.

No. 22-6074

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

Defendants - Appellees.

ASSOCIATION OF FEDERAL
HEALTH ORGANIZATIONS; STATE
OF MINNESOTA; STATE OF
ARIZONA; STATE OF ARKANSAS;
STATE OF CALIFORNIA; STATE OF
COLORADO; STATE OF
CONNECTICUT; STATE OF
DELAWARE; STATE OF FLORIDA;
STATE OF HAWAII; STATE OF
IDAHO; STATE OF ILLINOIS;
STATE OF INDIANA; STATE OF
KANSAS; STATE OF KENTUCKY;
STATE OF MAINE; STATE OF
MARYLAND; STATE OF
MASSACHUSETTS; STATE OF
MICHIGAN; STATE OF
MISSISSIPPI; STATE OF
NEBRASKA; STATE OF NEVADA;
STATE OF NEW JERSEY; STATE OF
NEW MEXICO; STATE OF NEW

YORK; STATE OF NORTH CAROLINA; STATE OF NORTH DAKOTA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF SOUTH CAROLINA; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VIRGINIA; STATE OF WASHINGTON; DISTRICT OF COLUMBIA; THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION; AMERICAN PHARMACISTS ASSOCIATION; NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.; AMERICAN PHARMACIES, INC.; OKLAHOMA PHARMACISTS ASSOCIATION; UNITED STATES OF AMERICA,

Amici Curiae.

**Appeal from the United States District Court
for the Western District of Oklahoma
(D.C. No. 5:19-CV-00977-J)**

Kristyn M. DeFilipp of Foley Hoag LLP, Boston, Massachusetts (Dean Richlin and Andrew M. London of Foley Hoag LLP, Boston, Massachusetts; Joel W. Harmon and Mary H. Tolbert of Crowe & Dunlevy, Oklahoma City, Oklahoma, with her on the briefs), for Plaintiff–Appellant.

Zach West, Director of Special Litigation, Oklahoma Office of the Attorney General (Garry M. Gaskins, II, Solicitor General; Will Flanagan, Assistant Solicitor General, with him on the briefs), Oklahoma City, Oklahoma, for Defendants–Appellees.

Benjamin W. Snyder, Assistant to the Solicitor General (Seema Nanda, Solicitor of Labor; Wayne R. Berry, Acting Associate Solicitor for Plan Benefits Security; Jeff Hahn, Garrett Traub, and Isidro Mariscal, Attorneys, Office of the Solicitor, Plan Benefits Security Division, U.S. Department of Labor; Brian M. Boynton, Principal Deputy Assistant Attorney General; Alisa B. Klein and Anna

O. Mohan, Attorneys, Appellate Staff, Civil Division, U.S. Department of Justice, with him on the amicus brief), Washington, D.C., for amicus curiae the United States of America.

Anthony F. Shelley of Miller & Chevalier Chartered, Washington, D.C.; and David M. Ermer of Ermer & Suter, PLLC, Washington, D.C., filed an amicus brief on behalf of Plaintiff–Appellant, for the Association of Federal Health Organizations.

Keith Ellison, Attorney General, State of Minnesota; Angela Behrens, Stephen Melchionne, and Allen Cook Barr, Assistant Attorneys General, St. Paul, Minnesota, filed an amicus brief on behalf of Defendants–Appellees, for the States of Minnesota, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, and the District of Columbia.

Robert T. Smith and Howard R. Rubin of Katten Muchin Rosenman LLP, Washington D.C., filed an amicus brief on behalf of Defendants–Appellees, for 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.

Before **PHILLIPS**, **MURPHY**, and **ROSSMAN**, Circuit Judges.

PHILLIPS, Circuit Judge.

The Constitution ordains a federal system under which the federal and state governments share power. But when federal and state laws collide, the Constitution is clear: Federal law wins. This case is about a collision between federal law and Oklahoma law.

In 2019, the Oklahoma legislature unanimously passed the Patient’s Right to Pharmacy Choice Act, Okla. Stat. tit. 36, § 6958 *et seq.* The Act, along with

later regulations promulgated by the Oklahoma Insurance Department, sought to regulate pharmacy benefit managers (PBMs)—third-party intermediaries between pharmacies and health plans. In response to the Act’s passage, the Pharmaceutical Care Management Association (PCMA), a trade association representing PBMs, sued to invalidate the Act, alleging that the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 *et seq.*, and Medicare Part D, 42 U.S.C. § 1395w-101 *et seq.*, preempted the Act. The district court ruled that ERISA did not preempt the Act but that Medicare Part D preempted six of the thirteen challenged provisions. PCMA now appeals the court’s ERISA ruling on four provisions of the Act and the court’s Medicare Part D ruling on one provision.

Exercising jurisdiction under 28 U.S.C. § 1291, we hold that ERISA and Medicare Part D preempt the four challenged provisions, and we reverse.

BACKGROUND

I. Factual Background

We begin with some context about the prescription-drug market and then discuss the Act’s history and passage.

A. The Prescription-Drug Market

Filling doctors’ prescriptions is a part of everyday life. Pharmacists dispense the prescribed drugs, and consumers pay, either by themselves or with copayments between them and their insurers. But beneath these commonplace transactions lies a complex web of contracts and business relationships,

anchored by five key players: drug manufacturers, wholesalers, pharmacies, health plans, and PBMs.

Drug manufacturers make drugs and drug ingredients, which they sell to *wholesalers*, who then sell to *pharmacies*. Pharmacies are places where patients fill prescriptions. Pharmacies that have a brick-and-mortar storefront are called retail pharmacies, and pharmacies that dispense drugs through the mail are called mail-order pharmacies. Retail pharmacies may belong to a chain, such as CVS or Walgreens, or they may be independently owned.

Many patients access prescription drugs through *health plans* that offer prescription-drug benefits. Health plans, which include employer-sponsored plans and Medicare plans, help pay for their beneficiaries' healthcare needs, such as by covering prescription-drug costs. Employer-sponsored plans can be fully insured, meaning the plans buy health insurance for their employees, or they can be self-insured, meaning the employers collect premiums from employees, pay those employees' medical claims, and bear the insurance risk. Except for plans offered by governmental entities and churches, all employer-sponsored plans are governed by ERISA. 29 U.S.C. § 1003(a)–(b).

Medicare is a federal health-insurance program for people over 65 years old, certain people with disabilities, people with amyotrophic lateral sclerosis, and people with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. Along with providing hospital insurance (Medicare Part A) and medical insurance (Medicare Part B), Medicare contains a prescription-drug benefit program

(Medicare Part D). *Id.* §§ 1395w-101, -102. Part D-eligible individuals can access prescription-drug coverage by joining a Part D plan. These plans are offered by private insurers, which must comply with Medicare requirements.

Yet health-plan beneficiaries cannot access every drug at every pharmacy. This would be prohibitively expensive for plans, which must control costs. Rather, each plan sets terms for its beneficiaries to use the plan’s prescription-drug benefits. These terms include what drugs the plan covers (the formulary), how much the plan will pay for those drugs (the cost-sharing terms), and at which pharmacies beneficiaries can have prescriptions filled (the pharmacy network). Together, the formulary, cost-sharing terms, and pharmacy network comprise the plan’s prescription-drug-benefit design or structure.

Finally, we meet the fifth key player: **PBMs**, “a little-known but important part of the process,” *Rutledge v. PCMA*, 141 S. Ct. 474, 478 (2020), and the center of this appeal. PBMs are third-party entities that oversee health plans’ prescription-drug benefits. As intermediaries, they contract with manufacturers to negotiate rebates on drugs, contract with health plans to manage the plans’ prescription-drug benefits, and contract with pharmacies to design pharmacy networks. PBMs also offer options for health plans to structure their benefits. Because of the economic efficiencies and administrative savvy that PBMs afford, most health plans choose to work with PBMs to manage their prescription-drug benefits. The parties estimate that PBMs manage the drug benefits for over 2.4 million Oklahomans. Nationally,

PBMs are ubiquitous, administering the drug benefits for around 270 million people—“[n]early everyone with a prescription drug benefit.” App. vol. 2, at 472–73 (Caldwell Decl.).

One advantage to a plan’s using a PBM is access to the PBM’s pharmacy networks. After all, most plans do not assemble their own pharmacy networks; they rely on PBMs to do the heavy lifting. Leveraging their relationships with plans, PBMs contract with pharmacies to set prices and terms for beneficiary access. PBMs can then package those pharmacies into networks. Depending on a plan’s goals, it may choose to offer its beneficiaries more or fewer pharmacy options, as tailored by the PBM’s network. For example, a plan serving employees across a wide geographic area may want to include more pharmacies in its network. By hiring a PBM to fine-tune its network, a plan can promote a higher quality of care and can reduce other costs to beneficiaries, such as insurance premiums.

PBMs also help keep plans’ costs low by offering several other options for refining plan networks. Some of the more common network designs and features include two-tiered networks (standard and preferred), mail-order pharmacies, and specialty pharmacies. First, preferred pharmacies have agreed to accept lower reimbursements from plans in exchange for higher customer volumes. Preferred pharmacies achieve this higher volume by lowering the required copayments owed by customers filling their prescriptions. Next, mail-order pharmacies deliver prescriptions by mail, which is cheaper for plans and

may help patients take their medications as prescribed. Finally, specialty pharmacies specialize in dispensing specialty drugs, which treat complex, chronic, and rare diseases. Specialty drugs represent just 1 to 3 percent of prescriptions but account for 50 percent of prescription costs. Specialty pharmacies employ staff who uniquely understand how to handle and store these drugs and how to monitor the patients who take them. Often specialty pharmacies also operate as mail-order pharmacies. And because specialty pharmacies can buy in bulk, plans usually require or encourage beneficiaries to use specialty pharmacies to get these costly drugs. All three of these designs save plans and patients money.

Part of a PBM's ongoing role is to process prescription-drug claims. When a plan beneficiary has a prescription filled, the pharmacy first checks with the PBM to determine the beneficiary's coverage and copayment information. Once the beneficiary pays his or her share, the PBM reimburses the pharmacy for the prescription, minus that copayment amount. Last, the health plan reimburses the PBM. But this isn't a dollar-for-dollar reimbursement; per its contract with the plan, the PBM derives a profit from charging the plan more than the PBM pays the pharmacy. The State amici tell us that although the exact figure is unknown, the PBM market generated \$28 billion in gross profits in 2019. Most of this pie belongs to the three largest PBMs: CVS Caremark (a CVS Health subsidiary), Express Scripts (a Cigna subsidiary), and OptumRx (a UnitedHealth Group subsidiary). Together, this

triumvirate controls 80% to 85% of the market, giving those PBMs tremendous leverage over manufacturers, health plans, and pharmacies.

PBMs wield their market power in another way too: by owning and operating pharmacies. PBMs often bestow preferred-provider status on their own pharmacies, many of which are mail-order pharmacies. PBMs designate many of their mail-order pharmacies as specialty pharmacies. Harnessing these three network features, PBMs can steer beneficiaries toward their own pharmacies. Meanwhile, some PBMs have prevented non-PBM pharmacies from filling specialty-drug prescriptions, reimbursed those pharmacies at less than the drugs' wholesale prices, assessed retroactive fees, and restricted other aspects of pharmacy practice. Many have linked these PBM practices with the shuttering of rural and independent pharmacies. Yet PBMs face little federal regulation, so nearly all States have tried to regulate PBMs.

B. The Act

In response to growing concerns about PBMs and the sway they hold over independent pharmacies, the Oklahoma Legislature unanimously passed a first version of the Act (called the Prescription Access and Affordability Act, S.B. 841) in April 2019. Okla. S. Journal, 57th Leg., 1st Reg. Sess. 597–98 (2019), <https://perma.cc/5W22-PMN7>; Okla. H. Journal, 57th Leg., 1st Reg. Sess. 1160 (2019), <https://perma.cc/6ND5-VMSM>. But Governor Kevin Stitt vetoed Enrolled S.B. 841, objecting that the bill “attempt[ed] to regulate certain health plans sponsored by Oklahoma employers in such a manner that is

preempted by, and disallowed by, federal law.” Okla. S. Journal, 57th Leg., 1st Reg. Sess. 1272 (2019), <https://perma.cc/SW6S-2ULG>. Just two weeks later, lawmakers unanimously passed a second version of the Act (H.B. 2632), which pared down some of S.B. 841’s provisions. Okla. H. Journal, 57th Leg., 1st Reg. Sess. 1281 (2019), <https://perma.cc/68HF-77N5>; Okla. S. Journal, 57th Leg., 1st Reg. Sess. 1363 (2019), <https://perma.cc/4D5N-AY7R>. His preemption fears assuaged, Governor Stitt signed the Act into law on May 21, 2019. Okla. H. Journal, 57th Leg., 1st Reg. Sess. 1384 (2019), <https://perma.cc/8DCV-B2G2>.

Codified in Title 36 of the Oklahoma Statutes—the Oklahoma Insurance Code—the Act sets out to “establish minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient’s right to choose a pharmacy provider.” Okla. Stat. tit. 36, § 6959 (2019). To fulfill that stated purpose, the Act targets PBMs and their pharmacy networks. As a practical matter, the Act also bolsters the bargaining power of independent Oklahoma pharmacies. The Act helps achieve these goals by four provisions relevant here.¹

¹ As shorthand, the parties identify the four provisions as the “Retail-Only Pharmacy-Access Standards,” “Cost-Sharing-Discount Prohibition,” “Any Willing Provider Provision,” and “Probation-Based Pharmacy-Limitation Prohibition.” Taking a page from Mark Twain, we cut these five-dollar labels down to their fifty-cent bones and simply call them the “Access Standards,” “Discount Prohibition,” “AWP Provision,” and “Probation Prohibition.”

#1: The Access Standards:

A. Pharmacy benefits managers (PBMs) shall comply with the following retail pharmacy network access standards:

1. At least ninety percent (90%) of covered individuals residing in an urban service area live within two (2) miles of a retail pharmacy participating in the PBM's retail pharmacy network;
2. At least ninety percent (90%) of covered individuals residing in an urban service area live within five (5) miles of a retail pharmacy designated as a preferred participating pharmacy in the PBM's retail pharmacy network;
3. At least ninety percent (90%) of covered individuals residing in a suburban service area live within five (5) miles of a retail pharmacy participating in the PBM's retail pharmacy network;
4. At least ninety percent (90%) of covered individuals residing in a suburban service area live within seven (7) miles of a retail pharmacy designated as a preferred participating pharmacy in the PBM's retail pharmacy network;
5. At least seventy percent (70%) of covered individuals residing in a rural service area live within fifteen (15) miles of a retail pharmacy participating in the PBM's retail pharmacy network; and
6. At least seventy percent (70%) of covered individuals residing in a rural service area live within eighteen (18) miles of a retail pharmacy designated as a preferred participating pharmacy in the PBM's retail pharmacy network.

B. Mail-order pharmacies shall not be used to meet access standards for retail pharmacy networks.

Okla. Stat. tit. 36, § 6961(A)–(B) (2019).

#2: The Discount Prohibition:

E. An individual's choice of in-network provider may include a retail pharmacy or a mail-order pharmacy. A health insurer or PBM shall not restrict such choice. Such health insurer or PBM shall not require or incentivize using 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.

Id. § 6963(E).

#3: The AWP Provision:

B. A PBM, or an agent of a PBM, shall not:

4. Deny a provider the opportunity to participate in any pharmacy network at preferred participation status if the provider 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).

#4: The Probation Prohibition:

B. A PBM, or an agent of a PBM, shall not:

5. Deny, limit or terminate a provider's contract based on employment status of any employee who has an active license to dispense, despite probation status, with the State Board of Pharmacy[.]

Id. § 6962(B)(5).

II. Procedural Background

In October 2019, one week before the Act would have taken effect, PCMA sued Oklahoma Insurance Commissioner Glen Mulready (in his official capacity) and the Oklahoma Insurance Department. (From here, we refer to Mulready and the Department together as “Oklahoma.”) In its complaint, PCMA sought a declaration that ERISA and Medicare Part D have preempted the Act and its accompanying regulations and sought injunctive relief against Oklahoma's enforcing the Act and regulations.²

² PCMA also challenged the regulations as violating the Oklahoma Administrative Procedures Act, but this claim is not before us.

Soon into the litigation, the parties notified the district court that the Supreme Court had recently granted certiorari in a similar case, *Rutledge v. PCMA*, 140 S. Ct. 812 (2020) (mem.). The district court thus stayed the proceedings pending a decision from the Court, though the district court quickly lifted the stay once COVID-19 caused the Court to delay hearing *Rutledge*. The Supreme Court decided *Rutledge* in December 2020, upholding an Arkansas PBM regulation over a PCMA preemption challenge. 141 S. Ct. at 483.

Nine months after *Rutledge*, the parties filed dueling motions for summary judgment. Relying only on undisputed facts, PCMA argued that the Act was preempted by ERISA and Medicare Part D, and Oklahoma argued that it wasn't preempted. The district court held that ERISA did not preempt the Act but that Medicare Part D preempted six of the thirteen challenged provisions.³ *PCMA v. Mulready*, 598 F. Supp. 3d 1200, 1213 (W.D. Okla. 2022). The court explained why ERISA did not preempt the four provisions now on appeal:

The Any Willing Provider Provision applies only to preferred network participation status of pharmacies that are already in the plan's pharmacy network and does not require a plan to accept any willing pharmacy into its pharmacy network. The Retail-Only Pharmacy Access Standards and Cost Sharing Discount Provision do not prohibit using mail-order pharmacies; the use of these pharmacies just does not count toward meeting the access standards, and the plan cannot restrict an individual's choice of an in-network pharmacy. . . . The Probation-Based Pharmacy Limitation Prohibition addresses a pharmacy's contract, which is with the PBM

³ Oklahoma does not cross-appeal the court's rulings on these six provisions.

and not the plan. . . . While 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. . . . Accordingly, the Court concludes the Act is not preempted by ERISA and Defendants are, therefore, entitled to summary judgment as to this claim.

Id. at 1207–09. And the court explained why Medicare Part D did not preempt the Act’s AWP Provision (a ruling also on appeal):

[W]hile Part D has an any willing provider standard in relation to a plan’s standard network, the Any Willing Provider Provision in the Act relates to the preferred network rather than the standard network. As such, the Any Willing Provider Provision does not act “with respect to” the Part D any willing provider standard and is not preempted by Medicare Part D.

Id. at 1209.⁴ The court entered a mixed judgment for both sides, and PCMA timely appealed.

STANDARD OF REVIEW

Because this appeal follows the district court’s granting summary judgment, our review is de novo. *Wilkins v. City of Tulsa*, 33 F.4th 1265, 1271–72 (10th Cir. 2022) (citation omitted). So we apply the same standard as the district court: Summary judgment is required “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). And our review concerns

⁴ Oklahoma had conceded that Medicare Part D preempted the Discount Prohibition, and the court held that Medicare Part D also preempted the Access Standards. *Mulready*, 598 F. Supp. 3d at 1209 & n.7. Only the AWP Provision and Probation Prohibition survived both ERISA and Medicare Part D preemption. *Id.* at 1209–10.

only the legal question of federal preemption, which we review de novo. *See Cerveney v. Aventis, Inc.*, 855 F.3d 1091, 1096 (10th Cir. 2017) (citations omitted).

DISCUSSION

The Supremacy Clause, which exalts the U.S. Constitution and federal law as “the supreme Law of the Land,” U.S. Const. art. VI, cl. 2, imbues Congress with “the power to preempt state law,” *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citations omitted). Congress can exercise this power expressly, by defining a statute’s preemptive reach in a preemption clause, or impliedly, by legislating in such a way to crowd out related state laws. *Id.* Implied preemption comes in two flavors. First, “field” preemption occurs when federal law extensively regulates in an area such that it implicitly precludes any state regulation in that area. *Id.* Second, “conflict” preemption forces a state law to yield to federal law either when it is impossible to comply with both laws or when the state law thwarts the federal law’s purposes and intended effects. *Id.* at 399–400.

ERISA and Medicare Part D both contain express preemption clauses. *See* 29 U.S.C. § 1144(a); 42 U.S.C. § 1395w-112(g) (incorporating § 1395w-26(b)(3)). When evaluating these clauses, we look to congressional intent as our “ultimate touchstone.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citations omitted). To this end, we “focus on the plain wording of the clause[s], which necessarily contain[] the best evidence of Congress’

preemptive intent.” *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011) (citation omitted).

PCMA contends that ERISA preempts the Access Standards, Discount Prohibition, AWP Provision, and Probation Prohibition. Separately, PCMA also argues that Medicare Part D preempts the AWP Provision. We take up these issues below.

I. ERISA Preemption

Enacted in 1974 to safeguard employee benefits, ERISA creates standard procedures and oversight systems for employer-sponsored retirement plans and health plans. *See Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 320–21 (2016) (citation omitted). Through ERISA, Congress “ensure[d] that plans and plan sponsors would be subject to a uniform body of benefits law, thereby minimizing the administrative and financial burden of complying with conflicting directives and ensuring that plans do not have to tailor substantive benefits to the particularities of multiple jurisdictions.” *Rutledge*, 141 S. Ct. at 480 (cleaned up) (citation omitted). ERISA’s promise of uniformity is vitally important for employers, who “have large leeway to design . . . plans as they see fit.” *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 833 (2003). As stated, ERISA contains an express preemption clause, which supersedes “any and all State laws insofar as they may now or hereafter relate to any employee

benefit plan.” 29 U.S.C. § 1144(a).⁵ A state law relates to an ERISA plan if it has (1) a “connection with” or (2) a “reference to” an ERISA plan. *Rutledge*, 141 S. Ct. at 479 (quoting *Egelhoff v. Egelhoff*, 532 U.S. 141, 147 (2001)). PCMA makes only a connection-with argument and disclaims any reliance on reference-to preemption.

In *Rutledge*, the Supreme Court identified two categories of state laws that have this impermissible connection with ERISA plans: “laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status,”⁶ and laws whose “acute, albeit indirect,

⁵ To sow a seed for later harvest, we note that deciding whether a state law relates to an ERISA plan may not always resolve disputes over ERISA preemption. This is so because ERISA also has a saving clause, which exempts from preemption “any law of any State which regulates insurance.” 29 U.S.C. § 1144(b)(2)(A). State laws that are “specifically directed toward entities engaged in insurance” and that “substantially affect the risk pooling arrangement between the insurer and the insured” qualify for saving-clause protection. *Ky. Ass’n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 342 (2003) (citations omitted). But to prevent States from improperly invoking the saving clause to skirt preemption, ERISA’s “deemer clause” clarifies that “an employee benefit plan . . . shall [not] be deemed to be an insurance company or other insurer . . . for purposes of any law of any State purporting to regulate insurance companies [or] insurance contracts.” § 1144(b)(2)(B); *see Miller*, 538 U.S. at 336 n.1. We will return to the saving and deemer clauses later.

⁶ Within this category, a state law can “mandate[] employee benefit structures,” *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 658 (1995), by “prohibit[ing] employers from structuring their employee benefit plans in a [certain] manner,” *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983) (preempting a New York law that restricted plans from discriminating based on pregnancy).

economic effects . . . force an ERISA plan to adopt a certain scheme of substantive coverage.” *Id.* at 480 (citations omitted). These two categories distill into a “shorthand” inquiry: Does the state law “govern[] a central matter of plan administration or interfere[] with nationally uniform plan administration”? *Id.* (second quoting *Gobeille*, 577 U.S. at 320). The Court clarified, however, that “ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage.” *Id.* (citations omitted).

A. Can Oklahoma’s PBM regulations qualify for ERISA preemption?

As a threshold matter, Oklahoma argues that the Act escapes preemption because it regulates PBMs, not health plans. For example, Oklahoma stresses that PBMs are not plans, nor fiduciaries to plans, and that plans need not contract with PBMs. We reject this argument for three reasons.

First, reference-to preemption considers whether a state law expressly targets ERISA plans, but PCMA doesn’t argue for this type of preemption. *See Cal. Div. of Lab. Standards Enf’t v. Dillingham Constr., N.A.*, 519 U.S. 316, 325 (1997) (“Where a State’s law acts immediately and exclusively upon ERISA plans, . . . or where the existence of ERISA plans is essential to the law’s operation, . . . that ‘reference’ will result in pre-emption.”). Compare that to connection-with preemption—the heart of this case—which looks to “the nature of the effect of the state law on ERISA plans.” *Id.* (citation omitted). Simply

put, a state law can affect ERISA plans even if it does not nominally regulate them. *Accord Am. 's Health Ins. Plans v. Hudgens*, 742 F.3d 1319, 1331 (11th Cir. 2014) (reasoning that “ERISA’s overarching purpose of uniform regulation of plan benefits overshadows th[e] distinction” between “ERISA entities” and non-ERISA entities); *Kollman v. Hewitt Assocs., LLC*, 487 F.3d 139, 148 (3d Cir. 2007) (noting that a State’s attempting to regulate entities that “undertake and perform administrative duties for and on behalf of ERISA plans” may hinder nationally uniform plan administration).

Second, the Supreme Court has never recognized Oklahoma’s distinction between ERISA plans and third parties. To the contrary, the Court has ruled that state laws can relate to ERISA plans even if they regulate only third parties. Two cases best exemplify this.

In *Metropolitan Life Insurance Co. v. Massachusetts*, the Court considered whether ERISA preempted a Massachusetts law that required health insurers to provide mental-health benefits to state residents. 471 U.S. 724, 734 (1985). In one paragraph, the Court noted that although the state law “is not denominated a benefit-plan law, it bears indirectly but substantially on all insured benefit plans, for it requires them to purchase the mental-health benefits specified in the statute when they purchase a certain kind of common insurance policy.” *Id.* at 739. It did not matter for preemption purposes that the

law did not apply to ERISA plans—the law regulated the third-party insurers with whom plans may choose to deal and thus bound those plans by proxy.⁷

In *Rush Prudential HMO, Inc. v. Moran*, the Court considered whether ERISA preempted an Illinois law that required health maintenance organizations (HMOs)—third parties that contract with ERISA plans to provide medical services—to provide an independent medical-review process for certain benefit denials. 536 U.S. 355, 359 (2002). Again, in one paragraph, the Court held that it was “beyond serious dispute” that the law related to ERISA plans, reasoning that ERISA plans that chose to “purchase medical coverage” through HMOs would be forced to comply with the review process. *Id.* at 365. As in *Metropolitan Life*, this law bore “indirectly but substantially on all insured benefit plans.” *Id.* (quoting *Metro. Life*, 471 U.S. at 739). The Court thus reasserted its ability to pierce the veil between plans and the third parties with whom those plans contract.⁸

⁷ Ultimately, however, the Court upheld the law under ERISA’s saving clause. *Id.* at 743–44 (reasoning that the Massachusetts law “obviously regulates the spreading of risk” and that “mandated-benefit laws directly regulate an integral part of the relationship between the insurer and the policyholder by limiting the type of insurance that an insurer may sell to the policyholder”).

⁸ And as in *Metropolitan Life*, ERISA’s saving clause applied. *Id.* at 372–73 (“HMOs . . . are almost universally regulated as insurers under state law. . . . Thus, the Illinois HMO Act is a law ‘directed toward’ the insurance industry, and an ‘insurance regulation’ under a ‘commonsense’ view.” (citation omitted)).

Third, the logic from *Metropolitan Life* and *Rush Prudential* applies even more so to PBMs, which predominate in the prescription-drug-benefits field. Indeed, according to one PCMA expert, “the vast majority of fully-insured and self-funded employee health plans engage PBMs to administer pharmacy benefits on their behalf.” App. vol. 3, at 544 (Zucarelli Report). Another PCMA expert tells us that PBMs administer drug benefits for around 270 million Americans, accounting for “[n]early everyone with a prescription drug benefit.” App. vol. 2, at 472–73 (Caldwell Decl.). Even Oklahoma’s pharmacist experts acknowledge the outsized role PBMs play in this field. App. vol. 1, at 132 (White Report) (reporting that “for many community pharmacies,” PBMs account for 95% of their pharmaceutical business); App vol. 1, at 147 (Wilson Report) (estimating that his three independent pharmacies use PBMs “for ~95% of all the prescriptions we fill on a daily basis”).

Courts understand this reality. As the D.C. Circuit has observed, it would be “practical[ly] impossib[le]” for an ERISA plan to manage its own pharmacy benefits and avoid using a PBM “because it would mean forgoing the economies of scale, purchasing leverage, and network of pharmacies only a PBM can offer.” *PCMA v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010). Because a plan’s choice between self-administering its benefits and using a PBM “is in reality no choice at all,” regulating PBMs “function[s] as a regulation of an ERISA plan itself.” *Id.* (second quoting *Travelers*, 514 U.S. at 659). Citing that reasoning, the Eighth Circuit has also elided the distinction

between PBMs and ERISA plans. *PCMA v. Wehbi*, 18 F.4th 956, 966–67 (8th Cir. 2021) (“[T]he challenged provisions do not escape preemption on this basis.”).

At bottom, ERISA preemption still depends on whether the Act’s PBM regulations “preclude[] the ability of plan administrators to administer their plans in a uniform fashion.” *See PCMA v. Rowe*, 429 F.3d 294, 302 (1st Cir. 2005) (majority op. of Torruella, J.). So we return to square one: Preemption rises or falls on whether the Act’s PBM regulations have an impermissible connection with ERISA plans.

B. Does the Act govern a central matter of plan administration or interfere with nationally uniform plan administration?

Taking a cue from PCMA’s complaint and the United States’ amicus brief, we divide the Act’s four provisions into two categories based on how they operate. The Access Standards, Discount Prohibition, and AWP Provision are “network restrictions,” and the Probation Prohibition is an “integrity and quality restriction.” We discuss them in order.

1. Network Restrictions

We begin by recounting the three network restrictions and how the district court interpreted them under ERISA.

The *Access Standards* outline various geographic parameters that PBMs must satisfy in fashioning their Oklahoma pharmacy networks. For urban areas, at least 90% of beneficiaries must live within 2 miles of a network pharmacy

and within 5 miles of a preferred pharmacy. Okla. Stat. tit. 36, § 6961(A)(1), (2) (2019). For suburban areas, those radii extend to 5 and 7 miles. *Id.* § 6961(A)(3), (4). And for rural areas, 70% of beneficiaries must live within 15 miles of a network pharmacy and within 18 miles of a preferred pharmacy. *Id.* § 6961(A)(5), (6). Critically, only brick-and-mortar pharmacies—not mail-order pharmacies—count toward these requirements. *Id.* § 6961(B). The district court read the Access Standards as “not prohibit[ing] using mail-order pharmacies” but as establishing that “the use of these pharmacies just does not count toward meeting the access standards.” *Mulready*, 598 F. Supp. 3d at 1208.

The ***Discount Prohibition*** bars PBMs from promoting in-network pharmacies to beneficiaries by offering cost-sharing discounts, such as reduced copayments. Okla. Stat. tit. 36, § 6963(E) (2019). The district court ruled that the Discount Prohibition “do[es] not prohibit using mail-order pharmacies” but that “the plan cannot restrict an individual’s choice of an in-network pharmacy.” *Mulready*, 598 F. Supp. 3d at 1208.

The ***AWP Provision*** requires PBMs to admit every pharmacy that is willing to accept the PBM’s preferred-network terms into that preferred network. Okla. Stat. tit. 36, § 6962(B)(4) (2019). The district court construed

the AWP Provision as applying only to “pharmacies that are already in the plan’s pharmacy network.” *Mulready*, 598 F. Supp. 3d at 1208.⁹

Ultimately, the court ruled that none of the three provisions had a connection with ERISA plans. *Id.* at 1207. By its reckoning, “these provisions may alter the incentives and limit some of the options that an ERISA plan can use,” but they do not “force[] ERISA plans to make any specific choices.” *Id.* at 1208. All three network restrictions thus survived ERISA preemption.

On appeal, PCMA seeks to invalidate the network restrictions on grounds that they “curtail[] and eliminat[e] certain widely-employed plan structures[] and impos[e] alternative benefit designs.” The upshot, according to PCMA, is that the network restrictions “mandate[] employee benefit structures,” *Travelers*, 514 U.S. at 658, “prohibit[] employers from structuring their employee benefit plans in a [certain] manner,” *Shaw*, 463 U.S. at 97, and “require providers to structure benefit plans in particular ways,” *Rutledge*, 141 S. Ct. at 480. Thus, PCMA maintains that the network restrictions

⁹ We think that this construction misapprehends the AWP Provision. That provision says that any willing provider may “participate in *any* pharmacy network at preferred participation status.” Okla. Stat. tit. 36, § 6962(B)(4) (2019) (emphasis added). The plain text isn’t limited to network pharmacies—we see no reason why it wouldn’t apply to an out-of-network pharmacy that could suddenly meet a PBM’s preferred-network terms. Faced with this textual objection from PCMA, Oklahoma doesn’t reply that the factual scenario is far-fetched or infeasible. We thus agree with PCMA’s interpretation of the AWP Provision.

“govern[] a central matter of plan administration”—benefit design. *Id.* (quoting *Gobeille*, 577 U.S. at 320).

We agree with PCMA and with the reasoning in cases from the Fifth and Sixth Circuits. Reviewing similar state AWP laws, both courts held that the laws were impermissibly connected with ERISA plans. *CIGNA Healthplan of La., Inc. v. Louisiana ex rel. Ieyoub*, 82 F.3d 642 (5th Cir. 1996) (Louisiana AWP law preempted and not saved by ERISA saving clause); *Ky. Ass’n of Health Plans v. Nichols*, 227 F.3d 352 (6th Cir. 2000) (Kentucky AWP law preempted but saved), *aff’d sub nom. Miller*, 538 U.S. 329. Both cases show why ERISA preempts the three network restrictions.

In *CIGNA*, Louisiana’s AWP law stated that for preferred-provider organizations (PPOs), “[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.” 82 F.3d at 645 (alterations in original). The Fifth Circuit, citing *Travelers’* admonition that “preemption is appropriate on this ground when statutes ‘mandat[e] employee benefit structures or their administration,’” held that ERISA preempted the AWP law. *Id.* at 648 (alteration in original). It reasoned that “ERISA plans that choose to offer coverage by PPOs are limited by the statute to using PPOs of a certain structure—i.e., a structure that includes every willing, licensed provider.” *Id.* Or said another way, the law *prohibited* ERISA plans from choosing a PPO that did not include all willing providers. *Id.*

The court then rejected Louisiana’s argument that nothing required ERISA plans to use PPOs. In the court’s view, “[i]t is sufficient for preemption purposes that the statute eliminates the choice of one method of structuring benefits.” *Id.* Louisiana’s law ensured that ERISA plans that chose to use a PPO had to “purchase benefits of a particular structure,” so it was preempted. *Id.* Oklahoma urges us to reject *CIGNA* because the Louisiana law also applied directly to ERISA plans. But that distinction is unpersuasive because the Fifth Circuit analyzed the statute as “bear[ing] indirectly but substantially on all insured plans.” *Id.*

Relatedly, in *Nichols*, Kentucky’s AWP law stated that “[h]ealth care benefit plans shall not discriminate against any provider who . . . is willing to meet the terms and conditions for participation established by the health benefit plan.” 227 F.3d at 355. After surveying *Travelers* and *CIGNA*, the Sixth Circuit endorsed the district court’s holding that ERISA preempted the AWP law. *Id.* at 363. It explained that “while the law did not operate directly on ERISA plans, it effectively required benefit plans to purchase benefits of a certain structure, thereby bearing indirectly but substantially on all insured plans. . . . [T]he AWP statutes did more than just indirectly affect the cost of ERISA plans; the AWP statutes mandated benefit structures.” *Id.* at 362. Thus, the Kentucky law “affect[ed] the benefits available by increasing the potential providers” and “directly affect[ed] the administration of the plans.” *Id.* at 363. As in *CIGNA*, the court determined that ERISA preempted the AWP law. Again, Oklahoma

asks us to disregard *Nichols* on grounds that the Kentucky law also applied directly to ERISA plans. But once more, that's not required for connection-with preemption; "bearing indirectly but substantially" on ERISA plans suffices. *Id.* at 362.

Applying *CIGNA* and *Nichols* here, the Act's three network restrictions succumb to ERISA preemption. As in *CIGNA*, we overlook the distinction between PBMs and ERISA plans because "plans that choose to [hire a PBM] are limited by the statute to using [PBM networks] of a certain structure." 82 F.3d at 648. Functionally, the network restrictions mandate benefit structures; they at least "eliminate[] the choice of one method of structuring benefits." *Id.* The Access Standards dictate which pharmacies must be included in a PBM's network, and on top of that, the AWP Provision requires that those pharmacies be invited to join the PBM's preferred network.¹⁰ The Discount Prohibition requires that cost-sharing and copayments be the same for all network pharmacies—whether retail or mail-order; standard or preferred. Each provision either directs or forbids an element of plan structure or benefit design.¹¹

¹⁰ The Access Standards also force PBMs to include some brick-and-mortar pharmacies in the preferred network regardless of those pharmacies' assenting to the preferred-network terms under the AWP Provision. If 70% of a rural area's beneficiaries must be within 18 miles of a preferred pharmacy, then the PBM must include some baseline number of preferred pharmacies just to meet the Access Standards.

¹¹ In this context, forbidding something is itself a requirement that the PBM do the opposite of what is forbidden. For example, as mentioned above, (footnote continued)

However sliced, the network restrictions “require providers to structure benefit plans in particular ways,” *Rutledge*, 141 S. Ct. at 480, and “prohibit[] employers from structuring their employee benefit plans in a [certain] manner,” *Shaw*, 463 U.S. at 97. And either way, ERISA preempts these provisions because a pharmacy network’s scope (which pharmacies are included) and differentiation (under what cost-sharing arrangements those pharmacies participate in the network), are key benefit designs for an ERISA plan. Indeed, at summary judgment, Oklahoma conceded that “[p]lans design pharmacy benefits by determining, among other factors, what drugs are covered, where beneficiaries can obtain these drugs using their plan benefits and any cost-sharing the plan member will be required to pay for the covered drug.” App. vol. 2, at 390 (PCMA motion); App. vol. 3, at 690 (Oklahoma response). The network restrictions “govern[] a central matter of plan administration” and thus have an impermissible connection with ERISA plans. *Rutledge*, 141 S. Ct. at 480.

Consider how the network provisions change the landscape for PBM networks in Oklahoma. Before the Act, PBMs could use mail-order pharmacies to serve rural Oklahomans and reduce plan costs. Now, to comply with the Access Standards, PBMs working for Oklahoma plans with rural-dwelling

the Discount Prohibition is phrased as a prohibition against differential cost-sharing structures, but it can also be construed as creating an obligation of identical cost structures.

employees must include many more brick-and-mortar pharmacies. Because adding pharmacies costs plans money, this is a choice that plans might not otherwise make. Before the Act, PBMs could help plans reduce expenses by crafting a limited preferred network. Now, to comply with the AWP Provision, PBMs must allow all pharmacies to join their preferred networks. Plus, PBMs that have preferred *specialty* networks must allow even the smallest pharmacy to dispense costly specialty drugs. This rule hurts the cooperative relationship between plans, which want to save money, and preferred pharmacies, which want the increased business that preferred status affords. Before the Act, PBMs could use cost-sharing discounts to encourage plan beneficiaries to use cheaper pharmacies. Now, to comply with the Discount Prohibition, PBMs are forbidden from doing just that. Each network restriction winnows the PBM-network-design options for ERISA plans, thereby hindering those plans from structuring their benefits as they choose. *See Black & Decker*, 538 U.S. at 833.

Taking the AWP Provision as an example, its logical endpoint compels a preemptive result. If any pharmacy can join the preferred network to attract business, then the preferred network loses its luster and will collapse into a de facto single tier. Thus, the AWP Provision hamstringing a key element of network design. Oklahoma proposes that PBMs could remedy this by making the preferred-network terms so onerous as to bar most otherwise-willing pharmacies from entering. Problem is, if PBMs impose arduous new terms to inflict pain on the preferred network, eventually even the current preferred

providers will abandon their preferred status and return to the standard network. So the result is the same: Whether by operation of law or by sheer practicality, PBMs could no longer add a second preferred tier to their pharmacy networks. Oklahoma's AWP Provision has an impermissible connection with ERISA plans and must be preempted.

Together, these three provisions effectively abolish the two-tiered network structure, eliminate any reason for plans to employ mail-order or specialty pharmacies, and oblige PBMs to embrace every pharmacy into the fold. After these three provisions have run their course, PBMs are left with a cramped capacity to craft customized pharmacy networks for plans. As we see it, all PBMs could offer Oklahoma ERISA plans is a single-tiered network with uniform copayments, unrestricted specialty-drug access, and complete patient freedom to choose a brick-and-mortar pharmacy. These network restrictions are quintessential state laws that mandate benefit structures. ERISA forbids this.

Rutledge does not change our conclusion. There, the Supreme Court took up PCMA's challenge to an Arkansas law that governed PBM–pharmacy reimbursement rates. 141 S. Ct. at 478–79. To support rural and independent pharmacies, Arkansas's law required PBMs to “tether reimbursement rates to pharmacies' acquisition costs,” compelled PBMs to create procedures for pharmacies to appeal their reimbursement rates, and empowered pharmacies to decline to dispense drugs when their acquisition costs exceeded the PBMs' reimbursement rates. *Id.* at 479. The unanimous Court held that this law was a

mere cost regulation that did not have an impermissible connection with ERISA plans. *Id.* at 481. In so holding, the Court recognized that “ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage.” *Id.* at 480 (citations omitted). Yet the Court also acknowledged that sometimes even cost regulations could go too far—by having such “acute, albeit indirect, economic effects” that ERISA plans would be forced “to adopt a certain scheme of substantive coverage.” *Id.* (quoting *Gobeille*, 577 U.S. at 320).

According to the Court, “the logic of *Travelers*”—another rate-regulation case—“decide[d] this case.” *Id.* at 481. In *Travelers*, over an ERISA-preemption challenge, the Court upheld a New York law that imposed hospital surcharges on treatments covered by certain insurers. 514 U.S. at 659. True, the insurers would likely pass on those costs to plans, and those higher costs would influence the plans’ insurance-shopping decisions. *Id.* But in the end, plans could still provide benefits as they saw fit; those hospital benefits would just cost more in New York. *Id.* at 660. In short, ERISA had nothing to say about state regulations that merely disrupt nationwide cost uniformity. *Id.* at 662. Arkansas’s law was no different. PBMs would certainly pay more for drugs in Arkansas, and they would likely pass on those costs to plans, but that disuniformity was permissible under ERISA. *Rutledge*, 141 S. Ct. at 481. Nor did the Arkansas law meet the acute-economic-effects exception, because it was

“less intrusive” than the New York law in *Travelers*, which also didn’t meet the test. *Id.*

Our holding today adheres to *Rutledge*. Unlike Arkansas’s reimbursement-rate regulations, Oklahoma’s network restrictions do more than increase costs. They home in on PBM pharmacy networks—the structures through which plan beneficiaries access their drug benefits. And they impede PBMs from offering plans some of the most fundamental network designs, such as preferred pharmacies, mail-order pharmacies, and specialty pharmacies. In sum, PCMA is not resisting the Act’s imposing higher costs, but Oklahoma’s attempting to “govern[] a central matter of plan administration” and “interfere[] with nationally uniform plan administration.” *Id.* at 480. *Rutledge* was a win for States and a loss for PBMs, but it does not shield the Act from preemption.¹²

Oklahoma offers six rejoinders.

First, it points out that the network restrictions burden PBMs, not plans. But as discussed earlier, most plans use PBMs, and so regulating PBMs “function[s] as a regulation of an ERISA plan itself.” *PCMA v. District of Columbia*, 613 F.3d at 188 (citation omitted). We have thus overlooked this

¹² According to Oklahoma, *Rutledge* stands for the broad proposition that PBMs “can be held accountable for their own decisions.” But *Rutledge* did not draw a bright line between PBMs and ERISA plans. If the Court had made that distinction, *Rutledge* may well have been a shorter opinion. Instead, the Court treated the Arkansas law like any other by analyzing the law’s effects on ERISA plans.

PBM–plan distinction and assessed the Act’s substantial, indirect effects on ERISA plans. *See Metro. Life*, 471 U.S. at 739.

Second, Oklahoma claims that the network restrictions are narrower than they may seem. We disagree for the reasons above; the Act’s effects on PBMs—and thus plans—are unmistakably broad.¹³

Third, Oklahoma reminds us that the network restrictions also apply to PBM networks for non-ERISA plans. Even so, we are concerned here with the effects on ERISA plans. This is all that ERISA demands. And this cabins our holding: The network restrictions are preempted *as applied to ERISA plans*.

Fourth, Oklahoma reports that ERISA doesn’t contain similar network restrictions. But ERISA’s preemption clause doesn’t require a conflict between federal and state directives or even “overlapping” standards. *Id.* (“The pre-emption provision was intended to displace all state laws that fall within its sphere, even including state laws that are consistent with ERISA’s substantive requirements.” (citation omitted)). In fact, ERISA preemption is more comprehensive than targeting “only state laws dealing with the subject matters covered by ERISA—reporting, disclosure, fiduciary responsibility, and the like.” *Shaw*, 463 U.S. at 98.

Fifth, Oklahoma argues that the network restrictions do not require plans “to provide any particular benefit to any particular beneficiary in any particular

¹³ Later, we will discuss and reject a similar *de minimis* effects test that the United States proposes for the Probation Prohibition.

way.” *Rutledge*, 141 S. Ct. at 482. But this formula from *Rutledge* is not the only way that ERISA preempts state laws; ERISA also forbids States from “requir[ing] providers to structure benefit plans in particular ways,” *id.* at 480, and “prohibit[ing] employers from structuring their employee benefit plans in a [certain] manner,” *Shaw*, 463 U.S. at 97.¹⁴ The network restrictions do both these things. As mentioned, a plan’s prescription-drug benefit design comprises the formulary, cost-sharing terms, and pharmacy network. Because pharmacy networks are cornerstones in plans’ prescription-drug benefit structures, state efforts to undermine those pharmacy networks diminish plans’ benefit options.

Sixth, Oklahoma contends that its standards are less restrictive than others that the Supreme Court has held are not preempted. But the state laws at issue in *Travelers*, *Dillingham*, and *De Buono* are distinguishable from the network restrictions. The New York law in *Travelers* imposed hospital surcharges on treatments covered by certain insurers, the California law in *Dillingham* regulated wages paid to employees in ERISA-covered apprenticeship programs, and the New York law in *De Buono* was a tax on ERISA-fund-operated healthcare facilities’ gross receipts. *Travelers*, 514 U.S. at 649; *Dillingham*, 519 U.S. at 319; *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 809 (1997). All three cases dealt purely with cost or

¹⁴ Nor does ERISA preempt only state laws that bind health plans to a “specific choice[.]” See *Mulready*, 598 F. Supp. 3d at 1208. If that were so, States could regulate plans in unlimited ways if they left plans at least two options from which to choose.

rate regulations, not regulations pertaining to employee benefits or benefit design. And of course, “ERISA does not pre-empt a state law that merely increases costs.” *Rutledge*, 141 S. Ct. at 483. The Act’s network restrictions say nothing about PBM costs; they instead target network design. Thus, *Travelers*, *Dillingham*, and *De Buono* offer little support for Oklahoma’s position.

We reject Oklahoma’s counterarguments and hold that ERISA preempts the network restrictions.

2. Probation Prohibition

Moving on to the lone integrity and quality restriction, the Probation Prohibition bars PBMs from denying, limiting, or terminating a pharmacy’s contract because one of its pharmacists is on probation with the Oklahoma State Board of Pharmacy. Okla. Stat. tit. 36, § 6962(B)(5) (2019). Citing the Probation Prohibition’s being limited to a pharmacy’s contract with a PBM and not a plan, the district court held that it may “alter the incentives and limit some of the options that an ERISA plan can use,” but it does not “force[] ERISA plans to make any specific choices.” *Mulready*, 598 F. Supp. 3d at 1208.

PCMA argues that this provision effectively “dictates the terms and conditions for network participation,” which it says are “integral” to a plan’s network-design goals. Being forced to allow pharmacists on probation into the network, PCMA contends, forecloses plans from crafting networks that exclude rogue pharmacists who threaten beneficiaries’ safety. Oklahoma counters that this provision just prevents PBMs from punishing pharmacists who, though on

probation, still hold licenses to dispense drugs, a move that would “usurp[] regulatory and disciplinary control from the State Pharmacy Board.”

The United States agrees with Oklahoma that ERISA does not preempt this provision. To reach this conclusion, the United States proposes a novel rule: ERISA does not preempt state laws that have only a *de minimis* effect on pharmacy-benefit design. It cites three sources to support this *de minimis* rule. First, the Supreme Court’s repeated invocations that ERISA preempts state laws that govern “a central matter of plan administration.” *E.g., Egelhoff*, 532 U.S. at 148. Inverting this maxim, the United States claims that ERISA does not preempt laws that regulate “noncentral,” or *de minimis*, matters of plan administration. Second, the Eighth Circuit’s recent *Wehbi* decision, which applied a similar rule, and which also held that ERISA could tolerate laws that produce “modest disuniformity in plan administration.” 18 F.4th at 968. And third, the Supreme Court’s *Shaw* decision, which surmised in a footnote that “some state actions may affect employee benefit plans in too tenuous, remote, or peripheral a manner to warrant a finding that the law ‘relates to’ the plan.” 463 U.S. at 100 n.21 (citation omitted). Applying its test, the United States says that the Probation Prohibition “eliminates one possible basis for excluding a pharmacy” but “does not mandate the inclusion of any pharmacy.” For that reason, the United States concludes that this provision’s effect on plan design is *de minimis* at most, so it should not be preempted.

Wehbi considered whether ERISA preempted two North Dakota laws that resemble the Probation Prohibition. Both provisions dictated that “[a] pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.” *Wehbi*, 18 F.4th at 966 (quoting N.D. Cent. Code § 19-02.1-16.2(4)); *see also* N.D. Cent. Code § 19-02.1-16.1(11) (nearly identical). But despite the provisions’ apparent breadth, the court rejected preemption. It explained in formulaic fashion that the provisions

merely limit the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network. Again, this constitutes, at most, regulation of a noncentral “matter of plan administration” with *de minimis* economic effects. It is possible that sections 16.1(11) and 16.2(4) will “cause[] some disuniformity in plan administration” by requiring PBMs to maintain different accreditation requirements in different states. But they do not “requir[e] payment of specific benefits” or “bind[] plan administrators to specific rules for determining beneficiary status.” Therefore, whatever modest disuniformity in plan administration sections 16.1(11) and 16.2(4) might cause does not warrant preemption.

Wehbi, 18 F.4th at 968 (citations omitted). Beyond these conclusions, the court did not explain why dictating network composition would not count as governing a central matter of plan administration. As PCMA identifies, *Wehbi* failed to “assess that law’s effects on the structure of the provider network and connected effect on plan design.” Though *Wehbi*’s conclusion aligns with

Oklahoma and the United States’ recommended result, we find *Wehbi*’s limited reasoning unhelpful here.

Nor does *Wehbi* support the United States’ proposed *de minimis* test. *Wehbi* described the two North Dakota provisions as having “*de minimis* economic effects,” not a *de minimis* effect on plan design. *Id.* (citations omitted). A *de minimis* test fits in the economic context. *Travelers* instructs that state laws may be preempted if they have such an “acute” economic effect that they “force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.” 514 U.S. at 668. If a state law causes only *de minimis* economic effects, it follows that ERISA plans wouldn’t be forced to adopt a certain substantive-coverage scheme, nor would their insurer choices be effectively restricted. *Id.* Finding no footing for a *de minimis* test for plan administration, we decline the United States’ invitation to invent one here.¹⁵

Even if using a *de minimis* test were sound, we cannot square the United States’ analysis with its ready conclusion that the network restrictions were preempted. As we see it, the Probation Prohibition cannot so easily be dismissed as *de minimis*. The provision no doubt “forc[es] plans to adopt [a]

¹⁵ *Shaw* admittedly “express[ed] no views about where it would be appropriate to draw the line” for state laws that affect ERISA plans in “too tenuous, remote, or peripheral a manner” for preemption purposes. 463 U.S. at 100 n.21. As in *Shaw*, this case “does not present a borderline question” that would require us to draw that line. *Id.*

particular scheme of substantive coverage.” *Rutledge*, 141 S. Ct. at 480. Much like the AWP Provision, this provision forces PBMs to capitulate to *all* pharmacies, even those employing pharmacists on probation. Plans that want to promote patient safety by maintaining quality-assurance standards cannot refuse to contract with disciplined pharmacists.¹⁶ This provision’s plain language forbids a PBM from blocking a disciplined pharmacist from joining the standard network (“[d]eny . . . a provider’s contract”), removing such a pharmacist from the network (“terminate a provider’s contract”), or even structuring network terms to keep disciplined pharmacists out of the *preferred* network (“limit . . . a provider’s contract”). In so requiring, the Probation Prohibition acts just like the network restrictions—dictating which pharmacies must be included in a plan’s PBM network.

And together with the network restrictions, the Probation Prohibition sweeps even more broadly. For one thing, the Access Standards require that PBMs include many more pharmacies in their networks, which may require embracing some pharmacies that employ pharmacists on probation. Then, the AWP Provision would require the PBM to accept those pharmacies into the preferred network. Bound by the Probation Prohibition, PBMs could not oppose pharmacies employing pharmacists on probation. By “limit[ing] the

¹⁶ Justin Wilson, a pharmacist and Oklahoma State Board of Pharmacy member, testified that the Board can put pharmacists on probation if they engage in drug diversion, make mistakes that harm patients, or dispense controlled substances without a prescription.

accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network,” *Wehbi*, 18 F.4th at 968, the Probation Prohibition “affect[s] the benefits available by increasing the potential providers,” *Nichols*, 227 F.3d at 363, and “eliminates the choice of one method of structuring benefits,” *CIGNA*, 82 F.3d at 648. Thus, “ERISA plans that choose to [hire a PBM] are limited by the statute to using [PBM networks] of a certain structure—i.e., a structure that includes [pharmacists on probation].” *Id.* So the Probation Prohibition is also preempted.¹⁷

C. Does ERISA’s saving clause apply?

To tie up some loose ends, we briefly address the saving and deemer clauses. Again, ERISA’s saving clause exempts from preemption “any law of any State which regulates insurance.” 29 U.S.C. § 1144(b)(2)(A). And then the deemer clause in one instance closes the saving clause’s loophole: “[A]n employee benefit plan . . . shall [not] be deemed to be an insurance company or other insurer . . . for purposes of any law of any State purporting to regulate insurance companies [or] insurance contracts.” *Id.* § 1144(b)(2)(B). In its amicus brief, the United States advocates that these two clauses allow

¹⁷ As an aside, we recognize Oklahoma’s interest in rehabilitating disciplined pharmacists and its concern about PBMs “usurp[ing] regulatory and disciplinary control from the State Pharmacy Board.” But if we allow the Probation Prohibition to stand, we see no end to a State’s ability to dictate PBM-network terms.

Oklahoma to enforce the Act's three network restrictions against PBMs and other third parties, but not against ERISA plans.

But Oklahoma did not preserve a saving-clause argument. Its answer to PCMA's complaint did not present the clause as an affirmative defense. Its summary-judgment motion neglected to cite the clause. Elsewhere, Oklahoma cited the clause twice, but both citations were in opposition briefs, in footnotes, and in passing. Perhaps owing to Oklahoma's minimal reliance on the saving clause, the district court never discussed the issue.

Even now, Oklahoma does not pursue the saving clause as an alternative reason to affirm. When PCMA argued in its opening appellate brief that Oklahoma had waived the issue, Oklahoma countered by importing its cursory footnote argument into yet another footnote. Only after the United States expounded the saving clause in its amicus brief did Oklahoma try to develop a saving-clause argument.¹⁸

We decline to address the saving clause for several reasons. *See In re Syngenta AG MIR 162 Corn Litig.*, 61 F.4th 1126, 1182 (10th Cir. 2023) (“[W]hether issues should be deemed waived is a matter of discretion.” (citations omitted)). First, Oklahoma inadequately briefed this issue before the district court, citing it only in passing. *See Rushton v. ANR Co. (In re C.W. Min. Co.)*, 740 F.3d 548, 564 (10th Cir. 2014). Second, Oklahoma has done the same

¹⁸ For its part, the United States takes no position on whether Oklahoma preserved a saving-clause argument.

here, borrowing a single footnote from below in its opening brief. *United States v. Hardman*, 297 F.3d 1116, 1131 (10th Cir. 2002) (en banc) (“Arguments raised in a perfunctory manner, such as in a footnote, are waived.” (citation omitted)).¹⁹ That footnote failed to give a “detailed evaluation” of the saving clause in the “somewhat Byzantine” and “analytically complex” area of ERISA preemption. *Cf. Day v. SkyWest Airlines*, 45 F.4th 1181, 1191–92 (10th Cir. 2022) (citations omitted) (rejecting appellee’s alternative preemption argument).²⁰ Third, the only litigant to introduce a saving-clause argument was the United States as amicus curiae, and we consider amici-raised issues only in “exceptional circumstances” not present here. *See Diné Citizens Against Ruining Our Env’t v. Haaland*, 59 F.4th 1016, 1042 n.11 (10th Cir. 2023) (citation omitted).

We conclude that Oklahoma has waived any saving-clause argument.

* * *

For the reasons discussed, ERISA preempts all four provisions as applied to ERISA plans.

¹⁹ Nor did Oklahoma argue for plain-error review on appeal. *In re Syngenta*, 61 F.4th at 1181.

²⁰ And Oklahoma has never mentioned the deemer clause, let alone discussed how it would apply.

II. Medicare Part D Preemption

Finally, we consider whether Medicare Part D preempts the AWP Provision as applied to Part D plans.

In 2003, Congress amended the Medicare statutes to create Medicare Part D, a public–private partnership between the Centers for Medicare & Medicaid Services (CMS) and private insurers (called plan sponsors). Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2066. Plan sponsors offer prescription-drug plans to Medicare recipients and must abide by Part D’s statutory provisions and CMS’s corresponding regulations. Against the backdrop of extensive federal regulation, Medicare Part D has a broad preemption clause taken from Medicare Part C. *See* 42 U.S.C. § 1395w-112(g).²¹ It provides that “[t]he standards established under [Part D] 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] which are offered by [prescription-drug-plan sponsors] under [Part D].” *Id.* § 1395w-26(b)(3).

A. How broad is Part D’s preemption clause?

The parties disagree about the scope of Part D’s preemption clause. PCMA argues that this clause’s effect is “akin to field preemption.” If PCMA is

²¹ Medicare Part C, commonly known as Medicare Advantage, is a similar public–private partnership under which private health plans offer Part A and Part B benefits to Medicare-eligible individuals.

correct, the AWP Provision will be preempted if it “diminish[es] the Federal Government’s control over enforcement and detract[s] from the integrated scheme of regulation created by Congress.” *Arizona v. United States*, 567 U.S. at 402 (cleaned up) (citation omitted). Oklahoma responds that the term “supersede” instead evokes a type of conflict-preemption standard, which in its view would require “an overlapping or on-point federal standard.”

Resolving this dispute requires us to decide when a state law acts “with respect to” Part D plans. The answer lies in the preemption clause’s plain wording. *Whiting*, 563 U.S. at 594. Congress used unmistakably broad language here. “Any” is expansive. *Black’s Law Dictionary* 94 (6th ed. 1990) (“some; one out of many; an indefinite number . . . often synonymous with either, every, or all” (internal quotation marks removed)); *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 220 & n.4 (2008) (describing “any” as an “expansive modifier”). Equally broad is the phrase “with respect to.” *Cf. Dan’s City Used Cars, Inc. v. Pelkey*, 569 U.S. 251, 259–61 (2013) (interpreting “with respect to” in a federal motor-carrier preemption clause to mean “concern[ing]”). Reading the clause naturally, Part D’s standards preempt all state laws concerning Part D plans.

Contrary to Oklahoma’s interpretation, nothing in the preemption clause’s text requires a federal–state overlap. “Supersede” can mean “replace,” as Oklahoma contends, but it can also mean “[o]bliterate, set aside, annul, . . . make void, inefficacious or useless, repeal.” *Black’s Law Dictionary* 1437 (6th ed. 1990). Relatedly, ERISA’s preemption clause also uses the term

supersede, but as we’ve established, courts have not interpreted it as meaning “replace” there, either. *Rutledge*, 141 S. Ct. at 479 (using “pre-empts” in place of “supersedes”). *But see id.* at 483 (Thomas, J., concurring) (reasoning that supersede “suggests a replacement or substitution instead of a blanket pre-emption”). Oklahoma’s textual argument might carry more weight if Medicare Part D superseded any state law concerning Part D *standards*. That might imply that there are gaps in the federal standards in which States can regulate. But Oklahoma has it backward. The Part D standards supersede any state law concerning Part D *plans*, not Part D standards. 42 U.S.C. § 1395w-26(b)(3). We thus agree with PCMA that the sweeping Part D preemption clause is “akin to field preemption” and precludes States from regulating Part D plans except for licensing and plan solvency. *Id.*²²

Though we need not venture outside the text to reach this conclusion, we note that the legislative and regulatory histories also support a spacious reading

²² Even though the clause contains broad language and only two narrow exceptions, we presume that Congress did not intend for Part D to preempt state laws of general applicability, such as “environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law.” Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194-01, 4319 (Jan. 28, 2005); *cf. Aetna Life Ins. Co. v. Borges*, 869 F.2d 142, 146 (2d Cir. 1989) (“Those [laws] that have not been preempted [by ERISA] are laws of general application—often traditional exercises of state power or regulatory authority—whose effect on ERISA plans is incidental.”); *Cal. Trucking Ass’n v. Bonta*, 996 F.3d 644, 657 (9th Cir. 2021) (defining a “generally applicable law” as “one that affects individuals solely in their capacity as members of the general public and applies to hundreds of different industries” (citations omitted)).

of the preemption clause. Before Congress enacted Medicare Part D, Part C’s preemption clause superseded state laws only “to the extent” that those laws were “inconsistent with [Part C regulations].” 42 U.S.C. § 1395w-26(b)(3)(A) (2000). In the MMA, Congress excised that conditional language. MMA § 232, 117 Stat. at 2208. Attributing the need for this change to some “confusion in recent court cases,” the congressional conference committee explained that “[Part C] is a federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency.” H.R. Rep. No. 108-391, at 557 (2003) (Conf. Rep.). “That passage indicates that Congress intended to expand the preemption provision beyond those state laws and regulations inconsistent with the enumerated standards.” *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1149–50 (9th Cir. 2010). In a 2005 final rulemaking, CMS agreed that the MMA “significantly broadened the scope of Federal preemption of State law.” Medicare Program; Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588-01, 4663 (Jan. 28, 2005). CMS thus concluded that “with those exceptions [for licensing laws and laws relating to plan solvency], State laws do not apply to [Medicare Advantage] plans offered by [Medicare Advantage] organizations.” *Id.*

Our understanding of the preemption clause isn’t iconoclastic. In a recent opinion, the First Circuit also reached this result for Part C preemption, which uses the same framework as Part D. *Medicaid & Medicare Advantage Prods.*

Ass'n of P.R. v. Emanuelli Hernández, 58 F.4th 5 (1st Cir. 2023). There, the court observed that the preemption clause's "plain language sweeps broadly" because Congress included the word "any" before "State law or regulation" and because Congress included just two exceptions—again, for state licensing laws and laws relating to plan solvency. *Id.* at 12. So the court agreed that the MMA "clearly expanded the scope of preemption beyond those laws that directly conflict with federal standards." *Id.* Though the court also pointed to the consistent legislative and regulatory histories, its conclusion was fully grounded in the text: "Congress intended for all state laws or regulations that purport to regulate Medicare Advantage plans offered by [Medicare Advantage organizations] to be preempted." *Id.* (cleaned up) (citation omitted); *see* 42 U.S.C. § 1395w-26(b)(3). It thus rejected Puerto Rico's argument requiring a "specific, overlapping federal standard" because this rule would amount to requiring conflict preemption and would "largely eviscerate the effect of the expansive preemption clause." *Emanuelli Hernández*, 58 F.4th at 13–14.

Oklahoma contends that a broad reading would contradict "every court" that has considered Part D preemption (except for *Emanuelli Hernández*, which was decided later). It marshals the Ninth Circuit's decision in *Do Sung Uhm*, 620 F.3d 1134, and the Eighth Circuit's decisions in *PCMA v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018), *rev'd on other grounds*, 141 S. Ct. 474 (2020); and *Wehbi*, 18 F.4th 956. We consider these three cases below.

In *Do Sung Uhm*, the Ninth Circuit teed up a thorough Part D preemption discussion by asking, “[W]hat qualifies as a state law or regulation ‘with respect to’ a [prescription-drug plan]?” 620 F.3d at 1149. But it sidestepped this question and concluded that “it is sufficient for our purposes that, at the very least, any state law or regulation falling within the specified categories and ‘inconsistent’ with a standard established under the [MMA] remains preempted. That limited scope, it turns out, is sufficient to decide this appeal.” *Id.* at 1150 (footnotes omitted). Because of *Do Sung Uhm*’s irresolution, we agree with PCMA that the case “provides no guidance on how to properly frame the Medicare preemption standard.”

In the portion of the Eighth Circuit’s *Rutledge* opinion that the Supreme Court left intact, the court of appeals had discussed Medicare Part D preemption. It framed the inquiry as whether Congress or CMS “has established ‘standards’ in the area regulated by the state law” and whether “the state law acts ‘with respect to’ those standards.” *Rutledge*, 891 F.3d at 1113 (citation omitted). And it concluded that two Arkansas provisions were preempted as applied to Part D plans because the provisions intruded on two areas—pharmacy rate negotiations and pharmacy-access standards—regulated by Part D. *See id.* at 1113–14. But as we have already shown, Medicare Part D preempts state laws “with respect to [Part D plans],” not Part D standards, 42 U.S.C. § 1395w-26(b)(3), so we respectfully disagree with the Eighth Circuit’s rule in *Rutledge*.

In *Wehbi*, the Eighth Circuit also confronted Part D preemption. It observed that its earlier *Rutledge* opinion hadn't fully analyzed that issue. 18 F.4th at 970. After recounting the legislative history, the court noted that “preemption occurs only when federal standards ‘supersede’ state law”; it defined supersede as “displace.” *Id.* at 971 (citations omitted). So, the court reasoned, Part D “preempts only those [state laws] that occupy the same ‘place’—that is, that regulate the same subject matter as—federal Medicare Part D standards.” *Id.* (citation omitted). But the court labeled this as a field-preemption standard rather than a conflict-preemption one. *Id.*

The Eighth Circuit scrutinized each of the twelve North Dakota provisions at issue. Eight provisions survived preemption because they regulated subject matters not covered by Part D. The court drew these distinctions quite narrowly. For example, a state provision that “addresse[d] certain conflicts of interest that PBMs might have” wasn't a close enough match to Part D regulations that “also address[ed] potential conflicts of interest,” because the two sets of laws concerned “different kinds of conflicts.” *Id.* at 976. But the court preempted four provisions that purported to regulate Part D subject matters, such as “quality-assurance measures and performance incentives.” *Id.* at 972–76.

Though we share *Wehbi*'s view that Part D's preemption clause mandates field preemption, we disagree with the court's fastidious approach here. Simply put, requiring such a close match between federal and state standards “is slicing

the baloney pretty thin.” *Andy Warhol Found. for the Visual Arts, Inc. v. Goldsmith*, 143 S. Ct. 1258, 1300 (2023) (Kagan, J., dissenting). More importantly, it departs from the preemption clause’s broad text. And despite how *Wehbi* framed the issue, its analysis went beyond field preemption. In our view, allowing States to regulate Part D plans above what Part D already requires would “detract[] from the integrated scheme of regulation created by Congress.” *Arizona v. United States*, 567 U.S. at 402 (quotations and citation omitted). *Emanuelli Hernández* rejected this approach, and so do we.

We proceed to decide whether the AWP Provision, already preempted as applied to ERISA plans, is also preempted as applied to Part D plans.

B. Does the AWP Provision concern Part D plans?

To comply with the Act’s AWP Provision, PBMs must allow all Oklahoma pharmacies that are willing to accept the PBMs’ preferred-network terms into their preferred networks. Okla. Stat. tit. 36, § 6962(B)(4) (2019). Citing only the Eighth Circuit’s *Rutledge* test, the district court concluded that the AWP Provision did not act “with respect to” a similar Part D AWP standard because the Part D standard deals with standard networks and the Act’s AWP Provision concerns preferred networks. *Mulready*, 598 F. Supp. 3d at 1209. But as stated, a specific federal–state overlap is unnecessary, and requiring such an overlap would violate Part D’s field-preemption standard. As in the ERISA context, regulating PBMs here “function[s] as a regulation of a[] [Part D] plan itself.” *PCMA v. District of Columbia*, 613 F.3d at 188 (citation omitted); *see* 42 C.F.R.

§ 423.505(i)(1) (“Notwithstanding any relationship(s) that the Part D plan sponsor may have with first tier, downstream, and related entities, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.”). The AWP Provision regulates “with respect to [Part D plans]” because it establishes a rule that governs PBM pharmacy networks for Part D plans. 42 U.S.C. § 1395w-26(b)(3). And because it is not a licensing law or a law relating to plan solvency, the AWP Provision is preempted.

But the result would be the same even under Oklahoma’s narrower approach. After all, the AWP Provision encroaches on an existing Medicare standard. Part D has its own AWP provision that requires Part D plans to allow any willing pharmacy to participate in the plan’s *standard* network. *Id.* § 1395w-104(b)(1)(A); *see also* 42 C.F.R. § 423.120(a)(8)(i) (“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[.]”). To that end, CMS has established guidelines about how Part D plan sponsors must construct their networks. For example, the plan sponsor must “agree to 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.” 42 C.F.R. § 423.505(b)(18).

CMS could have implemented an AWP provision like Oklahoma’s, but it didn’t. Congress and CMS instead allow plan sponsors to offer cost-sharing discounts to promote those sponsors’ hand-picked preferred pharmacies over non-preferred pharmacies. *See* 42 U.S.C. § 1395w-104(b)(1)(B) (for drugs “dispensed through in-network pharmacies,” plans may “reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required”); 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.”); 42 C.F.R. § 423.100 (defining a 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 under its pharmacy network contract with a Part D plan”). Collectively, the Part D regulations—which govern universal access only to plans’ standard networks and which give plans discretion to select preferred providers within their networks—overlap with Oklahoma’s AWP Provision and thus would preempt it.

All told, the AWP Provision is preempted as applied to Medicare Part D plans.

CONCLUSION

By passing laws like Oklahoma’s, States have repeatedly expressed their overwhelmingly bipartisan displeasure with the power of PBMs over their citizens’ healthcare decisions. Our role is to answer whether the Act’s four challenged provisions veer into the regulatory lanes that Congress has reserved for itself. For the reasons discussed, we conclude that they do. Though the Act avoids mentioning ERISA plans or Medicare Part D plans by name, it encompasses these plans by striking at the heart of network and benefit design. But the States have an avenue by which to meaningfully seek redress. They may approach Congress, the architect of ERISA and Medicare, to take up the mantle.

Today we hold that ERISA preempts the Access Standards, Discount Prohibition, AWP Provision, and Probation Prohibition as applied to ERISA plans. And we also hold that Medicare Part D preempts the AWP Provision as applied to Part D plans. We reverse and remand with instructions to the district court to enter judgment consistent with this opinion.

UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

Byron White United States Courthouse
1823 Stout Street
Denver, Colorado 80257
(303) 844-3157
Clerk@ca10.uscourts.gov

Christopher M. Wolpert
Clerk of Court

Jane K. Castro
Chief Deputy Clerk

August 15, 2023

Ms. Kristyn M. DeFilipp
Mr. Andrew M. London
Mr. Dean Richlin
Foley Hoag
155 Seaport Boulevard
Boston, MA 02210

Mr. Joel W. Harmon
Crowe & Dunlevy
324 North Robinson Avenue, Suite 100
Oklahoma City, OK 73102

Ms. Mary H. Tolbert
Steptoe & Johnson
101 North Robinson Avenue, Suite 500
Oklahoma City, OK 73102

RE: 22-6074, Pharmaceutical Care v. Mulready, et al
Dist/Ag docket: 5:19-CV-00977-J

Dear Counsel:

Enclosed is a copy of the opinion of the court issued today in this matter. The court has entered judgment on the docket pursuant to Fed. R. App. P. Rule 36.

Pursuant to Fed. R. App. P. 40(a)(1), any petition for rehearing must be filed within 14 days after entry of judgment. Please note, however, that if the appeal is a civil case in which the United States or its officer or agency is a party, any petition for rehearing must be filed within 45 days after entry of judgment. Parties should consult both the Federal Rules and local rules of this court with regard to applicable standards and requirements. In particular, petitions for rehearing may not exceed 3900 words or 15 pages in length, and no answer is permitted unless the court enters an order requiring a response. *See* Fed. R. App. P. Rules 35 and 40, and 10th Cir. R. 35 and 40 for further information governing petitions for rehearing.

Please contact this office if you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Wolpert', with a long horizontal line extending to the right.

Christopher M. Wolpert
Clerk of Court

cc: Angela Behrens
David M. Ermer
William S. Flanagan
Garry Michael Gaskins II
Sarah Hogarth
Michael B. Kimberly
Alisa Beth Klein
Andrew C. Liazos
Brandon P. Long
Anna O. Mohan
Howard R. Rubin
Anthony F. Shelley
Robert T Smith
Benjamin Snyder
Mark D. Spencer
Zachary Paul West

CMW/djd