APPENDIX

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UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

No. 22-6074

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff-Appellant,

v.

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

Defendants-Appellees.

Filed: Aug. 15, 2023

Before: PHILLIPS, MURPHY, and ROSSMAN, Circuit Judges

OPINION

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: The Access Standards:

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

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[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. 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:
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> > 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:
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> > 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]

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

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

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 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,

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

> 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 only the legal

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[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.

question of federal preemption, which we review de novo. *See Cerveny 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

[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

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, 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

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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).

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]

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[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

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]

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

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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)).

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*, 598F. Supp. 3d at1208.[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

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[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.

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 "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

[10] The Access Standards also force PBMs to include some brick-and-mortar pharmacies in the preferred network regardless of

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]

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

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those pharmacies' assenting to the preferred-network terms under the AWP Provision. If 70% of a rural area's beneficiaries must be with 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, the Discount Prohibition is phrased as a prohibition against differential cost-sharing structures, but it can be construed as creating an obligation of identical cost structures.

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 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 hamstrings 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.

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[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.

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 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

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

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 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

[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.

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 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]

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[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

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] 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

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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.*

[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.

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 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

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[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.

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 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

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

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 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.

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

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[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 correct,

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[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.

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]

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[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)).

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 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.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

No. 22-6074

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff-Appellant,

v.

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

Defendants-Appellees.

Filed: Dec. 12, 2023

Before: PHILLIPS, MURPHY, and ROSSMAN, Circuit Judges

ORDER

Appellees' petition for rehearing is denied.

The petition for rehearing en banc was transmitted to all of the judges of the court who are in regular active service. As no member of the panel and no judge in regular active service on the court

requested that the court be polled, that petition is also denied.

Entered for the Court

CHRISTOPHER M. WOLPERT,
Clerk

Appendix C

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

No. CIV-19-977-J

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

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

Defendants.

Filed: Apr. 4, 2022

ORDER

Before the Court are the parties' cross motions for summary judgment [Doc. Nos. 96 and 97].[1] The motions have been fully briefed. Based upon the

[1] In its motion, Plaintiff Pharmaceutical Care Management Association (PCMA) requests oral argument. Having reviewed the parties' submissions, the Court determines that oral argument is not necessary and denies PCMA's request.

parties' submissions, the Court makes its determination.[2]

I. Background

In simple terms, health insurance plans 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. The vast majority of health insurance plans providing drug benefits use a pharmacy benefit manager (PBM) to act as an intermediary in ensuring beneficiaries can use their drug benefits to obtain prescriptions. PBMs create pharmacy networks and then contract with pharmacies in those networks to provide prescriptions to beneficiaries. When a pharmacy dispenses the prescription, it then files a claim with the PBM. The PBM processes that claim and notifies the pharmacy how much the plan will pay and how much the beneficiary must pay. Afterwards, the PBM reimburses the pharmacy according to the contract between the PBM and the pharmacy. The contract between the PBM and the pharmacy determines the reimbursement rate, not the insurance plan. The PBM then bills the insurance plan according to its contract with the insurance plan, and the insurance plan pays the prescription benefit to the PBM.

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[2] PCMA has also filed a *Daubert* motion to exclude the expert testimony of Debra Billingsley [Doc. No. 99]. Because the Court has not relied on Ms. Billingsley's testimony in ruling on the parties' cross motions for summary judgment, the Court concludes that no ruling on PCMA's *Daubert* motion is necessary.

Several states, including Oklahoma, have sought to regulate PBMs. In 2019, the Oklahoma Legislature passed the Oklahoma's Patient's Right to Pharmacy Choice Act (Act), Okla. Stat. tit. 36, § 6958, *et seq*. To compliment the Act, the Oklahoma Insurance Department enacted various regulations.

PCMA is the national trade association for PBMs, representing sixteen PBMs. In this case, PCMA challenges the Act and the related regulations.[3] Specifically, PCMA alleges the Employment Retirement Income Security Act (ERISA) and Medicare Part D preempt the Act and related regulations and claims that the regulations were adopted in violation of the Oklahoma Administrative Procedures Act (OAPA). On July 9, 2020, the Court granted in part and denied in part PCMA's motion for preliminary injunction and enjoined enforcement of Okla. Stat. tit. 36, §§ 6961(A), (D) and Okla. Admin. Code 365:25-29-7.1(a)(3). PCMA and Defendants now each move for judgment as a matter of law.

II. Analysis

A. ERISA preemption

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA. 29 U.S.C. § 1144(a). "[A] state law relates to an ERISA plan if it has a connection with or reference to such a plan." *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 479 (2020)

[3] PCMA brings this litigation on behalf of its members.

(internal quotations and citation omitted).[4] Regarding "connection with" preemption, laws that require providers to structure benefit plans in certain ways or bind plan administrators to specific rules for beneficiary status are preempted. *See id.* at 480. Further, "[a] state law may also be subject to pre-emption if acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage." *Id.* (internal quotations and citation omitted). However, "not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan." *Id.* "[S]tate rate regulations 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.*

PCMA asserts the Act impermissibly dictates the design of ERISA plans by regulating the nature and scope of the plan's provider network and the programs an employee benefit plan may adopt to ensure network quality and integrity. Specifically, PCMA contends the Act's Any Willing Provider Provision, Okla. Stat. tit. 36, § 6962(B)(4); Retail-Only Pharmacy Access Standards, Okla. Stat. tit. 36, § 6961(A),(B); Affiliated Pharmacy Prohibition, Okla. Stat. tit. 36, § 6961(C); Probation-Based Pharmacy Limitation Prohibition, Okla. Stat. tit. 36, § 6962(B)(5); Network Provider Restriction Prohibition, Okla. Stat. tit. 36, § 6963(D); Cost Sharing Discount Provision, Okla. Stat. tit. 36,

[4] PCMA contends the Act only implicates "connection with" preemption. The Court will thus limit its analysis to "connection with" preemption.

§ 6963(E); and Promotional Materials Provision; Okla. Stat. tit. 36, § 6961(D),[5] dictate network composition, cost-sharing differentials, and communications with beneficiaries and thereby directly affect the benefits a plan offers to plan members. PCMA contends that as a result these provisions have an impermissible connection with ERISA plans and are thereby preempted.

Upon review of the specific language of these provisions, the Court concludes that they do not have a "connection with" an ERISA plan. 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 Affiliated Pharmacy Prohibition does not prohibit including affiliated pharmacies in the plan pharmacy network; the plan is just prohibited from requiring patients to use the affiliated pharmacies. The Probation-Based Pharmacy Limitation Prohibition addresses a pharmacy's contract, which is with the PBM and not the plan. The Network Provider Restriction Prohibition relates to pharmacies that are in-network providers and thus leaves the plan with options as to the composition of its in-network

[5] The Court will use the names given to these provisions by PCMA in its briefing.

providers. 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.

Regarding the Promotional Materials Provision, PCMA asserts the Act impermissibly prohibits plans from communicating their benefit design to beneficiaries by not allowing them to mention certain pharmacies without mentioning all pharmacies. The Act's Promotional Materials Provision, however, does not regulate benefit design disclosures to beneficiaries but regulates how PBMs can advertise its providers. This provision therefore does not relate to a central matter of plan administration nor undermine the uniform regulation of ERISA plans.

PCMA also asserts the Post-Sale Price Reduction Prohibition, Okla. Stat. tit. 36, § 6962(B)(6), and the Affiliated Pharmacy Price Match, Okla. Stat. tit. 36, § 6962(B)(3), impermissibly dictate the design of ERISA plans by regulating the programs an employee benefit plan may adopt to ensure network quality and integrity. While the Post-Sale Price Reduction Prohibition and the Affiliated Pharmacy Price Match will have some effect on the way PBMs pay and/or reimburse pharmacies, these provisions do not impermissibly dictate the design of ERISA plans by forcing the plans into making a specific choice.

Finally, PCMA contends the Act's Health Insurer Monitoring Requirement, Okla. Stat. tit. 36, § 6963(A), (B), is preempted by ERISA. Defendants assert PCMA lacks standing to challenge this provision because it imposes obligations exclusively

upon a health insurer,[6] and PCMA is made up exclusively of PBMs and does not contain any health insurers. PCMA asserts it has standing because complying with the insurers' monitoring activities required by this provision causes harm to PBMs by creating an administrative burden on them. An administrative burden can constitute an injury in fact for standing purposes. *See Okla. ex rel. Pruitt v. Sebelius*, No. CIV-11-30-RAW, 2013 WL 4052610 at *8 (E.D. Okla. Aug. 12, 2013). However, PCMA only makes a conclusory allegation of administrative burden in relation to the Health Insurer Monitoring Requirement. Having reviewed the parties' submissions, the Court finds that PCMA has not made a sufficient showing of injury and that PCMA lacks standing to raise an ERISA challenge to this provision.

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

B. Medicare Part D Preemption[7]

Medicare Part D incorporates the express preemption provision contained in Medicare Part C. *See* 42 U.S.C. § 1395w-112(g). Part C's preemption provision provides:

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[6] Under the Act, a "health insurer" is a separate and distinct entity from a PBM. *See* Okla. Stat. tit. 36, § 6960(1), (3).

[7] Defendants concede the Promotional Materials Provision and the Cost Sharing Discount Provision are preempted by Medicare Part D. *See* Defendants' Response to Plaintiff's Motion for Summary Judgment [Doc. No. 100] at 2, n.2.

> 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 MA plans which are offered by MA organizations under this part.

42 U.S.C. § 1395w-26(b)(3). The Tenth Circuit has not addressed the scope of Medicare Part D, but other appellate courts have found preemption where "(1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established 'standards' in the area regulated by state law; and (2) the state law acts 'with respect to those standards.'" *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018);[8] *see also Do Sung Uhm v. Humana*, 620 F.3d 1134, 1148 n.20, 1157-58 (9th Cir. 2010). The standards need not conflict for preemption to occur. *Rutledge*, 891 F.3d at 1113.

PCMA contends CMS has already established detailed standards regulating a Part D's sponsor's pharmacy networks. PCMA therefore asserts Medicare Part D preempts the Retail-Only Pharmacy Access Standards, Any Willing Provider Provision, Affiliated Pharmacy Prohibition, and Network Provider Restriction Prohibition. The Court will address each of these standards.

First, Part D has standards for convenient access to network pharmacies, and these standards contain geographic restrictions for pharmacy networks. The

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[8] In *Rutledge*, the Supreme Court did not review the Eighth Circuit's holding that the Arkansas statute was preempted by Medicare Part D.

Retail-Only Pharmacy Access Standards contain similar geographic restrictions on retail pharmacies in a PBM's network. Because CMS has established standards regarding convenient access to network pharmacies and the Retail-Only Pharmacy Access Standards act with respect to those standards, the Court concludes the Retail-Only Pharmacy Access Standards are preempted by Medicare Part D.

Second, while 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.

Third, PCMA asserts that Part D's Preferred Pharmacy Network Standard, 42 C.F.R. § 423.120(a)(9), expressly permits the use of preferred pharmacy networks, and the Act's Affiliated Pharmacy Prohibition and Network Provider Restriction are preempted because they set additional requirements for when a Part D sponsor may limit a beneficiary's choice of pharmacy. Part D's Preferred Pharmacy Network Standard simply provides that a Part D plan may include a preferred pharmacy network but does not regulate or provide any standards as to how such preferred pharmacy networks must be structured or managed. Because there are no standards to act "with respect to", the Affiliated Pharmacy Prohibition and Network Provider Restriction are not preempted by Medicare Part D.

Fourth, PCMA asserts the Service Fee Prohibition, Okla. Stat. tit. 36, § 6962(B)(2), Affiliated Pharmacy Price Match, and Post-Sale Price Reduction Prohibition are preempted. PCMA contends these provisions regulate a Part D sponsor's payment of claims that are in addition to, and in conflict with, the market-based model Congress sought to create in establishing the Part D program and create state specific standards for retroactive claims adjustments where exclusive federal regulation already exists. Medicare Part D prohibits interference with the negotiations between Part D Sponsors and pharmacies and prohibits any requirement of a particular formulary or price structure for the reimbursement of covered part D drugs. *See* 42 U.S.C. § 1395w-111(i). "[This] statute prohibits both federal and state interference in negotiations between Part D sponsors and pharmacies . . . ." *Rutledge*, 891 F.3d at 1113. Further, Medicare Part D defines "negotiated prices" in part as prices "The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug." 42 C.F.R. § 423.100. Additionally, Part D provides that a plan "must comply with all administrative processes and requirements established by CMS . . . for . . . (3) Retroactive claims adjustment, ..." 42 C.F.R. § 423.464(a). Because the Service Fee Prohibition, Affiliated Pharmacy Price Match, and Post-Sale Price Reduction Prohibition act with respect to Medicare Part D standards for negotiated prices and negotiations with pharmacies,

the Court concludes these provisions are preempted by Medicare Part D.

Fifth, PCMA asserts the Probation-Based Pharmacy Limitation Prohibition and Termination Payment Requirement, Okla. Stat. tit. 36, § 6962(B)(7), impermissibly infringe upon Medicare Part D's quality assurance standards and thus are preempted by Medicare Part D. The quality assurance standards set forth in Part D provide, in pertinent part: "A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use" and then sets forth certain measures that should be used. 42 C.F.R. § 423.153(c). Neither the Probation-Based Pharmacy Limitation Prohibition nor the Termination Payment Requirement act with respect to Medicare Part D's quality assurance standards and thus are not preempted.

Finally, PCMA asserts the Health Insurer Monitoring Requirement and the Contract Approval Rule, Okla. Admin. Code 365:25-29-9(c)(1), are preempted by Medicare Part D. As set forth above, PCMA has not made a sufficient showing of injury in relation to the Health Insurer Monitoring Requirement, and the Court concludes that PCMA lacks standing to raise a Medicare Part D challenge to this provision. PCMA, however, has made a sufficient showing of injury in relation to the Contract Approval Rule to have standing to challenge the rule.[9]

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[9] Under the Contract Approval Rule, PBMs are required to submit each contract used by the PBM and its pharmacy network

PCMA contends the Contract Approval Rule adds new monitoring requirements for Part D sponsors on top of those already created by the federal government. The Contract Approval Rule requires every insurer that uses the services of a PBM to approve all contracts used by the PBM and its retail pharmacy network to ensure compliance with the Act. Medicare Part D sets forth specific items that must be contained in the contract between the Part D plan sponsor and the PBM or other similar entity. Since the contracts at issue in the Contract Approval Rule and the Medicare Part D standards are different types of contracts, the Court concludes the Contract Approval Rule does not act with respect to the Medicare Part D standards and therefore is not preempted.[10]

C. OAPA Claims

1. Supplemental jurisdiction

Defendants assert this Court does not have supplemental jurisdiction over PCMA's OAPA claims. 28 U.S.C. § 1367 provides, in pertinent part:

> in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

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for approval, thereby creating a sufficient administrative burden to constitute an injury for standing purposes.

[10] However, as set forth below, the Court concludes the Contract Approval Rule is not valid.

28 U.S.C. § 1367(a). When the state and federal claims "derive from a common nucleus of operative fact" such that the relationship between the claims permits the conclusion that the entire action comprises one constitutional case, the state claims are within a court's supplemental jurisdiction. *See City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 164-65 (1997). PCMA's federal preemption claims and state OAPA claims all derive from a common nucleus of operative facts and comprise one constitutional case. This Court, accordingly, has supplemental jurisdiction over PCMA's OAPA claims.

Defendants further assert that even if this Court has supplemental jurisdiction, the Court should decline to exercise it. Section 1367(c) provides:

> The district courts may decline to exercise supplemental jurisdiction over a claim under subsection (a) if –
>
> > (1) the claim raises a novel or complex issue of State law,
> >
> > (2) the claim substantially predominates over the claim or claims over which the district court has original jurisdiction,
> >
> > (3) the district court has dismissed all claims over which it has original jurisdiction, or
> >
> > (4) in exceptional circumstances, there are other compelling reasons for declining jurisdiction.

28 U.S.C. § 1367(c). None of these bases is applicable in this case. While Defendants contend there is an independently compelling reason for declining

jurisdiction, the Court, upon reviewing the facts of this case, finds no compelling reason. The Court will, therefore, address PCMA's OAPA claims.

2. Merits

PCMA contends that certain Oklahoma administrative regulations were adopted in violation of the OAPA. Oklahoma allows challenges to administrative regulations under Okla. Stat. tit. 75, § 306(A). When a regulation is challenged, the agency which promulgated the regulation bears the burden of showing:

> 1. that the agency possessed the authority to promulgate the rule;
>
> 2. that the rule is consistent with any statute authorizing or controlling its issuance and does not exceed statutory authority;
>
> 3. that the rule is not violative of any other applicable statute or the Constitution; and
>
> 4. that the laws and administrative rules relating to the adoption, review and promulgation of such rules were faithfully followed.

Okla. Stat. tit. 75, § 306(C).

PCMA asserts the Promotional Materials Rule, Okla. Admin. Code 365:25-29-7.1(a)(3), is inconsistent with the Promotional Materials Provision because it leaves out a significant qualifying clause: "participating in the preferred and nonpreferred pharmacy and health networks." *Compare* Okla. Stat. tit. 36, § 6961(D) *with* Okla. Admin. Code 365:25-29-7.1(a)(3). Defendants do not deny the language is different in the statute and the regulation but urge the

Court to deviate from a literal reading that would lead to an absurd result even if the language is unambiguous. The Court declines to deviate because the plain language of the regulation places a burden on PBMs that is inconsistent with the Act and does more than the Act allows. Accordingly, the Court concludes the Promotional Materials Rule is not valid.

PCMA also asserts the Contract Approval Rule is inconsistent with the Health Insurer Monitoring Requirement because the rule appears to require each health insurer that contracts with a PBM to approve every contract a PBM enters into while the Act requires health insurers merely to "monitor" the activities of those with which they contract and ensure that the requirements of the Act are met. While a duty to approve contracts to ensure compliance with the Act could fall within the definition of monitor, the monitoring required under the Health Insurer Monitoring Requirement does not necessarily have to include approving all contractual documents utilized by the PBMs. Defendants contend the Contract Approval Rule provides an efficient means to administer the Health Insurer Monitoring Requirement. Defendants' cursory efficiency argument, however, does not satisfy their burden to show that the Contract Approval Rule does not exceed the statutory authority of the Act. Accordingly, the Court concludes the Contract Approval Rule is not valid.

Finally, PCMA asserts the Specialty Drugs Rule, Okla. Admin. Code 365:25-29-7.1(a)(2),[11] arbitrarily

[11] The Specialty Drugs Rule provides: "The act draws no distinction between regular or specialty drugs, both being

applies the Act to specialty drugs despite great differences between specialty and regular drugs and despite the Affiliated Pharmacy Prohibition that specifically explicates the distinction. Defendants contend there is no distinction between regular and specialty drugs in the Act and the Specialty Drugs Rule is consistent with the Act. Having reviewed the Act, the Court finds the Affiliated Pharmacy Prohibition does not create or imply a difference between specialty and standard drugs and the Act does in fact contemplate all prescription drugs regardless of whether they are specialty or not. Accordingly, the Court concludes the Specialty Drugs Rule is valid.

III. Conclusion

For the reasons set forth above, the Court GRANTS IN PART and DENIES IN PART PCMA's Motion for Summary Judgment [Doc. No. 97] and Defendants' Motion for Summary Judgment [Doc. No. 96] as follows:

(A) The Court GRANTS PCMA's Motion for Summary Judgment as to its Medicare Part D preemption claim with respect to the Act's Promotional Materials Provision, Cost Sharing Discount Provision, Retail-Only Pharmacy Access Standards, Service Fee Prohibition, Affiliated Pharmacy Price Match, and Post-Sale Price Reduction Prohibition and as to its OAPA claim with respect to the Promotional Materials Rule and Contract

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prescription medications, therefore, specialty drugs fall within the contemplation of the act."

Approval Rule and DENIES the remainder of PCMA's Motion for Summary Judgment, and

(B) The Court GRANTS Defendants' Motion for Summary Judgment as to PCMA's ERISA preemption claim; PCMA's Medicare Part D preemption claim with respect to the Act's Any Willing Provider Provision, Affiliated Pharmacy Prohibition, Network Provider Restriction, Probation-Based Pharmacy Limitation Prohibition, Termination Payment Requirement, and Contract Approval Rule; and PCMA's OAPA claim with respect to the Specialty Drugs Rule and DENIES the remainder of Defendants' Motion for Summary Judgment.

IT IS SO ORDERED this 4th day of April, 2022.

BERNARD M. JONES
UNITED STATES DISTRICT JUDGE

Appendix D

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

U.S. Const. art. VI, cl.2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

29 U.S.C. §1144. Other laws

(a) Supersedure; effective date

Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title. This section shall take effect on January 1, 1975.

(b) Construction and application

(1) This section shall not apply with respect to any cause of action which arose, or any act or omission which occurred, before January 1, 1975.

(2)(A) Except as provided in subparagraph (B), 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.

(B) Neither an employee benefit plan described in section 1003(a) of this title,

which is not exempt under section 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.

(3) Nothing in this section shall be construed to prohibit use by the Secretary of services or facilities of a State agency as permitted under section 1136 of this title.

(4) Subsection (a) shall not apply to any generally applicable criminal law of a State.

(5)(A) Except as provided in subparagraph (B), subsection (a) shall not apply to the Hawaii Prepaid Health Care Act (Haw. Rev. Stat. §§ 393-1 through 393-51).

(B) Nothing in subparagraph (A) shall be construed to exempt from subsection (a)--

(i) any State tax law relating to employee benefit plans, or

(ii) any amendment of the Hawaii Prepaid Health Care Act enacted after September 2, 1974, to the extent it provides for more than the effective administration of such Act as in effect on such date.

(C) Notwithstanding subparagraph (A), parts 1 and 4 of this subtitle, and the preceding sections of this part to the extent they govern matters which are governed by the provisions of such parts 1 and 4, shall supersede the Hawaii Prepaid Health Care Act (as in effect on or after January 14, 1983), but the Secretary may enter into cooperative arrangements under this paragraph and section 1136 of this title with officials of the State of Hawaii to assist them in effectuating the policies of provisions of such Act which are superseded by such parts 1 and 4 and the preceding sections of this part.

(6)(A) Notwithstanding any other provision of this section--

(i) in the case of an employee welfare benefit plan which is a multiple employer welfare arrangement and is fully insured (or which is a multiple employer welfare arrangement subject to an exemption under subparagraph (B)), any law of any State which regulates insurance may apply to such arrangement to the extent that such law provides--

(I) standards, requiring the maintenance of specified levels of reserves and specified levels of contributions, which any such plan, or any trust established under such a plan, must meet in order to be considered under such law able to pay benefits in full when due, and

(II) provisions to enforce such standards, and

(ii) in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement, in addition to this subchapter, any law of any State which regulates insurance may apply to the extent not inconsistent with the preceding sections of this subchapter.

(B) The Secretary may, under regulations which may be prescribed by the Secretary, exempt from subparagraph (A)(ii), individually or by class, multiple employer welfare arrangements which are not fully insured. Any such exemption may be granted with respect to any arrangement or class of arrangements only if such arrangement or each arrangement which is a member of such class meets the requirements of section 1002(1) and section 1003 of this title necessary to be considered an employee welfare benefit plan to which this subchapter applies.

(C) Nothing in subparagraph (A) shall affect the manner or extent to which the provisions of this subchapter apply to an employee welfare benefit plan which is not a multiple employer welfare arrangement and which is a plan, fund, or program participating in, subscribing to, or otherwise using a multiple employer welfare arrangement to fund or administer benefits to such plan's participants and beneficiaries.

(D) For purposes of this paragraph, a multiple employer welfare arrangement shall be considered fully insured only if the terms of the arrangement provide for benefits the amount of all of which the Secretary determines are guaranteed under a contract, or policy of insurance, issued by an insurance company, insurance service, or insurance organization, qualified to conduct business in a State.

(7) Subsection (a) shall not apply to qualified domestic relations orders (within the meaning of section 1056(d)(3)(B)(i) of this title), qualified medical child support orders (within the meaning of section 1169(a)(2)(A) of this title), and the provisions of law referred to in section 1169(a)(2)(B)(ii) of this title to the extent they apply to qualified medical child support orders.

(8) Subsection (a) of this section shall not be construed to preclude any State cause of action--

(A) with respect to which the State exercises its acquired rights under section 1169(b)(3) of this title with respect to a group health plan (as defined in section 1167(1) of this title), or

(B) for recoupment of payment with respect to items or services pursuant to a State plan for medical assistance approved under title XIX of the Social Security Act which would not have been payable if such acquired rights had been executed before payment with respect to such items or services by the group health plan.

(9) For additional provisions relating to group health plans, see section 1191 of this title.

(c) Definitions

For purposes of this section:

(1) The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) The term "State" includes a State, any political subdivisions thereof, or any agency or instrumentality of either, which purports to regulate, directly or indirectly, the terms and conditions of employee benefit plans covered by this subchapter.

(d) Alteration, amendment, modification, invalidation, impairment, or supersedure of any law of the United States prohibited

Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.

(e) Automatic contribution arrangements

(1) Notwithstanding any other provision of this section, this subchapter shall supersede any law of a State which would directly or indirectly prohibit or restrict the inclusion in any plan of an automatic contribution arrangement. The Secretary may prescribe regulations which would establish minimum standards that such an

arrangement would be required to satisfy in order for this subsection to apply in the case of such arrangement.

(2) For purposes of this subsection, the term "automatic contribution arrangement" means an arrangement--

(A) under which a participant may elect to have the plan sponsor make payments as contributions under the plan on behalf of the participant, or to the participant directly in cash,

(B) under which a participant is treated as having elected to have the plan sponsor make such contributions in an amount equal to a uniform percentage of compensation provided under the plan until the participant specifically elects not to have such contributions made (or specifically elects to have such contributions made at a different percentage), and

(C) under which such contributions are invested in accordance with regulations prescribed by the Secretary under section 1104(c)(5) of this title.

(3)(A) The plan administrator of an automatic contribution arrangement shall, within a reasonable period before such plan year, provide to each participant to whom the arrangement applies for such plan year notice of the participant's rights and obligations under the arrangement which--

(i) is sufficiently accurate and comprehensive to apprise the participant of such rights and obligations, and

(ii) is written in a manner calculated to be understood by the average participant to whom the arrangement applies.

(B) A notice shall not be treated as meeting the requirements of subparagraph (A) with respect to a participant unless--

(i) the notice includes an explanation of the participant's right under the arrangement not to have elective contributions made on the participant's behalf (or to elect to have such contributions made at a different percentage),

(ii) the participant has a reasonable period of time, after receipt of the notice described in clause (i) and before the first elective contribution is made, to make such election, and

(iii) the notice explains how contributions made under the arrangement will be invested in the absence of any investment election by the participant.

42 U.S.C. §1395w-26(b)(3). Establishment of standards

(b) Establishment of other standards

(3) Relation to State laws

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 MA plans which are offered by MA organizations under this part.

42 U.S.C. §1395w-112(g). Requirements for and contracts with prescription drug plan (PDP) sponsors

(g) Prohibition of State imposition of premium taxes; relation to State laws

The provisions of sections 1395w-24(g) and 1395w-26(b)(3) of this title shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

36 Okla Stat. §6958. Short title – Patient's Right to Pharmacy Choice Act

This act shall be known and may be cited as the "Patient's Right to Pharmacy Choice Act".

36 Okla Stat. §6959. Purpose of act

The purpose of the Patient's Right to Pharmacy Choice Act is 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.

36 Okla Stat. §6960. Definitions

1. "Health insurer" means any corporation, association, benefit society, exchange, partnership or individual licensed by the Oklahoma Insurance Code;

2. "Health insurer payor" means a health insurance company, health maintenance organization, union, hospital and medical services organization or any entity providing or administering a self-funded health benefit plan;

3. "Mail-order pharmacy" means a pharmacy licensed by this state that primarily dispenses and delivers covered drugs via common carrier;

4. "Pharmacy benefits manager" or "PBM" means a person that performs pharmacy benefits management and any other person acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management for a managed-care company, nonprofit hospital, medical service organization, insurance company, third-party payor or a health program administered by a department of this state;

5. "Provider" means a pharmacy, as defined in Section 353.1 of Title 59 of the Oklahoma Statutes or an agent or representative of a pharmacy;

6. "Retail pharmacy network" means retail pharmacy providers contracted with a PBM in which the pharmacy primarily fills and sells prescriptions via a retail, storefront location;

7. "Rural service area" means a five-digit ZIP code in which the population density is less than one thousand (1,000) individuals per square mile;

8. “Spread pricing” means a prescription drug pricing model utilized by a pharmacy benefits manager in which the PBM charges a health benefit plan a contracted price for prescription drugs that differs from the amount the PBM directly or indirectly pays the pharmacy or pharmacist for providing pharmacy services;

9. “Suburban service area” means a five-digit ZIP code in which the population density is between one thousand (1,000) and three thousand (3,000) individuals per square mile; and

10. “Urban service area” means a five-digit ZIP code in which the population density is greater than three thousand (3,000) individuals per square mile.

36 Okla Stat. §6961. Retail pharmacy network 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.

C. Pharmacy benefits managers shall not require patients to use pharmacies that are directly or indirectly owned by the pharmacy benefits manager, including all regular prescriptions, refills or specialty drugs regardless of day supply.

D. Pharmacy benefits managers shall not in any manner on any material, including but not limited to mail and ID cards, include the name of any pharmacy, hospital or other providers unless it specifically lists all pharmacies, hospitals and providers participating in the preferred and nonpreferred pharmacy and health networks.

36 Okla Stat. §6962. Compliance review

A. The Attorney General shall review and approve retail pharmacy network access for all pharmacy benefits managers (PBMs) to ensure compliance with Section 6961 of this title.

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

1. Cause or knowingly permit the use of advertisement, promotion, solicitation, representation, proposal or offer that is untrue, deceptive or misleading;

2. Charge a pharmacist or pharmacy a fee related to the adjudication of a claim including without limitation a fee for:

a. the submission of a claim,

b. enrollment or participation in a retail pharmacy network, or

c. the development or management of claims processing services or claims payment services related to participation in a retail pharmacy network;

3. Reimburse a pharmacy or pharmacist in the state an amount less than the amount that the PBM reimburses a pharmacy owned by or under common ownership with a PBM for providing the same covered services. The reimbursement amount paid to the pharmacy shall be equal to the reimbursement amount calculated on a per-unit basis using the same generic product identifier or generic code number paid to the PBM-owned or PBM-affiliated pharmacy;

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;

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;

6. Retroactively deny or reduce reimbursement for a covered service claim after returning a paid claim response as part of the adjudication of the claim, unless:

a. the original claim was submitted fraudulently, or

b. to correct errors identified in an audit, so long as the audit was conducted in compliance with Sections 356.2 and 356.3 of Title 59 of the Oklahoma Statutes;

7. Fail to make any payment due to a pharmacy or pharmacist for covered services properly rendered in the event a PBM terminates a provider from a pharmacy benefits manager network;

8. Conduct or practice spread pricing, as defined in Section 1 of this act, 1 in this state; or

9. Charge a pharmacist or pharmacy a fee related to participation in a retail pharmacy network including but not limited to the following:

a. an application fee,

b. an enrollment or participation fee,

c. a credentialing or re-credentialing fee,

d. a change of ownership fee, or

e. a fee for the development or management of claims processing services or claims payment services.

C. The prohibitions under this section shall apply to contracts between pharmacy benefits managers and providers for participation in retail pharmacy networks.

1. A PBM contract shall:

a. not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug from informing, or penalize such pharmacy for informing, an individual of any differential between the individual's out-of-pocket cost or coverage with respect to acquisition of the drug and the amount an individual would pay to purchase the drug directly, and

b. ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, with respect to such plan or coverage, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing, or penalize such pharmacy for informing, a covered individual of any differential between the individual's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would

pay for acquisition of the drug without using any health plan or health insurance coverage.

2. A pharmacy benefits manager's contract with a provider shall not prohibit, restrict or limit disclosure of information to the Attorney General, law enforcement or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefits manager's compliance with the requirements under the Patient's Right to Pharmacy Choice Act.

D. A pharmacy benefits manager shall:

1. Establish and maintain an electronic claim inquiry processing system using the National Council for Prescription Drug Programs' current standards to communicate information to pharmacies submitting claim inquiries;

2. Fully disclose to insurers, self-funded employers, unions or other PBM clients the existence of the respective aggregate prescription drug discounts, rebates received from drug manufacturers and pharmacy audit recoupments;

3. Provide the Attorney General, insurers, self-funded employer plans and unions unrestricted audit rights of and access to the respective PBM pharmaceutical manufacturer and provider contracts, plan utilization data, plan pricing data, pharmacy utilization data and pharmacy pricing data;

4. Maintain, for no less than three (3) years, documentation of all network development activities including but not limited to contract

negotiations and any denials to providers to join networks. This documentation shall be made available to the Attorney General upon request;

5. Report to the Attorney General, on a quarterly basis for each health insurer payor, on the following information:

a. the aggregate amount of rebates received by the PBM,

b. the aggregate amount of rebates distributed to the appropriate health insurer payor,

c. the aggregate amount of rebates passed on to the enrollees of each health insurer payor at the point of sale that reduced the applicable deductible, copayment, coinsure or other cost sharing amount of the enrollee,

d. the individual and aggregate amount paid by the health insurer payor to the PBM for pharmacy services itemized by pharmacy, drug product and service provided, and

e. the individual and aggregate amount a PBM paid a provider for pharmacy services itemized by pharmacy, drug product and service provided.

36 Okla Stat. §6963. Health insurer to monitor activities and ensure compliance

A. A health insurer shall be responsible for monitoring all activities carried out by, or on behalf of, the health insurer under the Patient's Right to Pharmacy Choice Act, and for ensuring that all requirements of this act are met.

B. Whenever a health insurer contracts with another person to perform activities required under this act, the health insurer shall be responsible for monitoring the activities of that person with whom the health insurer contracts and for ensuring that the requirements of this act are met.

C. An individual may be notified at the point of sale when the cash price for the purchase of a prescription drug is less than the individual's copayment or coinsurance price for the purchase of the same prescription drug.

D. A health insurer or pharmacy benefits manager (PBM) shall not restrict an individual's choice of in-network provider for prescription drugs.

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.

F. A health insurer, pharmacy or PBM shall adhere to all Oklahoma laws, statutes and rules when mailing, shipping and/or causing to be mailed or shipped prescription drugs into the State of Oklahoma.

36 Okla Stat. §6964. Formulary to identify drugs that offer greatest value

A. A health insurer's pharmacy and therapeutics committee (P&T committee) shall establish a formulary, which shall be a list of prescription drugs,

both generic and brand name, used by practitioners to identify drugs that offer the greatest overall value.

B. A health insurer shall prohibit conflicts of interest for members of the P&T committee.

1. A person may not serve on a P&T committee if the person is currently employed or was employed within the preceding year by a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor.

2. A health insurer shall require any member of the P&T committee to disclose any compensation or funding from a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor. Such P&T committee member shall be recused from voting on any product manufactured or sold by such pharmaceutical manufacturer, developer, labeler, wholesaler or distributor.

36 Okla Stat. §6965. Power to investigate

A. The Attorney General shall have power and authority to examine and investigate the affairs of every pharmacy benefits manager (PBM) engaged in pharmacy benefits management in this state in order to determine whether such entity is in compliance with the Patient's Right to Pharmacy Choice Act.

B. All PBM files and records shall be subject to examination by the Attorney General or by duly appointed designees. The Attorney General, authorized employees and examiners shall have access to any of a PBM's files and records that may relate to a particular complaint under investigation or to an inquiry or examination by the Attorney General.

C. Every officer, director, employee or agent of the PBM, upon receipt of any inquiry from the Attorney General shall, within twenty (20) days from the date the inquiry is sent, furnish the Attorney General with an adequate response to the inquiry.

D. When making an examination under this section, the Attorney General may retain subject matter experts, attorneys, appraisers, independent actuaries, independent certified public accountants or an accounting firm or individual holding a permit to practice public accounting, certified financial examiners or other professionals and specialists as examiners, the cost of which shall be borne by the PBM that is the subject of the examination.

36 Okla Stat. §6966. Patient's Right to Pharmacy Choice Commission – Complaints alleging violations

A. There is hereby created the Patient's Right to Pharmacy Choice Commission.

B. The Insurance Commissioner shall provide for the receiving and processing of individual complaints alleging violations of the provisions of the Patient's Right to Pharmacy Choice Act, the Pharmacy Audit Integrity Act and Sections 357 through 360 of Title 59 of the Oklahoma Statutes.

C. The Commissioner shall have the power and authority to review complaints, subpoena witnesses and records, initiate prosecution, reprimand, require restitution, approve and sign settlement agreements, place on probation, suspend, revoke and/or levy fines not to exceed Ten Thousand Dollars ($10,000.00) for each count for which any pharmacy benefits manager (PBM) has violated a provision of the Patient's Right

to Pharmacy Choice Act, the Pharmacy Integrity Audit Act and Sections 357 through 360 of Title 59 of the Oklahoma Statutes. Any violation that cannot be settled shall go to a hearing before the Pharmacy Choice Commission.

The Pharmacy Choice Commission shall hold hearings and may reprimand, require restitution, place on probation, suspend, revoke or levy fines not to exceed Ten Thousand Dollars ($10,000.00) for each count that a PBM has violated a provision of the Patient's Right to Pharmacy Choice Act, the Pharmacy Integrity Audit Act or Sections 357 through 360 of Title 59 of the Oklahoma Statutes. The Insurance Commissioner or the Pharmacy Choice Commission may impose as part of any disciplinary action restitution to the provider or patient and the payment of costs expended by the Pharmacy Choice Commission or Insurance Department for any legal fees and costs including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees. The Insurance Commissioner or the Pharmacy Choice Commission may review violations singularly or in combination, as the nature of the violation requires.

D. The Pharmacy Choice Commission shall consist of seven (7) persons who shall serve as hearing examiners and shall be appointed as follows:

1. Two persons who are members in good standing of the Oklahoma Pharmacists Association, who shall be appointed by the Oklahoma Board of Pharmacy; a list of eligible appointees shall be sent annually to the Oklahoma Board of Pharmacy by the Oklahoma Pharmacists Association;

2. Two consumer members not employed by or professionally related to the insurance, pharmacy or PBM industry appointed by the Office of the Governor;

3. Two persons representing the PBM or insurance industry appointed by the Insurance Commissioner; and

4. One person representing the Office of the Attorney General appointed by the Attorney General.

E. Pharmacy Choice Commission members first appointed shall serve the initial term staggered as follows: the two members appointed by the Office of the Governor shall serve for one (1) year, the two members appointed by the Insurance Commissioner shall serve for two (2) years, the two members appointed by the Oklahoma Pharmacists Association shall serve for two (2) years and the one member appointed by the Attorney General shall serve for three (3) years. Subsequent terms shall be for five (5) years. The terms of the members shall expire on the thirtieth day of June of the year designated for the expiration of the term for which appointed, but the member shall serve until a qualified successor has been duly appointed. Except for the initial term to establish the Pharmacy Choice Commission, no person shall be appointed to serve more than two consecutive terms. The Commission shall annually elect a chair and vice-chair from among its members. There shall be no limit on the number of times a member may serve as chair or vice-chair. A quorum shall consist of no less than five members and shall be required for the Commission to hold a hearing.

F. Hearings shall be held in the Insurance Commissioner's offices or at such other place as the Insurance Commissioner may deem convenient.

G. The Insurance Commissioner shall issue and serve upon the PBM a statement of the charges and a notice of hearing in accordance with the Administrative Procedures Act, Sections 250 through 323 of Title 75 of the Oklahoma Statutes. A hearing shall be set within thirty (30) days and notice of that hearing date shall be provided to the complainant within a reasonable time period.

H. At the time and place fixed for a hearing, the PBM shall have an opportunity to be heard and to show cause why the Pharmacy Choice Commission should not revoke or suspend the PBM's license and levy administrative fines for each violation. Upon good cause shown, the Commission shall permit any complainant or a duly authorized representative of the complainant to intervene, appear and be heard at the hearing by counsel or in person.

I. All hearings will be public and held in accordance with, and governed by, Sections 250 through 323 of Title 75 of the Oklahoma Statutes.

J. The Insurance Commissioner, upon written request reasonably made by the complainant or the licensed PBM affected by the hearing and at such expense of the requesting party, shall cause a full stenographic record of the proceedings to be made by a competent court reporter.

K. If the Insurance Commissioner or Pharmacy Choice Commission determines that a PBM has engaged in violations of the Patient's Right to Pharmacy Choice Act, the Pharmacy Integrity Act or

Sections 357 through 360 of Title 59 of the Oklahoma Statutes with such frequency as to indicate a general business practice and that such PBM should be subjected to closer supervision with respect to such practices, the Insurance Commissioner or the Pharmacy Choice Commission may require the PBM to file a report at such periodic intervals as the Insurance Commissioner or the Pharmacy Choice Commission deems necessary.

36 Okla Stat. §6966.1. Violations – Penalties -- Hearings

A. The Insurance Commissioner may censure, suspend, revoke or refuse to issue or renew a license of or levy a civil penalty against any person licensed under the insurance laws of this state for any violation of the Patient's Right to Pharmacy Choice Act, Section 6958 et seq. of this title.

B. 1. If the Attorney General finds, after notice and opportunity for hearing, that a pharmacy benefits manager (PBM) violated one or more provisions of the Patient's Right to Pharmacy Choice Act, the Pharmacy Audit Integrity Act[1] or the provisions of Sections 357 through 360 of Title 59 of the Oklahoma Statues, the Attorney General may recommend the PBM be censured, his or her license may be suspended or revoked and a penalty or remedy authorized by this act may be imposed. If the Attorney General makes such recommendation, the Commissioner shall take the recommended action.

[1] Title 59, §§ 356 to 356.5.

2. In addition to or in lieu of any censure, suspension or revocation of a license, a PBM may be subject to a civil fine of not less than One Hundred Dollars ($100.00) and not greater than Ten Thousand Dollars ($10,000.00) for each violation of the provisions of the Patient's Right to Pharmacy Choice Act, the Pharmacy Audit Integrity Act or the provisions of Sections 357 through 360 of Title 59 of the Oklahoma Statues, following notice and an opportunity for a hearing.

C. Notwithstanding whether the license of a PBM has been issued, suspended, revoked, surrendered or lapsed by operation of law, the Attorney General is hereby authorized to enforce the provisions of the Patient's Right to Pharmacy Choice Act and impose any penalty or remedy authorized under the act against a PBM under investigation for or charged with a violation of the Patient's Right to Pharmacy Choice Act, the Pharmacy Audit Integrity Act, the provisions of Sections 357 through 360 of Title 59 of the Oklahoma Statues or any provision of the insurance laws of this state.

D. Each day that a PBM conducts business in this state without a license from the Insurance Department shall be deemed a violation of the Patient's Right to Pharmacy Choice Act.

E. 1. All hearings conducted by the Office of the Attorney General pursuant to this section shall be public and held in accordance with the Administrative Procedures Act.[2]

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[2] Title 75, § 250 et seq.

2. Hearings shall be held at the office of the Attorney General or any other place the Attorney General may deem convenient.

3. The Attorney General, upon written request from a PBM affected by the hearing, shall cause a full stenographic record of the proceedings to be made by a competent court reporter. This record shall be at the expense of the PBM.

4. The ordinary fees and costs of the hearing examiner appointed pursuant to Section 319 of this title may be assessed by the hearing examiner against the respondent unless the respondent is the prevailing party.

F. Any PBM whose license has been censured, suspended, revoked or denied renewal or who has had a fine levied against him or her shall have the right of appeal from the final order of the Attorney General, pursuant to Section 318 et seq. of Title 75 of the Oklahoma Statutes.

G. If the Attorney General determines, based upon an investigation of complaints, that a PBM has engaged in violations of the provisions of the Patient's Right to Pharmacy Choice Act with such frequency as to indicate a general business practice, and that the PBM should be subjected to closer supervision with respect to those practices, the Attorney General may require the PBM to file a report at any periodic interval the Attorney General deems necessary.

36 Okla Stat. §6967. Confidentiality and privilege of information

A. Documents, evidence, materials, records, reports, complaints or other information in the possession or

control of the Insurance Department or the Right to Pharmacy Choice Commission that are obtained by, created by or disclosed to the Insurance Commissioner, Pharmacy Choice Commission or any other person in the course of an evaluation, examination, investigation or review made pursuant to the provisions of the Patient's Right to Pharmacy Choice Act, the Pharmacy Integrity Audit Act or Sections 357 through 360 of Title 59 of the Oklahoma Statutes shall be confidential by law and privileged, shall not be subject to open records request, shall not be subject to subpoena and shall not be subject to discovery or admissible in evidence in any private civil action if obtained from the Insurance Commissioner, the Pharmacy Choice Commission or any employees or representatives of the Insurance Commissioner.

B. Nothing in this section shall prevent the disclosure of a final order issued against a pharmacy benefits manager by the Insurance Commissioner or Pharmacy Choice Commission. Such orders shall be open records.

C. In the course of any hearing made pursuant to the provisions of the Patient's Right to Pharmacy Choice Act, the Pharmacy Integrity Audit Act or Sections 357 through 360 of Title 59 of the Oklahoma Statutes, nothing in this section shall be construed to prevent the Insurance Commissioner or any employees or representatives of the Insurance Commissioner from presenting admissible documents, evidence, materials, records, reports or complaints to the adjudicating authority.

36 Okla Stat. §6968. Severability

If any one or more provision, section, subsection, sentence, clause, phrase or word of this act or the application hereof to any person or circumstance is found to be unconstitutional, the same is hereby declared to be severable and the balance of this act shall remain effective notwithstanding such unconstitutionality. The Legislature hereby declares that it would have passed this act, and each provision, section, subsection, sentence, clause, phrase or word thereof, irrespective of the fact that any one or more provision, section, subsection, sentence, clause, phrase, or word be declared unconstitutional.