COMPLIANCE ALERT

Circuit Court Holds ERISA Preempts State PBM Law



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Quick Facts

- The Oklahoma Patient's Right to Pharmacy Choice Act (Oklahoma Act), passed in 2019, contains specific requirements for pharmacy benefit managers (PBMs) such as requirements for network access standards, mail-order pharmacies, advertisement and solicitation, claim reimbursement, and certain rights of plan participants.
- The Oklahoma Act was challenged as preempted by federal laws Employee Retirement Income Security Act (ERISA) and Medicare Part D.
- In August 2023, the 10th Circuit Court of Appeals held that the Oklahoma Act is preempted by both ERISA and Medicare Part D.
- Considering this ruling and the 2020 Supreme Court ruling in *Rutledge v. PCMA*, it remains difficult to predict the future of other state PBM legislation.

Background

In 2019, Oklahoma State Senator Greg McCortney (R) was the principal author of the Oklahoma Patient's Right to Pharmacy Choice Act (Oklahoma Act), which was later signed into law by Governor Kevin Stitt (R). The purpose of the law 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." The law intends to protect Oklahoma (OK) pharmacies from self-serving practices of pharmacy benefit managers (PBMs) that can be harmful to rural and independent pharmacies.

The Oklahoma Act was later challenged by the Pharmaceutical Care Management Association (PCMA), a trade association that represents PBMs as preempted by both ERISA and Medicare Part D. On April 4, 2022, United States District Court in the Western District of Oklahoma (District Court) Judge, Bernard Jones issued an order based on a motion for summary judgment filed by PCMA in the case *Pharmaceutical Care Management Association (PCMA) v. Mulready*, (*Mulready*) granting the motion for summary judgment in part and denying the motion in part.

PCMA asserted in its motion that the Oklahoma Act regulates "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." They further assert that the provisions of the Oklahoma Act have an impermissible connection with ERISA plans and thereby should be preempted. However, the court found that PCMA did not sufficiently show that the Oklahoma Act is preempted by ERISA and denied the motion for summary judgment regarding ERISA preemption.

On May 16, 2023, the United States Court of Appeals for the Tenth Circuit (10th Circuit) heard oral arguments in *PCMA v. Mulready*, after PCMA appealed the lower court ruling.



On August 15, 2023, the 10th Circuit issued its opinion, ruling in favor of PCMA. The 10th Circuit ruling focuses on preemption by both ERISA and Medicare Part D. We will primarily focus on the ERISA preemption aspect in the summary below.

The Oklahoma Act

As written, the Oklahoma Act has specific requirements for PBMs including, requirements about network access standards, cost-sharing, and contract requirements amongst other requirements. The 10th Circuit opinion breaks down the various requirements into four segments, the Access Standards, the Discount Prohibition, the Any Willing Provider (AWP) Provision, and the Probation Prohibition. The 10th Circuit holds that the first three segments listed below are preempted by ERISA, as described here in more detail.

Access Standards

The Oklahoma Act outlines specific geographical territory requirements that PBMs must adhere to for preferred network access, broken down by urban, suburban, and rural territories. Additionally, the Oklahoma Act states that mail-order pharmacies cannot be used to meet retail pharmacy access standards.

Discount Prohibition

This provision bars PBMs from promoting in-network pharmacies to beneficiaries by offering costsharing discounts, such as reduced copayments.

AWP Provision

This provision states that PBMs may not deny a pharmacy the opportunity to participate in any preferred pharmacy network if the pharmacy is willing to accept the terms and conditions for the preferred status set by the PBM.

Probation Prohibition

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. Note that regarding this provision, the 10th Circuit held that this provision is not preempted by ERISA because of its de minimis effect on plan benefit design.

The ERISA Preemption Rule

The "supremacy clause" of the U.S. Constitution allows federal laws to preempt state laws. ERISA is one such law. ERISA has an express preemption provision, which says that a state law that "relates to" an ERISA plan is preempted by federal law. There is an exception for state laws that regulate insurance, banking, or securities as provided for under the "saving clause" that allows insurers to be regulated by state law, meaning that states may regulate the insurers that provide services to an insurance plan, but not an employee benefit plan itself. The intent of ERISA preemption is for employee benefit plans to maintain plan uniformity across the country.

Courts use a test to determine whether a state law "relates to" an ERISA plan. As provided in §514, ERISA "shall supersede any and all State laws insofar as they may now and hereafter relate to any employee benefit plan". A state law "relates to" ERISA if it has a connection with or reference to the plan. A state law need not directly impact an ERISA plan to be preempted, but the more impact the law has on the central matter of plan design and administration the more likely it is to interfere with national plan uniformity and therefore the more likely it is to be preempted. Laws that have an incidental impact on a plan are less likely to be preempted.



ERISA Preemption of State PBM Laws

The Oklahoma Act is one of many across the United States currently being challenged on an ERISA preemption basis. Courts have largely decided against ERISA preemption in favor of the state laws, using a 2020 Supreme Court decision in the case *Rutledge v. PCMA*, (*Rutledge*) as precedent. In *Rutledge*, an Arkansas law required PBMs to reimburse pharmacies at a rate that, at the minimum, reimburses what the pharmacy paid for the drug from a wholesaler. In that case, the Supreme Court of the United States (SCOTUS) ruled that the Arkansas law that regulated the relationship between PBMs and pharmacies was not preempted by ERISA for two reasons. First, there is no impermissible connection to ERISA because the law is a form of cost regulation, and while the law may increase ERISA plan costs, it does not force plans to adopt any particular type of coverage and the cost increase would not impact plan choices. Second, the law does not "relate to" an ERISA plan because the law governs PBMs generally whether or not they manage ERISA plans.

Since the *Rutledge* decision, more than 100 PBM laws have been introduced in state legislatures around the country. Because the laws are different, applying the precedent from *Rutledge* is difficult, and predicting the outcome of an ERISA preemption claim is nearly impossible.

10th Circuit Opinion

On August 15, 2023, only three months after hearing oral arguments, the 10th Circuit Court held in a unanimous decision, that the Oklahoma Act is preempted by ERISA. The court holds that because the Oklahoma Act infers with matters that are central to benefit plan administration, it restricts the way ERISA plans structure their pharmacy networks. In its opinion, the court stated, "Though the Act avoids mentioning ERISA plans or Medicare Part D plans by name, it encompasses these plans by striking at the heart of the network and benefit design."

ERISA Preemption

In its August opinion, the 10th Circuit held that the Oklahoma Act's three network restrictions are preempted by ERISA because network restrictions affect benefit structures and therefore affect an element of plan structure or benefit design. Specifically:

- The Oklahoma Act's network access standards determine which pharmacies must be included in a PBM's network.
- The Oklahoma Act's willing provider provision requires that pharmacies be invited to join the PBM preferred network.
- The Oklahoma Act's discount prohibition requires that cost-sharing and copayments be the same for all PBMs in-network pharmacies, regardless of whether they are retail or mail order, standard or preferred.

The Court states:

"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."



Reference to the Rutledge Decision

In its opinion, the 10th Circuit refers to *Rutledge*, stating that they find the Oklahoma law to be preempted by ERISA because, unlike *Rutledge*, the restrictions on PBMs in the Oklahoma law do more than increase costs. The court states:

"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. They impede PBMs from offering plans for 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."

Summary

According to the 10th Circuit, "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."

It remains to be seen how this opinion will affect the future of other state PBM legislation. At this juncture, this is a major win for group health plans and Medicare Part D plans that prefer the simplicity of following a uniform set of requirements.

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