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ERISA Preemption Reaffirmed: Tenth Circuit Limits State PBM Regulation

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On August 15, 2023, the Tenth Circuit issued its much-anticipated decision in *PCMA v. Mulready*, rejecting Oklahoma’s position that its pharmacy network requirements were not preempted by ERISA.^[1] See our prior alert [here](#). *Mulready* has been closely watched by plan sponsors, pharmacy benefit managers, health insurance issuers, and third-party administrators because its outcome touches on not only state regulation of pharmacy benefit managers but also preemption under the Employee Retirement Income Security Act (“ERISA”) more broadly. Below, we provide an overview of *Mulready* and discuss what may happen next.

ERISA Preemption

ERISA’s broad preemption language has historically prevented states from regulating ERISA-covered plans if the state law included an impermissible reference to or had an impermissible connection with the ERISA-covered plan. The courts have found that an impermissible reference to an ERISA plan arises when the state law directly regulates the plan by its terms or where the existence of the ERISA plan is necessary for the operation of the state law. On the other hand, an impermissible connection with a plan can arise when the state law dictates the benefit design of the plan, upsets nationally uniform plan administration, or imposes parallel or additional requirements on central matters of plan administration governed by ERISA. The Supreme Court most recently refined its preemption jurisprudence in *Rutledge*^[2] in holding that a state law that regulated PBM costs, thereby imposing indirect economic burdens on ERISA-covered plans, was not preempted because the added economic burden did not bind plan sponsors to a certain benefit design.

Background

In *Mulready*, PCMA (the Pharmaceutical Care Management Association) challenged an Oklahoma law that regulated PBMs in various ways, arguing that the law was preempted by ERISA.^[3] In its decision, the federal district court in Oklahoma found

that none of the Oklahoma law provisions were preempted by ERISA. The district court’s opinion, which lacked significant detail, characterized each of the provisions of the Oklahoma law as either unrelated to an ERISA plan because the law is directed at PBMs or

as simply altering the incentives ERISA plans face without dictating plan design, analogizing the Oklahoma law's pharmacy network provisions to the cost regulation at issue in *Rutledge*.

PCMA appealed the district court's decision to the Tenth Circuit. The appeal focused on four provisions of the Oklahoma law: (1) a network adequacy provision imposing geographic requirements; (2) a provision prohibiting denying, limiting, or terminating a contract with a pharmacy because a pharmacist employed with the pharmacy is on probationary status with the State Board of Pharmacy; (3) an "any willing provider" or "AWP" provision requiring the admission of pharmacies that meet network requirements; and (4) a provision prohibiting requiring or incentivizing (including via discounts in cost-sharing or reduction in copay) the use of a particular in-network pharmacy.

During a briefing on the merits of the appeal, the Tenth Circuit panel hearing the appeal invited the Department of Justice ("DOJ"), in consultation with the Department of Labor ("DOL"), to file an amicus brief laying out its views on preemption of the four provisions. Significantly, DOJ argued that, while three of the four provisions had an impermissible connection with ERISA plans such that preemption would apply, those provisions should be saved from preemption by ERISA as applied to PBMs because the provisions met the *Miller*^[4] test—which applies ERISA's "Savings Clause" to protect states' historical regulatory authority over insurers and insurance policies. In addition to a broad reading of the Savings Clause, DOJ argued that ERISA's "Deemer Clause" (which historically permits self-insured plans to design their plans without regard to state law even if they utilize third-party entities to administer their plans) would only ensure preemption if the state law applied directly to the self-insured ERISA plan, as opposed to its service providers, like PBMs. This argument represents a novel position for DOJ and DOL in terms of their views of ERISA preemption.

The Tenth Circuit's Decision

The *Mulready* court squarely rejected the argument that ERISA preemption cannot reach the Oklahoma law simply because it regulates PBMs and not ERISA plans. The court rejected Oklahoma's argument based on three factors: (1) PCMA argued for "connection-with" preemption, which concerns "the nature of the effect of the state law on ERISA plans," and not for "reference-to" preemption, which only concerns laws that specifically target ERISA plans; (2) the Supreme Court itself had never recognized a distinction between ERISA plans and third parties as to connection-with preemption in its caselaw on the issue; and (3) PBMs "predominate in the prescription-drug-benefits field," and it was therefore "practically impossible for an ERISA plan to manage its own pharmacy benefits and avoid using a PBM."

The *Mulready* court then bifurcated its analysis: it considered three of the challenged provisions as a group (the access standard, discount prohibition, and the AWP provision) it referred to as the "Network Restrictions," and it considered the probation provision by itself.

The court found that the Network Restrictions impermissibly mandate benefit structures and therefore prevent the uniform national application of ERISA plan terms. Specifically, the court said that:

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 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.**^[5]

(emphasis added). The court specifically acknowledged that its ruling complied with the holding of *Rutledge* because the Network Restrictions "home in on PBM pharmacy networks...[a]nd...impede PBMs from offering plans some of the most fundamental network designs, such as preferred pharmacies, mail-order pharmacies, and specialty pharmacies"^[6] thereby imposing not just costs, but dictating plan design as well.

The court analyzed the probation prohibition and found that it too mandated benefit design and was thus preempted. The court specifically rejected Oklahoma's argument that laws with a "de minimis" effect on ERISA plan design were exempted from preemption because the caselaw it supported its argument with applied to "de minimis" economic effects, not de minimis effects on the design of the plan. The court went on, stating "the Probation Prohibition acts just like the network restrictions—dictating which pharmacies must be included in a plan's PBM network."

Finally, the court declined to address whether the Savings Clause applied because it found that Oklahoma had waived the argument by failing to raise it. Consequently, the *Mulready* court did not squarely address the issues raised by DOJ in its amicus brief.

What Comes After *Mulready*?

Following the Tenth Circuit's decision, the case has been remanded to the district court that originally heard the case. Pending the outcome of the district court proceedings, Oklahoma is likely to request that the Tenth Circuit rehear the case, and/or pursue an appeal to the Supreme Court. The outcome of that appeal, if accepted, is difficult to predict with certainty, but our reading of the *Mulready* decision is that it is a conservative, well-reasoned application of prior precedent. Had the Tenth Circuit reached an opposite conclusion, it would have been a sea change in the world of both ERISA preemption and state regulation of ERISA plans.

We will continue to monitor statements by DOJ/DOL to see if their amicus brief represents a long-term change in their position on ERISA preemption. In practical terms, a number of states have recently adopted PBM regulations that impose requirements similar to Oklahoma's, with some imposing much broader regulatory regimes. While the Tenth Circuit opinion reaffirms the breadth of ERISA preemption, we expect states to continue to seek broader regulation of plans through their service providers, especially for states outside of the Tenth Circuit where the Court's ruling does not have binding effect. As a result, plan sponsors and plan service providers should continue to monitor state legislative and enforcement activity as this newly unsettled area of the law continues to develop.