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State Regulation of Pharmacy Benefit Managers: Tenth Circuit Holds That ERISA and Medicare Part D Preempt Key Parts of Oklahoma PBM Law

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On August 15, 2023, the U.S. Court of Appeals for the Tenth Circuit (the "Tenth Circuit") issued its decision in *Pharmaceutical Care Management Association (PCMA) v. Mulready,[1]* one of the first major opinions to further define the contours of states' ability to regulate pharmacy benefit managers (PBMs) relative to the federal Employee Retirement Income Security Act (ERISA) since the U.S. Supreme Court appeared to broaden states' authority in a landmark decision, *Rutledge v. Pharmaceutical Care Management Association,*[2] in 2020.

The Tenth Circuit in *Mulready* held that ERISA preempted the Oklahoma Patient's Right to Pharmacy Choice Act (the "Act") as the provisions attempted to regulate central matters of plan administration. The Tenth Circuit also held that Medicare Part D preempted a specific provision of the Act addressed by existing Medicare regulations. When read in combination with *Rutledge*, *Mulready* helps delineate the scope of permissible state regulation of PBMs. While *Mulready* might be considered a "win" for PBMs, employer plans, and Part D plans after *Rutledge*, the *Mulready* decision comes at a time when PBM scrutiny and reform occupy the forefront of health legislative priorities on both the federal and state levels.

Enacted in 1974, ERISA sets minimum standards for most voluntarily established employee benefit plans ("ERISA plans"). ERISA expressly preempts state laws that relate to ERISA plans and provides that ERISA plans are not considered "insurance" under state laws that regulate insurance.[3] However, in the years prior to *Rutledge*, stakeholders lacked a clear understanding of the extent to which ERISA limited states' ability to regulate entities, such as PBMs, that perform certain administrative activities on behalf of ERISA plans. Despite this lack of clarity, states increasingly attempted to enact restrictions on PBMs. However, in what the Tenth Circuit in *Mulready* described as "a win for States and a loss for PBMs," on December 10, 2020, the Supreme Court in *Rutledge* held that ERISA did not preempt an Arkansas law that governed PBM-

pharmacy reimbursement rates—seemingly illuminating a clearer pathway for permissible state regulation of PBMs. While 16 states enacted PBM-related legislation in 2020, the post-*Rutledge* legislative sessions in 2021 resulted in the enactment of PBM-related legislation in 32 states.[4] In total, since *Rutledge*, 41 states have enacted 113 bills that address PBM-related issues.[5]

PCMA v. Mulready

In *Mulready*, the Tenth Circuit held that ERISA preempted the Act with respect to ERISA plans and that Medicare Part D preempted the Act's Any Willing Provider Provision ("AWP Provision") with respect to Part D plans. Enacted by Oklahoma's legislature in 2019 prior to *Rutledge* 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,"[6] the Act's four key provisions targeted PBMs and their pharmacy networks. The Tenth Circuit's analysis classified these four provisions into two categories—"network restrictions" and an "integrity and quality restriction"—as summarized below:

PROVISION	OVERVIEW	*MULREADY* HOLDING
Network Restriction: Retail-Only Pharmacy-Access Standards ("Access Standards")	Requires PBMs to construct their pharmacy networks so that a certain percentage of beneficiaries live within a stipulated distance of a network and/or preferred pharmacy, with percentages and distances varying for urban, suburban, and rural areas	**PREEMPTED BY ERISA**
Network Restriction: Cost-Sharing-Discount Prohibition ("Discount Prohibition")	Prohibits restriction of an individual's choice of in-network provider, which may include a retail pharmacy or mail-order pharmacyProhibits promoting in-network pharmacies to beneficiaries using cost-share and copay reductions	**PREEMPTED BY ERISA**
Network Restriction: AWP Provision	Prohibits denying 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	**PREEMPTED BY ERISA & MEDICARE PART D**
Integrity and Quality Restriction: Probation-Based Pharmacy-Limitation Prohibition ("Probation Prohibition")	Prohibits denying, limiting, or terminating a pharmacy's contract based on the probation status of a licensed pharmacist employed by the provider	**PREEMPTED BY ERISA**

ERISA Preemption

In *Mulready*, the Tenth Circuit held that ERISA preempted the Access Standards, Discount Prohibition, AWP Provision, and Probation Prohibition. ERISA's express preemption provision states that ERISA supersedes "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[7] A state law "relate[s] to" an ERISA plan if the law has (1) a "connection with" or (2) a "reference to" an ERISA plan.[8] The Supreme Court previously identified two categories of state laws that create an impermissible "connection with" an ERISA plan: (1) laws that require benefit plans to be structured in a particular way and (2) laws with "acute, albeit indirect, economic effects" that "force an ERISA plan to adopt a certain scheme of coverage."[9] The Tenth Circuit focused most of its analysis in *Mulready* on two steps: (1) whether the Act qualified for ERISA preemption and then (2) whether the Act governed "a central matter of plan administration or interfer[ed] with nationally uniform plan administration."[10]

1. **The Tenth Circuit held that despite the Act's application to PBMs rather than to ERISA plans directly, by "function[ing] as a regulation of an ERISA plan itself," the Act was not precluded from qualifying for ERISA preemption.[11]** Building on case law and information from PCMA experts, the Tenth Circuit emphasized that a state law targeted at a third party could still qualify for ERISA preemption and that "[a]t bottom, ERISA preemption still […] rises or falls on whether the Act's PBM regulations have an impermissible connection with ERISA plans."[12] The Tenth Circuit stated that previous case law holdings—that a state's law that "bear[ed] indirectly but substantially on all insured benefit plans […] bound [ERISA plans] by proxy"[13] and that a state's law could "pierce the veil between plans and the third parties with whom those plans contract"[14]—applied "even more so to PBMs."[15] Specifically, since PBMs "predominate in the prescription-drug-benefits field" and "the vast majority of fully-insured and self-funded employee health plans engage PBMs to administer pharmacy benefits on their behalf,"[16] the Tenth Circuit stated that "a plan's choice between self-administering its benefits and using a PBM 'is in reality no choice at all.'" [17] As such, the Tenth Circuit held that the Act still qualified for ERISA preemption.
2. **The Tenth Circuit also held that the Act's provisions struck "at the heart of network and benefit design."[18]** Particularly, the network restrictions governed benefit design—which the Tenth Circuit states is "a central matter of plan administration."[19] Specifically, the network restrictions "require providers to structure benefit plans in particular ways"[20] and "prohibit employers from structuring their employee benefit plans in a certain manner."[21] The Tenth Circuit stated that, when combined, the network restrictions "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."[22] Further, the Tenth Circuit stated that "[h]owever sliced, the network restrictions 'require providers to structure benefit plans in particular ways.'"[23] The Tenth Circuit also noted that a pharmacy's network scope and differentiation are "key benefit designs for an ERISA plan."[24]

   The Tenth Circuit held that the Probation Prohibition impermissibly forced plans to adopt a particular scheme of substantive coverage. Specifically, the Tenth Circuit noted that the provision dictated which pharmacies must be included in a plan's PBM network. In effect, ERISA plans would only be permitted to use PBMs with a particular PBM network structure.[25]

Medicare Part D Preemption

When Congress established the Medicare Part D drug benefit through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Congress included a broad express preemption provision, as it did in ERISA. Specifically, the MMA states 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]."[26] Only state licensing laws and state laws relating to plan solvency are excluded from the MMA's Part D preemption provision.[27]

The Tenth Circuit in *Mulready* held that Medicare Part D preempted the AWP Provision with respect to Part D plans, citing the "unmistakably broad language" of the MMA's Part D preemption provision.[28] By prohibiting PBMs from denying any provider the opportunity to participate in any pharmacy network at preferred participation status, the Tenth Circuit held that the AWP Provision attempted to regulate Part D plans by establishing a "rule that govern[ed] PBM pharmacy networks for Part D plans."[29] Moreover, the Tenth Circuit also noted that the AWP Provision was neither a licensing law nor a law related to plan solvency.[30] The Tenth Circuit held that "Part D's standards preempt all state laws concerning Part D plans."[31]

Notably, the Tenth Circuit's Part D preemption analysis in *Mulready* represented a departure from the more precise framework applied by the Eighth Circuit in 2021 in *PCMA v. Wehbi*.[32] The Eighth Circuit in *Wehbi* upheld certain provisions of a North Dakota PBM law using a Part D preemption framework that held state laws as applied to Medicare Part D plans would be preempted "if and only if they either (1) regulate the same subject matter as a federal Medicare Part D standard (in which case they are expressly preempted), or (2) otherwise frustrate the purpose of a federal Medicare Part D standard (in which case they are impliedly preempted)."[33]

Squaring *Mulready* with *Rutledge*

As *Mulready* notes, "*Rutledge* was a win for States and a loss for PBMs, but it does not shield the Act from preemption."[12] *Mulready* does not override the gains states made in *Rutledge* with respect to ERISA preemption. Rather, the Tenth Circuit decision fits within the framework set forth by *Rutledge* and clarifies the scope of the *Rutledge* decision to more clearly define when state regulation of PBMs may be permissible under ERISA. Specifically, while the *Rutledge* decision indicated that states may enact certain laws that increase ERISA plans' costs or alter incentives, *Mulready* reinforced that states may not force ERISA plans to adopt particular administrative, network, benefit design, or substantive coverage requirements.

In *Rutledge*, PCMA challenged an Arkansas law that governed PBM-pharmacy reimbursement rates—requiring "PBMs to tether reimbursement rates to pharmacies' acquisition costs" and allowing pharmacies to decline to dispense drugs if a PBM's reimbursement rate was lower than the pharmacy's acquisition costs.[34] The Supreme Court held that Arkansas' law was "a mere cost regulation that did not have an impermissible connection with ERISA plans." Notably, it was in *Rutledge* that the Supreme Court identified the two types of state laws that represented an impermissible regulation of ERISA plans: (1) "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," and (2) laws whose "acute, albeit indirect, economic effects . . . force an ERISA plan to adopt a certain scheme of substantive coverage."[35]

As such, the holding in *Mulready* provides additional examples of impermissible state regulation of

PBMs under the framework provided in *Rutledge*. In *Rutledge*, Arkansas' law increased costs and altered incentives for ERISA plans "without forcing plans to adopt a particular scheme of substantive coverage."[36] In contrast, the Tenth Circuit in *Mulready* notes that the Act was "attempting to "govern[] a central matter of plan administration" and "interfere[] with nationally uniform plan administration."[37]

Industry Implications Following *Mulready*

Prior to *Mulready*, many stakeholders believed the *Rutledge* decision significantly weakened ERISA preemption of PBM laws and would give states nearly free reign to regulate in the space.[38] However, the *Mulready* decision affirms that ERISA preemption does, in fact, still set the stage for state regulation of PBMs. While limited to the Tenth Circuit, *Mulready* serves as a demonstration case of how other circuits could further define the contours of the *Rutledge* decision. The PBM industry has already applauded *Mulready* for confirming the "breadth of ERISA preemption, which has been the linchpin for employer- and union-sponsored benefits" and enables "multi-state businesses to offer affordable, uniform, and equitable health coverage – including for prescription drugs – for their beneficiaries, regardless of where they live."[39] *Mulready* could also be considered a win for ERISA plans that contract with PBMs since ERISA preemption is intended to reduce state-specific regulatory burdens and maintain predictability. In contrast, *Mulready*—and future decisions that adopt a similar analysis—may significantly impede states' abilities to implement similar provisions that benefit and protect pharmacies. For instance, in describing *Mulready* as "an unfortunate – and arguably errant – legal development" in a news release, the National Association of Chain Drug Stores noted the organization would continue remaining "focused on confronting PBM tactics that harm patients" as states in the Tenth Circuit would be immediately impacted by *Mulready*.[40]

As noted, the holding of *Mulready* in the Tenth Circuit will have limited effects on a nationwide scale until similar holdings trend in other circuits or the U.S. Supreme Court takes up the issue. However, in addition to monitoring state laws and federal court decisions, stakeholders should also continue monitoring potential federal legislative approaches to addressing PBM-related issues—such as those proposed in the bipartisan bills currently being debated in both chambers of Congress—which could make squaring PBM and ERISA plan issues even more complex.

ENDNOTES

[1] *PCMA v. Mulready*, No. 22-6074 (10th Cir. 2023).

[2] *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474 (2020).

[3] 29 U.S.C. § 1144.

[4] National Conference of State Legislatures, Prescription Drug State Bill Tracking Database 2015-Present (July 31, 2023).

[5] *Id.*

[6] Mulready, No. 22-6074 at 10 (quoting Okla. Stat. tit. 36, § 6959 (2019)).

[7] 29 U.S.C. § 1144(a).

[8] *Mulready*, No. 22-6074 at 17 (quoting *Rutledge*, 141 S. Ct. at 479).

[9] *Id.*

[10] *Mulready*, No. 22-6074 at 18.

[11] *Id.* at 21 (quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 659 (1995)).

[12] *Id.* at 22.

[13] *Id.* at 20 (quoting *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724, 739 (1985)).

[14] *Id.* at 20 (quoting *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 359 (2002)).

[15] *Id.* at 21.

[16] *Id.* (internal citations omitted).

[17] *Id.* (quoting *PCMA v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010); second quoting *Travelers*, 514 U.S. at 659).

[18] *Id.* at 53.

[19] *Id.* at 24 (quoting *Rutledge*, 141 S. Ct. at 480) (internal citations omitted).

[20] *Id.* at 17-18 (quoting *Rutledge*, 141 S. Ct. at 480).

[21] *Mulready*, No. 22-6074 at 28 (quoting *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983)).

[22] *Id.* at 30.

[23] *Id.* at 28 (quoting *Rutledge*, 141 S. Ct. at 480).

[24] *Id.* at 29.

[25] *Id.* at 27.

[26] *Id.* at 43 (quoting 42 U.S.C. § 1395w-26(b)(3)).

[27] 42 U.S.C. § 1395w-26(b)(3).

[28] *Mulready*, No. 22-6074 at 44.

[29] *Id.* at 51.

[30] *Id.*

[31] *Id.* at 44.

[32] *PCMA v. Wehbi*, 18 F.4th 956, 966–67 (8th Cir. 2021).

[33] *Id.*

[34] *Rutledge*, 141 S. Ct. at 479.

[35] *Id.* at 480 (citations omitted).

[36] *Id.*

[37] *Mulready*, No. 22-6074 at 32 (quoting *Rutledge*, 141 S. Ct. at 480.).

[38] *See* Erin C. Fuse Brown Elizabeth Y. McCuskey, *The Implications Of Rutledge v. PCMA For State Health Care Cost Regulation*, Health Affairs Forefront (Dec. 17, 2020).

https://www.healthaffairs.org/content/forefront/implications-i-rutledge-v-pcma-i-state-health-care-cost-regulation ("Applying the logic of *Rutledge,* PBM laws are a form of health care cost regulation, and PBMs are not health plans but rather their administrative contractors, so ERISA should not preempt states' PBM regulations.").

[39] *PCMA Statement on the Tenth Circuit's Decision in PCMA v. Mulready*, *Pharm. Care Mgmt. Ass'n* (Aug. 16, 2023), https://www.pcmanet.org/pcma-statement-on-the-tenth-circuits-decision-in-pcma-v-mulready/.

[40] *Tenth Circuit Opinion in PCMA v. Mulready*, Nat'l Ass'n of Chain Drug Stores (Aug. 17, 2023); *PCMA v. Wehbi,* 18 F.4th 956, 968 (8th Cir. 2021).

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