

Publications

States Continue Expansion of PBM Regulation

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State legislatures over the past five years have focused heavily on the role of pharmacy benefit managers (“PBMs”) in the context of health care benefits. While initial efforts were focused largely on PBM services offered to health insurers and Medicaid, these efforts have more recently had material impacts on self-insured group health plans. In particular, since the Supreme Court’s 2020 *Rutledge*^{[11](#)} decision, there has been a wave of new laws regulating PBMs with respect to all of their business, including self-insured group health plans. These post-*Rutledge* enactments increasingly involve fundamental aspects of plan costs, design, and administration.

These laws have also been subject to litigation arguing that the laws should be preempted under ERISA. Both of these trends are ongoing, and we expect that they will continue to alter the PBM regulatory landscape and the state of ERISA preemption, both of which have material implications for PBMs, health insurance issuers, and group health plans. As these litigation trends continue to develop, additional effects of weakening preemption may be felt more broadly by other plan service providers, like third-party administrators (“TPAs”), if states were to apply the same underlying theory to medical benefits. We note that both Houses of Congress are currently considering legislation that would create specific federal rules governing PBM disclosure to plans and the structure of PBM compensation.

State PBM Laws

More than half the states have enacted PBM laws in the last three years – some of which specifically impact group health plans, such as Colorado, Oregon, New Mexico, Florida, North Carolina, and

Oklahoma. Below we outline the most common provisions in these laws that could impact plans, using laws in Oklahoma, North Carolina and Florida as examples of state laws that have been adopted or are being considered by state legislatures:

- *Prohibitions on Spread Pricing* – Prohibitions on the practice of “spread pricing” whereby a PBM charges a health plan an amount greater than the amount the PBM pays the pharmacy.
- *Anti-Gag Clause Prohibitions* – Contracts cannot restrict contracting pharmacies from telling participants what they would pay for a drug if they paid directly and did not engage their plan, including any contractual penalties imposed on pharmacies by PBMs for this type of disclosure.
- *Prohibition on Retroactive Reduction of Payment* – Prohibitions on retroactive reduction of payments made to pharmacies, except in cases of fraud or errors identified by an audit.
- *Network Participation Requirements* – Prohibitions on certain practices in admitting pharmacies to networks, such as requiring the admission of any pharmacy willing to meet terms of network participation, prohibiting a PBM from restricting a pharmacy’s participation in its network because the pharmacy is on probationary status with the state’s pharmacy regulator, prohibiting requiring payment of a fee for participation in a network, and prohibiting PBMs conditioning network admission on participation in another network.
- *Preferences or Incentives for Particular Pharmacies* – Prohibiting specific preferences for certain kinds of pharmacies. For example, prohibiting networks made up of only pharmacies affiliated via ownership with the PBMs or plan designs that require the use of mail order pharmacies, establishing network adequacy requirements and disallowing the use of mail order pharmacies from being used to meet them, and prohibiting requiring or incentivizing patients to use pharmacies affiliated by ownership to the PBM.

While these laws are common examples of state-level activity, there are numerous variations in both the substantive requirements and the scope of applicability of the dozens of state laws and legislative proposals enacted or considered in the last three years.

ERISA Preemption of State PBM Laws

Historically, ERISA’s broad preemption provision operated to protect self-insured group health plans and their service providers from state laws that would directly or indirectly interfere with nationally uniform plan administration or mandate the coverage of certain benefits. Recent case law developments around the scope of ERISA preemption have called this historical understanding into question, and many states have viewed this newly unsettled area of the law as an opportunity to regulate PBMs directly, and their ERISA-covered clients indirectly, in more robust ways.

The Supreme Court has held that ERISA’s broad preemption provision is designed to limit state efforts to upset nationally uniform plan administration, mandate the coverage of substantive benefits, or otherwise interfere with a central matter of plan administration. The Court has also been clear that state laws that directly reference or that require the existence of the ERISA-covered plan should be preempted.

However, in its 2020 *Rutledge* decision, the most recent Supreme Court decision on ERISA preemption, the Court held that regulation of the amount that a PBM pays a retail pharmacy was not preempted even though the ERISA-covered plans experienced indirect and non-acute economic burdens as a result of the state regulation. The Court held that an Arkansas statute that set rates with respect to PBMs did not have an impermissible reference to or connection with ERISA-covered plans. The Court found that any economic impact of the law on plans was indirect and did not bind plans’ benefit design choices. The Court did, however, affirm that preemption should apply where acute (even if indirect) economic effects effectively bind the benefit choices of plan sponsors under ERISA. The Court’s decision also affirmed long-standing precedent that state laws are preempted by ERISA when they impact a core function of plan administration, mandate a certain scheme of benefits coverage, or directly refer to the plan.

GROOM INSIGHT: The Court’s opinion was based on a longstanding case holding that preemption did not prevent New York from requiring hospitals to bill certain payers a surcharge, which created meaningful incentives for plan fiduciaries to select insurers not subject to the surcharge. The Court was careful to preserve the other fundamental goals of ERISA preemption: uniformity, flexibility in benefit design, and the core matters of plan administration. States, however, have increasingly viewed the *Rutledge* decision as an invitation to more heavily regulate PBMs in stated efforts to rein in the cost of prescription drugs.

Last year, a district court ruled in a case called *PCMA v. Mulready* that Oklahoma's PBM regulation directly impacting ERISA-covered plans benefit designs by materially limiting preferential cost-shares for certain types of pharmacies, like mail-order or affiliated pharmacies, was not preempted by ERISA, relying on *Rutledge*.^[2] The court, however, did not provide a thorough analysis of the impact of the state statute on ERISA-covered plans. Rather, the court's conclusory decision relies entirely on the fact that the statute regulates contracts between the PBM and the pharmacy (notwithstanding the direct economic and benefit design impacts of those contractual regulations on ERISA-covered plans).

This case is now on appeal to the Tenth Circuit and awaiting a decision. At issue in the appeal are four provisions in 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 probation status with the State Board of Pharmacy; (3) a 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.

As part of the appeal, the Tenth Circuit requested that DOL file an amicus brief concerning the preemption of the Oklahoma law. DOL argues in its amicus brief that the probationary pharmacist provision only has an incidental effect on plan administration and that the remaining provisions would be preempted as to the group health plan itself, but not as applied to the PBMs. That position, if accepted, would be a significant departure from prior case law and would represent a significant opening for additional state regulation of both PBMs and other plan service providers.

GROOM INSIGHT: Based on the questioning at oral argument before the Tenth Circuit and the weight of the existing case law, the Tenth Circuit appears relatively unlikely to adopt DOL's position on the preemption of the Oklahoma law to allow significant indirect regulation of ERISA plans. Fundamentally, DOL's position would gut the scope of ERISA preemption and effectively require self-insured ERISA plans to also self-administer their benefits to be sure to avoid state regulation. That said, because of the significant impact it could have if the court adopts DOL's position, the *Mulready* litigation is worth monitoring.

What's Next???

In the wake of the district court opinion in *Mulready*, the Oklahoma Insurance Commissioner quickly began enforcement of the new state PBM laws. These activities directly impact self-insured group health plans whose PBMs were no longer able to administer the plans' design as-is, leaving plan sponsors with the unprecedented decision of modifying the plans' benefit design for individuals subject to a single state's regulation. While the Oklahoma statute directly impacts fundamental benefit decisions preserved solely to the plan sponsors of ERISA-covered group health plans, the scope of later state laws, like Florida's, could implicate a much larger number of plan sponsors, PBMs, and aspects of plan design and administration. Additionally, depending on whether the Tenth's Circuit rules in favor of the state, the opinion could either further incentivize states to be aggressive in regulating PBMs or chill that behavior with respect to ERISA-covered plans. While these are battles likely to play out in federal appellate courts and state legislatures for years, the effects on plan sponsors have already begun and are likely to increase as newer state laws begin to be enforced. And, we expect more legal challenges to new laws that are particularly broad, such as Florida's.

Given the significant role that pharmaceuticals have in the larger health care delivery system, we expect that the current scope of ERISA preemption testing will continue, particularly with respect to broad laws, like Florida's. This will result in plan sponsors and plan service providers facing significant uncertainty around compliance and plan costs. We expect preemption challenges to continue, particularly with respect to broad laws, like Florida's. Plan sponsors, PBMs, health insurance issuers, and other plan service providers should consider whether state law legislative monitoring should begin or be enhanced to both ensure compliance and evaluate the potential cost implications for the benefits they offer and/or administer.