2024 NCCMP Annual Conference

State and Federal PBM Legislation & ERISA Preemption

Brigen Winters, Principal, Groom Law Group

March 9, 2024

GROOM LAW GROUP

Brigen Winters
Principal
bwinters@groom.com

Agenda

- Background
- Increased State Regulation of PBMs and Drug Prices
- Overview of Key State Laws
- ERISA Preemption
- Federal Legislation

GROOM LAW GROUP

Background

- More and more states have enacted or are considering enacting laws that regulate pharmacy benefit managers (PBMs)
- This type of state regulation can affect ERISA plan design and administration as well as plan cost
- State activity has increased in not only pace but *scope* since the Supreme Court's 2020 decision in *PCMA v. Rutledge* in which the court found that Arkansas's PBM law was not preempted by ERISA
- 2023 Tenth Circuit decision in *PCMA vs. Mulready* was a key development/favorable ruling in favor of preemption

Post-*Rutledge* – Increased State Regulation

- Emboldened by *Rutledge*, states have moved aggressively to enact similar and more far-reaching laws
- Initial PBM laws (*e.g.*, Arkansas) focused on the relationship between PBMs and pharmacies, including imposing disclosure requirements on PBMs and providing procedural rights to pharmacies
- Now states are going further than the Arkansas law in seeking to regulate PBM activities, business model, and revenues
- Newer state laws seek to regulate network access, use of affiliated pharmacies, use of mail-order and specialty pharmacies, and preferential cost-shares for certain types of pharmacies
- This increased state regulation of PBMs is increasing costs on plan sponsors with respect to their pharmacy benefits and affecting their ability to execute certain plan designs (*e.g.*, cost-sharing incentives) that they use to keep costs down for participants

Overview of Oklahoma PBM Law at Issue in *Mulready*

- Patient's Right to Pharmacy Choice Act (2019) imposed requirements on PBMs including:
  - Require PBMs to admit any pharmacy into their network that accepts terms and conditions
  - Remove the ability for PBMs to use discounts to incentivize use of a preferred provider
  - Prohibit plan sponsors from offering networks comprised exclusively of pharmacies that are owned by the PBM

Overview of Other State Activity Regarding Pharmacy Benefits & PBMs

- Maximum-Allowed-Charge (MAC) List Disclosure – AR
- Procedural Rights for Pharmacies (e.g., required appeal rights) – AR; multiple others
- Pharmacy Cost Protections (*e.g.*, required minimum payments to pharmacies; prohibition on reimbursing non-affiliated pharmacies less) – AR; OK
- Cost-sharing restrictions *(e.g.*, prohibit use of discounts or cost-sharing reductions to incentivize use of certain providers) – OK; WA (proposed)
- Pharmacy access (*e.g*., require PBMs to meet network adequacy standards for retail pharmacies; any willing pharmacy laws) – OK
- Specialty and mail order (*e.g.*, prohibit requirements to use affiliated pharmacies, including mail order; prohibit required use of a mail order pharmacy) - OK; WA (proposed)
- Prohibit PBMs from using spread pricing – WA (proposed)

Overview of Florida PBM Law

- On May 3, 2023, Florida Governor DeSantis signed into law the Prescription Drug Reform Act (PDRA)
- PDRA reforms laws governing PBMs operating in the state to create more transparency in prescription drug costs and protect independent pharmacies from alleged anticompetitive and unfair trade practices by PBMs
- Imposes new requirements for contracts between PBMs and plan sponsors including prohibiting spread pricing and passing all rebates to the plan sponsor
- Imposes network adequacy standards, and prohibits PBMs from mandating that consumers use a mail-order pharmacy, establishing networks comprised exclusively of PBM affiliated pharmacies, and instituting networks that require a pharmacy to meet standards more stringent than state or federal law
- PDRA applies to self-insured plans as well as commercial health plans, government-funded plans

GROOM LAW GROUP

Overview of Tennessee PBM Law

- P.C. 569 (2021)
  - Prohibits spread pricing
  - Mandates a 100% rebate pass-through
  - Requires PBMs to admit any pharmacy into their network that accepts terms and conditions
- P.C.1070 (2022) requires PBMs to create a process through which pharmacies can appeal reimbursements
- Regulations require data disclosures including from ERISA plans
- Enforcement could be imminent

Overview of Proposed Kentucky PBM Law

- Kentucky SB 188 (2024)
- Applicable to "an insurer, pharmacy benefit manager or any other administrator of pharmacy benefits" in state
  - Insurer defined broadly, includes self-insured plans
  - KY DOI must approve all plans –including self-insured plans
- Establishes government set payment mandate and dispensing fee for prescriptions dispensed in state
- Mandates that any network pharmacy can dispense specialty medications
- Restrictions on use of pharmacy networks – restricts plan sponsor design options to lower participant out-of-pocket costs
  - Places limitations on ability to use preferred networks
  - Restrictions on home delivery of prescriptions

Plan Sponsor Implications – Pharmacy Benefits

- Plan sponsors should expect that states will continue to increase both pace and scope of state laws regulating PBMs
- These laws are likely to continue to have a big impact on plan cost, benefit design and administration
- While many provisions of these laws may in fact be preempted by ERISA, absent a final decision by a court finding such law preempted, PBMs may feel compelled to comply with the state law
- Plan sponsors should expect they may need to react to these state laws with plan design changes and should discuss with their PBMs whether to operationalize state-specific carve-out designs or broader plan-level changes

ERISA Preemption

- ERISA shall "supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." ERISA 514(a).
- The preemption clause is "conspicuous for its breadth." *FMC v. Holliday* (1990).
- Congressman John Dent (D-PA) described preemption as "the crowning achievement of [ERISA], the reservation to Federal authority the sole power to regulate the field of employee benefit plans. With the preemption of the field, we round out the protection afforded participants by eliminating the threat of conflicting and inconsistent State and local regulation." 120 Cong. Rec. 29,197 (1974).
- In determining whether state laws "relate to" a plan, the Supreme Court looks to whether the state law has a "reference to" or a "connection with" a plan. *Shaw v. Delta Air Lines, Inc.* (1983).
- A state law has a "reference to" an ERISA plan if the law specifically refers to such a plan; "acts immediately and exclusively upon" the plan; or if the plan's existence "is essential to the law's operation." *Dillingham Construction* (1997).

The “In Connection With” Test

- A State law has an impermissible “connection with” an ERISA plans if it “governs a central matter of plan administration” and therefore interferes with “nationally uniform plan administration.”
- Laws that require plan sponsors or service providers to structure benefit plans in particular ways “impermissibly intrude on plan administration and preclude national uniformity.”
- The Supreme Court reaffirmed this test in 2016 in *Gobeille v. Liberty Mutual*, finding that a Vermont all payer claims database law was preempted since it created a duplicating reporting and disclosure requirement for ERISA plans.

ERISA - Insurance “Savings Clause” and “Deemer Clause”

- ERISA’s “savings” clause provides that “nothing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.” ERISA 514(b)(2)(A)
- ERISA’s “deemer clause” provides that no benefit plan under ERISA “shall 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.” ERISA 514(b)(2)(B)
- Under this framework state laws are preempted as applied to self-funded group health plans, but states can regulate the insurance policies that insurers issue to employers.

Limits on Preemption - *Travelers*

- New York state imposed a surcharge on hospital patients. Law targeted the providers, not the ERISA plan administrators
- Supreme Court in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins*. (1995).
  - An indirect economic influence, however, does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself … Nor does the indirect influence of the surcharges preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one …

Limits on Preemption - *Rutledge vs. PCMA*

- Supreme Court unanimously (8-0) upheld an Arkansas state law requiring PBMs to pay pharmacies no less than their acquisition costs for prescription drugs:
  - "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."
  - Like *Travelers*, the Court found that any economic impact of the state's rate setting on ERISA plans was indirect and did not bind plan benefit design choices.
- However, *Rutledge* did reaffirm *Gobeille*, stating that:
  - preemption should apply where acute, (even if indirect) economic effects effectively bind the benefit choices of plan sponsors under ERISA, and
  - 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.

Current State of ERISA Preemption Litigation

- In initial litigation after *Rutledge*, the results favored the states' legislative authority over ERISA's preemptive effect
- *PCMA v. Wehbi*, 18 F.4th 956, 964 (8th Cir. 2021) – *Rutledge* allows states to regulate accreditation standards imposed by PBMs
- *PCMA v. Mulready*, Case No. CIV-19-977-J (W.D. Okla. 2022) – District Court decision that Oklahoma's Patient's Right to Pharmacy Choice Act state laws that limits choice and incentives around benefit design and cost sharing survived preemption under *Rutledge*
- DOJ/DOL amicus brief in appeal of *PCMA v. Mulready* to Tenth Circuit stated that applying the OK law directly to ERISA plans would be prevented by the deemer clause, but that the law is *not* preempted by ERISA if applied only to the PBM, even if the PBM is acting as an administrator on behalf of a self-insured plan.
- The amicus brief rationale would leave large, self-insured national plans, including multiemployer plans, exposed to state laws that could circumvent preemption by imposing benefit design restrictions on the PBM rather than the self-insured ERISA plan itself.

PCMA v. Mulready

- On August 15, 2023, 10th Circuit ruled that the Oklahoma law was preempted by ERISA because the law governed a "central matter of plan administration" and mandated benefit structures interfering with "nationally uniform plan administration."
- State law 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.
- Court specifically acknowledged that its ruling complied with the holding of *Rutledge* because the Oklahoma network restrictions "impede PBMs from offering plans some of the most fundamental network designs, such as preferred pharmacies, mail-order pharmacies, and specialty pharmacies" thereby imposing not just costs, but dictating plan design.

Federal PBM and Prescription Drug Legislation

- Various bills and proposals
- Enhanced PBM to plan disclosure requirements
  - Annual reports with detailed data on prescription drug spending
  - Rebates, fees, alternative discounts, other remuneration received by PBMs, out-of-pocket spending, formulary placement rationale
- Prohibition on "spread pricing" where PBM charges plan sponsors more for a drug than the PBM pays the pharmacy based on the discounts it negotiates
- Limitations on PBM rebate retention -- mandating pass-throughs of rebates and discounts
- Regulating retail/specialist/mail pharmacy networks
- Significant limitations on use of step therapy for prescription drugs

Senate HELP Pharmacy Benefit Manager Reform Act (S. 1339)

- Introduced by Senator Bernie Sanders (I-VT); approved by Senate HELP Committee on bipartisan vote
- Limits the manner in which PBM services are priced and imposes comprehensive disclosure obligations on PBMs
- Eliminates spread pricing
- Requires PBMs to pass through all rebates, fees and alternative discounts from drug manufacturers, distributors, wholesalers, etc. to plan sponsors
- PBMs must submit annual reports to plan sponsors and health insurance issuers that include certain information, including:
  - total amount received by the plan or issuer in rebates, fees, alternative discounts, or other remuneration related to utilization of drugs or drug spending; and
  - an explanation of any benefit design parameters that encourage or require participants to fill prescriptions at mail order, specialty, or retail pharmacies affiliated with the PBM
- Includes an amendment from Senator Mike Braun (R-IN) adopted in the markup which directs the Secretary of Labor to study and report to Congress on the impact of including PBMs within the definition of a fiduciary under ERISA

Preemption-Related Provisions in Federal PBM Legislation?

- Community pharmacists and FMI have pushed anti-ERISA preemption "clarifications"
- Will need to stay vigilant in any final legislation
- Various NCCMP, employer trades and alliances' sign-on letters on importance of protecting ERISA preemption
- Education and the Workforce RFI
- NCCMP work on a possible legislative amendment to ensure that States may not indirectly regulate an ERISA group health plan through its regulation of PBMs

Questions?