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PBM Reform Legislation – Impact of State And Federal Legislation For Plans

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Agenda

- Background
- *Rutledge vs. PCMA*
- Post-*Rutledge* and State of ERISA preemption
- State Regulation of PBMs and Drug Prices
- Federal Legislation

Background

- More and more states have enacted or are considering enacting laws that regulate pharmacy benefit managers (PBMs)
- This type of state regulation, which typically applies via the state's PBM licensure laws, 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 decision in *PCMA v. Rutledge* in which the court found that Arkansas's PBM law was not preempted by ERISA

Rutledge v. PCMA

- At issue in *Rutledge* was an Arkansas law that required, in part, PBMs to:
 - Disclose Maximum Allowable Cost (MAC) lists
 - Meet short timeframes to alert pharmacies to updates to the MAC list
 - Develop appeals procedures for use by pharmacies
 - Allow pharmacies to resubmit challenged bills
 - Allow pharmacies to refuse to dispense drugs to plan participants if the reimbursement would be less than the pharmacy's cost

Rutledge v. PCMA

- PCMA sued in federal court, arguing that the Arkansas law was preempted by ERISA (and the Medicare statute)
- The district court and appellate court both ruled that ERISA **did** preempt the law
- Arkansas appealed to the Supreme Court
- The U.S. Supreme Court found **8–0** (Justice Barrett did not take part in the decision) that ERISA did **not** preempt the Arkansas state law
 - Justice Sotomayor explained that “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*” (emphasis added)

Post-Rutledge – Increased State Regulations

- 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, and has led to changes in plan design features like cost sharing or PBM fees paid by plans
- 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
- 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

Overview of Specific 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 the Prescription Drug Reform Act (PDRA) into law
- PDRA reforms laws governing PBMs operating in 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

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 have an even greater effect 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

Plan Sponsor Implications – Other

- It is conceivable that other state-level actors will use *Rutledge* roadmap to pursue state laws that go beyond pharmacy
 - *E.g.*, a state law that seeks to regulate a TPA's provider network
- Thus, the litigation over preemption of state pharmacy and PBM laws have implications for ERISA health and retirement plans generally

Current State of ERISA Preemption Litigation

- Initial litigation results favoring 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 state laws that limit choice and incentives around benefit design and cost sharing survive under *Rutledge*
 - DOL amicus brief in appeal of *PCMA v. Mulready* to Tenth Circuit

PCMA v. Mulready

- On August 15, 2023, Tenth Circuit rejected Oklahoma’s position that its pharmacy network requirements were not preempted by ERISA
- Court found that network restrictions in Oklahoma law impermissibly mandate benefit structures and therefore prevent the uniform national application of ERISA plan terms
- Together, 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

PCMA v. Mulready

- Case has been remanded to the district court that originally heard the case
- Oklahoma is likely to request that the Tenth Circuit rehear the case and/or pursue an appeal to the Supreme Court
- Unclear what will happen on appeal, but Tenth Circuit decision is well reasoned application of prior precedent
- But states will likely 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
- Plan sponsors and plan service providers should continue to monitor state legislative and enforcement activity as this unsettled area of the law continues to develop

Federal PBM and Prescription Drug Legislation

- Big focus on PBMs as the source of high drug costs
- Legislation aimed at regulating commercial relationships in this area have been advancing in the House and Senate
- House Committees
 - Energy and Commerce
 - Education and the Workforce
 - Ways and Means Committee
- Senate Committees
 - HELP
 - Commerce
 - Finance
- Legislation could be considered on the House and Senate floors this fall

Federal PBM and Prescription Drug Legislation

- 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 passthroughs 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) and Senator Bill Cassidy (R-LA) by the Senate HELP Committee on May 11, 2023
- 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?

- FMI and the community pharmacists have pushed anti-ERISA preemption “clarifications”
- Employer trades and alliances’ sign-on letters on importance of protecting ERISA preemption
- NCCMP efforts to get a positive legislative amendment to the federal legislation to ensure that States may not indirectly regulate an ERISA group health plan through its regulation of PBMs
- Conversations with employer trades on possible common ground

Questions?