US Supreme Court Decision
Rutledge v Pharmaceutical Care Management Association (PCMA)
Implications for State Drug Cost Containment Policies

Background

In December 2020, the US Supreme Court unanimously found that the State of Arkansas did not violate federal preemption of self-funded, federally regulated employer health plans (ERISA plans[1]) through State regulation of pharmacy benefit managers (PBMs). Arkansas regulates PBMs in a variety of ways but the key issue in the lawsuit was regulation of PBM business relationships with pharmacies.

This ruling is important for two reasons.

- First, Federal ERISA law had been construed to mean that states cannot extend health insurance regulation to ERISA plans. This decision draws clearer, and broader, parameters about acceptable state regulation that does not violate the federal ERISA preemption. States will have more latitude to improve healthcare operations for state businesses and residents.
- Second, this decision may have implications for how courts think about Dormant Commerce Clause challenges to state laws that establish payment rates to lower the cost of prescription drugs. This is because ERISA is similar in purpose to the Commerce Clause. Like ERISA, the Commerce Clause has been construed to exempt multi-state businesses from different types of state regulations because the Federal government regulates interstate commerce. Like ERISA caselaw, the courts have increasingly narrowed the types of acceptable state policy that steers clear of regulating interstate commerce.

Arkansas Act 900 PBM Business Practice Law

The Arkansas law at issue regulates PBM business practices vis a vis State-licensed pharmacies. The Arkansas law requires PBMs to:

- reimburse pharmacies at no less than the pharmacy's drug acquisition cost, at a minimum (and requires PBMs to update pricing files regularly to do so).
- meet new standards for appeals of pharmacy claims denials (and other appealable issues); and
- not penalize a pharmacy that denies service to PBM enrollees when PBM drug product reimbursement does not cover the pharmacy's cost to purchase/stock the drug.

Legal Issues in the Rutledge Case

The PBM trade association, PCMA, sued saying Act 900 provisions governing PBM/pharmacy interactions affect a PBM's ability to administer national pharmacy benefit plans on behalf of federally regulated ERISA plans. PCMA maintained that this effect goes beyond state borders and is therefore preempted under the ERISA law. PCMA successfully sued Iowa over a similar law.

The policy implications of the Rutledge decision are important since self-insured, employer health plans cover 67 percent of workers with workplace coverage -- including 23% of insured workers in small firms and 84% in large firms.[2],[3] Because of ERISA pre-emption, only a minority of residents in any state are in commercial, state regulated, health coverage which limits the impact of state efforts to improve the healthcare market.

The findings of the Supreme Court in Rutledge may have applicability to any drug industry Dormant Commerce Clause challenge to state laws establishing a prescription drug affordability board and statewide upper payment limits for certain drugs. The ERISA preemption and the Commerce Clause both protect multi-state companies from the different laws of different states in favor of national regulation of multi-state employer plans and multi-

[1] ERISA: Employee Retirement Income Security Act of 1974

[2] https://www.kff.org/report-section/ehbs-2020-summary-of-findings/

[3] Applicability of ERISA federal preemption of state laws has expanded over time as small businesses became self-funded employer plans for a variety of reasons.

state businesses.[4] The Court's finding are equally applicable to state regulation of drug costs through healthcare industry payment and reimbursement policies. The Rutledge decision was unanimous.

Key Rutledge Decision Findings Translated to Commerce Clause Concerns

In Rutledge, the Court found that ERISA does not preempt state rate regulations that merely increase costs and that do not require a substantive change in ERISA plan core functions – benefits coverage. *As for state drug policy,* setting statewide payment limits on what state-licensed healthcare providers and suppliers can pay for drugs arguably does not adversely impact the core business operations of drug manufacturers or the supply chain.

The Court also found that ERISA preemption would not be triggered even if the state law caused ERISA plans to limit benefits or charge higher premiums. *As for state drug policy*, even if statewide regulation of how much can be paid for certain drugs caused a diminution of industry revenues, this may not be sufficient grounds for upending state laws and regulations that protect the health and welfare of state residents.

The Court found that a state law *may* be subject to [ERISA} pre-emption if the law causes "acute, albeit indirect, economic effects….". *As for state drug policy*, regulation of what in-state payers, providers and consumers can pay for certain drugs would not cause acute economic effects for drug manufacturers. In fact, upper payment limits on what can be paid for drugs in a state should result in greater access – more sales – which certainly would not create an acute economic impact for a drug company.

The arguments of PCMA in Rutledge concerning state violation of ERISA preemption are similar to Dormant Commerce Clause arguments PhRMA has made in several lawsuits challenging state drug price laws. The Rutledge decision reinforces the state fundamental authority for rate regulation. Rate regulation is the heart of both the state prescription drug affordability board upper payment limits for certain drugs and state prescription drug reference pricing policies.

[4] Note that the upper payment limits of the PDAB model act are designed to succeed under industry challenge, and the Rutledge decision seems to bolster the view that PDAB statewide upper payment limits do not violate the Commerce Clause.