Supreme Court to Decide on ERISA Preemption of State Law Regulating Prescription Drug Pricing

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One of the cases heard by eight justices of the Supreme Court (after Justice Ruth Bader Ginsburg died and before Justice Amy Coney Barrett was appointed and sworn in), *Rutledge v. Pharmaceutical Care Management Association* involves the question of whether ERISA preempts or supersedes an Arkansas state law governing prescription drug pricing for generic drugs under an ERISA health benefit plan.

The case was brought by the Pharmaceutical Care Management Association (PCMA), a national trade association representing the eleven largest Pharmacy Benefit Managers (PBMs) in the country, as a challenge to an Arkansas state law regulating pricing for generic drugs by PBMs. The case carries national significance because over thirty other states have enacted similar laws to control PBMs' pricing practices, and those state laws might be deemed to interact with ERISA health benefit plans to implicate ERISA preemption. If state law is preempted by ERISA, the state law is, in effect, not applicable to ERISA plans.

Role of Pharmacy Benefit Managers

Pharmacy Benefit Managers act as "middlemen" between health plans and pharmacies, performing services such as processing claims, calculating benefit levels and making disbursements, as well as generating reports and data. PBMs enter into contracts with pharmacies to create pharmacy networks. In creating their networks, PBMs may select pharmacies willing to take lower reimbursements in exchange for being placed in a preferred network, thereby potentially increasing the pharmacy's business from participants and beneficiaries of the plans to which the PBM is a service provider. When a plan participant or beneficiary presents a prescription at a pharmacy, the participant or beneficiary does not pay the full price that the pharmacist receives for the drug but instead pays a portion, or copay, and the participant's or beneficiary's health plan

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covers the remaining cost. PBMs gather market data to create maximum allowable cost (MAC) lists. MAC lists are used to set reimbursement rates for pharmacies filling generic prescriptions.

Arkansas PBM Law — Act 900

In 2015, the Arkansas state legislature adopted Act 900, Arkansas Code Annotated § 17-92-507, to protect independent pharmacies, including those serving rural areas, in part from PBMs' pricing practices that affected the profitability of pharmacies, particularly with regard to generic drugs. Act 900:

- Requires pharmacies to be reimbursed for generic drugs at a price equal to or higher than the cost invoiced for the drug by the wholesaler to the pharmacy;
- Requires PBMs to update their MAC lists within at least seven days from the time there has been a certain increase in the costs of acquiring the generic drugs;
- Provides pharmacies with administrative appeal procedures that allow a pharmacy to reverse and rebill claims affected by a pharmacy's inability to procure the drug at a cost that is equal to or less than the cost on the relevant MAC list where the drug is not available "below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale"; and
- Provides a "decline-to-dispense" option for pharmacies to decline to fill a prescription where the transaction would result in the pharmacy losing money.

Challenges in the District Court and Circuit Court of Appeal

PCMA initially challenged the Arkansas law, Act 900, on the basis that it is preempted by ERISA and Medicare Part D and that it violates the U.S. Constitution and the Arkansas Constitution.

On motions for summary judgment, the U.S. District Court for the Eastern District of Arkansas held that Act 900 was preempted by ERISA as applied to ERISA plans but otherwise withstood the challenges PCMA brought as to its constitutionality and preemption by Medic are Part D. PCMA appealed the ruling on the lack of preemption under Medicare Part D. The Arkansas State Attorney General appealed the ruling on ERISA preemption.

Eighth Circuit Holds Arkansas Law Is Preempted, Based on Precedent

On appeal, the Eighth Circuit Court of Appeals, held that Act 900 was preempted by both ERISA and Medicare Part D.

Like the District Court, the Eighth Circuit looked to the Eighth Circuit's 2017 ruling in *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017), which held that an Iowa PBM law that had a similar purpose and effect as Act 900 was preempted by ERISA because it had a prohibited reference to ERISA and interfered with national uniform plan administration. The Iowa law required PBMs to provide information regarding their pricing methodologies to Iowa's insurance commissioner upon request. It limited the types of drugs to which a PBM could apply MAC pricing and limited the sources from which a PBM could obtain pricing information. In addition, it required

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PBMs to provide their pricing methodologies in their contracts with pharmacies and to provide procedures by which pharmacies could comment on and appeal MAC price lists or reimbursements. The Eighth Circuit ruled that the Iowa law had both an impermissible express reference to ERISA and an implicit reference to ERISA through regulation of PBMs who administer benefits for ERISA plans.

In *Rutledge*, the Eighth Circuit held that *Gerhart* dictated how the court must rule — that ERISA preempted Act 900. The court held that Act 900 both relates to and has a connection with employee benefit plans and is therefore preempted. The State of Arkansas sought Supreme Court review.

Supreme Court Review

The Supreme Court accepted review of Eighth Circuit's ruling that Act 900 was preempted. After postponement earlier this year, the Court heard oral argument last month, after Justice Ginsburg had passed away, but before Justice Barrett was confirmed. Justice Barrett, barring any recusal, will participate in deciding the case. Oral argument occurred on October 6, 2020, as one of the cases heard via telephone by the Court during the pandemic.

Arkansas argued that the Eighth Circuit improperly expanded ERISA preemption in that ERISA ordinarily does not preempt state rate regulation, and Act 900 qualifies as state rate regulation. The state argued that when ERISA plans are purchasing goods or services for the purposes of providing benefits to their participants and beneficiaries, they are acting like any other consumer in the marketplace and, as such, are subject to market regulation. Arkansas relied heavily on the Supreme Court's decision in *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co*., 514 U.S. 645, (1995), which upheld a New York law requiring hospitals to add a surcharge on patients with certain types of insurance rates, in which the Court stated, "ERISA was not meant to pre-empt basic rate regulation." *Id.* at 667 n.6. Arkansas argued that Act 900 regulates drug reimbursement rates and provides mechanisms for enforcing that rate regulation, including requiring PBMs to provide pharmacies with internal appeals to challenge rates and the option to decline to dispense drugs if the reimbursement rate set by the PBM is below a certain cost threshold. Arkansas also argued that ERISA preemption is not implicated because Act 900 does not regulate claims processing — because resolving a pharmacy's reimbursement dispute is not a step in processing a health plan beneficiary's claim. According to Arkansas, the claims processing function of PBMs is complete before any ERISA plan participant pays the pharmacy co-pay — and the reimbursement paid to a pharmacy through a PBM does not affect what part or percentage the participant pays (because that is set by the plan document and determined before any reimbursement dispute between the pharmacy and the PBM). Arkansas takes the position that Act 900 does not regulate prescription drug benefits and therefore does not trigger ERISA preemption.

The U.S. Solicitor General argued in favor of Arkansas — i.e., that Act 900 was not preempted by ERISA because it affected only the reimbursement to pharmacies by PBMs (as third-party administrators of plan benefits), and such reimbursement between the PBMs and the pharmacies was not a matter central to ERISA plan administration.

PCMA argued for ERISA preemption in that Act 900 does not regulate rates for goods and services in the marketplace — it is silent as to pharmacy pricing, never directly stating that pharmacies get

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$X for Y drugs — and instead erects procedures that affect plan administration and erode national uniformity. Addressing the arguments made by the United States that preemption applies only when the state law directly affects plan management and not when the law only affects the PBM as a third-party administrator, PCMA argued that there was no distinction, for ERISA preemption purposes, between PBM administration and ERISA plan administration. PCMA asserted that Act 900 establishes state-specific rules controlling the amount plans must pay for benefits, the methodology for determining that amount, the timing and procedures for updating payment schedules, and dispute-resolution processes and remedies — all of which are matters central to plan administration. According to PCMA, Act 900's decline-to-dispense provision was particularly problematic in that it controls whether plan participants will receive benefits promised under their plans. Addressing Arkansas' reliance on Court precedent in *Travelers*, PCMA pointed out that *Travelers* implied that preemption was appropriate if the state law produces economic effects (even indirectly) that force an ERISA plan to adopt a certain scheme of coverage or binds plan administrators to particular choices such that the law functions as a regulation of plan administration itself. PCMA argued that Act 900 was such a regulation impacting the plan itself.

Oral Argument at the Supreme Court — Hard to Predict Outcome

At oral argument on October 6, 2020, the justices seemed to ask questions challenging both sides, and it is difficult to predict how the Court will decide the case. Notably, Chief Justice Roberts commented that it was not the fault of Arkansas or the pharmacies that "PBMs have such byzantine procedures that affect drug prices" — a comment which might suggest that the state law has a purpose worthy of being upheld. Several justices (including conservative justices) asked questions on the issue of costs and impact on benefits — specifically, whether Act 900 increased drug costs for employee benefit plans and participants, and whether that triggered ERISA preemption. The justices also asked about the scope of ERISA preemption, particularly in light of the Court's 2016 decision in *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936 (2016), which held that ERISA preempted a Vermont law that required plans to report to a state health claims database — i.e., if reporting related to health plans triggered ERISA preemption, wouldn't legislation affecting payment for prescription drugs do so, too, as paying for prescription drugs would seem to be a central function of a health plan? Answering a question from Justice Gorsuch, Arkansas Attorney General Nicholas Bronni answered that the situation was different from *Gobeille* in that while ERISA has specific reporting and recordkeeping provisions with which the Vermont law conflicted, there are no ERISA provisions that govern what Act 900 does — a dispute between a third-party administrator and service provider, or between a plan and a service provider.

If the Court affirms the Eighth Circuit's decision holding that Act 900 is preempted, the ruling could have broad application beyond Act 900 and could result in challenges to state laws governing PBMs in the approximately 40 states that have adopted such legislation. A Supreme Court ruling in *Rutledge* could even effect change in ERISA preemption jurisprudence for state laws other than ones regulating PBMs. The case presents an opportunity for the Court to revisit its ERISA preemption decisions, particularly *Travelers* and *Gobeille*, to provide more details on when state law is preempted by ERISA.

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