# Supreme Court Gives Green Light to States to Regulate Pharmacy Benefit Managers

**Clarissa A. Kang, Director**
*Trucker Huss, APC*

*Ms. Kang represents plans and plan fiduciaries in ERISA litigation in district and appellate courts, including matters in which ERISA preemption is a key issue.*

**Joseph C. Faucher, Director**
*Trucker Huss, APC*

*Mr. Faucher has been litigating ERISA and other employee benefit cases for over thirty years, and has substantial experience litigating complex ERISA preemption issues.*

As legislatures around the country continue to regulate health care within their states, courts continue to wrestle with the question of when those state laws are preempted or superseded by the Employee Retirement Income Security Act ("ERISA"). In *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 208 L. Ed. 2d 327 (2020) ("*Rutledge*"), the U.S. Supreme Court decided that an Arkansas state law governing prescription drug pricing for generic drugs under an ERISA health benefit plan is *not* preempted by ERISA.

Plaintiff in *Rutledge* was the Pharmaceutical Care Management Association (PCMA), a national trade association representing the eleven largest Pharmacy Benefit Managers (PBMs) in the country. PCMA challenged an Arkansas state law regulating pricing for generic drugs by PBMs. The case is significant not only in Arkansas, but nationwide, since over thirty other states have enacted laws similar to Arkansas's to control PBMs' pricing practices.

## I. Role of Pharmacy Benefit Managers

PBMs act as "middlemen" between health plans and pharmacies. They process claims, calculate benefit levels, determine copayment information, make disbursements, and generate reports and data. PBMs reimburse pharmacies for prescriptions issued to participants and beneficiaries, and in turn, are reimbursed by health plans.

PBMs enter into contracts with pharmacies to create pharmacy networks. In creating these networks, PBMs select pharmacies willing to take lower reimbursements in exchange for being placed in a preferred network. When health plan participants and beneficiaries present 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 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.

## II. Arkansas PBM Law — Act 900

In 2015, the Arkansas state legislature adopted Act 900, Ark. Code Ann. § 17-92-507 (West) ("Act 900"), to protect pharmacies from PBMs' pricing practices that affected the profitability of pharmacies, particularly with regard to generic drugs. The state's

concern was that pharmacies, particularly rural and independent pharmacies, were at risk because the reimbursement rates set by PBMs were often too low to cover their costs. Pharmacies were therefore at risk of closing. Accordingly, Act 900:

- Required 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;
- Required 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;
- Provided 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
- Provided a "decline-to-dispense" option for pharmacies to decline to fill a prescription where the transaction would result in the pharmacy losing money.

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## III. Challenges in the District Court and Circuit Court of Appeal

PCMA initially challenged Act 900 on the grounds 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 Medicare 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.

## IV. Eighth Circuit Holds Arkansas Law Is Preempted

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 its earlier ruling in *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017), which held that an Iowa PBM law similar to Act 900 was preempted by ERISA because it had a prohibited reference to ERISA and interfered with nationally 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 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.

The Eighth Circuit held that *Gerhart* dictated the outcome in *Rutledge,* and therefore, concluded 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.

## V. The Supreme Court Reverses, and Holds ERISA Does Not Preempt Act 900

The Supreme Court accepted review of the Eighth Circuit's ruling that Act 900 was preempted, and heard oral argument after Justice Ginsburg had passed away, but before Justice Amy Coney Barrett was confirmed as the Court's ninth justice.

ERISA preempts state laws that "… relate to" any employee benefit plan.[1] The Supreme Court has long held that a state law relates to an ERISA plan if it has "a connection with" or "reference to" a plan.[2] In a unanimous decision (except for Justice Barrett, who took no part in the consideration of the case) issued on December 10, 2020, the Court reversed the Eighth Circuit's holding, concluding that Act 900 neither has any impermissible "connection with" ERISA plans, nor "refers to" ERISA. The Court first analyzed the "connection with" question, noting that ERISA is "… primarily concerned with preempting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits."[3] The Court also considered whether the law "governs a central matter of plan administration or interferes with nationally uniform plan administration."[4] The Court concluded that Act 900 "is merely a form of cost regulation," and that "cost uniformity was almost certainly not an object of pre-emption."[5] Thus, the Court held that Act 900 was not preempted under the "connection with" prong of the analysis.

The Court also held that Act 900 does not "refer to" ERISA. In order for a state law to "refer to" ERISA it must "act[] immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation."[6] The Court dispensed quickly with this issue, finding that Act 900 "does not act immediately and exclusively upon ERISA plans because it applies to PBMs whether or not they

manage an ERISA plan. Indeed, the Act does not directly regulate health benefit plans at all, ERISA or otherwise. It affects plans only insofar as PBMs may pass along higher pharmacy rates to plans with which they contract.

*Rutledge* is but the latest in a long line of Supreme Court cases examining the concept of ERISA preemption. It will almost certainly have a significant impact on ERISA jurisprudence generally, including cases outside the PBM regulation arena. But it is certainly not going to be the final word. In a concurring opinion in *Rutledge,* Justice Clarence Thomas criticized Supreme Court jurisprudence, stating that the Court will declare as preempted "state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law."[7] Justice Thomas concluded that under that "objectives and purposes" preemption approach, a state law is preempted if it has a "reference to" or "connection with" ERISA plans, and stated "… this vague test offered 'no more help than' the 'relate to' one."[8] Justice Thomas advocated for a "text-based" approach, stating, as he has in other cases, that ERISA's preemption clause should not be considered to be "sweeping" in its approach: "Congress knows how to write sweeping pre-emption statutes. But it did not do so here. Applying the statutory text, the first step is to ask whether a provision in ERISA governs the same matter as the disputed state law, and thus could replace it."[9]

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It remains to be seen if Justice Thomas's generalized criticisms of the Supreme Court's preemption jurisprudence ever gain traction among the Court's other justices. For now, even Justice Thomas acknowledges that "the outcomes of our recent cases—if not the reasoning—are generally consistent with a text-based approach." This concession makes it somewhat unlikely that a majority of the Court's other justices will adopt Justice Thomas's preferred "text-based" approach in the face of decades of the Court's application of the somewhat amorphous "connection with" and "reference to" tests, with which the lower courts will likely continue to struggle.

**Endnotes**

1 29 U.S.C.A. § 1144(a) (West).
2 *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 147, 121 S. Ct. 1322, 149 L. Ed. 2d 264 (2001).
3 *Rutledge* at 480.
4 *Id.*
5 *Id.* at 481.
6 *Id.*
7 *Rutledge* at 485 (Thomas, concurring).
8 *Id.*
9 *Id.* at 484.