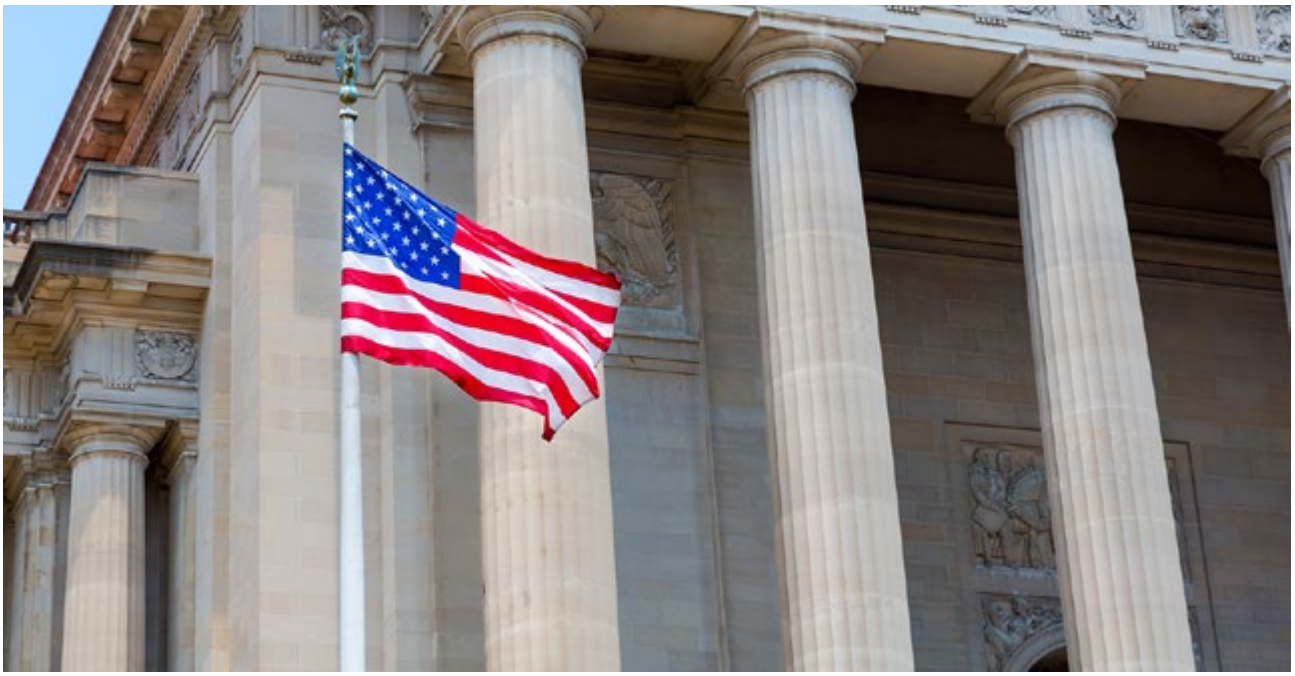

SUPREME COURT UPHOLDS STATE REGULATION OF PBMS – OTHER VENDORS COULD BE NEXT

Written By Brady Bizarro, Esq.

The United States Supreme Court has experienced a whirlwind of a year. Early on, the threat of COVID-19 forced the Court to take the unprecedented step of hearing oral argument via telephone conference call.

Other notable headlines throughout the year included the Court deciding important cases on abortion, religion, and immigration, hearing a crucial case on the Affordable Care Act, rejecting an urgent case on the 2020 presidential election, mourning the loss of an esteemed colleague, and welcoming a new justice to the bench.

You would be forgiven, then, if you missed the case of *Rutledge v. Pharmaceutical Care Management Association*, decided on December 10, 2020. For employer-sponsored health plans and the healthcare industry as a whole, this 8-0 decision may prove to be the most important of its kind in the last several years because of what it foreshadows – more state regulation of PBMs and the possible regulation of other third-party vendors involved in ERISA plan administration.


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At its core, *Rutledge* involved an attempt by a state to regulate its own healthcare market in the face of federal preemption under the Employee Retirement Income Security Act of 1974 ("ERISA"). To properly understand the context of the state law at issue, a brief overview of drug pricing and the process by which many Americans get their prescription drugs is required.

Most Americans are covered by private health insurance (specifically, employer-sponsored health plans) and they purchase prescription drugs from retail pharmacies. Hardly any health plans contract directly with pharmacies. Instead, they contract with pharmacy benefit managers ("PBMs"). PBMs are an integral part of this process, serving as intermediaries between health plans and the pharmacies that plan members use.

When a plan member fills a prescription at a pharmacy, the pharmacy checks with the contracted PBM to confirm insurance coverage and determine any cost sharing requirements. After the plan member's transaction is complete, the PBM reimburses the pharmacy for the prescription (less any cost sharing). Finally, the health plan reimburses the PBM.

The amount at which a PBM reimburses a pharmacy for a drug is set by a contract between the PBM and the pharmacy. In that contract, rates are set according to a list specifying the maximum allowable cost ("MAC"). Similarly, the amount at which a health plan reimburses a PBM is set by contract. These contractual arrangements are often crucial to the success of each entity because each relies on access and steerage to some degree.

Consider the following scenario: a pharmacy pays a drug manufacturer $250 to obtain a drug. The PBM has set a MAC of $200 for the drug. If a plan member pays a $15 copay for the drug, the PBM would reimburse the pharmacy $185.

Under its contract with the PBM, the health plan reimburses the PBM $300, which includes a spread price or fee for the drug (in some cases a manufacturer rebate is involved). In this example, the pharmacy lost money because the MAC was less than the price the pharmacy paid the manufacturer to obtain the drug in the first place.

How or why this occurs is disputed by pharmacies and PBMs alike; however, this situation has caused many independent and rural pharmacies to lose money and close over the past few decades.

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In 2015, the Arkansas state legislature took action to protect its independent pharmacies (which are common in rural Arkansas) from this fate. It passed Act 900, which regulates the price at which PBMs reimburse pharmacies for the cost of drugs covered by health plans.

Specifically, the bill requires that PBMs reimburse pharmacies at or above their acquisition costs, and it included three key enforcement mechanisms. First, the law requires PBMs to tether reimbursement rates to pharmacies' acquisition costs by timely updating their MAC lists when drug wholesale prices increase.

Second, PBMs must provide administrative appeal procedures for pharmacies to challenge MAC reimbursement prices that are below the pharmacies' acquisition costs. Finally, the law permits a pharmacy to decline to sell a drug to a beneficiary if the PBM at issue will reimburse the pharmacy at less than its acquisition cost. *Ark. Code Ann. § 17-92-507(c)-(e).*

Soon after the law passed, the Pharmaceutical Care Management Association ("PCMA"), representing the eleven largest PBMs in the country, filed suit against the state, alleging that Act 900 was pre-empted by ERISA. Under *29 U.S.C. § 1144(a)*, ERISA pre-empts "any and all [s]tate laws insofar as they may now or hereafter relate to any employee benefit plan."

Courts have broadened the scope of pre-emption over time to include state laws that have a "connection with" or "reference to" an ERISA plan; though the Supreme Court's jurisprudence in this area has arguably been conflicting.

The lower courts, including the Eighth Circuit Court of Appeals, sided with the PCMA, ruling that the Arkansas law had an impermissible "connection with" ERISA plans by interfering with central plan functions and nationally uniform plan administration, as well as an impermissible "reference to" ERISA plans by regulating PBMs that administered benefits for those plans. Arkansas appealed this decision to the U.S. Supreme Court.

To resolve this case, the Court considered whether the Arkansas law had an impermissible "connection with" or "reference to" an ERISA plan. In its brief to the Court, PCMA argued that Act 900 impermissibly affected plan design by mandating a particular pricing methodology for pharmacy benefits.

Then, it argued that the law's appeal procedure interfered with central matters of plan administration. Further, PCMA asserted that the enforcement mechanisms interfered with nationally uniform plan administration by creating "operational inefficiencies."

Finally, PCMA contended that by allowing pharmacies to decline to dispense prescriptions in certain cases, the law effectively denied plan members their benefits.

Writing for a unanimous Court (Justice Amy Cony Barret took no part in the consideration or decision of the case), Justice Sonia Sotomayor first outlined the Court's ERISA pre-emption scheme. Then, she dealt with the two issue in turn.

First, she noted that "not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan . . . especially so if a law merely affects costs." *Rutledge*, 2020 U.S. LEXIS 5988, at 10. For support, she cited to *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995).

In that case, New York state imposed a surcharge of up to 13% on hospital billing rates for patients covered by insurers other than Blue Cross and Blue Shield ("BCBS"). The Court presumed that the surcharges would be passed on to ERISA plan members, which in turn would incentivize ERISA plans to steer their plan members to BCBS networks. Still, the Court found that the "indirect economic influence" did not create an impermissible connection between the state law and ERISA plans because it did not "bind plan administrators to any particular choice." *Travelers*, at 659.

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Justice Sotomayor reasoned that the Arkansas law in this case was merely a form of cost regulation, much like the New York law which had been upheld by the Supreme Court in *Travelers*. She rejected all of PCMA's arguments, finding that Act 900, as a form of cost regulation, and despite its enforcement mechanisms, did not require plan administrators to structure their benefit plans in any particular manner and did not lead to anything more than potential operational inefficiencies, which by themselves are insufficient to trigger ERISA pre-emption.

Having dealt with the first issue, Justice Sotomayor then easily dispatched the second issue; whether Act 900 impermissibly referenced an ERISA plan. She argued that the law does not act immediately and exclusively upon ERISA plans because it applies to PBMs whether or not they manage an ERISA plan. It affects ERISA plans only insofar as PBMs pay pass along higher pharmacy rates to plans with which they contract. *Rutledge*, at 12.

After the Court's decision, the PCMA released a statement expressing disappointment and noting, "As states across the country consider this outcome, we would encourage they proceed with caution and avoid any regulations around prescription drug benefits that will result in higher healthcare costs for consumers and employers."

It is possible, as the Court noted, that one consequence of this decision will be higher drug prices for employer-sponsored health plans and their plan members as PBMs look to recoup losses in revenue. It is far more likely, however, that more states will pass laws modeled on Arkansas's Act 900, without fear of them being pre-empted by ERISA (though additional litigation is likely to ensue).

Having announced a distinction between cost regulations and dictating plan choices, the Court has also opened up the possibility that states may try to regulate other third-party vendors involved in ERISA plan administration; from third party administrators to provider networks to audit firms.

As we in the self-funded space have been saying for years, on issues where the federal government and the relevant industry players have failed to provide relief; prescription drug pricing, balance billing, and price transparency (just to name a few), states will step in to fill the void.

Now, with a unanimous Supreme Court restricting the scope of ERISA pre-emption, those state have new latitude to enact laws which may ultimately prove unpopular or even counterproductive for all involved in the fight to contain healthcare costs. ■

Brady joined The Phia Group as a healthcare attorney in early 2016. As the Director of Legal Compliance & Regulatory Affairs for The Phia Group, he specializes in regulatory, transactional, and compliance matters related to healthcare and employee benefits law. He provides general consulting services to clients, including employers, third-party administrators, brokers, and vendors associated with health benefit plans on matters related to the health insurance industry, including ERISA, ACA, and HIPAA compliance.

He also performs contract review and due diligence on healthcare transactions and assists with dispute resolution efforts between the various players in the healthcare industry in an effort to protect plan members and plan sponsors. Brady has previously spoken at numerous industry conferences, including those held by the Self-Insurance Institute of America ("SIIA") and the Health Care Administrator's Association ("HCAA"). He currently serves as a member of SIIA's Future Leaders Committee and is a regular contributor to The Self-Insurer, the world's leading alternative risk transfer journal.

Attorney Bizarro earned his law degree from Boston University School of Law, concentrating in health law. During law school, Brady served as an editor for BU Law's International Law Journal, participated in the Edward C. Stone Moot Court Competition, completed a legal internship in the U.S. House of Representatives, and wrote for the National Security Law Brief. He also worked as a summer associate at Greene LLP, a complex civil litigation firm in Boston that specializes in healthcare fraud cases, and as a Rule 3:03 attorney with BU Law's Civil Litigation Clinic, where he represented indigent defendants in employment and discrimination cases in state court. Prior to law school, he worked as a mediator for a local consumer advocacy arm of the Massachusetts Attorney General's Office. Brady graduated magna cum laude in 2010 from Boston University, where he was the recipient of the Herbert and Mary Greig Scholarship in American History.