

Legal Challenges Against State PBM Laws May Culminate in Supreme Court Review

As states step up their efforts to control prescription drug prices, many state legislatures have targeted pharmacy benefit managers (PBMs) and their role in rising prices by introducing legislation to bring greater transparency to the inner workings of PBMs. As a result of these efforts, however, states increasingly face challenges from the pharmaceutical industry, specifically the Pharmaceutical Care Management Association (PCMA), a trade association representing PBMs. Over the years, PCMA has brought a number of lawsuits challenging state legislation regulating PBMs, claiming that the Employee Retirement Income Security Act (ERISA) preempts them.

The latest state to face such legal challenge is Oklahoma, which passed HB 2632 in the 2019 legislative session. This new lawsuit adds to a string of similar challenges which could shed light on how the court may rule in this case. Not surprisingly, PCMA filed all the major precedent-setting cases in this area, arguing that the state laws interfere with ERISA and impose costly mandates on PBMs that raise costs for consumers. In this Litigation Highlights post, we take a look back at the road so far and discuss where it may lead.

The Initial Wave

Maine (PCMA v. Rowe)

Maine's Unfair Prescription Drug Practices Act ("UPDPA"), enacted in 2003, was one of the first PBM laws in the nation to be challenged by PCMA. The law requires PBMs to disclose

any payments they receive from pharmaceutical companies and to pass discounts that they receive from pharmaceutical companies on to their clients and to serve as a fiduciary for their clients. On appeal, the 1st Circuit Court of Appeals [affirmed](#) the lower court decision and held that the Maine law was neither unconstitutional nor preempted by ERISA.[\[1\]](#) In June 2006, the U.S. Supreme Court denied review of the appellate decision,[\[2\]](#) thereby upholding the PBM law.

District of Columbia (PCMA v. Dist. of Columbia)

Soon after Maine's law, the District of Columbia enacted a similar PBM law in 2004, which PCMA quickly challenged. The law, Title II of the Access Rx Act of 2004, required PBMs to act as fiduciaries, disclose the content of their contracts with pharmacies and manufacturers, and pass on any payments or discounts they receive from pharmacies or manufacturers. The legal challenge went all the way up to the Court of Appeals of the D.C. Circuit, and the court, affirming the lower court decision, [struck down](#) key provisions of the law on the basis of ERISA preemption.[\[3\]](#)

8th Circuit Preemption Rulings

Iowa (PCMA v. Gerhart)

Fast-forward ten years, Iowa revived the dispute regarding federal preemption of PBM laws with its 2014 law, which regulated how PBMs establish generic drug pricing and required PBMS to make certain disclosures on their drug pricing methodology to their network pharmacies as well as Iowa's insurance commissioner. In January 2017, on appeal from the district court's [ruling to dismiss](#) the case, the 8th Circuit reversed,[\[4\]](#) [holding unanimously](#) that the Iowa law impermissibly interferes with the PBM function of ERISA plans operating in Iowa, as it "imposes mandates and restrictions on

a PBM's relationship with Iowa and its pharmacies that run counter to ERISA's intent of making plan oversight and plan procedures uniform."

Arkansas (PCMA v. Rutledge)

Arkansas followed in Iowa's footsteps by enacting a largely similar law the following year. Act 900, enacted in 2015, required disclosure of generic drug pricing and sets a floor on prices that PBMs can pay to pharmacies for generic drugs. Unfortunately for Arkansas, the legal decision of the preemption challenge that ensued also mirrored the Iowa case. Closely following the 8th Circuit decision in PCMA v. Gerhart handed down just two months earlier, the District Court of Arkansas was compelled to strike down the Arkansas law in March 2017.[\[5\]](#) The 8th Circuit then [affirmed](#) on appeal.[\[6\]](#) Arkansas filed a [petition for certiorari](#), requesting the Supreme Court to review the case, citing split circuit court decisions in the matter of ERISA preemption of PBM laws among the 1st Circuit, 8th Circuit, and D.C. Circuit, which created "'confusion and uncertainty' about state power to regulate drug prices." Since then, 32 states, including California and New York, have signed on the [amicus brief](#) to the Supreme Court, urging review of the case.

New Pending Cases

North Dakota (PCMA v. Tufte)

North Dakota passed two bills in 2017 that regulate PBM reimbursement to pharmacies for prescription drugs and how much PBMs profit from such practice. Specifically, the legislation requires disclosures of drug pricing and keeping the reimbursement rate above certain levels. In September 2018, a federal judge in North Dakota [upheld](#) the laws by ruling that they do not implicitly include ERISA plans. PCMA

has appealed the case to the 8th Circuit Court of Appeals, [\[7\]](#) which previously struck down the Arkansas and Iowa laws. In distinguishing the North Dakota laws, the AG asserts that contrary to the other invalidated state laws, its laws do not regulate the methodology used to calculate prescription drug reimbursements.

Oklahoma (PCMA v. Mulready)

The 2019 Oklahoma law, Patient's Right to Pharmacy Choice Act, targets PBM conflict of interest by prohibiting higher reimbursement rates for PBM-owned pharmacies and bans PBMs from preventing pharmacies to disclose cost information to consumers. PCMA [filed suit](#) in Oklahoma district court last month, [\[8\]](#) just before the new law takes effect on November 1, arguing that the law "operates primarily to weaken competition among pharmacies by limiting the ability of PBMs to offer their cost-saving and quality assurance initiatives within the State of Oklahoma." The case is currently pending in Oklahoma district court.

As seen by the litigious history spanning over a decade, federal preemption of state legislation regulating PBMs has been a longstanding issue debated in courts across the country, with both district courts and circuit courts reaching opposite conclusions (see Table 1.) For a comparison and analysis of the policies and specific provisions of the laws, see [Navigating Legal Challenges to State Efforts to Control Drug Prices: Pharmacy Benefit Manager Regulation, Anti-Price Gouging Laws, and Price Transparency](#), a brief written by The Source's Katie Gudiksen, Sammy Chang, and Jaime King.

On the litigation front, with the North Dakota law headed to the 8th Circuit and the new Oklahoma law potentially headed to the 10th Circuit, the existing and impending clash of the

appellate courts is ripe for Supreme Court review. In April, the Supreme Court indicated its interest in hearing the case, asking the U.S. solicitor to weigh in on the states' petition for certiorari of the 8th Circuit's preemption ruling of the Arkansas law in PCMA v. Rutledge. Stay tuned to find out whether the high court will shed light on the boundaries of state regulation to better guide state legislative efforts.

Table 1: PCMA Legal Challenges against State PBM Laws

| State/Jurisdiction | PBM Law | PCMA Challenge | District Court Decision | Court of Appeals Decision | Supreme Court Review |
|-----------------------------|--|--|---|---|----------------------|
| Maine | 2003 – Unfair Prescription Drug Practices Act (Maine Rev. Stats., Title 22 § 2699) | Pharm. Care Mgmt. Assn. v. Rowe | Not preempted, District Court of Maine (2005) | Not preempted, 1 st Circuit (2005) | Review denied (2006) |
| District of Columbia | 2004 – Title II of Access Rx Act (D.C. Code § 48-832.01 et seq.) | Pharm. Care Mgmt. Assn. v. Dist. of Columbia | Preempted, District Court of District Columbia (2009) | Partially preempted, D.C. Circuit (2010) | |
| Iowa | 2014 – Act Relating to the Regulation of Pharmacy Benefits Managers (Iowa Code § 510B.8) | Pharm. Care Mgmt. Ass'n v. Gerhart | Not preempted, District Court of the Southern District of Iowa (2015) | Preempted, 8 th Circuit (2017) | |

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|---------------------|---|---------------------------------------|--|---|------------------------------|
| Arkansas | 2015 – Act 900 (Arkansas Code § 17-92-507) | Pharm. Care. Mgmt. Assoc. v. Rutledge | Preempted, District Court of Eastern District of Arkansas (2017) | Preempted, 8 th Circuit (2018) | Review requested and pending |
| North Dakota | 2017 – SB 2258 and SB 2301 | Pharm. Care Mgmt. Assoc. v. Tufte | Not preempted, District Court of North Dakota (2018) | Pending, 8 th Circuit | |
| Oklahoma | 2019 – Patient’s Right to Pharmacy Choice Act | Pharm. Care Mgmt. Assoc. v. Mulready | Pending, Western District of Oklahoma | | |

[\[1\]](#) Pharm. Care Mgmt. Assn. v. Rowe, 429 F.3d 294, 36 EBC 1065 (1st Cir. 2005).

[\[2\]](#) PCMA v. Rowe, U.S., No. 05-1297 (2006).

[\[3\]](#) Pharm. Care Mgmt. Assn. v. Dist. of Columbia, 613 F.3d 179, 392 U.S. App. D.C. 14, 49 EBC 1609 (D.C. Cir. 2010).

[\[4\]](#) Pharmaceutical Care Mgmt. Assoc. v. Gerhart, 2017 BL 7351, 8th Cir., No. 15-3292.

[\[5\]](#) Pharm. Care. Mgmt. Assoc. v. Rutledge, E.D. Ark., No. 4:15-cv-00510-BSM, 3/1/17.

[\[6\]](#) Pharm. Care Mgmt. Ass’n v. Gerhart, 852 F.3d 722, 63 EBC 1085 (8th Cir. 2017).

[\[7\]](#) Pharm. Care Mgmt. Assoc. v. Tufte, 8th Cir., No. 18-2926.

[\[8\]](#) Pharm. Care Mgmt. Assoc. v. Mulready, W.D. Okla., No. 5:19-cv-00977-SLP, 10/25/19.