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Legal Update on State PBM Regulation After *Rutledge*

NCPA 2024 Annual Convention and Expo
Columbus, Ohio

Speaker



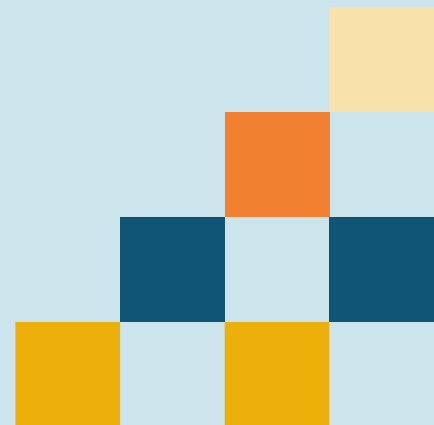
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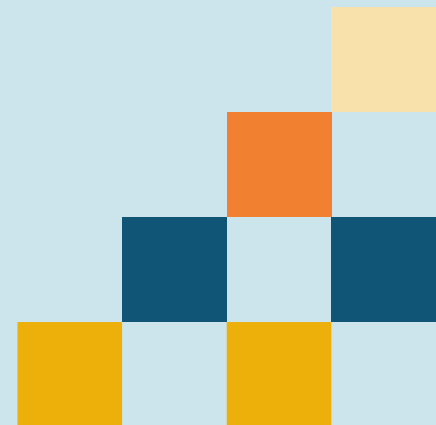
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Pharmacist and Technician Learning Objectives

1. Summarize the Supreme Court's decision regarding *Rutledge v. PCMA*.
2. Discuss state efforts to regulate PBMs and the federal statutes and cases that place potential limits on that authority.
3. Review various state-law regulations of PBMs and the lawsuits PBMs have filed to place limits on that authority.





State PBM Regulation

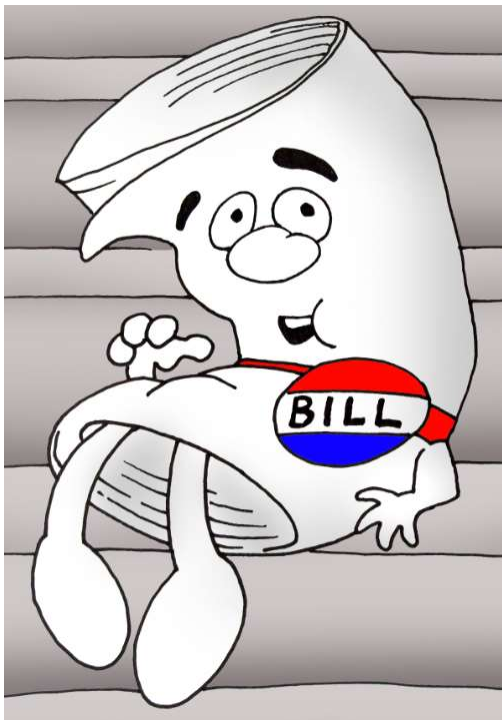
State Efforts and Potential Limits on State Authority

State Authority to Regulate PBMs



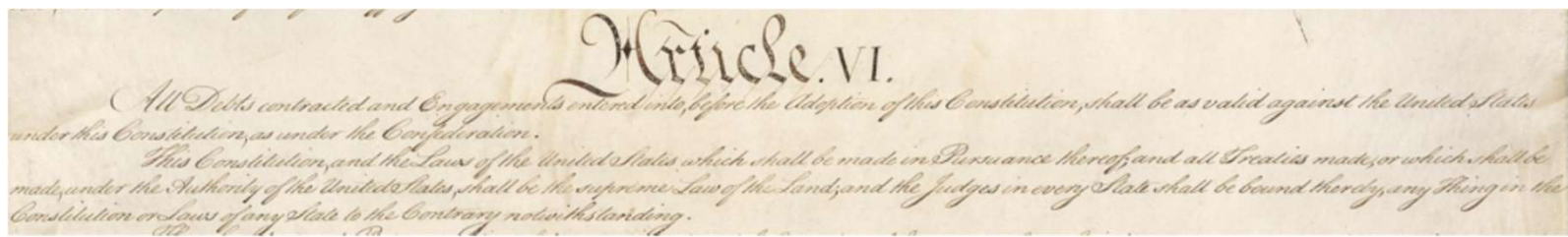
- **State Regulation of PBMs:**
 - PBMs are largely unregulated by the federal government.
 - To fill this void, many States started regulating PBMs.
 - Today, nearly every State regulates PBMs in some capacity.
- **PBMs challenge State authority:**
 - Beginning in 2004, PCMA, a national trade association that represents the 11 largest PBMs, began challenging these State laws.
 - Even though PBMs are not regulated directly by the federal government, PCMA has argued that federal law prevents the States from regulating PBMs.
 - PCMA's strategy is apparently to use federal preemption to avoid State regulation even while opposing federal legislation that would regulate PBMs, leaving PBMs free to operate in a regulatory vacuum.
 - PCMA also uses its lawsuits to intimidate States from passing new PBM legislation.
 - PCMA's lawsuits culminated in the U.S. Supreme Court's landmark decision in *Rutledge v. PCMA*, 592 U.S. 80 (2020).

The Types of State PBM Laws



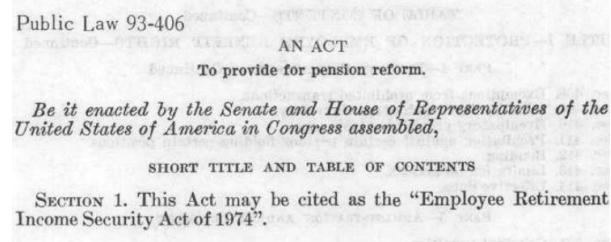
- **Licensing laws:**
 - Typically, a State's first foray into PBM regulation, these laws are generally limited to setting up a framework for the State to begin regulating PBMs.
 - Sometimes, this authority is granted to the Insurance Department.
- **Reimbursement regulation:**
 - These laws regulate PBM-pharmacy reimbursements.
 - They can regulate MAC, set up an appeals process, ban claw backs, and even dictate the amount of reimbursement for the ingredient costs of a drug and mandate a dispensing fee.
- **Network regulation:**
 - These laws can include any-willing-pharmacy provisions, network-adequacy requirements, and restrictions on a PBM's ability to force patients to use PBM-affiliated pharmacies.
- **Pharmacy and patient rights:**
 - These laws can provide pharmacists and patients with certain rights—e.g., banning gag clauses, barring retaliation, and regulating audits.

A Potential Limit on State Authority: The Supremacy Clause and Preemption



- **Federal Preemption:** An outgrowth of the Supremacy Clause of the U.S. Constitution—
 - “the Laws of the United States . . . Shall be the supreme Law of the Land . . . , and any thing in the Constitution and Laws of any State to the Contrary notwithstanding.
- **Potential Sources of Federal Law that Could Preempt State PBM Laws:**
 - Employee Retirement Income Security Act of 1974 (ERISA)
 - Medicare Part D (we will only discuss ERISA preemption today)

A Potential Limit on State Authority: The Supremacy Clause and Preemption



- What is ERISA?

- ERISA regulates private employer and union-sponsored pension and welfare plans, including dental, healthcare, and prescription-drug benefit plans.
- ERISA is concerned principally with the relationship between the plan and its beneficiaries.
- ERISA is limited to establishing uniform standards for plan administration:
 - Establishes fiduciary duties for plan sponsors and administrators;
 - Mandates reporting and disclosure obligations;
 - Requires standards for participation and vesting; and
 - Establishes funding standards.
- Generally, ERISA does not dictate what benefits employers must provide.

A Potential Limit on State Authority: The Supremacy Clause and Preemption

- ERISA Preemption—a Three-Step Mess:
 - Step 1: Does the State law “relate to” ERISA plans?
 - Yes: Go to step 2.
 - No: The law is not preempted.
 - Step 2: If the law “relates to” ERISA plans, does it regulate insurance?
 - Yes: Go to step 3.
 - No: The law is preempted
 - Step 3: What is the law regulating?
 - Insurance Companies and Others Touching Upon the Business of Insurance: The law is not preempted as applied to insurance companies and others touching upon the business of insurance.
 - Self-funded ERISA plans: The law is preempted.
 - * A self-funded ERISA plan bears its own risk.



A Potential Limit on State Authority: The Supremacy Clause and Preemption



- **ERISA’s First Step is Key:**
 - The Statutory Text: “[T]he provisions of [ERISA] shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.” 29 U.S.C. §1144(a).
- **The Supreme Court Has Described the Statutory Text as “Unhelpful”:**
 - Anything can be said to “relate to” something else.
- **The Supreme Court’s Gloss on the Text:**
 - A State law is preempted if it has a “connection with” or “reference to” ERISA plans.
- **What the heck does that mean?**
 - The Court provided clarity in *Rutledge v. PCMA*, 592 U.S. 80 (2020).

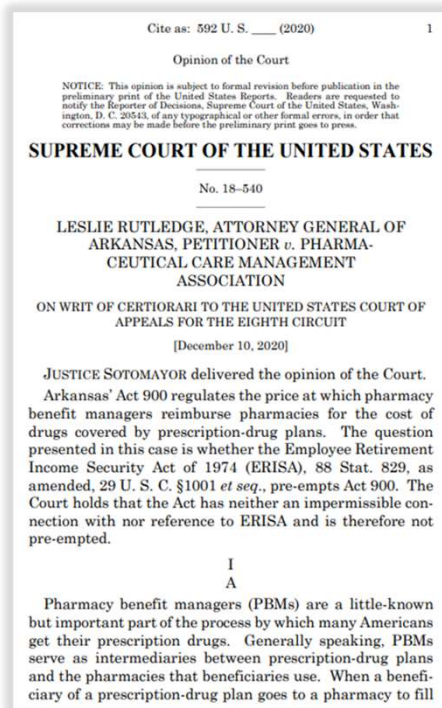


Rutledge v. PCMA

592 U.S. 80 (2020)

Rutledge v. PCMA

- Why is *Rutledge* so important?
 - The Court clarified that ERISA is concerned mainly about State laws that interfere with plan administration by:
 - (1) dictating benefits;
 - (2) determining who is eligible for coverage, or
 - (3) regulating in areas that ERISA regulates.
 - There's a narrow and broad way to read *Rutledge*. I'll discuss both.
 - Before I do so, however, I'll give some practical examples to illustrate the scope of ERISA preemption.



Rutledge v. PCMA: Examples of Impermissible State Laws

- Impermissible State Laws:
 - State laws that mandate particular benefits. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983).
 - State laws that dictate who is eligible for coverage. *Egelhoff v. Egelhoff*, 532 U.S. 141 (2001).
 - State laws that compel plans to disclose to State officials “detailed information about claims and plan members,” because ERISA regulates in this area. *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312 (2016).
 - State laws that treat ERISA plans differently than non-ERISA plans. *Mackey v. Lanier Collection Agency*, 486 U.S. 825 (1988).


Rutledge v. PCMA: Examples of Permissible State Laws

- Permissible State Laws:
 - State laws that regulate the rates or costs that an ERISA plan must pay for services that are covered by the plan. *N.Y. Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995); *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806 (1997).
 - State “laws that regulate only the insurer, or the way in which it may sell insurance.” *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 741 (1985).
 - State laws that regulate third-parties that merely sell goods or services to an ERISA plan.
 - *E.g.*, State laws regulating “medical-care quality standards,” *Cal. Div. of Labor Stds. Enf’t v. Dillingham Constr., N.A.*, 519 U.S. 316, 329 (1997), or “general health care regulation,” *Travelers*, 514 U.S. at 661.

Rutledge v. PCMA: The Holding



- **The Issue:** Whether ERISA preempts Act 900, an Arkansas law that:
 - regulates the amounts that PBMs reimburse pharmacies for dispensing generic drugs and
 - includes certain enforcement mechanisms to ensure PBM compliance, including appeal and decline-to-dispense provisions.
- **The Ruling:** The Court ruled 8-0 that ERISA does not preempt Act 900.
- **The Reasoning:** The Court held that ERISA preempts State laws only where those laws dictate benefits (e.g., which drugs a plan must cover) or eligibility determinations (e.g., mandating that plans cover adult children of beneficiaries), or where the law regulates in an area already regulated by ERISA.
 - **Act 900's Reimbursement Provisions:** ERISA does not preempt cost regulations.
 - **Act 900's Enforcement Provisions – appeal, rebill, and decline to dispense:** ERISA does not preempt the services provided by third parties, including Act 900's regulation of PBMs.



Post-Rutledge Confusion

The Federal Courts of Appeals are Divided

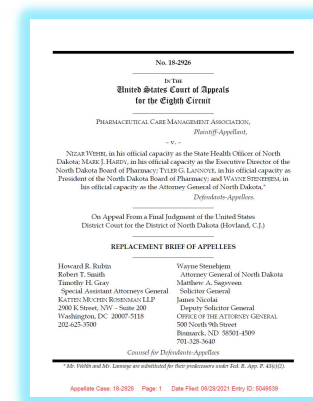
Rutledge v. PCMA: Broad v. Narrow Reading

- There are two possible readings of *Rutledge*:
 - **Narrow:** *Rutledge* simply involved a State law regulating rates and costs.
 - **Broad:** *Rutledge* was about far more than rate regulation, and States have wide authority to regulate PBMs, which merely sell goods and services to ERISA plans.
- Following *Rutledge*, the lower courts have divided:
 - *PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021): Largely upholds two North Dakota laws that regulate PBM – reads *Rutledge* broadly.
 - *PCMA v. Mulready*, 78 F.4th 1183 (10th Cir. 2023): Largely sets aside an Oklahoma law that regulates PBMs – reads *Rutledge* narrowly.
- Even before *Rutledge*, the lower courts had divided:
 - *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005): Upheld a Maine law that mandated PBMs serve as fiduciaries of the plans they serve – held that PBMs are not ERISA plans and therefore fall outside ERISA’s reach.
 - *PCMA v. District of Columbia*, 613 F.3d 179 (D.C. Cir. 2010): Largely set aside a D.C. law that mandated that PBMs serve as fiduciaries of the plans they serve – held that PBMs serve in a function similar to ERISA plans, and as a result, ERISA preempts State and local PBM laws.



PCMA v. Wehbi, 18 F.4th 956 (8th Cir. 2021):

- **Background:** North Dakota enacts two laws that regulate:
 - certain fees that PBMs charge pharmacies,
 - which drugs pharmacies are allowed to dispense,
 - what pharmacists are allowed to say to their patients, and
 - the accreditation standards PBMs can require of pharmacies.
- **Issue:** PCMA sues the State, arguing that ERISA preempts North Dakota's PBM laws.
- **Procedural History:** The Eighth Circuit had ruled against North Dakota, but following *Rutledge*, the Supreme Court sent *Wehbi* back to the Eighth Circuit for reconsideration.
- **Holding:** On remand, the Eighth Circuit holds that ERISA preemption is focused on State laws that dictate benefits or coverage determinations. North Dakota's laws do none of these things, and so, they are not preempted by ERISA.



PCMA v. Mulready, 78 F.4th 1183 (10th Cir. 2023):

- **Background:** Oklahoma enacted a law that:
 - regulates PBM-pharmacy networks and includes an any-willing-provider (AWP) provision,
 - prevents PBMs from requiring patients to use PBM-affiliated pharmacies,
 - prohibits PBMs from reimbursing an unaffiliated pharmacy less than it reimburses an affiliated pharmacy, and
 - regulates fees and claw backs.
- **Procedural Posture:** PCMA sued the State, arguing that ERISA preempts Oklahoma's PBM law.
 - **Emergency Injunction Denied:** The Tenth Circuit issued an order denying PCMA's request for an emergency injunction to prevent enforcement of the law while PCMA litigated its claims.
 - **District Court Rules Against PCMA:** The District Court issued a final judgment rejecting all of PCMA's claims under ERISA.
 - **PCMA Limits Its Appeal:** On appeal, PCMA challenged only the network provisions.
- **Holding:** The Tenth Circuit invalidated each of the network provisions that PCMA challenged on appeal. The court read *Rutledge* narrowly to apply only to State laws regulating costs. And it otherwise read ERISA preemption broadly, reasoning that Oklahoma's law would limit the options an ERISA plan could purchase from a PBM.



Mulready v. PCMA, No. 23-1213 (U.S.): Oklahoma Petitions the Supreme Court to Review

- **Oklahoma Petitions the Supreme Court:**
 - Oklahoma has filed a petition with the Supreme Court, asking it to review the Tenth Circuit's decision.
- **The Supreme Court Requests the Views of the Federal Government:**
 - On October 7, 2024, the Supreme Court issued an order requesting the views of the Solicitor General of the United States.
 - Because the case involves the scope of a federal statute, the Court wanted to determine whether the Solicitor General deems the case important enough to warrant the Supreme Court's review.
 - The United States government previously took the position that the Tenth Circuit should uphold Oklahoma's law. And the Tenth Circuit's reasoning conflicts with that of the Eighth Circuit.
 - As a result, it is likely that the Solicitor General will recommend that the Court agree to hear Oklahoma's appeal.
 - Referred to as the Tenth Justice, the Solicitor General is highly influential in those cases where the Court solicits her views.
 - There is no deadline for the Solicitor General's brief (likely in Spring 2025).

No. _____

In the
Supreme Court of the United States

GLEN MULREADY, in his official capacity as
Insurance Commissioner of Oklahoma;
OKLAHOMA INSURANCE DEPARTMENT,
Petitioners,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

**On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Tenth Circuit**

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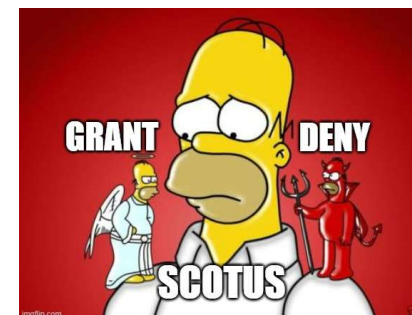
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Counsel for Petitioners

May 10, 2024

Mulready v. PCMA, No. 23-1213 (U.S.): What Happens Next?

- **The Supreme Court Grants Review:** If the Supreme Court grants review, *Mulready* provides it with an opportunity to clarify the scope of ERISA preemption as it applies to a full suite of State-law PBM regulations.
 - A decision in Oklahoma's favor would empower States to take action unless and until Congress enacts national reforms.
 - That, in turn, could increase pressure on Congress to act.
 - In the interim, PBMs would not be able to resist State regulatory efforts.
- **The Supreme Court Denies Review:** If the Supreme Court denies review, it will lead to divergent standards.
 - **States with Limited Authority:** States within the Tenth Circuit (Colorado, Kansas, New Mexico, Oklahoma, Wyoming, and Utah) will lack full authority to regulate PBMs.
 - **States with Robust Authority:** States within the First Circuit (Maine, Massachusetts, New Hampshire, Puerto Rico, and Rhode Island) and Eighth Circuits (Arkansas, Iowa, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota) would have robust authority to regulate PBMs.
 - **Every Other State?:** For other States, the outcome is unclear. PCMA could attempt to use *Mulready's* reasoning to convince other courts of appeals to rule in its favor, and it could continue to claim that States should not enact legislation because it is vulnerable to challenge.





Questions?



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