

Pharmacy Benefit Managers Under Legal Scrutiny – U.S. Supreme Court to Decide if States Can Regulate PBM Reimbursement to Pharmacies

On October 6, the Supreme Court will hear oral arguments in the case *Rutledge v. Pharmaceutical Care Management Association (PCMA)*. A decision in this case will resolve whether an Arkansas law to regulate pharmacy benefit managers (PBMs), Act 900, is preempted by federal law and may affect the enforceability of similar laws passed by at least thirty-five other states.[\[1\]](#) Arkansas passed Act 900 to protect pharmacies from dispensing drugs at a loss. Specifically, the law requires PBMs, when challenged by a pharmacy, to raise the reimbursement rate for a drug above the cost the pharmacy pays to wholesaler to acquire the drug or allows a pharmacy to refuse to dispense a drug if the anticipated reimbursement rate paid by a PBM falls below this acquisition cost.[\[2\]](#) While a challenge to this law may seem unimportant against the backdrop of other cases and news surrounding the Supreme Court, if the court strikes down this law, the decision may broaden the already immense preemptive reach of the Employee Retirement Income Security Act and further shackle state efforts to control pharmaceutical costs.

Why do states pass laws regulating PBMs? What does Act 900 do?

PBMs are intermediaries in the pharmaceutical industry and typically handle pharmaceutical claims on behalf of insurers and employers.[\[3\]](#) Pharmacies purchase their drugs through

wholesalers and are then reimbursed for dispensing them to patients by the PBM operating on behalf of a patient's insurance. When a patient with insurance coverage obtains a generic drug or a branded drug with an available generic version (multi-source brand drug) from a pharmacy, the PBM operating on behalf of the payer typically reimburses the pharmacy using a maximum allowable cost (MAC) list. Ideally, a MAC list will be based on the typical cost of the drug to the pharmacy plus a reasonable markup for dispensing the drug. Some PBMs collect only administrative fees (i.e. per-member, per-month fees) and pay the pharmacy and charge the health plan covering the patient the same MAC list price. Most PBMs, however, use one MAC list (typically with lower prices) to reimburse pharmacies and another MAC list (typically with higher prices) to charge health plans when an enrollee fills a prescription. This arrangement allows PBMs to profit from the spread between the two MAC lists (a process known as "spread pricing").

These PBM billing practices are often shrouded in secrecy and claims of confidentiality. As some billing practices could be used to amass excessive profits at the expense of pharmacies, patients, or employers, most states have considered laws to regulate how PBMs use MAC lists.[\[4\]](#) Many of these laws require disclosure to plan sponsors and pharmacies about how MAC prices are set, regulate how PBMs can set MAC lists for mail-order pharmacies owned by the PBM, or provide a way for pharmacies to increase PBM reimbursement rates when MAC prices fall below their cost of acquiring the drugs. Specifically, Arkansas passed Act 900 in 2015 to create an appeal process for pharmacies to challenge PBM reimbursement rates. If a pharmacy challenges the reimbursement rate based on the MAC list, the PBMs must either provide the name of a wholesaler operating in Arkansas with the specific drug in stock at a price lower than the MAC list price *or* raise the MAC list price above the challenging pharmacy's cost and allow that pharmacy to reverse and rebill any claim affected by this

appeal.[\[5\]](#) The law was intended to protect pharmacies by requiring PBMs to reimburse pharmacies at rates above the pharmacies' cost of acquisition while allowing the PBM to handle the appeal process and demonstrate that the pharmacy should have been able to obtain the drug more cheaply.

The Arkansas Attorney General argues that protection for independent, rural pharmacies as required in Act 900 is necessary as "[i]n the last fifteen years, 16.1 percent of independently owned rural pharmacies in the United States have closed, and 630 rural communities that had one or more pharmacies, independent or otherwise, lost their only pharmacy."[\[6\]](#) As one of the reasons for such closures, the Arkansas Attorney General cites a hearing in Iowa in which "the state insurance commissioner found that twenty-three community pharmacies closed due to below-cost PBM reimbursement rates."[\[7\]](#) Because of this national phenomenon, at least forty-four states have passed laws in the last five years to regulate PBMs.[\[8\]](#) Of those, at least thirty-five states passed laws like Arkansas to protect pharmacies from PBM payment processes that cause them to lose money when filling certain prescriptions by establishing an appeals process.[\[9\]](#) For example, Iowa passed a law in 2014 requiring PBMs to disclose MAC lists and pricing methodology to the state insurance commissioner, upon request.[\[10\]](#) The Pharmaceutical Care Management Association (PCMA), the trade organization representing PBM members, challenged the Iowa law, and the Eighth Circuit held that the provisions requiring disclosure of pricing information to a state agency were preempted by the Employee Retirement Income Security Act of 1974 (ERISA).[\[11\]](#)

What is the legal challenge to Arkansas' Act 900?

In the case currently before the Supreme Court, PCMA alleges that Arkansas' Act 900 is also preempted by ERISA.[\[12\]](#) In its

ruling, the District Court upheld Arkansas' law, but ruled that Act 900 was "invalid" "as applied to PBMs in their administration and management of prescription drug benefits for ERISA plans."[\[13\]](#) In reaching this conclusion, the court cited the U.S. Supreme Court decision in *Gobeille v. Liberty Mut. Ins. Co.*, in which the Court upheld a Vermont law requiring payers to submit claims data to a state database but invalidated the reporting requirements for any self-funded employee health plans.[\[14\]](#) On appeal, the Eighth Circuit affirmed that the law was preempted by ERISA. The Arkansas Attorney General, Leslie Rutledge, appealed to the Supreme Court claiming that the Eighth Circuit misapplied the standards for ERISA preemption and that the circuit courts were applying ERISA preemption inconsistently as the First Circuit upheld a Maine PBM law in *Pharmaceutical Care Management Association v. Rowe*.[\[15\]](#)

What is ERISA preemption and how might it apply to Act 900?

Congress passed ERISA in 1974 to allow multi-state employers to establish uniform benefit programs with an express preemption to "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[\[16\]](#) Noting that, if taken to the logical extreme, "pre-emption would never run its course, [as] 'really, universally, relations stop nowhere,'" [\[17\]](#) the Supreme Court described two categories of laws that are preempted by ERISA.[\[18\]](#) First, ERISA preempts laws that make impermissible explicit *reference to ERISA plans* – those that "act immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation[.]"[\[19\]](#) Second, ERISA preempts laws that have impermissible *connections with ERISA plans*, including "state law[s] that 'govern a central matter of plan administration'."[\[20\]](#) In *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers*, the Supreme Court clarified "that ERISA was not meant to pre-empt basic rate

regulation” [\[21\]](#) on the grounds that ERISA has no provisions related to rate regulation and the same Congress that passed ERISA subsequently passed a law regarding state rate setting for hospital services.

Within these somewhat murky bounds of ERISA preemption, the Eighth Circuit upheld a district court decision that ERISA preempted Arkansas’s statute. In her petition to the Supreme Court, the Arkansas Attorney General describes the Eighth Circuit standard, which she believes to be misapplied, as saying that Act 900 was preempted under ERISA “because: (1) it impermissibly referred to ERISA plans, given that PBMs’ customers *include* ERISA plans; and (2) it had an impermissible connection with ERISA plans, given a prior panel’s reasoning that the rates at which plans or their intermediaries reimburse pharmacies for prescription drugs are an ‘area central to plan administration,’ sacrosanct from state regulation.” [\[22\]](#) PCMA’s response to that petition argues that Arkansas’s Act “directly regulates the administration of prescription-drug benefits on behalf of ERISA-governed plans. It establishes state-specific rules controlling the amount plans must pay for benefits, the methodology for determining the amount to be paid, the timing and procedures for updating payment schedules, and dispute-resolution processes and remedies—matters that are central to plan administration... By granting pharmacies a right to decline to dispense, Act 900 even controls whether plan participants will receive benefits promised under their plans.” [\[23\]](#)

What are the legal arguments surrounding Act 900 and ERISA preemption?

Arkansas Attorney General argues in his brief to the Supreme Court that the law does not have an impermissible connection with ERISA plans and that in deciding the case, the Eighth Circuit misapplied the Supreme Court’s standards. [\[24\]](#) The

brief draws a connection between the rate regulation in Act 900 and a legal challenge to a New York law requiring hospitals to charge a surcharge to any non-Blues insurer. In *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers*,[\[25\]](#) the Supreme Court explained that preemption of provider rate regulation would be both “unsettling” and “startling” given that many states already regulated hospital and medical billing rates when ERISA was enacted. Arkansas’s Attorney General argues that the challenged provisions in Act 900 are an analogous rate setting regulation like in *Travelers*, because it regulates the rates at which third-party plan administrators reimburse providers of healthcare benefits and provides mechanisms for enforcing that rate regulation. The brief argues that “[a]ny impact on plan administration is necessary and incidental to rate regulation.”[\[26\]](#) Furthermore, Arkansas’s Attorney General argues that since providers have recourse under state laws, not ERISA, for non-payment or other reimbursement suits, these same protections should apply to pharmacies under laws like Act 900.[\[27\]](#)

The attorneys general of 45 states and the District of Columbia filed an amicus brief with additional legal reasoning in support of the Arkansas law and a description of how billing practices of PBMs harm patients, pharmacies, and the states themselves.[\[28\]](#) Further, the state attorneys general argue that Congress did not intend for ERISA to preempt business practices of PBMs, especially as the state laws govern the relationship between a PBM and a pharmacy (and *not* between the PBM and an ERISA plan). Furthermore, the brief states that “Arkansas’s Act 900 and similar statutes in other States regulate the conduct and business relationships of PBMs in order to protect consumers and facilitate access to prescription drugs—subjects that ERISA does not address.”[\[29\]](#) The states further point out that:

“[e]ven where state laws do address the relationship between PBMs and health plans (including ERISA plans), they

generally impose obligations on the PBMs, not on the plans. For example, some States require PBMs to exercise good faith and fair dealing in their relationships with plan sponsors. While ERISA might well preempt a law seeking to impose such an obligation on ERISA plans, it does not preempt state laws imposing the obligation on PBMs.”[\[30\]](#)

PCMA’s brief in opposition acknowledges that state rate regulation is not preempted by ERISA. However, PCMA argues that Act 900 does not regulate rates and that the Act is not “incident to permissible rate regulation...It operates directly on the administration of benefits on behalf of ERISA plans, controlling the standards and procedures for determining and paying for benefits and processing claims. Indeed, it goes so far as to dictate whether a beneficiary may even obtain a promised benefit.”[\[31\]](#) PCMA’s brief also details the different standards and appeals processes among the many states that have passed laws regulating how PBMs use MAC lists, arguing that “[p]lans and their benefit managers cannot comply with this crazy-quilt regime while maintaining nationally uniform plan administration.”[\[32\]](#)

In short, both sides seem to agree that states can regulate rates paid for health care services and that ERISA preempts any state law that governs which services are covered or how those benefits are administered. PCMA and Rutledge disagree as to how the provisions of Act 900 should be construed within the amorphous bounds of ERISA preemption. As such, the ruling in this case may depend on whether the Supreme Court views Act 900 as governing things central to plan administration or as a rate regulation that aims to set a floor for reimbursement to pharmacies for dispensed drugs.

What are the implications of this case for other states?

At the time the case was filed, thirty-five states had passed

similar legislation.[\[33\]](#) If the Supreme Court holds that ERISA preempts Act 900, many other state laws will also likely be challenged and states may find it very difficult to craft legislation restricting PBM billing practices. Some existing state laws, including those requiring PBMs operating in the state to obtain a license, may survive preemption because they do not regulate something central to ERISA plan administration. However, a ruling against Act 900 may present significant legal obstacles for more restrictive laws that attempt to regulate the methods PBMs use to establish prices or to regulate billing practices that protect independent pharmacies. As a result, a broad decision striking down Act 900 could have large ramifications on how, or even if, states can regulate PBMs to ensure that their business practices benefit the public and do not harm patients.

Beyond the risk to state laws regulating PBMs, a ruling striking down Act 900 would further extend the reach of ERISA preemption. A ruling that holds that ERISA preempts any state effort to regulate the way an entire industry conducts business could cripple any state efforts to control drug prices. ERISA has become a major impediment to state regulations to control healthcare costs. Legal scholars assert that ERISA preemption already greatly exceed the bounds conceived by the authors of ERISA,[\[34\]](#) and a ruling against Arkansas would further expand that reach.

Nonetheless, neither party asserts that ERISA preempts rate regulation. As a result, states may be able to enact laws setting rates for pharmaceuticals without facing legal challenges based on ERISA. At least one Federal Circuit decision,[\[35\]](#) however, appears to hold that federal patent law limits a state's ability to determine what constitutes an "excessive price" for patented pharmaceuticals. While some legal scholars criticize this interpretation,[\[36\]](#) states should expect legal challenges to restrictive rate regulation laws. As a result, states may find it very difficult to

navigate the complex preemption waters any state legislation would face to regulate the pharmaceutical industry. If patent law hampers a state's ability to set prices and ERISA limits its ability to regulate middlemen in the pharmaceutical industry, state legislatures may need to pass laws to regulate many aspects of pharmaceutical pricing and be prepared to defend those laws in court. Nonetheless, the legal challenges brought by the pharmaceutical industry and the secrecy with which players in the industry determine prices underscore the need for legislative action. Misaligned incentives around drug prices mean that the industry will not regulate itself – for example, both manufacturers and PBMs benefit from [higher list prices with large discounts](#) while patients face much higher co-payments. Regardless of the ruling in this case, policymakers should redouble their efforts to improve competition in the drug industry and protect the public from excessive prices and price increases.

[\[1\]](#) Brief for California, 44 other states, and the District of Columbia as Amici Curiae in Support of Petitioner, at 15, *Rutledge v. Pharmaceutical Care Management Association*. 140 S.Ct. 812 (2020)(no. 18-540).

[\[2\]](#) Ark. Code. Ann. § 17-92-507 saying “A pharmacy benefits manager shall: .. Provide a reasonable administrative appeal procedure to allow pharmacies to challenge Maximum Allowable Cost List and reimbursements made under a Maximum Allowable Cost List for a specific drug or drugs as:...(b) Being below the pharmacy acquisition cost.” § 17-92-507 (c)(4)(A)(i) If a pharmacy appeals the price as below the acquisition costs, the PBM must “provide the challenging pharmacy or pharmacist the National Drug Code and the name of the national or regional pharmaceutical wholesalers operating in Arkansas that have the drug currently in stock at a price below the maximum allowable

cost as listed on the Maximum Allowable Cost List” § 17-92-507 (c)(4)(C)(ii) or “adjust the maximum allowable cost as listed on the Maximum Allowable Cost List above the challenging pharmacy’s pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.” § 17-92-507 (c)(4)(C)(iii) In addition, Act 900 provides “adjust the maximum allowable cost as listed on the Maximum Allowable Cost List above the challenging pharmacy’s pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.” §17-92-507(e).

[3] See Francis Ying, Julie Appleby, and Stephanie Stapleton, **Middlemen Who Save \$\$ On Medicines – But Maybe Not For You**, Kaiser Health News, June 26, 2019. Available from: <https://khn.org/news/little-known-middlemen-save-money-on-medicines-but-maybe-not-for-you/>.

[4] National Community Pharmacists Association. The Need for Legislation Regarding “Maximum Allowable Cost” (MAC) Reimbursement. Available at: <http://www.ncpa.co/pdf/leg/mac-one-pager.pdf>.

[5] Ark. Code § 17-92-507 – Requiring a PBM to “[u]pdate its Maximum Allowable Cost List on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesaler doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology” (§ 507(c)(2)) and to “[p]rovide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs and reimbursements made under a maximum allowable cost for a specific drug or drugs as: (a) not meeting the requirement of

this section or (b) being below the pharmacy acquisition cost.” (Id. § 507(c)(4)(A)(i)).

[\[6\]](#) On Petition For A Writ Of Certiorari To The Court Of Appeals For The Eighth Circuit at 10, Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540) citing Aboidun Salako, Fred Ullrich & Keith J. Mueller, Update: Independently Owned Pharmacy Closures in Rural America, 2003–2018, Rural Pol’y Brief (July 2018), at 1, available at <https://perma.cc/54YD-X9BM>.

[\[7\]](#) On Petition For A Writ Of Certiorari To The Court Of Appeals For The Eighth Circuit at 9, Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540) citing Video Remarks on Iowa H.F. 2297, at 10:20–21 A.M. (Mar. 4, 2014) (statement of Rep. Linden);5

[\[8\]](#) National Conference of State Legislatures, 2018 Enacted States Laws Affecting Pharmacy Benefit Managers (Jan. 2019), at 2, <https://tinyurl.com/uh7lftn>.

[\[9\]](#) See Alaska Stat. Ann. § 21.27.950(a); Ariz. Rev. Stat. Ann. § 20-3331(A)(3); Cal. Bus. & Prof. Code § 4440(f); Colo. Rev. Stat. Ann. § 25-37-103.5(3); Del. Code Ann. tit. 18, § 3324A; Ga. Code Ann. § 33-64-9(d); Haw. Rev. Stat. Ann. § 328-106(f); 215 Ill. Comp. Stat. Ann. 5/513b1(b)(4); Iowa Code Ann. § 510B.8(3); Kan. Stat. Ann. § 40-3830(f); Ky. Rev. Stat. Ann. § 304.17A-162(1)(b); La. Stat. Ann. § 22:1865(A); Me. Rev. Stat., tit. 24-A, § 4350(5); Md. Code Ann., Ins. § 15-1628.1(f); Minn. Stat. Ann. § 62W.08(c); Mo. Ann. Stat. § 376.388(5); Mont. Code Ann. § 33-22-173(1)(a); N.H. Rev. Stat. Ann. § 420-J:8(a)(2); N.J. Stat. Ann. § 17B:27F-4; N.M. Stat. Ann. § 59A-61-4(5); N.Y. Pub. Health Law § 280-a(2); N.D. Cent. Code Ann. § 19-02.1-14.2(2)(e); Ohio Rev. Code Ann. § 3959.111(A)(1)(b)(3); Okla. Stat. Ann. tit. 59, § 360(4); Or. Rev. Stat. Ann. § 735.534(4); 40 Pa. Stat. Ann. § 4533(a); R.I. Gen. Laws § 27-41-38.2(d); S.C. Code Ann. § 38-71-2140(A); Tenn. Code Ann. § 56-7-3108(a); Tex. Ins. Code

Ann. § 1369.357(a); Utah Code Ann. § 31A-46-303(5)(c); Vt. Stat. Ann. tit. 18, § 9473(c)(3); Wash. Rev. Code Ann. § 19.340.100(3); Wis. Stat. Ann. §632.865(2)(b); Wyo. Stat. Ann. § 26-52-104(e).

[\[10\]](#) Iowa Code Ann. § 510B.8.

[\[11\]](#) Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722 (8th Cir. 2017).

[\[12\]](#) See Complaint for Declaratory, Injunctive, and other Relief against Leslie Rutledge, filed by Pharmaceutical Care Management Association. Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540). PCMA also alleged the law was preempted by the Dormant Commerce Clause, the Contract Clause, and Medicare Part D and was void for vagueness, but the Supreme Court is only considering whether Act 900 is preempted by ERISA.

[\[13\]](#) Pharm. Care Mgmt. Ass'n v. Rutledge, 240 F. Supp. 3d 951, 958 (E.D. Ark. 2017), aff'd in part, rev'd in part and remanded, 891 F.3d 1109 (8th Cir. 2018).

[\[14\]](#) *Gobeille v. Liberty Mut. Ins. Co.* 136 S.Ct. 936 (2016).

[\[15\]](#) Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 301 (1st Cir. 2005).

[\[16\]](#) 29 U.S.C. 1144(a).

[\[17\]](#) Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 656 (1997).

[\[18\]](#) *New York State Conference of Blue Cross & Blue Shield Plans v. Traveler* 514 U.S. at 656 (1995).

[\[19\]](#) On Petition For A Writ Of Certiorari To The Court Of Appeals For The Eighth Circuit at 6, Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540) quoting Gobeille quoting Dillingham, 519

U.S. at 325.

[20] *Id* citing Gobielle quoting Egelhoff, 532 U.S. at 148.

[21] *New York State Conference of Blue Cross & Blue Shield Plans v. Traveler* 514 U.S. at 667 (1995).

[22] On Petition For A Writ Of Certiorari To The Court Of Appeals For The Eighth Circuit at 4, Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540).

[23] Brief for Respondent on Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit, at. 2, Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540).

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https://www.supremecourt.gov/DocketPDF/18/18-540/134044/20200224200530453_18-540BriefForPetitioner.pdf.

[25] *New York State Conference of Blue Cross & Blue Shield Plans v. Traveler* 514 U.S. at 664 (1995).

[26] Brief for Petitioner On Petition For A Writ Of Certiorari To The Court Of Appeals For The Eighth Circuit at 15 et seq., Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540).

[27] Brief for Petitioner On Petition For A Writ Of Certiorari To The Court Of Appeals For The Eighth Circuit at 31 et seq., Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540).

[28] Brief for California, 44 other states, and the District of Columbia as Amici Curiae in Support of Petitioner, at 5 et seq., Rutledge v. Pharmaceutical Care Management Association. 140 S.Ct. 812 (2020)(no. 18-540).

[29] *Id* at 21.

[\[30\]](#) *Id* at 55.

[\[31\]](#) Brief for Respondent on Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit, at 19, *Rutledge v. Pharmaceutical Care Management Association*. 140 S.Ct. 812 (2020)(no. 18-540).

[\[32\]](#) Brief for Respondent on Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit, at 31, *Rutledge v. Pharmaceutical Care Management Association*. 140 S.Ct. 812 (2020)(no. 18-540).

[\[33\]](#) *Supra* note 7

[\[34\]](#) Erin Fuse Brown and Trish Riley. **Empowering and Protecting Consumers: ERISA Thwarts State Innovation**. NASHP. February 2017. Available at <https://www.nashp.org/empowering-and-protecting-consumers-erisa-thwarts-state-innovation/>.

[\[35\]](#) *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).

[\[36\]](#) Robin Feldman, Betty Chang Rowe, Rabiah Oral, Amy Y. Gu, and Katherine Gudiksen. **States' Rights: A Patent Law Analysis of NASHP Rate-Setting Model Act**. NASHP. March 2018. <https://www.nashp.org/wp-content/uploads/2018/03/White-Paper-2018.pdf>.