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### Pharmaceutical Care Management Association v. Rutledge

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## Pharmaceutical Care Management Association v. Rutledge

### Abstract

On June 8, 2018 the federal Eighth Circuit Court of Appeals announced its decision concerning Arkansas' attempt to regulate perceived unfair payment practices of pharmacy benefit managers (PBMs) in the case *Pharmaceutical Care Management Association v. Rutledge*.<sup>1</sup> Because pharmacies across the country face similar problems, and this ruling may influence other federal appellate courts, review and discussion is useful for the purpose of making strategic decisions.

### Disciplines

Pharmacy and Pharmaceutical Sciences

### Comments

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# Pharmaceutical Care Management Association v. Rutledge

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On June 8, 2018 the federal Eighth Circuit Court of Appeals announced its decision concerning Arkansas' attempt to regulate perceived unfair payment practices of pharmacy benefit managers (PBMs) in the case Pharmaceutical Care Management Association v. Rutledge.<sup>1</sup> Because pharmacies across the country face similar problems, and this ruling may influence other federal appellate courts, review and discussion is useful for the purpose of making strategic decisions.

**Background:** Pharmacy benefit managers, among other services provided to plan "sponsors" (health insurance plans, unions, state Medicaid providers, and Medicare Part D), compensate pharmacies for generic medication based on a "maximum allowable cost" for each medication. Maximum allowable cost ("MAC") lists offered to pharmacies without negotiation, and remain in effect for the contract period. Different manufacturers will charge different prices for interchangeable generic drugs; in theory, MAC pricing creates an incentive for pharmacies to purchase the least costly generic medication available in the market. However, because the MAC price is fixed, and not subject to changes in cost, pharmacies might often be required to dispense medication at a price that is lower than their actual cost. The Arkansas state legislature attempted to address disastrous effects this was having on independent pharmacies. Act 900<sup>2</sup> provided compensation for generic drugs at a price equal to or higher than the pharmacies' cost based on the invoice from the wholesaler. The act also requires PBMs to update their Maximum Allowable Cost (MAC) list within seven days from the time of a certain increase in acquisition cost. Act 900 further

allows pharmacies the ability to "decline to dispense" when the pharmacy would otherwise be dispensing at less the cost.

Pharmaceutical Care Management Association (PCMA) sued the state alleging that Arkansas key provisions were "preempted" by both Employee Retirement Income Security Act (ERISA) and the Medicare Modernization Act's Medicare Part D. The federal District Court for the Eastern District of Arkansas ruled the state statute preempted by ERISA, but *not* preempted by Medicare Part D.<sup>3</sup> PCMA appealed the Medicare Part D ruling, and the state cross-appealed the ERISA ruling to the federal Court of Appeals for the Eighth Circuit.

"Preemption doctrine" is the pivotal legal principle in this case. Rooted in the Supremacy Clause<sup>4</sup> of the US Constitution, the legal doctrine provides that when the federal law 'intends' to preempt state law, federal law controls. Congress' intent may be implied or expressed. Preemption may be inferred when the federal law is so comprehensive that any state attempt to regulate would be in conflict or defeat the intended regulation. Congress may also expressly preempt state laws, by specifically stating in statute specific state actions that are off limits. ERISA and Medicare Part D both expressly preempt conflicting state actions. In this case the courts were asked to decide whether the elements of Act 900 were distinguishable from ERISA and Medicare Part D.

**ERISA:** Enacted in 1974, the purpose of ERISA was setting minimum standards for employer-sponsored health and pension plans. ERISA case law long ago established that a "state law is preempted if

*(continued on page 30)*

*(continued from page 29)*

it 'relates to' or has "a connection with reference to such a plan";<sup>5</sup> a very broad standard. In this case, the District court relied on legal precedent from an Iowa case (in the same federal circuit as Arkansas).<sup>6</sup> The court ruled the Iowa law preempted because it had a prohibited "reference to" ERISA and it interfered with "national uniform plan administration". Specifically, the Iowa statute required PBMs to provide information about their pricing methodologies and limited the types of drugs PBMs could apply MAC pricing to. By regulating the conduct of PBMs administering or managing pharmacy benefits, the court held that the Iowa statute "both explicitly and implicitly referred to ERISA". The District court determined the Iowa precedent to control the outcome in Arkansas because PBMs "administer benefits for 'covered entities' ... which include health benefit plans", the object of ERISA. That is, ERISA provides shelter for a PBM, not because they are a health plan, but due to their contractual relationship with a health plan. With little additional analysis, the Eighth Circuit appellate court agreed, upholding the lower court's decision.

**Medicare Part D:** The Medicare Modernization Act (Medicare Part D) prohibits interference with any government entity in negotiations between PBMs and pharmacies. Popularly known as the "non-interference clause",<sup>7</sup> explicit preemption exists for state laws that act "with respect to" standards established by Congress or CMS. The Medicare Part D statute requires the creation of a network of pharmacies "to ensure convenient access"<sup>8</sup> by patients. Also, CMS regulations provide a definition for "negotiated prices" (the MAC list).

PCMA argued that Act 900's regulation of prices interfered with both the negotiated prices standard and the convenient access to pharmacy provisions, and were preempted interference by the state. The district court disagreed with this interpretation,

reasoning that the negotiated MAC prices were insubstantial and that the alternative pricing structure was to provide transparency and to control the PBM practices. Also, declining to dispense on a single occasion, the District court reasoned, does not take the pharmacy out of the network and deprive the patient of convenient access. As a result, the lower court ruled that Act 900 did not interfere and not preempted by Medicare Part D.

The Eighth Circuit overruled the decision of the District court, criticizing the lower court for its 'cursory' reasoning. The appellate court reasoned that Act 900 essentially replaces the negotiated MAC price with the pharmacy acquisition cost when the MAC rate is below the pharmacy's invoice cost, thus acting "with respect to" 'negotiated' MAC prices

Medicare Part D has a Pharmacy Access Standard that gives recipients access to pharmacies. A PBM "shall secure the participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients to ensure convenient access." The district court decided that Act 900 did not act with respect to that pharmacy access standard because the decline-to-dispense provisions do not render a pharmacy as out of network. The Eighth Circuit court of Appeals disagreed. The Eighth Circuit decided that a pharmacy that refused to dispense becomes "in effect" an out-of-network pharmacy for that transaction. This is enough, reasoned the appellate court, to preempt the Arkansas state law.

**Comments:** The Eighth Circuit's rulings have effectively gutted the Arkansas law with extremely superficial reasoning regarding both ERISA and Medicare Part D. A contractual relationship with a health care plan sponsor does not make a PBM a health plan. They are merely a conduit that is not worthy of derivative shelter under the ERISA law. Also, Arkansas was correct that "negotiation" of MAC

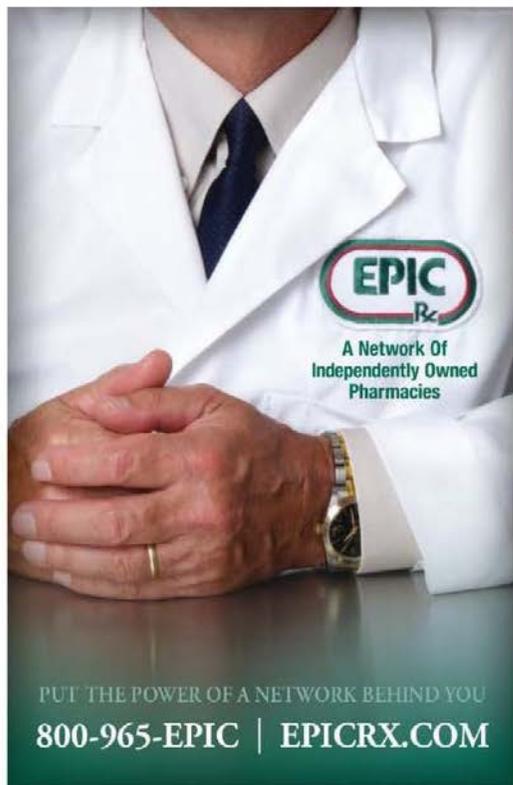
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prices had no substantial meaning; every pharmacy owner appreciates that there is no negotiation with PBMs over MAC prices. In this context, 'take-it or leave-it' offers do not constitute 'negotiation' under any common understanding of the word.

The Eighth Circuit has made its decisions relative to this business practice. Given the well-appreciated imbalance of bargaining power between PBMs and pharmacies, and the effects on pharmacies (small businesses failing), consumer prices (increasing), and costs to plan sponsors (skyrocketing) it will be interesting to see how states respond. If indeed the Eighth Circuit's analysis proves influential, additional state actions will be futile. It would be up to Congress to adjust the preemption provisions in ERISA and Medicare Part D.

## References:

1. 891 F.3d 1109.
2. Arkansas Code Annotated 17-92-507
3. 240 F. Supp.3d 951, US District Court, Eastern District, Little Rock, Ark, March 1, 2017.
4. US Constitution, Article VI, provides that the federal law is the "supreme law of the land".
5. NYS Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co., 514 US 645, 655, (1995), and Express Scripts, Inc. v. Wenzel, 262 F. 3d 829, 833 (8<sup>th</sup> Circuit, 2001).
6. PCMA v. Gerhart, 852 F. 3d 722 (2017).
7. 42 USC §1395w-111(i).
8. 42 USC §1395w-104(b)(1)(C).



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