THE SCOTUS *RUTLEDGE* OPINION

Pharmacy Benefit Managers Cannot Duck Pro-Patient State Reform Laws Using ERISA Preemption Arguments

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On December 10, 2020—in a decision decades in the making—the U.S. Supreme Court delivered its opinion in *Rutledge v. Pharmaceutical Care Management Association*, which upheld that states *are* permitted to regulate pharmacy benefit managers (PBMs). Justice Sotomayor wrote the court's opinion, which was joined by all members of the Supreme Court except Justice Barrett, who did not participate.

For years, independent pharmacies (i.e., pharmacies not owned by national chains) have been at risk of closure due to unfair practices by PBMs and competitors, which are sometimes one in the same. PBMs are third-party administrators of prescription-drug programs that affect more than 270 million Americans with health insurance. The role of PBMs is to act as intermediaries by negotiating with health care plans, drug manufacturers, and pharmacies to set drug pricing for consumers and determine how much pharmacies are reimbursed. The goal in creating these intermediaries was for them to be able to lower drug costs and spending. In practice, however, PBMs leverage their status to maximize their own profits, while simultaneously harming pharmacies and increasing patient costs.

Why did PBMs stray so far from their purpose? Because a number of the largest PBMs in the country have considerable conflicts of interest. For example, certain PBMs are affiliated with some of the largest pharmacy chains in the world, like CVS Health owning both CVS Pharmacy and CVS Caremark. PBMs also operate with little oversight by regulators and do not provide much transparency into their operations. As a result, they are able to exploit the marketplace, resulting in higher drug costs, and use exclusionary practices to eliminate competition—independent pharmacies. So, what happened when states caught wind of these practices and attempted to introduce legislation that would protect independent pharmacies from this abuse? The Pharmaceutical Care Management Association (PCMA), which represents the 11 largest PBMs in the country, commenced lawsuits, declaring that the states were restricted from regulating PBMs due to existing federal law. The U.S. Supreme Court's decision finally quashed the argument PCMA used for years that, in essence, all regulation was preempted by the Employee Retirement Income Security Act of 1974 (ERISA). This decision has opened the door for much-needed change in the pharmacy industry and hopefully will level the playing field.

One of the most significant issues that independent pharmacies face with regard to PBM practices concerns reimbursement rates. In 2015, Arkansas passed Act 900 because the reimbursement rates set by PBMs were too low to cover the acquisition cost of the drugs by an independent pharmacy. Act 900 required PBMs to reimburse Arkansas pharmacies at a price equal to or higher than the pharmacy's wholesale cost. Due to the unworkable reimbursement rates set by PBMs, many independent pharmacies—particularly those in rural areas—were at risk of being unable to cover their costs and having to close their doors for good. Obviously, a business cannot sustain itself if it is required to operate at a loss, which is exactly what was happening to these independent pharmacies.

In response to Act 900, PCMA alleged that the state law was preempted by ERISA. PCMA argued that Act 900 created inefficiencies in employer-sponsored health plans, threatened access to prescription drugs, and eliminated important tools that help employers manage prescription drug costs and provide access to medications. PCMA also asserted that these matters were

central to plan administration and protecting ERISA's promise of uniformity is more critical than ever, as ERISA had long enabled employers to provide uniform benefit plans to employees nationwide due to ERISA's preemption of state laws. While it is true that ERISA broadly asserts that it preempts state laws that relate to employee benefits—which is why previous PBM regulations have been such an uphill battle—Justice Sotomayor wrote that "[s]tate regulations that merely increase the costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted by ERISA." Therefore, the *Rutledge* decision establishes that price regulation is not an issue that can be considered as preempted by ERISA. In this monumental win for independent pharmacies, the Supreme Court unanimously held that Arkansas's law was *not* preempted by ERISA and overturned the Eighth Circuit's decision that held the opposite. By doing so, the Supreme Court effectively ruled that PCMA's ERISA arguments, which have been victorious for PBMs in numerous other cases across the country concerning state laws regulating PBMs, do not hold up. This is a huge blow to PBMs because they have relied on ERISA preemption to avoid meaningful oversight by states for decades.

Significantly, Justice Sotomayor's opinion sweeps broadly enough that it is not limited to the particulars of only Act 900. Applying the logic of *Rutledge*, PBM laws are a form of health care cost regulation, and PBMs are not health plans, but rather their administrative contractors, so ERISA should not preempt states' PBM regulations. However, the *Rutledge* decision does not stop there. It is also a win for pharmacies and consumers to the extent that it broadens states' protective powers. Significantly, the Supreme Court upheld Arkansas's requirement that PBMs participate in the pharmacy appeal process and abide by its enforcement mechanisms, including recalculating and reprocessing how much they pay the pharmacy. This is in stark contrast with the seemingly unlimited power PBMs have previously held where independent pharmacies were often at the mercy of the not-so-transparent PBM audit process and frequently denied due process. It seems as though the Supreme Court has taken notice of these predatory practices and provided states the tools to finally combat it.

Following *Rutledge*, the ongoing lawsuits brought by the PCMA against states like Arkansas that sought to regulate PBM activities will be greatly impacted. For one thing, more than 45 states have passed PBM regulations that will now have the backing of U.S. Supreme Court precedent. Among other things, some of these regulations ban PBM gag clauses that prevent pharmacies from telling consumers about lower-cost options, while others limit patient cost sharing and require PBMs to disclose their price lists and manufacturer rebates to improve transparency, or prohibit spread pricing, which is when PBMs charge plans more than they reimburse pharmacies.

Even though *Rutledge* was just decided in December 2020, its effects are already being significantly felt. For example, the 2021 New York Executive Budget Bill included requirements that PBMs register and become licensed by the Department of Financial Services (DFS). DFS may set minimum standards for issuance of a PBM license, including standards of conduct that may address things like prohibitions on anticompetitive conduct and spread pricing. DFS also has the authority to suspend, revoke, or refuse to renew or issue a PBM. With the Supreme Court's ruling in *Rutledge*, it is more likely than ever that this PBM reform will pass. Additionally, on January 21, 2021, North Dakota petitioned the Supreme Court to vacate a different, yet similar, Eighth Circuit decision, which found North Dakota's PBM regulations to be preempted by ERISA—PCMA even supported the state's position that the ruling should be vacated.

As a result of their loss in *Rutledge*, PBMs are now scrambling to change public opinion. The National Community Pharmacists Association (NCPA) has stated that "when the Supreme Court declared states can regulate PBMs, the PBMs launched campaigns in 18 states to date to besmirch community pharmacies, lie to patients, and avoid overdue state legislation AND regulation." On January 12, 2021, PCMA also filed a lawsuit against the Trump Administration for its executive order Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, which would directly affect rebates to PBMs, aiming to save patients money on prescription costs. Following this lawsuit and the transition of the Biden Administration, which called into question the legality of several last-minute Executive Orders, the rebate rule has been postponed pending a 60-day review period, but a recent court order has postponed the effective date of the discount safe harbor provision of the rule until January 1, 2023. It is unclear at this time whether the new administration will adopt this rule, which would undoubtedly be another blow to PBMs, or whether it will succumb to pressure brought on by the PCMA and rewrite or veto the rule.

Without state laws like Act 900 that underlie the precedent set by *Rutledge*, pharmacies would have a harder time operating in an already challenging marketplace and from a disadvantageous position. Now, states have the ability to push back against draconian PBM practices. With the Supreme Court behind them, states can end PBM greed and get them on track to do what they were originally tasked with—lowering the cost of prescription drugs and making it easier for the average American consumer to have access to necessary medication at their pharmacy of choice. Although this important battle has already started, it is far from over. It is imperative that states take this opportunity to make real change for the sake of consumers, independent pharmacies, and the health care system.

Barclay Damon assists independent pharmacies in all aspects of their business operations. If you have any questions or would like to schedule a legal and compliance checkup, please contact Linda Clark, Health Care Controversies Team leader, at lclark@barclaydamon.com, or Brad Gallagher, counsel, at bgallagher@barclaydamon.com. Special thanks to Jen Cruz, law clerk, for her assistance in writing this article.

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