



AND THE LAW

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THE SUPREME COURT AND PBM REGULATION

The case of Rutledge vs. Pharmaceutical Care Management Association (PMCA) is to be heard by the U.S. Supreme Court in late April 2020. It is a very important case for the pharmacy profession in their ongoing battle with Pharmacy Benefits Managers (PBM). The individual legal issues in the case are complicated, but the general point of the case is fairly simple; can an individual state regulate PBMs within its borders?

The law at issue was passed by the Arkansas General Assembly in 2015. The law contained many provisions, but the major ones address Maximum Allowable Cost (MAC) and pharmacy reimbursements. It provided that pharmacies must be reimbursed at a cost higher than or equal to the pharmacy's cost, even if this amount would be greater than the MAC. It also required the PBM to update MAC lists within 7 days of an increase in costs. The law also allowed a pharmacy to reverse a charge and re-bill it if the pharmacy was unable to order the drug at less than or equal to the MAC. It also introduced a "decline to dispense" option if the pharmacy would lose money on the transaction.

PCMA brought suit in Federal Court for the Eastern District of Arkansas asserting that Arkansas' law was preempted by the Employee Retirement Income Security Act of 1974 (ERISA) and by Medicare Part D regulations. The District Court ruled that Arkansas' law was preempted by ERISA based on a previous 8th Circuit Court of Appeals case, but was not preempted by Medicare Part D regulations. PCMA appealed to the 8th Circuit and the appeals court ruled that the Arkansas law was preempted by both sets of laws. ERISA preempts any state law relating to employee benefit plans. Medicare Part D regulations prohibit interference with CMS standards that exist between Plan D sponsors and pharmacies.

The Solicitor General of the United States asked the U.S. Supreme Court to take the case because he believes the ruling is contrary to prior Supreme Court precedent. The Attorneys General from 31 states and the District of Columbia also asked the Supreme Court to take the case. The Supreme Court is not required to take all appeals, and it often doesn't, so it is significant that the Court decided to take this case.

The major importance of the case is that states have had difficulty in passing laws to regulate PBMs that aren't later found to be preempted by Federal law. The ERISA precedent that the District Court relied on came from a previous attempt by Iowa to regulate PBMs. Iowa's law specifically mentioned ERISA and Arkansas had tried to avoid a similar fate by not mentioning ERISA in their law.

PMCA argues the Arkansas law interferes with 2 different CMS standards. The first is the Negotiated Price standard. This standard addresses the price for a particular drug that has been negotiated between the part D sponsor and the network dispensing pharmacy. Under this standard, the District Court found this law didn't directly affect the CMS standard because the negotiated prices provisions are not a substantive standard. The appeals court disagreed because of the number of provisions that dealt directly with reimbursements to the pharmacy. The second standard is the Pharmacy Access standard. This standard requires plans to have sufficient numbers of pharmacies in their network to assure convenient access for the plan participants. The appeals court found here that the "decline to dispense" option would decrease pharmacy availability for the plan participants. The most novel argument in the case concerns the question of the ERISA preemption. This has been interpreted very broadly in the past. If the state law relates to and has a connection with an employee health plan, then ERISA controls and the state law is preempted. The argument in this case is that Arkansas' law doesn't affect ERISA plans because it acts on the third party administrators and claims processors, some of whose customers include ERISA plans. Arkansas argues their law affects the relationship between PBMs and pharmacies, not ERISA plans.

Once the case is heard, it will likely take months for a ruling to be handed down. If the Supreme Court can be persuaded that the Arkansas law is not directed at ERISA plans, the ruling would allow that law to stand and create a roadmap for other states to follow Arkansas' lead. If unpersuaded, the Arkansas law will be struck down. While other attempts could be made by individual states, the ultimate solution will most likely have to come from the Federal level.

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