Supreme Court: State Regulations on PBM Reimbursements to Pharmacies Not Preempted by ERISA

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A recent Supreme Court decision gives states leeway to impose new regulations on pharmacy benefit managers (PBMs), even when PBMs are acting on behalf of ERISA plans. On December 10, 2020, in an 8-0 unanimous decision (with newly-seated Justice Barrett not participating) the Court held, in *Rutledge v. Pharmaceutical Care Management Association*, that states may regulate, among other things, the amounts for which PBMs must reimburse pharmacies for prescription drugs, clarifying that such regulations are not preempted by ERISA.

As background, plans often contract with PBMs to administer their prescription drug benefits, with the plan paying the drug costs. Because PBMs administer many such plans, covering large numbers of participants, they can often negotiate favorable drug pricing with manufacturers and pharmacies to reduce drug costs for the plans they administer. The Arkansas law, which was aimed at providing financial protection for retail pharmacies, required PBMs to tie their reimbursement rates to pharmacies' costs as drug wholesale prices increase and to provide administrative appeal procedures for pharmacies to challenge reimbursement rates below cost, and further permitted pharmacies to decline to sell drugs if the PBM's reimbursement rate was below the pharmacy's cost.

Under the Court's prior decisions, a state law is preempted if it has a connection with or refers to an ERISA plan. However, in *Rutledge*, the Court clarified that "not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan," such that it would be preempted. In particular, the Court emphasized that a law that "merely affects costs" may not be preempted, explaining that "ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." Applying that standard, the Court held that the Arkansas law was not pre-empted because it "is merely a form of cost regulation." The Court further noted that the effect of the Arkansas law was not "so acute that it will effectively dictate plan choices."

The Court also rejected the argument that the Arkansas law "refers to" ERISA. Under the Court's prior case law, in order for a state law to be preempted by referring to ERISA, it must act immediately and exclusively upon ERISA plans or the existence of ERISA plans must be essential to the operation of the state law. The Court held that this standard was not met because the law applies to all PBMs regardless of whether they manage ERISA plans, and because ERISA plans are only affected insofar as PBMs may pass along their higher costs.

The Court also rejected several other arguments for preemption, including the argument that the law directly affects central matters of plan administration and interferes with nationally-uniform plan administration, finding that it does not require plan administrators to structure their plans in any particular manner and does not lead to anything more than potential operational inefficiencies. The Court also rejected the argument that the law could affect plan design because plans might prefer using older reimbursement rates to contain costs and ensure predictability, noting that this was purely a manner of cost regulation, which is not within the scope of preemption. The Court further rejected the argument that the law interferes with central matters of plan administration by permitting pharmacies to decline to dispense prescriptions if the reimbursement rate would be below cost, finding that this is the consequence of the PBM offering the pharmacy less than its costs. Finally, the Court rejected the argument that the law would interfere with nationally uniform plan administration by creating inefficiencies, which the Court ruled was insufficient to trigger preemption. It should be noted, however, that the Court did not significantly analyze the claims of inefficiencies that would be created as a result of the law.

This decision has significant implications for ERISA plans. For one thing, ERISA plans that utilize PBMs and have participants in Arkansas or other states with similar regulations may see price increases as PBMs are required to increase their reimbursement costs, which will presumably be passed along to plans. This could lead to ERISA plans paying significantly different drug costs depending upon the state in which the drugs were dispensed. This could also increase the PBM's administrative costs, which will also likely be passed along to the plans, either immediately or at the plan's next contract renewal.

More broadly, this decision has potential impacts for ERISA plans – especially self-insured plans – beyond PBMs. While fully-insured plans have historically been subject to state regulation, that has not been the case for self-insured plans as state regulation of self-insured plans has typically been found to be preempted. However, the *Rutledge* decision seems to open up an entire new avenue for states to use their regulatory powers to at least regulate issues relating to costs for self-insured plans, just as they can for fully-insured plans, provided that any such laws are generally applicable to all health plans and not targeted at ERISA plans specifically.

This decision also seems to leave room for substantial future litigation on whether purported "cost regulations" effectively dictate plan choices. Without providing significant clarity, the Court seems to have allowed the possibility that cost regulation that effectively forces the Plan to be administered in a particular way may still result in preemption. Undoubtedly, future cases will argue that cost regulations have crossed the line into dictating the plan's choices. There may also be future litigation as to whether inefficiencies created as a result of state action are of the type of cost regulations held to not be preempted in *Rutledge*, or more significant ones that may more significantly interfere with plan administration.

Please contact Slevin & Hart for more information about this case and how it could affect your plan.

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