High Court Faces Preemption Dilemma In Drug Benefits Case

News 10.16.20

On Oct. 2, the eight current justices of the U.S. Supreme Court held oral argument in a hotly contested lawsuit of significant importance to America's health care stakeholders — and in particular, to pharmacies, pharmacy benefits managers, or PBMs, and employer-sponsored health plans, or ERISA plans, that pay for their beneficiaries' pharmaceuticals.

The case raises an important question of federal ERISA preemption of state laws — and the Supreme Court's application of ERISA's preemptive powers has been, to be charitable, somewhat hard historically to reconcile.

Of particular interest is how the court will apply preemption in the context of the business relationship between ERISA plans as payors and pharmacies as providers. Also of interest is whether the court's reasoning will be consistent with its analysis of the McCarran-Ferguson Act's preemption of state laws, in the very close and patently analogous context of state laws that attempt to regulate the relationship between private insurers, again, as payors, and pharmacies and other providers.

The pending case, *Rutledge v. Pharmaceutical Care Management Association*, challenges an Arkansas state law that regulates the minimum prices that PBMs can pay pharmacies for drugs provided. In essence, the Arkansas law mandates that PBMs pay dispensing pharmacies no less than the pharmacies' actual costs of acquiring the drugs.

Although that proposition may seem commonsense and uncontroversial on its face — and indeed, 37 states have such laws — the marketplace reality is complex and problematic. To summarize the difficulties, the marketplace historically has been rife with hidden discounts, rebates and other incentives that can cause an absence of transparency with respect to how much a given drug actually costs. Indeed, as Chief Justice John Roberts put it during oral argument in Rutledge, PBMs employ "Byzantine procedures that affect drug prices," and the pharmacies should not suffer under them.

PBMs are essentially middlemen. They purchase pharmaceuticals from manufacturers and pharmacies, distribute them to patients and other users, and charge health plans, insurers and self-funded ERISA plans more for them, and pocket the difference. The arrangement is akin to a common trade circumstance in which a large distributor purchases goods in bulk, and then distributes them to smaller retailers or the public.

But here, the independent pharmacies claim that PBMs routinely pay them less than their actual cost for certain drugs, as opposed to the higher prices paid by PBMs to their chosen affiliated pharmacies, resulting in the failure, according to the Arkansas attorney general, of more than 16% of rural independent pharmacies in the U.S.

Arkansas and other states have an obvious interest in preserving their existing local pharmacies, in the interest of patient access. PBMs, of course, resist any law that constitutes price-setting, and hence constraint on their operations and profits. ERISA plan administrators, for their part, have an interest in uniform national application of law, rather than a state-by-state regulatory patchwork; indeed, this efficiency and uniformity was Congress' stated intent in crafting ERISA's preemptive provisions when the law was enacted.

At oral argument in Rutledge, Justices Elena Kagan, Samuel Alito and Brett Kavanaugh voiced skepticism that, under its prior ERISA preemption precedent, Arkansas' law could stand. But the state argued that the law did not affect plan administration per se, since it only regulated the prices paid by a middleman — not the plan itself — for such drugs.

Moreover, the pharmaceuticals in question had already been determined, under the ERISA plans' design, to be a covered benefit; obviously, the plans would not have authorized their purchase and distribution were it otherwise. Thus, the rationale

offered by Arkansas and amici was that, in effect, the law had no direct impact upon the operation of the plan administrators, and also would have no impact upon the plans' beneficiary patients — because they would receive the drugs under the terms of their plan design, regardless of how much money the PBMs pay the pharmacies for them.

In rebuttal of these arguments against preemption, the PBM trade group argued in Rutledge that the Arkansas law necessarily would cause PBMs to incur increased costs, leading to higher charges by the PBMs to the ERISA plans, and creating a risk that ERISA plans, in turn, would reduce their pharmaceutical benefit to their beneficiaries, either through increased costs imposed upon beneficiaries, or narrowing of the lists of covered drugs, termed formularies.

Justice Kavanaugh, in particular, appeared potentially swayed by this basis for applying ERISA preemption, asking Arkansas' counsel, "Why shouldn't ERISA care about costs that are going to be increased and then passed on in the form of worse benefits to Arkansas workers?" But Justice Alito, for his part, probed at whether increased costs for plans and their beneficiaries were inevitable, or merely a convenient supposition by the PBMs.

Justice Alito noted, for example, it was conceivable that PBMs would simply absorb the increased costs themselves. The PBMs' counsel conceded, in response, that he had "no specific data" conclusively showing that laws such as Arkansas' had resulted in higher charges to plans, or reduced benefits to plan participants.

What's interesting is how the Supreme Court has addressed this very economic downstream cause-and-effect analysis, when determining whether state laws that regulate the business arrangements between private insurance companies and health care service plans, on the one hand, and providers — including pharmacies — on the other, are preempted under the federal McCarran-Ferguson Act.

Under McCarran-Ferguson, the court has repeatedly rejected preemption, despite the existence of similar factual circumstances, and despite the fact that the same arguments made by the PBM industry in Rutledge would appear equally compelling and applicable to the private insurance context.

The McCarran-Ferguson Act, Title 15 of the U.S. Code, Section 1012(b), contains a unique preemption provision which allows it to preempt other federal laws of general application, such as the Federal Arbitration Act, and hence provides that a state law is saved from preemption if the state law "regulates the business of insurance." What proves controversial, however, is whether a state law which governs the relationship between health plan and provider — and not between health plan and insured — regulates the business of insurance within the meaning of McCarran-Ferguson.

For example, in *Group Life & Health Insurance Co. v. Royal Drug Co.*,[1] a group of pharmacies brought an antitrust action against insurance companies, contending the insurance companies entered into arrangements with pharmacies that illegally fixed the prices of drugs. The insurance companies argued that federal antitrust law did not apply because it was reverse-preempted by the McCarran-Ferguson Act, since, according to them, the challenged practice constituted the business of insurance.

The Supreme Court rejected that argument, holding that agreements between the insurance companies and pharmacies did not constitute the business of insurance within the meaning of Section 1012(b) of the McCarran-Ferguson Act. In reaching that conclusion, the court reasoned the agreements did not involve underwriting of policies or spreading of risk, but were "merely arrangements for the purchase of goods and services" by the insurance companies. [2]

The court noted that the benefit provided to policyholders is that their premiums would cover the cost of prescription drugs: "So long as that promise is kept, policyholders are basically unconcerned with arrangements made between [the insurance company] and participating pharmacies."

Yet the situation in Rutledge is arguably the same. On the one hand, the plan beneficiaries in Rutledge receive the drugs to which they are entitled under their ERISA plan design, and they too — like the private insureds in Royal Drug — presumably are "basically unconcerned" with the payment arrangements between the PBMs and the pharmacies.

Yet one would easily imagine that the same arguments made by the PBMs in Rutledge would apply to Royal Drug's facts as well. Surely, one would reason, the existence of an antitrust conspiracy in the supply chain would, a fortiori, ultimately have a negative financial or access impact, or both, upon policyholders.

Yet, the Supreme Court has consistently applied the Royal Globe analysis when construing McCarran-Ferguson's preemptive effect in situations involving payment arrangements between insurers and health care providers. As another example, in U*nion Labor Life Insurance Co. v. Pireno*,[3] the plaintiff chiropractors sued the defendant insurance company, contending the insurer's internal review practice for deciding whether charges for certain chiropractic care were reasonable, and whether such care and services were necessary and therefore covered by insurance policies, violated federal antitrust laws.

Here too, the insurance company argued that its payment review practice constituted the business of insurance, and was therefore exempted by the McCarran-Ferguson Act from federal antitrust laws. The Supreme Court disagreed.

The Pireno court reasoned once again that the payment review process did not involve the underwriting of policies or spreading the risk, saying that the peer review process "takes place only after the risk has been transferred by means of the policy," and is "logically and temporally unconnected to the transfer of risk accomplished by the defendant's insurance policies."[4] The court also determined that the peer review process was "not an integral part of the policy relationship between the insurer and insured," was "obviously distinct" from the defendant's contracts with its policyholders, and was a "separate arrangement between the insurer and third parties not engaged in the business of insurance." [5]

In this decision as well, the Supreme Court reasoned that any decision of the payment review committee "is a matter of indifference to the policyholder, whose only concern is whether his claim is paid, not why it is paid." [6] Yet once again, one could easily make an argument similar to those made in Rutledge — namely, that the payors' decisions regarding what charges to pay the provider, and in what amount, necessary could act to reduce benefits to policyholders, and/or increase their costs, not to mention lessen their access to providers by putting some of them out of business.

ERISA plans and private insurance plans are different — but not to the covered individuals. The proverbial man on the street would almost surely be unable to tell you whether his health insurance is governed by ERISA or by state insurance charter.

Moreover, the same theorization about possible downstream economic effects on beneficiaries of payors' pricing decisions would seem equally applicable to either context. Whether the Supreme Court will recognize and address the corollary or not will ultimately be revealed in the Rutledge decision.

---

[1] *Group Life & Health Insurance Co. v. Royal Drug Co*., 440 U.S. 205 (1979).
[2] Id. at 214.
[3] *Union Labor Life Insurance Co. v. Pireno*, 458 U.S. 119, 126 (1982), at 122.
[4] Id. at 130.
[5] Id. at 131.
[6] Id. at 132.