



Supreme Court Decision Sheds Light on State Authority to Regulate Health Care Costs

March 26, 2021

Alongside recent federal efforts to combat escalating prescription drug costs, state governments have sought to address these high costs within their borders. Many state efforts involve restrictions on pharmacy benefit managers (PBMs), companies that facilitate the purchase of drugs through the pharmaceutical distribution chain and administer prescription drug coverage on behalf of health insurers, employers, and others. While many states have enacted legislative measures intended to hold PBMs accountable for their role in the pharmaceutical marketplace, PBMs have challenged some of these measures on the basis that they are preempted by the federal Employee Retirement Income Security Act (ERISA). On December 10, 2020, in *Rutledge v. Pharmaceutical Care Management Ass'n*, the Supreme Court weighed in on this issue, concluding that a state PBM law withstood preemption by the federal act.

Why does this case warrant attention for the Biden Administration and the 117th Congress? In the past, courts have concluded that ERISA restricts states from enacting certain health care regulatory measures that affect employment-based health coverage. In the wake of *Rutledge*, questions may arise about the degree to which states have leeway to regulate health care costs in the context of PBMs and beyond. This Legal Sidebar provides background on ERISA preemption; examines the *Rutledge* decision; and concludes with selected legal considerations for Congress as it continues to address drug pricing reforms.

ERISA Preemption Overview

ERISA provides a comprehensive federal scheme for the regulation of private-sector employee benefit plans. Although ERISA was enacted in 1974 primarily to regulate pension plans following some notable pension defaults, the Act also regulates employment-based plans that provide medical, surgical, and other health benefits. Under ERISA, health plans must comply with various standards, including plan fiduciary standards, reporting and disclosure requirements, and numerous private health insurance market reforms established by the Patient Protection and Affordable Care Act. Recent reports estimate that approximately 135 million individuals in the United States have employer-sponsored health coverage to which ERISA applies.

According to the Supreme Court, Congress, through ERISA, federalized the regulation of plan administration "to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government." This goal is carried out in part

Congressional Research Service

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LSB10587

through a critical feature of ERISA: its express preemption clause. Under Section 514 of the Act, ERISA broadly preempts "any and all State laws insofar as they may now or hereafter *relate to* any employee benefit plan." The question whether ERISA preempts state law is an issue of frequent litigation, finding its way to the Supreme Court almost two dozen times. In numerous opinions, the Court has interpreted the "relate to" language as applying to any state law that "has a connection with or reference to [an employee benefit] plan." The Court has observed that a state law has an impermissible "connection with" an ERISA plan if it "governs . . . a central matter of plan administration" or "interferes with nationally uniform plan administration." A state law has a "reference to" an ERISA plan if it acts "immediately and exclusively" on ERISA plans, or if the existence of such a plan is essential to the law's operations. In the health care context, states cannot, for instance, require employers to provide a minimum level of health coverage or specific health benefits as part of their benefit plans.

The Supreme Court's 2016 decision in *Gobeille v. Liberty Mutual Insurance Co.* illustrates how ERISA's express preemption provision can affect state efforts to enact health care regulatory initiatives. In *Gobeille*, the Court examined a Vermont law that required employer-sponsored health plans and other entities to report health care claims information for inclusion in an all-payer claims database (APCD). APCD data can generally be used by researchers to study the cost, use, and quality of health care within a state. In a 6-2 decision, the Supreme Court concluded that Vermont's reporting law was preempted to the extent it applied to ERISA plans. Citing ERISA's extensive reporting, disclosure, and recordkeeping requirements, the Court held that Vermont's reporting regime "imposes duties that are inconsistent with the central design of ERISA, which is to provide a single uniform national scheme for the administration of ERISA plans without interference from laws of the several States." Even though the Vermont law's objective was to better control health care costs and outcomes, not to regulate employee benefit plans, the Court's majority reasoned the state law's reporting scheme was a "direct regulation of a fundamental ERISA function," and that any difference in purpose did not convert this regulation "into an innocuous set of additional rules."

Despite ERISA Section 514's broad scope, the Supreme Court has articulated that "[s]ome state actions may affect employee benefit plans in too tenuous, remote, or peripheral a manner to warrant a finding that the law 'relates to' the plan." For instance, in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, insurance companies providing health coverage to ERISA-governed plans challenged a state law that required them, but not Blue Cross & Blue Shield, to pay hospital surcharges. Although the state law at issue triggered higher costs for ERISA-plans, the Court upheld the law, concluding it had an "indirect economic influence" that did not bind administrators to particular choices with respect to a plan. In the wake of *Gobeille, Travelers*, and other cases, lower courts have grappled with applying the Court's ERISA precedent and determining whether state legislation survives ERISA preemption.

The Rutledge Decision

At issue in *Rutledge* was Arkansas Act 900, a state statute intended to manage PBM pharmacy reimbursement practices. As intermediaries between health insurance plans and pharmacies, PBMs may receive payment from health insurers for drug benefit administration and reimburse pharmacies for dispensing drugs to insured individuals. Certain rural and independent pharmacies expressed concerns that PBMs' reimbursement rates for drugs were frequently less than what the pharmacies paid to obtain them. To protect the financial viability of these pharmacies, the Arkansas statute established certain mechanisms designed to anchor PBM pharmacy reimbursement rates to the pharmacies' acquisition costs. A PBM trade association sued the state, claiming, among other things, that ERISA preempted the Arkansas state law as it applied to PBMs that service ERISA plans. The association further argued that the state law had a direct regulatory effect on ERISA plans, plan design, and how these plans manage drug

benefits. The district court agreed with the association's contention that ERISA superseded the state law, and the U.S. Court of Appeals for the Eighth Circuit affirmed.

In an 8-0 decision, the Supreme Court reversed the Eighth Circuit's judgment, holding that ERISA does not preempt Arkansas's PBM law. (Justice Amy Coney Barrett did not participate in the consideration or decision in the case.) Writing for the Court, Justice Sonia Sotomayor employed the Court's traditional test for ERISA preemption: whether the state law has "a connection with or reference to" an ERISA plan. The Court concluded that the Arkansas statute fell outside of these categories and was beyond ERISA's preemptive reach. In discussing why the Arkansas law lacked a prohibited "connection with" an ERISA plan, the Court explained that ERISA is "primarily concerned with preempting laws that require providers to structure benefit plans in particular ways," such as requiring payment for a specific benefit. ERISA does not, the Court found, preempt state requirements that "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." The Court maintained that the Arkansas statute was similar to the state law at issue in *Travelers*—a type of cost regulation that did not compel plans to offer coverage in a particular manner. The Court further determined that the Arkansas law did not impermissibly "refer to" ERISA plans because ERISA plans are unrelated to the state law's operation—the law applies to PBMs regardless of whether they manage ERISA plans or not.

Justice Clarence Thomas authored a concurring opinion in *Rutledge*, expressing support for the case's outcome, but a desire for the Court to revisit its ERISA preemption jurisprudence. According to Justice Thomas, the Court's current test for ERISA preemption departs from the law's text and "offers little guidance or predictability" to lower courts. To remedy this, Justice Thomas suggests that the Court adopt a different test to determine whether ERISA supplants state law: a two-part test that asks (1) whether any ERISA provisions govern the same matter as the state law at issue, and (2) whether the state law bears a meaningful relationship to ERISA plans. Such a test would seemingly be a narrower standard for ERISA preemption, but one that Justice Thomas believes would apply ERISA Section 514 as written.

Considerations for Congress

In *Rutledge*, the Supreme Court clarified that state laws regulating health care costs may be immune from ERISA preemption, even if the laws indirectly affect costs or alter incentives for providing benefits in ERISA-governed plans. Following the path of *Travelers*, the *Rutledge* decision appears to signal that states may regulate the rates that health care providers and other entities charge for drugs or other items and services covered by ERISA plans. However, similar to *Travelers* and other cases, the Court recognized limits on this flexibility: the state requirement at issue cannot compel plans to offer a certain type of coverage or administer benefits in a particular manner. The question of which state laws permissibly regulate health care costs for plans and which ones impermissibly "dictate plan choices" will likely be the subject of future litigation.

While the practical impact of *Rutledge* remains to be seen, the decision is notable in that it may preserve states' ability to regulate the business practices of PBMs more comprehensively, even when PBMs are servicing ERISA plans. To address states' concerns that PBMs have impeded access to affordable prescription drugs, over 44 states have enacted a variety of legislation targeting these entities. State requirements include provisions that require PBMs to disclose their price lists and other information to improve transparency, as well as requirements that PBMs engage in good faith and fair dealing in their business relationships with plan sponsors and pharmacies. While the Court in *Rutledge* only analyzed Arkansas's PBM statute, it appears the decision's reasoning may apply to other state laws addressing PBM payment rates or other functions. Additionally, it is possible that *Rutledge*'s reasoning may extend beyond the PBM context to the regulation of other entities that contract with ERISA plans. ERISA plan sponsors rely on various third parties to provide services to plan participants, including health care

facilities and provider networks. It seems possible that the Court's decision in *Rutledge* may lend support for state regulation of the costs of services by these or other entities.

Congress remains free to enact legislation that further defines ERISA's preemptive reach. Federal legislation could, among other things, address a PBM's role in service to ERISA plans, or more broadly speak to states' ability to enact reforms that affect private-sector, employment-based health coverage. Such legislation could explicitly restrict state authority to pass cost-control measures affecting ERISA plans to promote a more uniform, federal regulatory approach, or alternatively articulate the degree to which states may experiment with measures designed to improve health care financing and access. Federal legislation articulating the parameters of ERISA preemption may help guide the courts as they examine likely future legal challenges to state health reform efforts.

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