January 13, 2021

Rutledge vs. PCMA: SCOTUS Greenlights State Regulation of Pharmacy Benefit Manager Drug Reimbursement

Introduction

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On December 10, 2020, the Supreme Court, in a unanimous opinion, held that the Employee Retirement Income Security Act ("ERISA") does not preempt an Arkansas law regulating pharmacy benefit manager ("PBM") reimbursement to pharmacies. The Court's decision provides a potential avenue for states to increase regulation of PBMs and other service providers that help administer ERISA-regulated group health plans, and therefore holds potential significance for, among others, PBMs, pharmacies, pharmaceutical manufacturers, and employers that sponsor ERISA-regulated group health plans. It also lays the foundation for states to play an even greater role in regulating drug pricing and reimbursement activities of various entities involved in the pharmaceutical supply chain.

This Alert summarizes the decision and discusses key implications for state regulation of PBMs and other companies that administer ERISA-regulated plans and, relatedly, drug pricing and reimbursement.

Background and the Supreme Court's Decision

In recent years, an increasing number of states have sought to regulate PBM activities—oftentimes, as part of a state's broader efforts to address prescription drug pricing and reimbursement, or to rein in business practices such as pharmacist "gag clauses" that are seen as detrimental to patients or pharmacies. The Pharmaceutical Care Management Association ("PCMA") (a trade association representing the largest eleven PBMs in the country) has played an active role in challenging many state statutes under the theory of legal preemption, with somewhat inconsistent results across cases and jurisdictions.[1]

In 2015, the Arkansas state legislature passed Act 900 (the "Arkansas Law") to regulate PBMs' reimbursement rate for pharmacies.[2] The Arkansas Law, in effect, establishes a reimbursement floor that requires PBMs to reimburse pharmacies at a rate that, at a minimum, reflects the pharmacy's acquisition cost for the drug in question.[3] The Arkansas Law accomplishes this by tethering reimbursement rates to acquisition costs, providing for an appeals process when reimbursement falls below a pharmacy's acquisition costs, and allowing pharmacies to refuse to fill prescriptions if the applicable PBM will not reimburse at a rate at least equal to the acquisition cost.[4]

In response to the passage of the Arkansas Law, PCMA filed suit in the Eastern District of Arkansas, claiming that the Arkansas Law is preempted under ERISA's statutory preemption provision, which preempts those state laws that "may now or hereafter relate to any employee benefit plan."[5] The Eastern District of Arkansas and, on appeal, the U.S. Court of Appeals for the Eighth Circuit held that ERISA preempted the Arkansas Law.[6] On December 10, 2020, however, the U.S. Supreme Court, reversed the Eighth Circuit's decision regarding the Arkansas Law in an 8-0 ruling (with Justice Barrett abstaining).[7]

Justice Sotomayor, writing for the *Court in Rutledge v. PCMA*, assessed whether the Arkansas Law "relates to" (and is therefore preempted by) ERISA, by considering whether the Arkansas Law "has a connection with" or "refers to" an ERISA plan.[8] Ultimately, the Court concluded that the Arkansas Law is not preempted by ERISA for two reasons. *First*, because the law at issue is a form of "cost regulation," the Court held that the Arkansas Law does not have an "impermissible connection" with an ERISA plan. *Second*, because the Arkansas Law applies generally to PBMs (regardless of whether they manage an ERISA plan), the Court held that it does not "refer to" an ERISA plan.

With respect to the first rationale, the Court concluded that the Arkansas Law is not preempted by ERISA because it does not create an "impermissible connection with" an ERISA plan. To determine whether the Arkansas Law has an "impermissible connection with" an ERISA plan, the Court considered ERISA's ultimate policy objectives, namely, whether the law "governs a central matter of plan administration or interferes with nationally uniform plan administration."[9] The Court explained that state laws that "merely affect the costs" of ERISA plans do not have an impermissible connection with ERISA plans because such laws have only an "indirect economic effect" on plan administrators and do not "bind" plan administrators to take certain action.[10] In keeping with its consideration of the ultimate policy goals of ERISA, the Court noted that "cost uniformity [among states] was almost certainly not an object of pre-emption."[11] The Court acknowledged, however, that certain "acute, albeit indirect, economic effects" of a given state law may necessitate preemption if such acuity will "effectively dictate plan choices," forcing an ERISA plan to "adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers."[12] Applying this standard, the Court found that the Arkansas Law would have an "indirect economic influence" of increasing PBMs' costs of doing business in Arkansas (and these costs likely will be passed on to ERISA plans); nonetheless, the Court found that such an "indirect economic influence" was not enough to "effectively dictate plan choices" and does not create an "impermissible connection" that warrants preemption.[13]

In addition, the Court held that the Arkansas Law does not "refer to" ERISA plans in such a manner as to require preemption. For a law to "refer to" an ERISA plan, (1) the law must "act immediately and exclusively" upon such a plan or (2) the existence of ERISA plans must be "essential to the law's operation."[14] Here, the Court noted that the Arkansas Law applies to PBMs regardless of whether they manage an ERISA plan, meaning that the Arkansas Law clearly does not act "exclusively" on ERISA plans.[15] Importantly, the Court found that the Arkansas Law "does not directly regulate health benefit plans at all, ERISA or otherwise."[16] Rather, the only impact on plans comes from the PBMs' ability to pass along higher pharmacy rates to plans with which they contract.[17] The Court also noted that the Arkansas Law's broad definition of a PBM as any "plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in Arkansas" applies regardless of the type of plan a PBM administers.[18] The general applicability of this PBM definition led the Court to conclude that any particular plan's status as an ERISA plan was not "essential to the law's operation" and further reason that the Arkansas Law was not preempted by ERISA.[19]

The Decision's Impact

The Court's decision in *Rutledge* has immediate implications for the regulation of PBMs and the regulation of health benefit plans more broadly, as it appears to expand states' opportunity to regulate actors and industries that are adjacent to, but have a cost impact on, ERISA plans.

Currently, more than 40 states have implemented laws or regulations that seek to regulate PBMs.[20] While the specific subjects of each state's laws may differ in substance from the Arkansas Law, the Court's decision in *Rutledge* may help to protect certain laws and regulations—as well as future laws that certainly will be enacted—from successful ERISA-preemption challenges.[21] Although these laws take many forms—and regulate everything from gag clauses to price lists and disclosure of manufacturer rebates—and, in many cases, are not facially focused on cost, states still may be able to rely on the Court's precedent and general reasoning in *Rutledge* to withstand ERISA-based preemption challenges, provided that their legislative and regulatory actions place obligations on entities other than, exclusively, ERISA plans.[22] In some cases, such laws could now be interpreted by courts as not specifically "binding" a plan administrator because the added obligations would only have an indirect effect on ERISA plans in the form of increased costs.[23] Importantly, while the Court acknowledged limits to its ruling—recognizing that certain "acute" indirect economic effects may result in ERISA preemption—the pharmacy and PBM industries appear to anticipate that states have ample room to regulate PBMs long before reaching any upper limit on "indirect economic effects."[24] Similar impacts are anticipated for other ERISA plan-adjacent entities, like third-party administrators contracted to administer self-funded employer group health plans.[25]

The extent to which states will increase regulation of these industries based on *Rutledge* is presently unknown, but Justice Thomas, in his concurrence in *Rutledge*, attempts to chart a bright line on the Court's ERISA preemption jurisprudence. In *Rutledge*, the Court relied heavily on the logic of its decision in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, which established the principle that cost regulations survive ERISA preemption.[26] Justice Thomas noted that since the Court's opinion in *Travelers*, the only state laws that have been preempted by ERISA are those that regulate an area on which ERISA already directly speaks, and suggests adopting a new standard for ERISA preemption whereby a state law is preempted only if it has a direct ERISA counterpart and only if it has a meaningful relationship to an ERISA plan.[27]

While the majority was not persuaded by the approach advocated by Justice Thomas, its opinion nonetheless raises the distinct possibility that actors who work either as or with ERISA plan administrators might expect to see increased state level regulation of other areas that ERISA does not expressly regulate and employers will have to take into account the financial impact of such regulation when considering the benefits they offer to their employees.

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1. *See, e.g., Pharm. Care Mgmt. Ass'n v. Gerhart* 852 F. 3d 722 (8th Cir. 2017) (holding that an Iowa statute that regulated how PBMs establish generic drug pricing and required disclosure of pricing methodologies was preempted by ERISA); *Pharm. Care Mgmt. Ass'n v. D.C.* 613 F. 3d 179 (D.C. Cir. 2010) (holding that a D.C. statute's provisions (1) requiring PBM disclosure of drugs purchased by covered entities, net cost to covered entities, and the terms and arrangements for remuneration with drug manufacturers and (2) implementing a usage discount pass-back to covered entities were not preempted by ERISA, but the statute's provisions (1) requiring PBMs to act as fiduciaries for covered entities and its requirement that PBMs disclose conflicts of interest and the cost of the prescribed drugs and substitute drugs, and (2) implementing a substitution discount pass back to covered entities were preempted by ERISA); and *Pharm. Care Mgmt. Ass'n v. Rowe* 429 F. 3d 294 (1st Cir. 2005) (holding that a Maine statute requiring PBMs to act as fiduciaries for their clients and mandating certain disclosures was not preempted by ERISA).
2. *See* Ark. Code Ann. § 17-92-507.
3. *Id.*
4. *Id.*
5. Pharm. Care Mgmt. Ass'n v. Rutledge 240 F.Supp. 3d 951 (E.D. Ark. 2017).
6. *Pharm. Care Mgmt. Ass'n v. Rutledge* 240 F.3d 1109 (8th Cir. 2018).
7. No. 18-549, slip op. (Dec. 10, 2020).
8. *Id.* at 3.
9. *Id.* at 5 (quoting *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 320 (2016)).
10. *Id.*
11. *Id.* at 6 (*quoting New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.* 514 U.S. 645, 662 (1995)).
12. *Id.* at 4, 6.
13. See *id.*
14. *Id.* (quoting , 577 U.S., at 319–320).
15. *Id.* at 7.
16. *Id.*
17. *Id.*
18. *Id*;Ark. Code Ann. §§ 17-92-507(a)(7), (9).
19. *Id.*
20. National Academy for State Health Policy, State Drug Pricing Laws: 2017–2020, *available at* https://www.nashp.org/rx-laws/.
21. Erin C. Fuse Brown & Elizabeth Y. McCuskey, The Implications of *Rutledge v. PCMA* For State Health Care Cost Regulation, Health Affairs Blog (Dec. 17, 2020), *available at* https://www.healthaffairs.org/do/10.1377/hblog20201216.909942/full/#:~:text=In%20Rutledge%20v.%20Pharmaceutical%20Care,drug%20benefits%20for%20health%20plans.
22. National Academy for State Health Policy, *supra* note 18.

23. Brown, *supra* note 19.
24. *See Rutledge v. Pharm. Care Mgmt. Ass'n*, No. 18-549, slip op. at 6 (Dec. 10, 2020); Steve Anderson, Pharmacy Groups Hail Supreme Court's Rutledge Decision, Chain Drug Review (Dec. 10, 2020), *available at* https://www.chaindrugreview.com/pharmacy-groups-hail-supreme-courts-rutledge-decision/; PCMA Statement on U.S. Supreme Court Decision in *Rutledge v. Pharmaceutical Care Management Association (PCMA)* (Dec. 10, 2010), *available at* https://www.pcmanet.org/pcma-statement-on-u-s-supreme-court-decision-in-rutledge-v-pharmaceutical-care-management-association-pcma/.
25. Brown, *supra* note 19.
26. *Rutledge v. Pharm. Care Mgmt. Ass'n*, No. 18-549, slip op. at 5 (Dec. 10, 2020) (Thomas, J., concurring).
27. *Id.* at 5–6.