340B UPDATE: RECENT SUPREME COURT RULING MAY CURTAIL 340B PROGRAM DISCRIMINATORY PRICING

Date: 22 December 2020

U.S. Health Care Alert

By: Richard P. Church, Gary S. Qualls, Leah D'Aurora Richardson, Victoria K. Hamscho

The U.S. Supreme Court recently issued a unanimous decision[1] in *Rutledge v. Pharmaceutical Care Management Ass'n*,[2] which supports the validity of state statutes that regulate reimbursement rates pharmacy benefit managers (PBMs) pay to pharmacies. Specifically, the Supreme Court's ruling upheld Arkansas's Act 900 (the Act)[3] requiring PBMs to reimburse pharmacies at a rate equal to or greater than the pharmacies' acquisition costs, concluding that the Act was not preempted by the Employee Retirement Income Security Act of 1974 (ERISA),[4] even though it regulates the price at which PBMs must reimburse pharmacies for drugs covered by prescription drug plans.

Rutledge is a significant win for pharmacies and health care providers with pharmacy operations, and particularly health care providers participating in the 340B Drug Discount Program (the 340B Program). In recent years, numerous states have enacted laws prohibiting PBMs from imposing a discriminatory two-tier pricing model for drugs purchased under the 340B Program. The Rutledge opinion supports the validity of these state laws.

RUTLEDGE BACKGROUND

The Supreme Court succinctly described the backdrop to the Rutledge case and the Arkansas law at issue as follows:

> In 2015, Arkansas adopted Act 900 in response to concerns that the reimbursement rates set by PBMs were often too low to cover pharmacies' costs, and that many pharmacies, particularly rural and independent ones, were at risk of losing money and closing . . . . In effect, Act 900 requires PBMs to reimburse Arkansas pharmacies at a price equal to or higher than that which the pharmacy paid to buy the drug from a wholesaler.[5]

In addition, under the Act, PBMs must provide administrative appeal procedures for pharmacies to challenge maximum allowable cost (MAC) reimbursement prices that are below the pharmacies' acquisition costs. Specifically, PBMs must increase reimbursement rates to cover the pharmacy's acquisition cost if a pharmacy could not have acquired the drug at a lower price from its typical wholesaler and allow pharmacies to "reverse and rebill" each reimbursement claim affected by the pharmacy's inability to procure the drug from its typical

©2005-2021 K&L Gates LLP. All Rights Reserved.

wholesaler at a price equal to or less than the MAC reimbursement price. Finally, the Act allows a pharmacy to decline to dispense a drug if the PBM's reimbursement rate is less than its acquisition cost.[6]

The Pharmaceutical Care Management Association (PCMA)—a trade group representing the interests of PBMs—filed suit in the Eastern District of Arkansas, claiming the provisions of the Act were preempted by Medicare Part D and ERISA, among other constitutional claims. The U.S. District Court for the Eastern District of Arkansas held that that the Act was preempted by ERISA, but it rejected PCMA's argument that the Act was subject to Medicare Part D preemption as well as PCMA's other claims.[7]

PCMA appealed the Part D preemption holding, and Arkansas cross-appealed the district court's ERISA preemption holding. The U.S. Court of Appeals for the Eighth Circuit struck down the law in 2018, holding that the Arkansas law was preempted by both Medicare Part D and ERISA. The Supreme Court appeal is focused only on the ERISA preemption issue.

THE RUTLEDGE HOLDING REGARDING NO ERISA PREEMPTION

As the Supreme Court noted, ERISA preemption jurisprudence is famously complex and often confusing.[9] Thus, it is not shocking that the Supreme Court would unanimously reverse the Eight Circuit's interpretation of prior ERISA opinions, including the Supreme Court's own precedent.

In analyzing the Act, the Supreme Court noted “ERISA is . . . primarily concerned with preempting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits” and that ERISA focuses on “binding plan administrators to specific rules for determining beneficiary status [citation omitted].”[10] As such, a state law may also be subject to preemption if “acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage.”[11]

As a shorthand for these considerations, the Supreme Court has often assessed whether a state law “governs a central matter of plan administration or interferes with nationally uniform plan administration.” If it does, it is preempted. Under that analytical framework, the Supreme Court pointed out that state laws merely affecting costs to plans are not preempted:

> Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan. That is especially so if a law merely affects costs.[12]

Citing to prior Supreme Court ERISA preemption precedent, the Supreme Court explained that a state law that has an “indirect economic influence” on an ERISA plan (such as impacting plan costs) does not “create an impermissible connection” between a state law and ERISA plans where it does not “bind plan administrators to any particular choice.”[13]

Accordingly, the Supreme Court held that the Act's price-floor requirements were too remote from ERISA and ERISA plans to have an “impermissible connection” with ERISA plans, even though the state law has an indirect effect on what ERISA plans pay for prescription drugs, and state regulations that merely increase the costs or

©2005-2021 K&L Gates LLP. All Rights Reserved.

alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted by ERISA.[14]

SIGNIFICANCE FOR 340B PROGRAM-COVERED ENTITIES

The Supreme Court's decision in Rutledge will have a significant impact on a number of state laws prohibiting PBMs from paying lower reimbursement, charging additional fees, or limiting network access on the basis of participation in the 340B Program. The Health Resources and Services Administration, the agency that administers the 340B Program, has acknowledged the practice of discriminatory pricing, encouraging the covered entity to reach out to the payer to "craft an alternative business solution that permits each of the parties to fulfill their goals" but has stated that "there is no statutory provision in section 340B of the Public Health Service Act prohibiting" a payer from reimbursing a 340B covered entity at a level that may be different than a non-340B entity.[15]

Just in the past two years, at least eight states have responded by enacting 340B Program legislation prohibiting PBMs from setting lower reimbursement rates for drugs provided by 340B Program-covered entities, including Minnesota, South Dakota, West Virginia, Montana, Massachusetts, Rhode Island, Oregon, and Utah, with additional states also considering legislation. As 340B Program-covered entities continue to engage with state policymakers arguing that discriminatory pricing violates the intent of the 340B Program, the Supreme Court's decision in Rutledge will have a significant impact on the nearly 40 state laws regulating PBMs and, more specifically, on the number of state laws prohibiting PBMs from engaging in 340B Program discriminatory pricing.

As noted above, however, the Eighth Circuit held that the Act was preempted by Medicare Part D because it interfered with the negotiated prices and pharmacy access standards. Arkansas only appealed the ERISA ruling, and therefore, the Medicare Part D preemption issue was not before the Supreme Court in Rutledge. Accordingly, state statutes regulating PBM pricing may still be subject to litigation related to Medicare Part D preemption.

KEY TAKEAWAYS

Even though the Rutledge case dealt with PBM pricing more generally (a pricing floor), the reasoning of the Rutledge opinion should extend to state laws seeking to protect against PBM's creating discriminatory pricing directed at 340B Program participants and has further clarified the scope of ERISA preemption, which could also have an impact on other types of state laws that regulate health care and encourage states to pass more aggressive laws aimed at PBM regulations. Numerous additional states have been considering similar 340B Program PBM pricing regulations. The decision in Rutledge will likely encourage state legislators and 340B Program-covered entities to consider these measures again in 2021 and beyond.

Stakeholders—including 340B Program-covered entities and pharmacies—should carefully consider the potential impact of these developments. Our health care and FDA practice regularly advise stakeholders on 340B Program and other pharmacy matters and are able to assist in this regard.

FOOTNOTES

[1] Justice Sonia Sotomayor wrote the unanimous Supreme Court opinion. Justice Clarence Thomas filed a concurring opinion. Justice Amy Coney Barrett did not participate.

©2005-2021 K&L Gates LLP. All Rights Reserved.

[2] Rutledge v. Pharm. Care Mgmt. Ass'n, No. 18-540, 2020 WL 7250098 (S. Ct. 10 Dec. 2020).

[3] ARK. CODE § 17-92-507 (2015).

[4] 88 Stat. 829, as amended, 29 U.S.C. § 1001 *et. seq*.

[5] *Rutledge*, slip op. at 2 (citations omitted).

[6] *Id*. at 2–3.

[7] Pharm. Care Mgmt. Ass'n v. Rutledge, 240 F. Supp. 3d 951 (E.D. Ark. 2017).

[8] Pharm. Care Mgmt. Ass'n v. Rutledge, 891 F.3d 1109 (8th Cir. 2018), *cert. granted*, 140 S. Ct. 812 (2020), *rev'd and remanded*, No. 18-540, 2020 WL 7250098 (U.S. 10 Dec. 2020). The Eighth Circuit found that it was bound by its reasoning in an earlier case, Pharm. Care Mgmt. Ass'n v. v. Gerhart, 852 F.3d 722 (8th Cir. 2017), where it struck down a similar Iowa statute. Following the *Rutledge* case, the Eighth Circuit invalidated another similar North Dakota state statute. Pharm. Care Mgmt. Ass'n v. v. Tufte, 968 F.3d 901 (8th Cir. 2020).

[9] This is a point lamented in Justice Thomas's concurring opinion.

[10] *Rutledge*, slip op. at 4–5.

[11] *Id*.

[12] *Id*. at 5 (emphasis added).

[13] *Id*. (citing N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U. S. 645 (1995)).

[14] *Rutledge*, slip op. at 6.

[15] See Letter from Krista M. Pedley, Director, Off. of Pharmacy Affs., Dep't of Health & Hum. Servs., Health Res. Servs. Admin. to Greg Doggett, Assoc. Counsel, Safety Net Hosps. for Pharm. Access (30 Nov. 2011).

KEY CONTACTS

RICHARD P. CHURCH
PARTNER
RESEARCH TRIANGLE PARK, CHICAGO
+1.919.466.1187
RICHARD.CHURCH@KLGATES.COM

GARY S. QUALLS
PARTNER
RESEARCH TRIANGLE PARK
+1.919.466.1182
GARY.QUALLS@KLGATES.COM

LEAH D'AURORA RICHARDSON
PARTNER
RESEARCH TRIANGLE PARK
+1.919.466.1126
LEAH.RICHARDSON@KLGATES.COM

VICTORIA K. HAMSCHO
ASSOCIATE
WASHINGTON DC
+1.202.778.9137
VICTORIA.HAMSCHO@KLGATES.COM

©2005-2021 K&L Gates LLP. All Rights Reserved.

This publication/newsletter is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer. Any views expressed herein are those of the author(s) and not necessarily those of the law firm's clients.

©2005-2021 K&L Gates LLP. All Rights Reserved.