

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

Pharmaceutical Care Management Association v. Mylynn Tufte

No. 18-2926, United States Court of Appeals for the Eighth Circuit (August 7, 2020)

SUMMARY

The Eighth Circuit held that North Dakota's legislation regulating pharmacy benefits managers (PBMs) was preempted by ERISA because it impermissibly "referenced" ERISA plans through its definitions of "third-party payer" and "plan sponsor," making the existence of ERISA plans essential to the law's operation. Following prior circuit precedent (Gerhart and Rutledge), the court found that the statute implicitly regulated ERISA plans even though it also covered non-ERISA entities, and thus the entire legislation was preempted. The court did not reach Medicare Part D preemption issues and deemed the state's savings clause argument waived. The district court's partial denial of preemption was reversed, and the case was remanded for entry of judgment in favor of PCMA.

CASE DETAILS

COURT	United States Court of Appeals for the Eighth Circuit
WRITING FOR THE COURT	GRUENDER; SMITH; BENTON
JURISDICTION	Federal
DECIDED	August 7, 2020
DOCKET	18-2926
DISPOSITION	reversed_and_remanded
PROCEDURAL POSTURE	Appeal from the United States District Court for the District of North Dakota - Bismarck. The district court granted in part and denied in part cross-motions for summary judgment, finding only one provision preempted by Medicare Part D. PCMA appeals.
STANDARD OF REVIEW	de novo
PRECEDENTIAL VALUE	Published
PARTIES	Pharmaceutical Care Management Association v. Mylynn Tufte, in her official capacity as the State Health Officer of North Dakota; Mark J. Hardy, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy; Steven P. Irsfeld, in his official capacity as President of the North Dakota Board of Pharmacy; Wayne Stenehjem, in his official capacity as the Attorney General of North Dakota

TOPICS

erisa

summary judgment

statutory interpretation

appellate procedure

PRACTICE AREAS

ERISA

Health Law

Preemption

QUESTIONS PRESENTED

1. Whether the North Dakota legislation is preempted by ERISA because it has an impermissible 'reference to' ERISA plans.

HOLDINGS

1. The North Dakota legislation is preempted by ERISA because it has an impermissible 'reference to' ERISA plans through its definitions of 'third-party payer' and 'plan sponsor,' which make the existence of ERISA plans essential to the law's operation.
2. North Dakota has waived this argument because it was raised only in a footnote and not properly argued.

KEY QUOTATIONS

"A state law has an impermissible 'reference to' ERISA plans where it (1) 'acts immediately and exclusively upon ERISA plans' or (2) 'where the existence of ERISA plans is essential to the law's operation.'" (3)

"the existence of ERISA plans is essential to the law's operation because 'it cannot be said that the . . . law functions irrespective of the existence of an ERISA plan.'" (5)

"the North Dakota legislation is preempted because it 'relates to' ERISA plans 'by regulating the conduct of PBMs administering or managing pharmacy benefits.'" (6)

FACTUAL BACKGROUND

In 2017, North Dakota passed N.D. Cent. Code sections 19-02.1-16.1 and 19.02.1-16.2, which regulate the relationship between pharmacies, pharmacy benefits managers (PBMs), and third-party payers. The legislation imposes various requirements on PBMs and third-party payers, including fee restrictions, copayment limits, quality metrics, ownership prohibitions, disclosure requirements, and anti-gag clauses. Violations are class B misdemeanors. PCMA is a national trade association that represents PBMs.

PROCEDURAL HISTORY

PCMA filed a complaint seeking a declaration of preemption and an injunction. The district court determined that none of the statutory provisions were preempted by ERISA and that only one provision was preempted by Medicare Part D. PCMA appealed.

DISPOSITION

reversed_and_remanded

REMAND INSTRUCTIONS

with directions to enter judgment in favor of PCMA.

CASES CITED

- *Gobeille v. Liberty Mut. Ins.*, 577 U.S. ---, 136 S. Ct. 936 (2016)
- *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins.*, 514 U.S. 645 (1995)
- *Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316 (1997)
- *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018)
- *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017)
- *Metro. Life Ins. v Massachusetts*, 471 U.S. 724 (1985)
- *Express Scripts, Inc. v. Wenzel*, 262 F.3d 829 (8th Cir. 2001)
- *Mader v. United States*, 654 F.3d 794 (8th Cir. 2011) (en banc)
- *Mahler v. First Dakota Title Ltd. P'ship*, 931 F.3d 799 (8th Cir. 2019)
- *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012)
- *Duffner v. City of St. Peters*, 930 F.3d 973 (8th Cir. 2019)
- *Pharm. Care Mgmt. Ass'n v. District of Columbia*, 613 F.3d 179 (D.C. Cir. 2010)
- *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005)
- *Pharm. Care Mgmt. Ass'n v. Rutledge*, 589 U.S. ---, 140 S. Ct. 812 (2020) (mem.)

OPINION

PER CURIAM.

United States Court of Appeals For the Eighth Circuit _____ No. 18-2926 _____ Pharmaceutical Care Management Association Plaintiff - Appellant v. Mylynn Tufte, in her official capacity as the State Health Officer of North Dakota; Mark J. Hardy, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy; Steven P. Irsfeld, in his official capacity as President of the North Dakota Board of Pharmacy; Wayne Stenehjem, in his official capacity as the Attorney General of North Dakota Defendants - Appellees _____ Appeal from United States District Court for the District of North Dakota - Bismarck _____ Submitted: October 15, 2019 Filed: August 7, 2020 _____ Before SMITH, Chief Judge, GRUENDER and BENTON, Circuit Judges. _____ GRUENDER, Circuit Judge.

This case concerns Pharmaceutical Care Management Association's ("PCMA") claim that the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Part D"), 42 U.S.C. § 1395w-101 et seq., preempt two sections of the North Dakota Century Code (the "legislation") regulating the relationship between pharmacies, pharmacy benefits managers ("PBMs"), and other third parties that finance personal health services.

After PCMA and the State of North Dakota¹ cross-moved for summary judgment, the district court determined that only one provision in the legislation was preempted by Medicare Part D and entered judgment in favor of North Dakota on the remainder of PCMA's claims.

We affirm in part, reverse in part, and remand with directions that judgment be entered in favor of PCMA. PCMA is a national trade association that represents PBMs. PBMs are third-party health plan administrators that manage prescription drug benefits on behalf of health insurance plans.

In this role, PBMs negotiate prescription drug prices with drug manufacturers and pharmacies, create networks of pharmacies to fill prescriptions for insured individuals, and process insurance claims when prescriptions are filled.

In 2017, North Dakota passed N.D. Century Code sections 19-02.1-16.1 and 19.02.1-16.2, which, according to North Dakota, "sought to define the rights of pharmacist[s] in relation to [PBMs], and to regulate certain practices by PBMs." The legislation regulates the fees PBMs and "third-party payer[s]" may charge pharmacies, N.D. Cent. Code § 19-02.1-16.1(2); limits what copayments PBMs or third-party payers may charge, id. § 19-02.1-16.1(4); dictates the quality metrics PBMs and third-party payers may use to evaluate pharmacies and structures how they may reward performance, id. §§ 19-02.1-16.1(3), (11), -16.2(4); prohibits, subject to certain exceptions, PBMs from having "an ownership interest in a patient assistance program and a mail order specialty pharmacy," id. § 19.02.1-16.2(3); 1 PCMA sued Mylynn Tufte, State Health Officer of North Dakota, Mark Hardy, Executive Director of the North Dakota Board of Pharmacy, Fran Gronberg, President of the North Dakota Board of Pharmacy, and Wayne Stenehjem, Attorney General of North Dakota, in their official capacities.

Because of the nature of PCMA's claims, we refer to the defendants collectively as "North Dakota." -2- regulates benefits provisions and plan structures, id. §§ 19-02.1-16.1(3), (4), (5) (8), (9), (11), -16.2(5); and requires certain disclosures on the part of PBMs and prohibits PBMs from setting limits on information pharmacists may provide patients, id. §§ 19-02.1-16.1(6), (7), (10), -16.2(2).

A PBM or third-party payer that violates any section of the legislation is guilty of a class B misdemeanor. Id. §§ 19-02.1- 16.1(12), -16.2(6). Shortly after the legislation's enactment in 2017, PCMA filed a complaint seeking a declaration of preemption and an injunction prohibiting the enforcement of the legislation. At summary judgment, the district court determined that none of the statutory provisions were preempted by ERISA and that only one of the provisions was preempted by Medicare Part D. PCMA appeals, renewing its argument that both ERISA and Medicare Part D preempt the entire legislation.

We review de novo the district court's preemption and statutory interpretation rulings. Pharm. Care Mgmt. Ass'n v. Rutledge, 891 F.3d 1109, 1112 (8th Cir. 2018). With certain limited exceptions,

ERISA preempts “any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.” 29 U.S.C. § 1144(a) (emphasis added). “The breadth of this section is well known,” Rutledge, 891 F.3d at 1112, and courts have struggled for decades to cabin its reach in order to prevent the clause from becoming “limitless,” *Gobeille v. Liberty Mut.*

Ins., 577 U.S. ---, 136 S. Ct. 936, 943 (2016); *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins.*, 514 U.S. 645, 655-56 (1995) (rejecting an “uncritical literalism” that extends ERISA’s preemption clause to the “furthest stretch of its indeterminacy”); see also *Cal. Div. of Labor Standards Enf’t v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 335 (1997) (Scalia, J., concurring) (counseling courts to avoid reading the clause too broadly because, “as many a curbstone philosopher has observed, everything is related to everything else”).

Endeavoring to clarify ERISA’s “unhelpful text,” *Travelers Ins.*, 514 U.S. at 656, the Supreme Court has determined the clause preempts a state law that “relates to” an ERISA plan by having an impermissible “reference to” or “connection with” -3- an ERISA plan, *id.* Here, we need not address the “connection with” element of the analysis because we conclude the legislation is preempted due to its impermissible “reference to” ERISA plans.

See *Pharm. Care Mgmt. Ass’n v. Gerhart*, 852 F.3d 722, 730 (8th Cir. 2017) (“Where a State law is preempted because it has a prohibited ‘reference to’ ERISA or ERISA plans, we need not reach the question of whether it is also preempted under the ‘connection with’ prong of the analysis.”). A state law has an impermissible “reference to” ERISA plans where it (1) “acts immediately and exclusively upon ERISA plans” or (2) “where the existence of ERISA plans is essential to the law’s operation.” *Gobeille*, 136 S. Ct. at 943.

PCMA asserts that the legislation is preempted because it imposes requirements by reference to ERISA plans through its definitions of “third-party payers” and “plan sponsors.” According to PCMA, these references “ensure[] that the existence of an ERISA plan triggers application” of the legislation’s provisions.

The district court disagreed, determining that, because the legislation also covers entities that are not ERISA plans, it neither acts immediately and exclusively upon ERISA plans nor does it make the existence of an ERISA plan essential to the operation of the regulatory scheme.

We agree with PCMA that the legislation is preempted because its references to “third-party payers” and “plan sponsors” impermissibly relate to ERISA benefit plans. Sections 19-02.1-16.1 and -16.2 regulate “[p]harmacy benefits manger[s]” and “[t]hird-party payer[s].” N.D. Cent. Code §§ 19-02.1-16.1(1), -16.2(1). They then define a “[p]harmacy benefits manager” as “a person that performs pharmacy benefits management... for a... third-party payer.” *Id.* § 19-03.6-01(4) (emphasis added). “Third-party payer” is defined as “an organization other than the patient or health care provider involved in the financing of personal health services.” *Id.* § 19- 03.6-01(6).

This definition includes ERISA plans, which are necessarily “involved in the financing of personal health services” and are distinct from “the patient or health care provider.” See *id.*; 29 U.S.C. § 1002(1) (explaining that, for the purposes of ERISA, an employee benefit plan is one that is established “for the purpose of providing” “medical, surgical, or hospital care or benefits”).

The legislation also -4- regulates “[p]lan sponsor[s],” which it defines as “the employer in the case of an employee benefit plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization.” N.D. Cent. Code § 19-03.6-01(5) (emphasis added). This definition is taken verbatim from ERISA, see 29 U.S.C. § 1002(16)(B), and these “plan sponsors,” depending on their functions, may qualify as ERISA fiduciaries, see *id.* § 1002(21)(A).

Two of our prior cases dictate that regulating by implicit reference to ERISA plans results in preemption. First, in *Gerhart*, we determined that an Iowa statute was preempted because it had a prohibited “reference to” ERISA. 852 F.3d at 729- 30.

Although we found that the Iowa act at issue contained an “express reference” to ERISA, see *id.* at 729, we also noted that “the Iowa law... makes implicit reference to ERISA through regulation of PBMs who administer benefits for ‘covered entities,’ which, by definition, include health benefit plans and employers, labor unions, or other groups ‘that provide[] health coverage,’” *id.* (emphasis added).

We explained that because “[t]hese entities are necessarily subject to ERISA regulation,” the requirements “necessarily affect[] ERISA plans,” and, as a result, the Iowa law contained an “impermissible reference to” ERISA. *Id.* at 729-30. One year later, in *Rutledge*, we followed this reasoning in evaluating an Arkansas statute that was “similar in purpose and effect” to the Iowa law at issue in *Gerhart*.

See *Rutledge*, 891 F.3d at 1112. There, we determined the Arkansas law contained an impermissible “reference to” ERISA plans, see *id.* at 1112-13, because the challenged law regulated PBMs that administered a “pharmacy benefits plan or program,” see Ark. Code. Ann. § 17-92-507(a)(7) (2017), which in turn was defined as any plan or program that “pays for... pharmacist services,” *id.* § 17-92-507(a)(9).

We concluded the Arkansas law “implicitly referred to ERISA by regulating the conduct of PBMs administering or managing pharmacy benefits” on behalf of ERISA plans. See *Rutledge*, 891 F.3d at 1112. -5- As in *Gerhart* and *Rutledge*, so too here.

The North Dakota legislation’s definitions of and references to “pharmacy benefits manager,” “third-party payer,” and “plan sponsor” mean the legislation’s provisions apply to plans “subject to ERISA regulation.” *Id.* “Because benefits affected by [the statute] are provided by ERISA-covered

programs, the requirements imposed for the management and administration of these benefits necessarily affects ERISA plans.” Gerhart, 852 F.3d at 729.

Thus, the existence of an ERISA plan is essential to the law’s operation because “it cannot be said that the... law functions irrespective of the existence of an ERISA plan.” Id. at 729-30 (internal quotation marks, ellipses, and brackets omitted).

As the State of Arkansas did in Rutledge, North Dakota argues that Gerhart should be limited to its consideration of the Iowa law’s “express reference” to ERISA plans and that Gerhart’s “implicit reference” analysis is dicta inconsistent with Supreme Court precedent. 2 But we have already rejected this argument. Rutledge, 891 F.3d at 1112 (“The state argues that Gerhart should be limited to its consideration of the Iowa Act’s ‘express reference’ to ERISA, and that Gerhart’s ‘implicit reference’ analysis is dicta inconsistent with Supreme Court precedent.

We disagree.”). Instead, Gerhart and Rutledge control, and a statute that implicitly regulates ERISA plans as part of its regulatory scheme is preempted by ERISA and 2 Citing Dillingham Construction, 519 U.S. at 325, North Dakota argues that our cases construing the scope of ERISA’s preemption clause conflict with Supreme Court precedent.

The State suggests that if a law regulates a class of third-party administrators or claim processors whose customers merely include but are not limited to ERISA plans, it logically follows that the law does not act immediately and exclusively upon ERISA plans and that the existence of ERISA plans is not essential to the law’s operation. See also Pharm. Care Mgmt.

Ass’n v. District of Columbia, 613 F.3d 179, 189-90 (D.C. Cir. 2010) (reasoning similarly); Pharm. Care Mgmt. Ass’n v. Rowe, 429 F.3d 294, 304 (1st Cir. 2005) (same). The Supreme Court recently granted a writ of certiorari in Rutledge, 589 U.S. ---, 140 S. Ct. 812 (2020) (mem.), to resolve this question. But regardless of whether Gerhart and Rutledge were rightly decided, we are bound by those panel decisions unless they are abrogated by the Supreme Court or overruled by this circuit sitting en banc.

See Mader v. United States, 654 F.3d 794, 800 (8th Cir. 2011) (en banc). -6- cannot be saved merely because the reference also includes entities not covered by ERISA. See id. (rejecting Arkansas’s argument that “we are not completely bound by” the Gerhart panel’s reasoning).

Accordingly, the North Dakota legislation is preempted because it “relates to” ERISA plans “by regulating the conduct of PBMs administering or managing pharmacy benefits.” See Rutledge, 891 F.3d at 1112; see also Metro. Life Ins. v Massachusetts, 471 U.S. 724, 739 (1985) (“Even indirect state action bearing on private pensions may encroach upon the area of exclusive federal concern.” (brackets omitted)); Express Scripts, Inc. v. Wenzel, 262 F.3d 829, 833 (8th Cir.

2001) (“State laws that are not targeted at ERISA plans, but which indirectly force a plan administrator to make a particular decision or take a particular action may be held to ‘relate to’ employee benefit plans.”). Next, North Dakota urges in a footnote at the end of its argument regarding ERISA preemption that, if we find the legislation to be preempted, we should “remand for a determination of which provisions are saved from preemption under ERISA’s Savings Clause.” The district court did not address this issue and North Dakota provides no argument as to which provisions might be saved by the savings clause.

See 29 U.S.C. § 1144(b)(2)(A). We therefore conclude that North Dakota has waived this issue. See *Mahler v. First Dakota Title Ltd. P’ship*, 931 F.3d 799, 807 (8th Cir. 2019) (finding an issue waived where plaintiff mentioned it only in passing and did not include the issue in the statement of issues); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316, 1318-19 (11th Cir.

2012) (holding that appellee’s failure to raise an affirmative defense on appeal waives any right to claim such a defense on appeal). -7- For the reasons above, we affirm in part, reverse in part, and remand with directions to enter judgment in favor of PCMA.³

_____ 3 North Dakota does not cross-appeal the district court’s determination that Medicare Part D preempts North Dakota Century Code section 19-02.1-16.2(2).

And because *Gerhart* and *Rutledge* dictate that ERISA preempts the North Dakota legislation in its entirety, we need not address that determination. See *Duffner v. City of St. Peters*, 930 F.3d 973, 976 (8th Cir. 2019) (noting that “[w]e may affirm on any ground supported by the record”). -8-