

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);

¹PCMA 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.”

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”

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

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.

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

²Citing *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).

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).

For the reasons above, we affirm in part, reverse in part, and remand with directions to enter judgment in favor of PCMA.³

³North 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”).

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August 07, 2020

Ms. Sarah Hogarth
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RE: 18-2926 Pharmaceutical Care Management v. Mylynn Tufte, et al

Dear Counsel:

The court has issued an opinion in this case. Judgment has been entered in accordance with the opinion. The opinion will be released to the public at 10:00 a.m. today. Please hold the opinion in confidence until that time.

Please review [Federal Rules of Appellate Procedure](#) and the [Eighth Circuit Rules](#) on post-submission procedure to ensure that any contemplated filing is timely and in compliance with the rules. Note particularly that petitions for rehearing and petitions for rehearing en banc must be received in the clerk's office within 14 days of the date of the entry of judgment. Counsel-filed petitions must be filed electronically in CM/ECF. Paper copies are not required. No grace period for mailing is allowed, and the date of the postmark is irrelevant for pro-se-filed petitions. Any petition for rehearing or petition for rehearing en banc which is not received within the 14 day period for filing permitted by FRAP 40 may be denied as untimely.

Michael E. Gans
Clerk of Court

MDS

Enclosure(s)

cc: Mr. Clerk, U.S. District Court, North Dakota
Mr. Michael B. Kimberly
Mr. Alexander J. Kritikos
Mr. Howard Robert Rubin
Mr. Matthew A Sagsveen
Mr. Robert Thomas Smith
Mr. Robert B. Stock
Mr. Mart Daniel Vogel

District Court/Agency Case Number(s): 1:17-cv-00141-DLH

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August 07, 2020

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RE: 18-2926 Pharmaceutical Care Management v. Mylynn Tufte, et al

Dear Sirs:

A published opinion was filed today in the above case.

Counsel who presented argument on behalf of the appellant was M. Miller Baker, of Washington, DC. The following attorney appeared on the appellant brief; Sarah Hogarth, of Washington, DC.

Counsel who presented argument on behalf of the appellee was Robert Thomas Smith, of Washington, DC. The following attorney(s) appeared on the appellee brief; Matthew A Sagsveen, AAG, of Bismarck, ND., Howard Robert Rubin, of Washington, DC., Daniel E. Lipton, of Washington, DC.

The judge who heard the case in the district court was Honorable Daniel L. Hovland. The judgment of the district court was entered on September 5, 2018.

If you have any questions concerning this case, please call this office.

Michael E. Gans
Clerk of Court

MDS

Enclosure(s)

cc: MO Lawyers Weekly

District Court/Agency Case Number(s): 1:17-cv-00141-DLH