United States Court of Appeals
For the Eighth Circuit

No. 15-3292

Pharmaceutical Care Management Association

Plaintiff - Appellant

v.

Nick Gerhart, In his official capacity as Insurance Commissioner of the State of Iowa; Thomas J. Miller, In his official capacity as Attorney General of the State of Iowa

Defendants - Appellees

National Community Pharmacists Association; Iowa Pharmacy Association

Amici on Behalf of Appellees

Appeal from United States District Court
for the Southern District of Iowa - Des Moines

Submitted: June 14, 2016
Filed: January 11, 2017

Before MURPHY and SHEPHERD, Circuit Judges, and PERRY[1], District Judge.

PERRY, District Judge.

This case involves the question of whether the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. §§ 1001, *et seq.*, expressly preempts section 510B.8 of the Iowa Code. The district court determined that it did not and dismissed Pharmaceutical Care Management Association's (PCMA's) complaint seeking a declaration of preemption. We reverse and remand with direction that judgment be entered for PCMA.

Iowa Code § 510B.8 regulates how pharmacy benefits managers (PBMs) establish generic drug pricing, and requires that certain disclosures on their drug pricing methodology be made to their network pharmacies as well as to Iowa's insurance commissioner. Shortly after the statute went into effect, PCMA brought this action against Iowa's insurance commissioner and its attorney general (collectively, "the State"), seeking a declaration that the statute places restrictions and requirements on PBMs that impermissibly reference or are connected with ERISA plans, thus making the statute expressly preempted by ERISA. PCMA further sought a declaration that the statute violates the dormant Commerce Clause of the United States Constitution.

The district court granted the State's motions to dismiss these claims under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, and PCMA

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[1]The Honorable Catherine D. Perry, United States District Judge for the Eastern District of Missouri, sitting by designation.

appeals.[2] We review *de novo* the district court's grant of a Rule 12(b)(6) motion to dismiss, accepting the facts alleged in the complaint as true. *Gorog v. Best Buy Co.*, 760 F.3d 787, 792 (8th Cir. 2014); *Hafley v. Lohman*, 90 F.3d 264, 266 (8th Cir. 1996). We also review *de novo* the question of whether ERISA preempts a State law, given that it is a matter of federal law involving statutory interpretation. *See Shea v. Esensten*, 208 F.3d 712, 717 (8th Cir. 2000).

I.

PCMA is a national trade association representing PBMs. PBMs are third-party plan administrators who manage and administer prescription drug benefits on behalf of health plans subject to ERISA, as well as for non-ERISA plans.

The retail pharmacies in a PBM's network fill prescriptions of health plan participants with drugs the pharmacies purchase from wholesalers or manufacturers. When a plan participant fills a prescription at a pharmacy, the pharmacy checks with the PBM to determine coverage and obtain copayment information. After the pharmacy fills the prescription, the PBM reimburses the pharmacy at a contractually-agreed rate, minus the copay collected by the pharmacy from the plan participant. The PBM then separately bills the health plan at the rate negotiated between the PBM and the health plan.

Contracts between PBMs and their network pharmacies contain agreements about the maximum amount that the PBM will reimburse a pharmacy for generic drugs. To determine this maximum amount, PBMs use what is called a "maximum allowable cost" (MAC) methodology. Each PBM uses its own methodology and

[2]The district court also dismissed PCMA's due process and conflict preemption claims, as well as its Takings claims under the United States and Iowa constitutions, and the clerk entered judgment on the case in favor of the State. PCMA does not appeal the district court's dismissal of these other claims.

develops its own price list for generic drugs. PCMA claims that the reimbursement limits established by the PBMs through their MAC price lists motivate pharmacies to seek and purchase generic drugs at the lowest available prices, which ultimately results in a cost-effective benefit to health plans.

In early 2014, the Iowa General Assembly passed an "Act Relating to the Regulation of Pharmacy Benefits Managers." The Act was signed into law on March 14, 2014, and became effective July 1, 2014. The Act added a new section to Chapter 510B of the Iowa Code, namely section 510B.8, which provides as follows:

> 1. The commissioner may require a pharmacy benefits manager to submit information to the commissioner related to the pharmacy benefits manager's pricing methodology for maximum reimbursement amount.
>
> 2. For purposes of the disclosure of pricing methodology, maximum reimbursement amounts shall be implemented as follows:
>
> a. Established for multiple-source prescription drugs prescribed after the expiration of any generic exclusivity period.
>
> b. Established for any prescription drug with at least two or more A-rated therapeutically equivalent, multiple-source prescription drugs with a significant cost difference.
>
> c. Determined using comparable prescription drug prices obtained from multiple nationally recognized comprehensive data sources including wholesalers, prescription drug file vendors, and pharmaceutical manufacturers for prescription drugs that are nationally available and available for purchase locally by multiple pharmacies in the state.
>
> 3. For those prescription drugs to which maximum reimbursement amount pricing applies, a pharmacy benefits manager shall include in a contract with a pharmacy information regarding which of the national compendia is used to obtain pricing data used in the calculation of the

> maximum reimbursement amount pricing and shall provide a process to allow a pharmacy to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list. The right to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list shall be limited in duration and allow for retroactive payment in the event that it is determined that maximum reimbursement amount pricing has been applied incorrectly.

Iowa Code § 510B.8. In short, Subsection 1 requires PBMs to provide information regarding their pricing methodologies to Iowa's insurance commissioner at the commissioner's request; Subsection 2 limits the types of drugs to which a PBM can apply MAC pricing and limits the sources from which a PBM may obtain pricing information; and Subsection 3 requires PBMs to provide information regarding their pricing methodologies in their contracts with pharmacies and to provide procedures by which pharmacies can comment on and appeal MAC price lists or rates, with potential retroactive payment to pharmacies for incorrect pricing.

Two months after § 510B.8 went into effect, appellant PCMA brought this declaratory judgment action seeking, *inter alia*, a declaration that the statute is expressly preempted by ERISA. The State moved to dismiss PCMA's claim of express preemption under Fed. R. Civ. P. 12(b)(6), arguing that the claim failed to state a claim upon which relief can be granted. The district court granted the motion after concluding that, while the statute "does regulate an area of ERISA concern by regulating PBMs" in the manner prescribed, it does not unduly restrict the administration of any ERISA plan, require a particular price or pricing methodology for drugs, or mandate the provision of any benefits. Because PBMs continue to have "sufficient choice and control," the district court found the statute not to have an impermissible connection with ERISA.

The district court also found the statute not to impermissibly reference ERISA, concluding that the existence of ERISA plans is not essential to the law's operation and, further, that the statute does not act "immediately and exclusively" on ERISA plans. The district court further found that, while the definitions portion of the statute makes a specific and express reference to ERISA, the reference is too far removed from § 510B.8 to find that § 510B.8 itself references ERISA.

III.

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). A State law "'relates to' an ERISA plan and is preempted if it has 'a connection with or a reference to such a plan.'" *Express Scripts, Inc. v. Wenzel*, 262 F.3d 829, 833 (8th Cir. 2001) (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 656 (1995)). A State law need not act directly on an ERISA plan in order to be preempted. *Id.* (citing *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139 (1990)). Where a State law indirectly forces a plan administrator to make a particular decision or take a particular action, the law may be held to "relate to" employee benefit plans. *Id.* (citing *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 739 (1985)).

A State law has an impermissible "reference to" ERISA plans where it "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation[.]" *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016) (internal citation and quotation marks omitted). A State law has an impermissible "connection with" ERISA plans where it "governs . . . a central matter of plan administration" or "interferes with nationally uniform plan administration." *Id.* (internal citation and quotation marks omitted). ERISA expressly preempts the law if it either refers to or has an impermissible connection with ERISA. Section 510B.8 does both.

A.

A State law has a prohibited "reference to" ERISA or ERISA plans when that law (1) imposes requirements by reference to ERISA-covered programs, (2) specifically exempts ERISA plans from an otherwise generally applicable statute, or (3) premises a cause of action on the existence of an ERISA plan. *Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr., Inc.*, 154 F.3d 812, 822 (8th Cir. 1998) (quoting *California Div. of Labor Standards Enf. v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 324-25 (1997)).

The parties do not dispute that § 510B.8 regulates the manner by which PBMs manage and administer prescription drug benefits by overseeing their MAC pricing methodologies, limiting the drugs subject to MAC pricing, and dictating the manner by which PBMs contract with pharmacies regarding MAC pricing. Although § 510B.8 does not appear on its face to impermissibly refer to ERISA when read alone, we may not look only at an isolated provision of a statute to construe its meaning. *Gustafson v. Alloyd Co.*, 513 U.S. 561, 568 (1995) (citing *Philbrook v. Glodgett*, 421 U.S. 707, 713 (1975); *Kokoszka v. Belford*, 417 U.S. 642, 650 (1974)). Instead, we must construe a statute "'so that effect is given to all of its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . .'" *Corley v. United States*, 556 U.S. 303, 314 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 201 (2004)). Terms should be construed to have consistent meaning throughout a statute. *Gustafson*, 513 U.S. at 568.

Iowa Code § 510B.1 contains definitions for terms "as used in" Chapter 510B, which necessarily includes § 510B.8. A "pharmacy benefits manager" is defined as "a person who performs pharmacy benefits management services," § 510B.1(9), which, by definition, is "the administration or management of prescription drug benefits provided by a covered entity under the terms and conditions of the contract between the pharmacy benefits manager and the covered entity." Iowa Code §

510B.1(8). A "pharmacy benefits manager" includes persons "acting on behalf of a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management services for a covered entity." Iowa Code § 510B.1(9). "Covered entity" is defined as:

> a nonprofit hospital or medical services corporation, health insurer, health benefit plan, or health maintenance organization; a health program administered by a department or the state in the capacity of provider of health coverage; or an employer, labor union, or other group of persons organized in the state that provides health coverage.

Iowa Code § 510B.1(2).

Section 510B.1 also contains specific exclusions from what is considered a "covered entity" for purposes of Chapter 510B:

> "Covered entity" does not include a self-funded health coverage plan that is exempt from state regulation pursuant to the federal Employee Retirement Income Security Act of 1974 (ERISA), as codified at 29 U.S.C. § 1001, et seq.; a plan issued for health coverage for federal employees; or a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medical supplemental, disability income, or long-term care, or other limited benefit health insurance policy or contract.

Iowa Code § 510B.1(2). Accordingly, when Chapter 510B's defined terms are considered *in toto*, it is apparent that § 510B.8 applies to only those PBMs who administer or manage benefits provided by a "covered entity," which, by definition, specifically excludes certain plans under ERISA. Because by its express terms, the statute cannot reach PBMs who manage benefits for certain exempted ERISA plans, § 510B.8 specifically exempts certain ERISA plans from its otherwise general application. If the effect of a State law is to exclude some employee benefits plans

from its coverage, that law has a prohibited reference to ERISA and is preempted under 29 U.S.C. § 1144(a). *Prudential Ins. Co. of Am.*, 154 F.3d at 823-24 (quoting *Ingersoll-Rand*, 498 U.S. at 140).

In addition to this express reference to ERISA, the Iowa law also 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." These entities are necessarily subject to ERISA regulation. *Prudential Ins. Co. of Am.*, 154 F.3d at 824-25; 29 U.S.C. §§ 1002(1), 1003(a). Because benefits affected by § 510B.8 are provided by ERISA-covered programs, the requirements imposed for the management and administration of these benefits necessarily affects ERISA plans. "Thus, it cannot be said that the [Iowa law] 'functions irrespective of . . . the existence of an ERISA plan.'" *Prudential Ins. Co. of Am.*, 154 F.3d at 825 (quoting *Dillingham*, 519 U.S. at 328).

Section 510B.8 applies to only those PBMs who administer prescription drug benefits for plans subject to ERISA regulation, and specifically exempts certain ERISA plans from its application. Because of this impermissible reference to ERISA or ERISA plans, Iowa Code § 510B.8 is preempted under 29 U.S.C. § 1144(a).

B.

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. *Prudential Ins. Co. of Am.*, 154 F.3d at 825. Nevertheless, our review of § 510B.8 shows it to have a prohibited connection with ERISA.

A State law "has an impermissible 'connection with' ERISA plans" when it "'governs . . . a central matter of plan administration' or 'interferes with nationally uniform plan administration." *Gobeille*, 136 S. Ct. at 943 (quoting *Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001)) (omission in *Gobeille*). Obligations undertaken with plan administration include "determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements." *Fort Halifax Packing Co., Inc. v. Coyne*, 482 U.S. 1, 9 (1987).

> The most efficient way to meet these responsibilities is to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits. Such a system is difficult to achieve, however, if a benefit plan is subject to differing regulatory requirements of differing States. A plan would be required to keep certain records in some States but not in others; to make certain benefits available in some States but not in others; to process claims in a certain way in some States but not in others; and to comply with certain fiduciary standards in some States but not in others.

Id. Where a State's law creates the prospect that a plan's administrative scheme will be subject to conflicting requirements, ERISA's preemption provision is enforced. *Id.* at 10. "Preemption ensures that the administrative practices of a benefit plan will be governed by only a single set of regulations." *Id.* at 11. These oversight systems and other standard procedures "are intended to be uniform." *Gobeille*, 136 S. Ct. at 944 (citing *Travelers*, 514 U.S. at 656).

PCMA argues that, contrary to ERISA's intent to maintain a uniform scheme of plan administration, all facets of § 510B.8 interfere with the structure and administration of ERISA plans in Iowa and require administrative processes unique to that State. The State and its amici argue that the statute regulates interactions

between PBMs and pharmacies only and does not involve ERISA plans or their beneficiaries. This argument is foreclosed by our discussion above. They further argue that the mere possibility that the statute may indirectly increase costs to health plans is an insufficient basis for preemption. Economic cost to a plan, however, is not the only measure of a law's connection with ERISA. *See Gobeille*, 136 S. Ct. at 945. "[R]eporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform system of plan administration contemplated by ERISA. . . . [I]n fact, . . . these requirements are integral aspects of ERISA." *Id.* Direct regulation of these fundamental aspects of ERISA necessitates preemption. *Id.* at 946.

Here, Iowa's law compels PBMs as third-party administrators to report to the commissioner and to network pharmacies their methodology for establishing reimbursement amounts paid to pharmacies for providing certain generic drugs to plan participants. Requiring reports and disclosures to a State official and to private enterprise about the economic bases for a plan's provision of prescription drug benefits in that State intrudes upon a matter central to plan administration and interferes with nationally uniform plan administration. *See Gobeille*, 136 S. Ct. at 945. Iowa's law also restricts the class of drugs to which these third-party administrators may establish maximum reimbursement amounts and limits the sources from which they may obtain pricing information, implicating another area central to plan administration – that is, the calculation of prescription benefit levels and making disbursements for these benefits. *See Coyne*, 482 U.S. at 9. Finally, the law requires these third-party administrators to include in their contracts with network pharmacies provisions that allow pharmacies to contest and appeal reimbursement rates and to "allow for retroactive payment in the event that it is determined" that the reimbursement rates were applied incorrectly. Not only does this provision restrict an administrator's control in the calculation of drug benefits, it also removes their ability to conclusively determine final drug benefit payments and monitor funds. In addition, while Iowa's insurance commissioner presumably has the duty to determine

whether reimbursement rates are applied "incorrectly," *see* Iowa Code § 510B.3(1),[3] there is nothing in the statute identifying the yardstick against which any measure of "correctness" is made – further exacerbating the administrator's lack of control over the calculation and disbursement of benefits.

ERISA's central design "is to provide a single uniform national scheme for the administration of ERISA plans without interference from the laws of the several States[.]" *Gobeille*, 136 S. Ct. at 947. Section 510B.8 imposes mandates and restrictions on a PBM's relationship with Iowa and its pharmacies that run counter to ERISA's intent of making plan oversight and procedures uniform. "Requiring ERISA administrators to master the relevant laws of 50 States and to contend with litigation would undermine the congressional goal of minimizing the administrative and financial burden[s] on plan administrators – burdens ultimately borne by the beneficiaries." *Gobeille*, 136 S. Ct. at 944 (internal quotation marks and citations omitted) (alteration in *Gobeille*).

Because the duties and restrictions imposed by § 510B.8 on PBMs in their role as third-party administrators for ERISA plans are inconsistent with ERISA's central design, ERISA's express preemption clause requires invalidation of the statute as applied to PBMs in their administration and management of prescription drug benefits for ERISA plans. *Gobeille*, 136 S. Ct. at 947. We therefore reverse the district court's finding that the statute is not expressly preempted under ERISA.

IV.

We may reverse any judgment or order of a district court lawfully before us for review and "remand the cause and direct the entry of such appropriate judgment . . . as may be just under the circumstances." 28 U.S.C. § 2106. Directing the entry of

[3]"The commissioner shall enforce the provisions of this chapter."

judgment is appropriate where no relevant factual dispute exists, the record on the issue is sufficiently developed, and the parties had a fair opportunity to dispute and develop the issue before the district court. *Union Elec. v. Southwest Bell Tel. L.P.*, 378 F.3d 781, 786 (8th Cir. 2004); *Fabric v. Provident Life & Accident Ins. Co.*, 115 F.3d 908, 915 (11th Cir. 1997) (cited approvingly in *Union Elec.*, 378 F.3d at 786). This is so even in circumstances where a party did not move for entry of judgment in the district court. *Fabric*, 115 F.3d at 914-15 (and cases cited therein).

Here, although there was no development of a factual record in the district court, the issue of express preemption in this case involves pure statutory interpretation with no factual matters to be considered other than the text of the statute itself. There simply is no factual record to be developed. Further, the parties had a fair opportunity to dispute and develop the issue before the district court, and they fully developed the issue on appeal. Indeed, the issue of whether to direct the entry of judgment has itself been developed before us in this appeal. Given all of these considerations, there is no prejudice to the State by our directing the district court to enter judgment on PCMA's claim of express preemption, which we find to be appropriate and just under the circumstances.

V.

For the foregoing reasons, the judgment of the district court is reversed and the case is remanded for entry of judgment in favor of PCMA on the issue of express preemption. In view of our holding, we do not reach the dormant Commerce Clause issue raised by PCMA in this appeal.
