No. 17-1609
United States Court of Appeals, Eighth Circuit.

Pharm. Care Mgmt. Ass'n v. Rutledge

891 F.3d 1109 (8th Cir. 2018)
Decided Jun 8, 2018

No. 17-1609 No. 17-1629

06-08-2018

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff–Appellant v. Leslie RUTLEDGE, in her official capacity as Attorney General of Arkansas, Defendant–Appellee Arkansas Pharmacists Association ; National Community Pharmacists Association, Amici on Behalf of Appellee(s). Pharmaceutical Care Management Association, Plaintiff–Appellee v. Leslie Rutledge, in her official capacity as Attorney General of Arkansas, Defendant–Appellant National Community Pharmacists Association; Arkansas Pharmacists Association, Amici on Behalf of Appellant(s).

Kristyn Marie DeFilipp, Andrew M. London, Dean Richlin, Foley & Hoag, Boston, MA, Lyn Peoples Pruitt, Mitchell & Williams, Little Rock, AR, for Plaintiff–Appellant. Shawn J. Johnson, Sarah R. Tacker, Attorney General's Office, Little Rock, AR, for Defendant–Appellee. Daniel Lipton, Howard R. Rubin, Robert Thomas Smith, Katten & Muchin, Washington, DC, for Amicus on Behalf of Appellee(s).

BEAM, Circuit Judge.

Kristyn Marie DeFilipp, Andrew M. London, Dean Richlin, Foley & Hoag, Boston, MA, Lyn Peoples Pruitt, Mitchell & Williams, Little Rock, AR, for Plaintiff–Appellant.

Shawn J. Johnson, Sarah R. Tacker, Attorney General's Office, Little Rock, AR, for Defendant–Appellee.

Daniel Lipton, Howard R. Rubin, Robert Thomas Smith, Katten & Muchin, Washington, DC, for Amicus on Behalf of Appellee(s).

Before LOKEN, BEAM, and KELLY, Circuit Judges.

1111 BEAM, Circuit Judge.*1111 In this dispute between a pharmacy trade association, Pharmaceutical Care Management Association (PCMA) and the State of Arkansas, PCMA appeals the district court's ruling that an Arkansas state statute is not preempted by Medicare Part D, 42 U.S.C. § 1395w–26(b)(3), and the State of Arkansas appeals the district court's ruling that the statute *is* preempted by ERISA, 29 U.S.C. § 1144(a). Because the state statute in question is preempted by both ERISA and the Medicare Part D statutes, we affirm in part, reverse in part, and remand.

I. BACKGROUND

In 2015, the Arkansas General Assembly passed a state law which attempted to govern the conduct of pharmacy benefits managers ("PBMs")—the entities that verify benefits and manage financial transactions among pharmacies, healthcare payors, and patients. PBMs are intermediaries between health plans and

pharmacies, and provide services such as claims processing, managing data, mail-order drug sales, calculating benefit levels and making disbursements. Pharmacies acquire their drug inventories from wholesalers. The patient buys the drug from the pharmacy, but often at a lower price due to participation in a health plan that covers part of the price. Further, the PBMs create a maximum allowable cost ("MAC") list which sets reimbursement rates to pharmacies dispensing generic drugs. Contracts between PBMs and pharmacies create pharmacy networks. Based upon these contracts and in order to participate in a preferred network, some pharmacies choose to accept lower reimbursements for dispensed prescriptions. Thus, unfortunately, a pharmacy might actually lose money on a given prescription transaction.

In an attempt to address the trend in Arkansas of significantly fewer independent and rural-serving pharmacies in the state, the state legislature adopted Act 900, Arkansas Code Annotated § 17–92–507, an amendment to the state's then-existing MAC law, to "Amend the Laws Regarding Maximum Allowable Cost Lists; to Create Accountability in the Establishment of Prescription Drug Pricing." 2015 Ark. Laws Act 900, S.B. 688 (Ark. 2015). The Act mandates that pharmacies be reimbursed for generic drugs at a price equal to or higher than the pharmacies' cost for the drug based on the invoice from the wholesaler. It did this by defining "pharmacy acquisition cost" as the amount charged by the wholesaler as evidenced by the invoice. Ark. Code Ann. § 17–92–507(a)(6). The Act further imposes requirements on PBMs in their use of the MAC lists by making them update the lists within at least seven days from the time there has been a certain increase in acquisition costs. Id. § 17–92–507(c)(2). The Act also contains administrative appeal procedures, id. § 17–92–507(c)(4)(A)(i), and allows the pharmacies to reverse and re-bill each claim affected by the pharmacies' inability to procure the drug at a cost that is equal to or less than the cost on the relevant MAC list where the drug is not available "below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale." Id. § 17–92–507(c)(4)(C)(iii). Finally, the Act contains a "decline-to-dispense" option for pharmacies that will lose money on a transaction. Id. § 17–92–507(e).

PCMA brought this action on behalf of its members, the nation's leading PBMs, claiming Act 900 is preempted by both ERISA and Medicare Part D, and also that it is unconstitutional on a number of other grounds not at issue on appeal (because PCMA did not appeal the district court's adverse ruling on these claims). The district court agreed that the pertinent *1112 portions of Act 900 were preempted by ERISA based upon controlling Eighth Circuit case law. See Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722 (8th Cir. 2017). However, the district court found that Medicare Part D did *not* preempt Act 900, nor was the law unconstitutional on any of the several bases advanced by PCMA. PCMA appeals the Medicare Part D ruling, and the state cross-appeals the ERISA ruling.

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II. DISCUSSION

We review de novo the district court's preemption/statutory interpretation rulings. Id. at 726.

A. ERISA Preemption

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plans." 29 U.S.C. § 1144(a). The breadth of this section is well known. See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995). A state law is preempted if it " 'relates to' " an ERISA plan by having " 'a connection with or a reference to such a plan.' " Express Scripts, Inc. v. Wenzel, 262 F.3d 829, 833 (8th Cir. 2001) (quoting Travelers, 514 U.S. at 656, 115 S.Ct. 1671). In Gerhart, we held that an Iowa statute, similar in purpose and effect to Act 900, was preempted by ERISA because it had a prohibited "reference to" ERISA, and because it interfered with national

uniform plan administration. 852 F.3d at 729, 731. The district court found that Gerhart controlled the outcome of the ERISA preemption claim in the instant case. We agree. The Iowa statute in Gerhart required PBMs to provide information regarding their pricing methodologies to Iowa's insurance commissioner at the commissioner's request. Id. at 727. The statute further limited the types of drugs to which a PBM could apply MAC pricing and limited the sources from which a PBM obtained pricing information. Id. Finally, the statute required PBMs to provide information regarding their pricing methodologies in their contracts with pharmacies and to provide procedures by which pharmacies could comment on and appeal MAC price lists or rates, with potential retroactive payment to pharmacies for incorrect pricing. Id. We held that the Iowa statute both explicitly and implicitly referred to ERISA by regulating the conduct of PBMs administering or managing pharmacy benefits, and also had a connection with ERISA. It was therefore preempted. Id. at 729–30.

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. In addition to finding that Iowa Code § 510B.8 had a prohibited express reference to ERISA, the Gerhart court found that 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." 852 F.3d at 729. None of the state's arguments convince us that we are not completely bound by a prior panel's reasoning on the exact question before us. Nor do we believe Gerhart to be inconsistent with the Supreme Court's precedent in Travelers or De Buono v. NYSA–ILA Medical and Clinical Services Fund, 520 U.S. 806, 117 S.Ct. 1747, 138 L.Ed.2d 21 (1997). While both cases indicate there is generally a presumption against preemption, De Buono, 520 U.S. at 813, 117 S.Ct. 1747 ; Travelers, 514 U.S. at 654, 115 S.Ct. 1671, where, as here, the state law both relates to and has a connection with employee benefit plans, the presumption
1113 is *1113 gone and the law is preempted. Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 324–25, 117 S.Ct. 832, 136 L.Ed.2d 791 (1997). The district court correctly found that Act 900 was preempted by ERISA.

B. Medicare Part D and Preemption

Medicare Part D is a comprehensive statutory and regulatory scheme for prescription drugs, which aims to balance cost with access to those drugs. The Part D program funds prescription drug benefits through payments from the Medicare government trust fund, and beneficiaries generally get prescriptions through a Part D network provider. See 42 C.F.R. §§ 423.120, 423.124. The statute prohibits both federal and state interference in negotiations between Part D sponsors and pharmacies (known as the "non-interference" clause, 42 U.S.C. § 1395w–111(i)). The federal scheme preempts a state law when (1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established "standards" in the area regulated by the state law; and (2) the state law acts "with respect to" those standards. Id. § 1395w–26(b)(3) Conflict between the state law and the federal standard is unnecessary. PCMA argues the district court erred in holding that Act 900 was not preempted by Medicare Part D. It contends that Act 900 acts "with respect to" two standards created by Congress and CMS for Medicare Part D–the Negotiated Prices Standard, and the Pharmacy Access Standard.

1. Negotiated Prices Standard

42 U.S.C. § 1395w–102 sets forth several requirements for standard prescription drug coverage and access to negotiated prices. Most specifically, the regulation defines "negotiated prices" for Part D drugs as the price: "the part D sponsor (or other intermediary contracting organization) [such as a PBM] and the network dispensing pharmacy ... have negotiated as the amount such network entity will receive, in total, for a particular

drug." 42 C.F.R. § 423.100. Negotiated prices are "inclusive of all price concessions from network pharmacies" but "exclude[ ] contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale." Id.

Act 900 acts "with respect to" the Negotiated Price Standard, first and most obviously by regulating the price of retail drugs. Act 900 effectively replaces the negotiated MAC price with the pharmacy acquisition cost when the MAC rate is below the pharmacy's invoice cost, Arkansas Code Annotated § 17–92–507(b)(4)(A)(i)(b), and requires that the price paid by pharmacy customers be no less than the price negotiated by the pharmacy with its wholesaler, id. § 17–92–507(c)(4)(C)(iii). The appeals process which allows the pharmacy to reverse and re-bill the claim, eliminates "negative reimbursements" for the pharmacies, resulting in an increase in the retail price of prescription drugs. Id. The state's efforts to change the pricing model from PBMs negotiating with pharmacies to pharmacies negotiating with wholesalers easily acts "with respect to" the Part D standard.

The state argues the district court correctly found that Act 900 did not act "with respect to" the Negotiated Price Standard because Part D's "negotiated prices" provisions are not a substantive standard,[1] and in any event these
1114 provisions *1114 exclude Act 900's contingent amounts from its meaning. Further it argues the CMS did not mean to control prices by regulating, but instead merely meant to provide transparency and to control entities such as the PBMs. The district court cursorily reasoned that Act 900 was not preempted, in part because it did not affect negotiated prices. The court found that Act 900 would only act to increase prices, leading to an appeal, and the resulting price after the appeal would fall into the category of a "contingent" amount, which Part D expressly excludes from its standard, 42 C.F.R. § 423.100. PCMA points out that the appeal process does not make the price "contingent" because even after the appeal, the resulting price could be one of three pre-determined amounts—the MAC price, the invoice price, or the best price from the wholesaler higher than the MAC. All three amounts can be determined at the point of sale. We agree that the appeal provisions do not render the price "contingent."

[1] It is, in fact a standard, as a standard within the meaning of the preemption provision is either a statutory provision or a regulation duly promulgated and published in the Code of Federal Regulations. Do Sung Uhm v. Humana, Inc., 620 F.3d 1134, 1148 n.20 (9th Cir. 2010).

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2. Pharmacy Access Standard

Medicare Part D also sets forth requirements with regard to Medicare recipients' access to pharmacies. 42 U.S.C. § 1395w–104(b)(1)(C) provides that a prescription drug plan "shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary)." The regulations in 42 C.F.R. § 423.120(a) further spell out the need for assuring pharmacy access. Thus, the Pharmacy Access Standard requires that networks be structured so that a certain percentage of beneficiaries live within a certain distance to a network pharmacy.

The district court found that because the decline-to-dispense provisions do not render a pharmacy as out-of-network, Act 900 did not act "with respect to" the standard. We disagree, and find that Act 900 indeed acts "with respect to" the Pharmacy Access Standard, because a pharmacy that refuses to dispense drugs becomes, in effect, an out-of-network pharmacy. Act 900's decline-to-dispense clause could conceivably, and likely would, lead to a beneficiary being unable to fill a prescription in his or her geographical location. This would

actually interfere with convenient access to prescription drug availability, which is more than is required for preemption. Again, if the state law in question merely acts "with respect to" the standard, it is preempted. It clearly does in this instance. Accordingly, we find that Act 900 is preempted by Medicare Part D.

III. CONCLUSION

We affirm the district court's ERISA ruling, reverse the Medicare Part D ruling, and remand for entry of judgment in PCMA's favor.