United States Court of Appeals
For the Eighth Circuit

No. 15-1578

Grasso Enterprises, LLC, et al.

Plaintiffs - Appellants

v.

Express Scripts, Inc.

Defendant - Appellee

Appeal from United States District Court
for the Eastern District of Missouri - St. Louis

Submitted: September 24, 2015
Filed: January 11, 2016

Before LOKEN, BEAM, and SHEPHERD, Circuit Judges.

LOKEN, Circuit Judge.

Plaintiffs Grasso Enterprises, NERxD, and Wiley's Pharmacy and Compounding Services are compounding pharmacies that prepare and sell customized compound drugs made in accordance with doctors' prescriptions. Express Scripts, Inc. ("ESI"), is a pharmacy benefits manager that contracts with health plan sponsors and administrators to administer the pharmacy benefits provided in their group health plans, many of which are governed by the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1001 *et seq.* Plaintiffs have entered into separate Provider

Agreements with ESI, which provide that, as members of ESI's pharmacy provider network, Plaintiffs "look solely to ESI for payment of Covered Medications" provided to health plan participants and beneficiaries. ESI pays Plaintiffs pursuant to the Provider Agreements; the health plans reimburse ESI.

In June 2014, ESI announced a program to reduce the increasing costs being incurred by health plans for compound drugs. As explained in a Declaration by ESI's Director of Investigations in Fraud, Waste, and Abuse Services, ESI "made recommendations to its client health plan sponsors to help control the cost of compound prescriptions, such as . . . removing coverage for certain expensive compound ingredients." ESI began denying compound drug claims in July 2014 and fully implemented the program on January 1, 2015. Plaintiffs commenced this action on November 18, 2014, alleging that ESI is systematically denying payment of compound drug claims without adhering to the procedural requirements of ERISA's "Claims Regulation," 29 C.F.R. § 2560.503-1. Plaintiffs asserted claims for relief under two ERISA remedial provisions, §§ 502(a)(1)(B) and (a)(3), codified at 29 U.S.C. §§ 1132(a)(1)(B) and (a)(3).

Plaintiffs amended their complaint and moved for a preliminary injunction declaring that ESI must pay all claims for compound medications until it is in compliance with the Claims Regulation, ordering ESI to issue explanation-of-benefit (EOB) forms complying with the Claims Regulation, and declaring that ESI must provide a procedure for patients to request access to compound medications to comply with the Patient Protection and Affordable Care Act, 42 U.S.C. § 300gg-6. After hearing oral arguments, the district court[1] denied the requested preliminary injunction on numerous grounds. Plaintiffs appeal. We have jurisdiction to consider an interlocutory appeal from the denial of a preliminary injunction. 28 U.S.C.

[1] The Honorable Henry E. Autrey, United States District Judge for the Eastern District of Missouri.

§ 1292(a)(1). Concluding that Plaintiffs failed to meet the well-established standards for preliminary injunctive relief, we affirm.[2]

I. Background

Plaintiffs attached to the First Amended Complaint summary plan descriptions for four health plans (two not governed by ERISA). These documents describe the role of ESI in administering the plans' pharmacy programs. Some expressly caution that not all compound drugs may be covered by the plan. But none describe the coverage of compound drug benefits in detail. Plaintiffs allege that ESI determines whether to pay or deny compound drug claims to plan beneficiaries. ESI asserts that health plan sponsors set the plan terms, including which treatments and medications are covered for plan participants and beneficiaries.[3] The record does not clarify these issues, which would be critical to judicial review of an adverse benefits determination under ERISA. Plaintiffs assert these issues are irrelevant because they do not seek review of any specific claim denial.

In the First Amended Complaint, each Plaintiff asserted claims for injunctive relief in two capacities, as a "Plan-Designated Beneficiary," based on the plan descriptions of ESI's role in the pharmacy programs, and as a "Participant-Designated Beneficiary," based on assignments Plaintiffs received from health plan beneficiaries of "all rights to payment and other benefits" that the beneficiaries may have under

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[2]In deciding a preliminary injunction motion, the district court considers four factors: "(1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict . . . ; (3) the probability that movant will succeed on the merits; and (4) the public interest." Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 114 (8th Cir. 1981) (en banc).

[3]The record contains evidence that one health plan sponsor notified plan participants that it adjusted the plan by introducing a list of non-covered compound ingredients following ESI's announcement of its compound drug program.

their applicable health plans "for past, current, or future compounds, ingredients, or medications," and authorizing the pharmacy "to pursue any and all remedies to which [the beneficiaries] may be entitled, including the use of legal action in any court against the health plan, insurer, or its administrator." One assignment document for each Plaintiff was attached to the First Amended Complaint. The assignors were identified as Patients "A," "B," and "C," with their names redacted. The district court concluded that Plaintiffs have standing to assert ERISA claims only as assignees of patient beneficiaries.

The First Amended Complaint alleged that ESI, implementing its compound drug program, denied claims by Patients A, B, and C for refills of existing compound drug prescriptions that ESI had previously filled. Plaintiffs alleged that "ESI's legally defective and void computer-generated boilerplate notifications" violated numerous subparts of the detailed Claims Regulation. In support of Plaintiffs' motion for a preliminary injunction, the managing member of Grasso Enterprises declared that, "[s]ince the roll out of the program in June, approximately 60-70% of existing ESI prescriptions that have always been approved are now being rejected." The managing member of NERxD LLC declared that "[w]e are experiencing a 20-40% drop in our monthly gross revenues, and it appears that the key reason is ESI's scheme." The owner of Wiley's Pharmacy declared that the ESI portion of his business began declining in June 2014.

II. The Statutory Framework

ERISA includes a provision addressing the procedures for resolving disputes between health plan administrators and plan participants and beneficiaries:

§ 1133. Claims procedure

> In accordance with regulations of the Secretary [of Labor], every employee benefit plan shall --
>
> (1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and
>
> (2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

29 U.S.C. § 1133. The ERISA Claims Regulation implements this provision, setting forth detailed procedural requirements that apply when a plan sponsor or administrator denies a claim for health care benefits. "The statute and the regulations were intended to help claimants process their claims efficiently and fairly" by requiring plan administrators to support their decisions so that claimants can "adequately prepare . . . for any further administrative review, as well as an appeal to the federal courts." Richardson v. Cent. States, S.E. & S.W. Areas Pension Fund, 645 F.2d 660, 665 (8th Cir. 1981). Consistent with this focus, the Claims Regulation provides a specific remedy for non-compliance:

> (l) . . . In the case of the failure of a plan to establish or follow claims procedures consistent with the requirements of this section, a claimant shall be deemed to have exhausted the administrative remedies available under the plan and shall be entitled to pursue any available remedies under section 502(a) of the Act on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim.

29 C.F.R. § 2560.503-1(l) (emphasis added); see Brown v. J.B. Hunt Transp. Servs., Inc., 586 F.3d 1079, 1085-86 (8th Cir. 2009) (failure to provide claimant a full and

fair review of the decision to discontinue plan benefits "excuses [claimant's] failure to exhaust before bringing suit under § 1132(a)").

Because administrative exhaustion "serves many important purposes," review of benefits appeal procedures is more appropriate when "the reviewing court reviews the claims administrator's final decision to deny a claim, rather than the initial denial." Galman v. Prudential Ins. Co. of Am., 254 F.3d 768, 770 (8th Cir. 2001). In conducting this review, our sister circuits do not require technical compliance with each subpart of the Claims Regulation. Rather, "[c]hallenges to ERISA procedures are evaluated under the substantial compliance standard." Lafleur v. La. Health Serv. & Indem. Co., 563 F.3d 148, 154 (5th Cir. 2009), quoting Wade v. Hewlett-Packard Dev. Co. LP Short Term Disability Plan, 493 F.3d 533, 539 (5th Cir. 2007), and cases cited. While we have not expressly adopted this substantial compliance standard, we have applied a substantively equivalent standard, evaluating whether a plan's entire claim denial process provided the claimant "a full and fair review of her claim." Midgett v. Wash. Grp. Int'l Long Term Disability Plan, 561 F.3d 887, 896 (8th Cir. 2009); see Davidson v. Prudential Ins. Co. of Am., 953 F.2d 1093, 1096 (8th Cir. 1992).

As the Supreme Court has repeatedly emphasized, "ERISA's carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." Great-W. Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204, 209 (2002) (quotations omitted). Plaintiffs seek preliminary and permanent injunctive relief under two of these remedial provisions. Section 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B), provides that "a participant or beneficiary" may sue "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." Section 502(a)(3), 29 U.S.C. § 1132(a)(3), provides that "a participant, beneficiary, or fiduciary" may sue "(A) to enjoin any act or practice which violates any provision of this subchapter or the terms

of the plan, or (B) to obtain other appropriate equitable relief" to redress violations or enforce the provisions of ERISA or the terms of the plan. "[T]he term 'equitable relief' in § 502(a)(3) must refer to those categories of relief that were *typically* available in equity." Great-W., 534 U.S. at 210 (quotation omitted).

III. Discussion

A. Plaintiffs seek injunctive relief as assignees of patients who claim coverage of their compound drug prescriptions as participants or beneficiaries of health care plans. Like a number of circuits, we have held that an assignee of welfare plan medical benefits may sue under § 502(a)(1)(B) for wrongful denial of a benefit claim, provided the assignment was authorized by the ERISA plan. See Lutheran Med. Ctr. of Omaha v. Contractors Health & Welfare Plan, 25 F.3d 616, 619 (8th Cir. 1994); Ark. Blue Cross & Blue Shield v. St. Mary's Hosp., 947 F.2d 1341, 1349-50 (8th Cir. 1991) (ERISA preempts contrary state law); accord City of Hope Nat'l Med. Ctr. v. HealthPlus, Inc., 156 F.3d 223, 228-29 (1st Cir. 1998); Cagle v. Bruner, 112 F.3d 1510, 1515 (11th Cir. 1997), and cases cited; see also Pascack Valley Hosp. v. Local 464A UFCW Welfare Reimb. Plan, 388 F.3d 393, 400-01 n.7 (3d Cir. 2004). "Anti-assignment clauses in ERISA plans are valid and enforceable." Spinedex Physical Therapy USA Inc. v. United Healthcare of Ariz., Inc., 770 F.3d 1282, 1296 (9th Cir. 2014). ESI does not challenge Plaintiffs' assertion that they are holders of valid assignments from patient beneficiaries.

Each Plaintiff as assignee "stands in the shoes of the assignor, and, if the assignment is valid, has standing to assert whatever rights the assignor possessed." Misic v. Bldg. Serv. Emps. Health & Welfare Trust, 789 F.2d 1374, 1378 n.4 (9th Cir. 1986). The assignor -- and therefore each Plaintiff as assignee -- may sue "to recover benefits due to him under the terms of his plan." § 502(a)(1)(B). If the plan's failure to follow claims procedures consistent with the requirements of the Claims Regulation denied the claimant a reasonable opportunity for full and fair review of

the decision to discontinue pharmacy benefits, the claimant may sue without exhausting plan remedies. Brown, 586 F.3d at 1084-86. This allows for timely judicial enforcement of the claimant's right to benefits under the plan.

In most cases, the appropriate remedy for a violation of 29 U.S.C. § 1133(2) and the Claims Regulation is not an award of benefits by the court, but rather a "remand to the plan administrator so the claimant gets the benefit of a full and fair review." Id. at 1087, quoting Syed v. Hercules Inc., 214 F.3d 155, 162 (3d Cir. 2000) (Alito, J.). In some cases, however, the reviewing court may determine that the administrative record, though procedurally flawed, established that the denial of benefits "was not supportable," in which case the court may award the denied benefit rather than remanding. Richardson, 645 F.2d at 665. And the Seventh Circuit adds an additional remedy in a situation that has not come before this court but could be relevant to these prescription benefit disputes with ESI -- if the plan fails to substantially comply with the Claims Regulation in terminating a benefit "to which the administrator had previously determined the claimant was entitled," the court may order reinstatement of the benefit as of the date it was terminated and remand to the plan for reconsideration of its procedurally flawed decision to terminate. Compare Schneider v. Sentry Grp. Long Term Disability Plan, 422 F.3d 621, 629 (7th Cir. 2005), quoting Hackett v. Xerox Corp. Long-Term Disability Income Plan, 315 F.3d 771, 775 (7th Cir. 2003), with Love v. Nat'l City Corp. Welfare Benefits Plan, 574 F.3d 392, 398 (7th Cir. 2009).

"The basis of injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies." Beacon Theatres, Inc. v. Westover, 359 U.S. 500, 506-07 (1959). "Failure to show irreparable harm is an independently sufficient ground upon which to deny a preliminary injunction." Watkins Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003). It is well established that "[i]rreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." Gen. Motors

Corp. v. Harry Brown's, LLC, 563 F.3d 312, 319 (8th Cir. 2009). Here, plan beneficiaries have an adequate remedy at law, a suit under § 502(a)(1)(B) that will overturn the initial denial of a compound drug pharmacy benefit if that medication was in fact covered under the plan. There is no need for injunctive relief under § 502(a)(3), or for equitable relief to enforce or clarify the beneficiary's rights under the plan under § 502(a)(1)(B). Indeed, the grant of equitable relief declaring what procedures are needed to substantially comply with the Claims Regulation would disrupt efficient plan administration and in some cases would conflict with the ERISA policy that reviewing courts should review final decisions to deny claims for benefits, rather than the initial denials.

In these circumstances, the district court did not abuse its discretion in denying the preliminary injunction requested by Plaintiffs as assignees of plan beneficiaries. Indeed, it would have been legal error to grant that relief. It is telling that Plaintiffs cite no reported decision, and we have found none, where a circuit court has upheld a private plaintiff's claim for injunctive relief mandating the future procedures an ERISA plan must follow to comply with the Claims Regulation.

B. Alternatively, Plaintiffs argue they have standing to bring a civil action under ERISA § 502(a)(1) or (3) in their own right, as "plan-designated beneficiaries," based on summary plan descriptions describing how pharmacy benefit programs administered by ESI will be implemented. The district court, consistent with every circuit that has considered the question, concluded that "the Pharmacies do not have standing under ERISA to assert harm to themselves" because they are not ERISA beneficiaries. We agree. As the Second Circuit cryptically resolved this issue in Rojas v. Cigna Health & Life Ins. Co., 793 F.3d 253, 258 (2d Cir. 2015), "right to payment [directly from ESI] does not a beneficiary make."

The Seventh Circuit recently explained that this is not an issue of Article III standing to seek relief in federal court. "The issue . . . is not whether [the health care

providers] have standing but whether their claim comes within the zone of interests regulated by a specific statute." Pa. Chiropractic Ass'n v. Indep. Hosp. Indem. Plan, Inc., 802 F.3d 926, 928 (7th Cir. 2015). "Whether a plaintiff comes within the zone of interests is an issue that requires us to determine, using traditional tools of statutory interpretation, whether a legislatively conferred cause of action encompasses a particular plaintiff's claim." Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1387 (2014) (quotations omitted).

ERISA defines a "beneficiary" as "a person designated by a [plan] participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit thereunder." 29 U.S.C. § 1002(8). While Plaintiffs may be entitled to direct payments from ESI by operation of one or more ERISA plans, direct payment is simply a convenient way to reimburse health care providers, whereas the statutory term beneficiary "clearly refers to those individuals who share in the benefits of coverage -- medical services and supplies covered under their health care policy." Rojas, 793 F.3d at 258. Thus, "Plaintiffs are not 'beneficiaries' as ERISA uses that term, so they are not entitled to the procedures established by § 1133 and the [Claims Regulation]." Pa. Chiropractic, 802 F.3d at 930.

Based on these persuasive authorities, the district court correctly determined that Plaintiffs may only seek injunctive relief under § 502(a)(1)(B) or (a)(3) as assignees of ERISA plan beneficiaries.[4] Of course, Plaintiffs may also have claims

[4]Even if Plaintiffs did have "standing" to assert ERISA claims as plan "beneficiaries," the district court did not abuse its discretion in denying the requested preliminary injunction because (i) Plaintiffs requested a preliminary injunction requiring affirmative action providing them substantially the relief sought after a trial on the merits, which "goes beyond the purpose of a *preliminary* injunction." Sanborn Mfg. Co. v. Campbell Hausfeld/Scott Fetzer Co., 997 F.2d 484, 490 (8th Cir. 1993); and (ii) Plaintiffs' speculative claim that ESI's compound drug program was irreparably injuring their revenues, profits, and customer base failed to meet their burden to establish irreparable injury. "In order to demonstrate irreparable harm, a

against ESI for breach of their separate Provider Agreements, but no such claims have been asserted and, if asserted, would not be governed by ERISA and the Claims Regulation. As the Seventh Circuit wisely noted in Pa. Chiropractic, 802 F.3d at 928, to resolve separate contractual disputes between health care providers and claims administrators, ERISA does not require the administrator "to use procedures that are designed for retail-level disputes between a plan's participants and their . . . plan administrator [the Claims Regulation] rather than procedures designed for wholesale-level disputes between an [administrator] and providers under network contracts." See also Alt. Med. & Pharmacy, Inc., v. Express Scripts, Inc., No. 4:14 CV 1469, 2014 WL 4988199, at *6-7 (E.D. Mo. Oct. 7, 2014).

The district court's Memorandum and Order dated March 4, 2015, denying Plaintiffs motion for a preliminary injunction is affirmed.

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party must show that the harm is certain and great and of such imminence that there is a clear and present need for equitable relief." Novus Franchising, Inc. v. Dawson, 725 F.3d 885, 895 (8th Cir. 2013) (quotation omitted). Plaintiffs' additional contention that they are entitled to a preliminary injunction under the Patient Protection and Affordable Care Act was so inadequately presented that it requires no further discussion.