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ARKANSAS COURT OF APPEALS

DIVISION II
No. CV-20-253

ARKANSAS DEPARTMENT OF HUMAN SERVICES AND CINDY GILLESPIE, IN HER OFFICIAL CAPACITY APPELLANTS V. SAREPTA THERAPEUTICS, INC. APPELLEE	Opinion Delivered September 15, 2021 APPEAL FROM THE PULASKI COUNTY CIRCUIT COURT, SIXTH DIVISION [NO. 60CV-18-8359] HONORABLE TIMOTHY DAVIS FOX, JUDGE AFFIRMED

RAYMOND R. ABRAMSON, Judge

This case arose because the Arkansas Department of Human Services (DHS) refused to provide coverage for Exondys, the only drug approved by the Federal Drug Administration (FDA)for treatment of the root cause of Duchenne muscular dystrophy (DMD), a debilitating and ultimately fatal disease that strikes young children. Sarepta Therapeutics, Inc. (Sarepta), is the sole manufacturer of Exondys. This appeal follows a January 2, 2020 decision by the Pulaski County Circuit Court granting Sarepta's motion for summary judgment. For the following reasons, we affirm.

In 2016, Exondys was approved through an accelerated process that allows FDA to speed to market new breakthrough drugs that treat serious and life-threatening conditions and for which there is an unmet medical need. 21 U.S.C. § 356(c)(1)(A). Sarepta participates in the Medicaid Drug Rebate Program (MDRP) and provides rebates to state Medicaid

agencies for prescriptions written for Medicaid beneficiaries. DHS also participates in the MDRP, through which it receives federal Medicaid funds in exchange for adhering to federal Medicaid requirements. The Social Security Act, 42 U.S.C. § 1396r-8, requires state Medicaid agencies that participate in the MDRP to cover all FDA-approved drugs when prescribed for their FDA-approved indications, subject to narrow exceptions that are not applicable here. We emphasize that the facts of this case do not mandate coverage under these exceptions.

In 2017, a physician prescribed Exondys to a young Arkansas Medicaid patient with DMD. DHS denied coverage relying on a provision of the Arkansas Medicaid Provider Manual that requires that "[a]ll services must be medically necessary." Ark. Admin. Code 016.06.35-142.100 (Westlaw current through July 15, 2021). In denying coverage, DHS reviewed the available "clinical data" and deemed Exondys "unproven" and "experimental" and thus not "medically necessary," notwithstanding that the drug had been approved by the FDA.

From January to October 2018, Sarepta representatives engaged with DHS to request that the agency take immediate action to comply with federal law and approve coverage. DHS maintained that it would apply its "medically necessary" rule to determine coverage of Exondys when prescribed for its FDA-approved indication.

On December 7, 2018, Sarepta filed a petition for declaratory judgment asking the court to find that DHS's medical-necessity rule, Ark. Admin. Code 016.06.35–142.100, is

not an appropriate basis on which to deny coverage of Exondys when a doctor has prescribed the drug to a Medicaid beneficiary for its FDA-approved indication.

On January 22, 2019, DHS filed a motion to dismiss for lack of subject-matter jurisdiction arguing that Sarepta's petition should be treated as an impermissible challenge to the application of a rule. The circuit court denied DHS's motion to dismiss on March 4, 2019. DHS then served discovery requests on Sarepta, which prompted Sarepta to move for a protective order because the Arkansas Administrative Procedure Act (APA) bars discovery beyond the administrative record in a declaratory-judgment action.

At a hearing on that motion on July 5, 2019, Sarepta agreed to limit its prayer for relief to the applicability of the medical-necessity rule as of "the July 2017 time frame," when DHS had denied coverage of Exondys as a result of its determination that Exondys was "not medically necessary." The parties filed cross-motions for summary judgment in August 2019.

On January 2, 2020, the circuit court granted Sarepta's motion for summary judgment, finding that DHS had "no legal authority" to make a threshold decision that there was a "lack of medical necessity" for a prescription of Exondys. This appeal follows.

As Sarepta correctly points out in its brief, while judgment was entered on its motion for summary judgment, the appeal turns on the question of whether the circuit court had jurisdiction to grant the relief Sarepta sought. Subject-matter jurisdiction is the power of the court to hear and determine the subject matter in controversy between the parties. *Perroni v. Sachar*, 2017 Ark. 59, at 4, 513 S.W.3d 239, 242. "An Arkansas court lacks subject-matter jurisdiction if it cannot hear a matter 'under any circumstances' and is 'wholly incompetent

to grant the relief sought.'" *Id.* (quoting *Edwards v. Edwards*, 2009 Ark. 580, at 4, 357 S.W.3d 445, 448). Subject-matter jurisdiction is determined from the pleadings and not proof. *See Ark. Dep't of Fin. & Admin. v. Naturalis Health, LLC*, 2018 Ark. 224, at 6, 549 S.W.3d 901, 906. When the issue of subject-matter jurisdiction requires interpretation of a statute, our review is de novo. *Id.*

The circuit court properly denied DHS's motion to dismiss and found that it had subject-matter jurisdiction over this dispute. Sarepta rooted its petition below in the statutory framework that Congress established in 1990 for Medicaid, the national healthcare program in which states receive federal funding to cover the costs of health coverage for low-income residents. Federal funding for state Medicaid programs is predicated on the states following the requirements of the Social Security Act. In particular, although states may administer Medicaid programs differently in some respects, Congress intended a broad system with uniformity in Medicaid prescription-drug coverage. *See Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1338 (S.D. Fla. 2006). Congress thus designed a "statutory scheme, which sets forth very specific criteria and means by which a state may exclude coverage for specific drugs or use of such drugs." *Id.*

States that opt into outpatient prescription-drug assistance must provide coverage for "covered outpatient drugs"—drugs that may be dispensed only by prescription and that FDA has approved. 42 U.S.C. § 1396r-8(k)(2)(A). States may restrict or exclude coverage of such drugs only in narrow and specified circumstances, primarily if "the prescribed use is not for a medically accepted indication." *Id.* § 1396r-8(d)(1)(B)(i). A "medically accepted indication"

is "any use for a covered outpatient drug which is approved [by the FDA] or the use of which is supported . . . in [specified] compendia." *Id.* § 1396r-8(k)(6). Other narrow exceptions to the coverage requirement are not in dispute here.

In limited circumstances, states may require prior authorization before a drug is dispensed. *Id.* § 1396r-8(d)(4)(D), (d)(5). Prior authorization is a time-limited, administrative process for ensuring that a doctor has prescribed the covered outpatient drug for a medically accepted indication. *Id.* The prior-authorization process may not interfere with the ability of physicians to prescribe treatments that, in the physician's independent judgment, are medically necessary. *See id.* § 1396r-8(d)(1)(A) & (d)(5). On June 27, 2018, the federal Centers for Medicare and Medicaid Services (CMS) reiterated that drugs approved through the accelerated approval pathway have full FDA approval and that state Medicaid agencies must cover these drugs as they would any other FDA-approved medication.

Both DHS and Sarepta participate in MDRP and are bound to follow the federal Social Security Act rules. Exondys is a covered outpatient drug. DHS denied coverage of Exondys on the basis of its own determination that the drug is not "medically necessary" and "not regarded as unexperimental" (relying on the Arkansas Medicaid Manual for the proposition that "[a]ll services provided must be medically necessary," a determination that "may be made by the Medical Director for the Medicaid Program"). In so doing, as Sarepta argued, DHS impermissibly substituted its judgment about the efficacy of the drug for that of FDA and the patient's prescribing physician.

Sarepta's petition challenged the applicability of the rule in this manner to Exondys, a challenge that conferred subject-matter jurisdiction on the circuit court under the declaratory-judgment statute. *See* Ark. Code Ann. § 25-15-207 (Repl. 2014) ("The validity or applicability of a rule may be determined in an action for declaratory judgment if it is alleged that the rule, or its threatened application, injures or threatens to injure the plaintiff in his or her person, business, or property.").

DHS's motion to dismiss did not challenge the merits of Sarepta's claims. Instead, DHS rested its argument solely on *Naturalis Health*, 2018 Ark. 224, 549 S.W.3d 901, a case in which the Arkansas Supreme Court distinguished between "application" and "applicability" in interpreting Arkansas's declaratory-judgment statute. Under *Naturalis Health*, "an inquiry into the '*application*' of a rule would ask *how* the rule should be applied given a particular set of facts or circumstances." *Id.* at 9, 549 S.W.3d at 907 (emphasis added). On the other hand, an *applicability* challenge, to which section 207 is limited, addresses "whether the rule *should* be applied to a particular person or situation." *Id.* (emphasis added).

We agree with Sarepta that *Naturalis Health* is readily distinguishable from the present case. In that case, the petitioners challenged the scoring process the Arkansas Medical Marijuana Commission (MMC) used to award cultivation facility licenses, arguing that the MMC "carried out the application process in a flawed, biased, and arbitrary and capricious manner, and that the commissioners failed to uniformly apply their rules when scoring the applications." *Id.* at 2–3, 549 S.W.3d at 904. The *Naturalis Health* court held that this was not a proper challenge because the declaratory-judgment statute is limited to declarations

concerning "whether the rule should be applied to a particular person or situation." *Id.* It found this reading consistent with the purpose of the APA, "which is to allow circuit courts to review judicial or quasi-judicial decisions of state agencies after notice and a hearing." *Id.*

Unlike the petitioners in *Naturalis Health*, Sarepta did not allege that DHS violated its rules and procedures. Sarepta did not, for example, object to "how" the rule was applied, such as by questioning "the process by which a decision-maker categorize[d] the legal facts at issue." *See Naturalis Health*, 2018 Ark. 224, at 9, 549 S.W.3d at 907. Instead, Sarepta challenged whether DHS could apply the rule to the situation at hand, where (a) Exondys is an FDA-approved medication with an indication and medically accepted use to treat certain patients with DMD; (b) Sarepta has had a signed Medicaid Drug Rebate Agreement in place at all relevant times; and (c) the Social Security Act requires the Arkansas Medicaid program to cover all FDA-approved drugs for FDA-approved indications and medically accepted uses. Sarepta argued that there is no manner in which DHS could validly apply the medical-necessity rule to deny coverage of a prescription for FDA-approved use of Exondys without contravening federal law. *See* 42 U.S.C. § 1396r-8(d)(1)(B)(i); *see also, e.g.*, *Edmonds*, 417 F. Supp. 2d at 1323 (granting summary judgment and requiring the Florida Medicaid agency to cover the prescription drug Neurontin when prescribed for its medically accepted indications). We agree that it was unlawful for DHS to deny coverage, and the circuit court had authority to so declare.

Turning to other arguments, we further hold that this case presents an ongoing dispute. DHS admits its coverage denial in 2017 was based on "the clinical data that was

available at the time," and "[a]ny future medical necessity determination for Exondys will be based on the clinical data available at that future date." During the November 22, 2019 hearing, DHS reiterated this position. When asked whether it would continue to apply its medical-necessity rule to Exondys in the future, DHS's counsel confirmed its continuing policy of basing coverage decisions on its assessment of current "clinical data" for Exondys, regardless of whether Exondys remains an FDA-approved product prescribed for its FDA-approved indication.

As Sarepta argues, it is the FDA's job, not that of the Arkansas Medicaid agency, to evaluate the clinical data to determine whether a drug meets efficacy and safety standards. So long as FDA has approved the drug and the manufacturer has signed a Medicaid Drug Rebate Agreement—facts that are not contested here—the Social Security Act mandates that a state Medicaid agency cannot rely on new or different clinical data to determine whether it deems a drug worthy of coverage. *Id.*; 42 U.S.C. § 1396r-8.

On appeal, DHS specifically argues that the petition for declaratory judgment became moot when Sarepta dropped its request for injunctive relief. However, this argument is predicated on an erroneous interpretation of Sarepta's stipulation at the July 5, 2019 hearing on Sarepta's motion for a protective order. At that hearing, Sarepta agreed to limit its prayer for relief to the applicability of the medical-necessity rule "as of July 2017," the time frame when DHS denied coverage of Exondys to an Arkansas child whose doctor had prescribed Exondys. The July 2017 denial provides the best illustration to date of DHS's policy regarding the applicability of the medical-necessity rule to Exondys.

The agreement to confine the time period of the court's review to the applicability of the rule did not transform this case into a judicial review of the administrative decision as to the particular patient. It simply established a time parameter for evaluating DHS's approach to applying the medical-necessity rule more generally to Exondys, which, for the reasons stated above, was inconsistent with the requirements of federal law.

DHS's reliance on *Arkansas Department of Human Services v. Civitan Center*, 2012 Ark. 40, 386 S.W.3d 432, is also unavailing. In that case, the petitioner requested declaratory judgment that the DHS Division of Developmental Disabilities Services (DDS) could not lawfully license any new health-services provider in any county until the DDS policy in question was properly promulgated and published. *Id.* at 8, 386 S.W.3d at 437. The court held that this request did not present a justiciable issue because it was based on "hypothetical future events" involving a hypothetical provider in a hypothetical place pursuant to a policy that had not yet been promulgated. *Id.* Here, however, Sarepta sought a declaration that pertains to a real, concrete factual situation: DHS's established policy of applying its medical-necessity rule to make a threshold-coverage determination for Exondys, as illustrated by the 2017 administrative case. We hold that Sarepta's petition presented a justiciable controversy, and the case is not mooted by Sarepta's agreement that the circuit court confine its review to the record at the time of DHS's coverage denial in 2017.

We note again that Sarepta did not challenge that denial in that particular case itself on case-specific facts; rather, it challenged the rationale on which DHS based its decision. DHS has maintained that it will continue to improperly apply its medical-necessity rule to

Exondys in the same manner, as evidenced by its service of discovery requests so that it can "verify[] any clinical benefit" of Exondys. Accordingly, the circuit court was well within its authority to determine the applicability of the medical-necessity rule where "it [was] alleged that the rule, or its threatened application, injure[d] or threaten[ed] to injure the plaintiff in his person, business, or property." Ark. Code Ann. § 25-15-207.

For the same reason, Sarepta met the requirements of the declaratory-judgment statute, and the circuit court's order was not a mere advisory opinion as DHS argues in its final appellate point. DHS contends that the circuit court's order was incorrect because it did not explicitly describe the rule as "invalid" or explicitly state that the rule "cannot be applied" to Exondys. DHS does not cite a single authority to support its position. In fact, the declaratory-judgment statute does not require courts to address a challenged rule using any prescribed terms. *See* Ark. Code Ann. § 25-15-207. To the contrary, the statute is to be "liberally construed and administered." *Travelers Indem. Co. v. Olive's Sporting Goods, Inc.*, 297 Ark. 516, 519, 764 S.W.2d 596, 597 (1989). Further, its purpose is broad: "to settle and to afford relief from uncertainty and insecurity with respect to rights, status, and other legal relations." *Civitan Ctr.*, 2012 Ark. 40, at 8, 386 S.W.3d at 437 (citing Ark. Code Ann. § 16-111-102(b) (Repl. 2006)).

The circuit court properly granted declaratory judgment on behalf of Sarepta because Sarepta's petition clearly satisfied the declaratory-judgment criteria. There was a justiciable controversy based on the financial injury to Sarepta, whose only product on the market was Exondys. Because Sarepta brought suit against the agency that promulgated the rule, the

controversy was sufficiently situated "between persons whose interests are adverse." *See Reagan v. City of Piggott*, 305 Ark. 77, 82, 805 S.W.2d 636, 639 (1991) (purpose of this section is to ensure that the issues raised are "adequately argued or briefed by truly adversarial parties"). Given the risk of significant financial harm, Sarepta had a legal interest in this controversy. *See* Ark. Code Ann. § 25-15-207(a) (declaratory judgment appropriate when the injury or threat of injury is to a petitioner in its "business[] or property"). Finally, this issue was ripe for judicial determination because DHS had made clear its policy of applying the medical-necessity rule to deny coverage of Exondys on the basis of DHS's judgment—rather than that of the FDA—regarding the level of clinical evidence supporting the product's efficacy.

In light of the facts before the circuit court and the record before us, we hold that the circuit court directly addressed the dispute at hand, holding "DHS had no legal authority to make a threshold decision that there was a 'lack of medical necessity' for a prescription of Exondys, a 'covered outpatient drug.'" The declaratory-judgment statute requires no more; accordingly, we affirm the circuit court's denial of DHS's motion to dismiss and grant of summary judgment for Sarepta.

Affirmed.

VIRDEN and HIXSON, JJ., agree.

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