SUPREME COURT NO. 101414-7
COA NO. 54870-4-II

SUPREME COURT OF THE STATE OF WASHINGTON

SAREPTA THERAPEUTICS, INC.,

Petitioner,

v.

WASHINGTON STATE HEALTH CARE AUTHORITY,

Respondent.

SAREPTA THERAPEUTICS, INC.'S PETITION FOR REVIEW

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Federal Cases

State Cases

Federal Statutes

State Statutes

Rules & Regulations

Other Authorities

I. INTRODUCTION AND IDENTITY OF PETITIONER

Petitioner Sarepta Therapeutics, Inc. ("Sarepta") seeks review of the Court of Appeals' Decision designated in Part II of this Petition.

The Court of Appeals' decision implicates the substantial public interest in access to essential prescription drugs for low-income Washingtonians on Medicaid. The central question is whether Washington's Medicaid agency, the Health Care Authority ("HCA"), can choose to deny coverage of a physician-prescribed medication to patients diagnosed with Duchenne muscular dystrophy ("DMD"), a debilitating and ultimately fatal disease that strikes young children. Sarepta developed EXONDYS 51 ("Exondys"), the only drug approved by the U.S. Food and Drug Administration ("FDA") that treats a particular underlying cause of DMD. The Court of Appeals' rejection of mandatory coverage of Exondys when prescribed for its FDA-approved indication allows HCA to substitute its judgment for that of the FDA and treating physicians in violation of federal law.

This Court should intervene to protect public access to medications that Washington State physicians have determined are necessary to treat Medicaid patients with DMD.

The Court of Appeals reversed the Superior Court, holding that Sarepta lacked standing to petition for judicial review of HCA's drug coverage rules. In doing so, the Court of Appeals has authorized HCA to deprive Washington children with DMD of the only FDA-approved treatment aimed at a particular cause of their disease. The Court of Appeals' Decision conflicts with decisions of this Court, ignores the text and purpose of the federal statute in question, and raises an issue of substantial public interest.

The Court should grant Sarepta's petition and find that the Court of Appeals erred for three independent reasons. ***First***, the Court of Appeals applied the incorrect standard when analyzing standing. The zone of interests test requires a "lenient approach" in which "the benefit of any doubt goes to the plaintiff." This Court's precedent provides that "the test is not especially demanding," particularly when legislative means and ends are

"inextricably tied." The Court of Appeals applied a stricter standard inconsistent with the decisions of this Court.

Second, the Court of Appeals' Decision is incorrect as a matter of law and contrary to a host of other authorities omitted from the Decision, as well as the federal Social Security Act and the Medicaid Drug Rebate Program (the "MDRP"). The Social Security Act and the MDRP establish a covenant between the federal government, state governments, and drug manufacturers. Drug manufacturers that voluntarily sign rebate agreements and participate in this framework, like Sarepta, are crucial stakeholders in the system and meet the zone of interests test. Moreover, the bargained-for coverage under the MDRP has meaning only if coverage results in payment. Under the Court of Appeals' reading—which distinguishes coverage from payment—the coverage requirement becomes a dead letter. When the Medicaid system is properly understood, Sarepta easily satisfies the zone of interests test.

Third, the Court of Appeals conflated its analysis of standing with the merits. By distinguishing between coverage and payment in the MDRP, the Court of Appeals answered the question at the heart of Sarepta's claim. In blurring this line between standing and the merits, the Court of Appeals ran afoul of this Court's precedent and widely accepted general principles of standing.

For these reasons, this Court should grant review under RAP 13.4(b)(1) and (4).

II. DECISION BELOW

Sarepta seeks review of the decision filed by Division II on October 26, 2021 (the "Decision"), holding that Sarepta lacks standing to petition for judicial review. A copy of the Decision is included in the Appendix, *see* App. B.

III. ISSUES PRESENTED FOR REVIEW

1. Did the Court of Appeals err by applying the incorrect standard under the zone of interests test?

2. Did the Court of Appeals err by ruling that Sarepta does not satisfy the zone of interests test?

3. Did the Court of Appeals err by conflating its standing analysis with the merits of Sarepta's claim?

IV. STATEMENT OF THE CASE

FDA's Accelerated Approval of Exondys. Duchenne muscular dystrophy ("DMD") is a rare genetic disorder that generally affects boys in early childhood. Children with DMD have a genetic mutation that impedes the production of dystrophin, a protein found in muscle cells that is critical for muscle structure, function, and preservation. Patients with DMD are typically dependent on a wheelchair by the age of 10 and have a life expectancy of approximately 27 years. CP 107. The disease is universally fatal.

Before 2016, the only available therapies focused on improving symptoms, enhancing quality of life, and decreasing disease progression. CP 108. But on September 19, 2016, through an accelerated approval process, Exondys became the

first therapy approved by the U.S. Food and Drug Administration ("FDA") to treat the underlying cause of DMD. In approving Exondys, the FDA concluded that the drug met the full statutory standards for safety and effectiveness required for all FDA-approved prescription drugs. CP 180. As such, the approval of Exondys marked a significant advance in the fight against DMD.

Prescription Drug Coverage under the Social Security Act. The Social Security Act dictates how a state Medicaid agency must provide coverage for FDA-approved drugs made by manufacturers that have signed Medicaid rebate agreements. 42 U.S.C. § 1396r-8. The Social Security Act generally requires states that opt in to outpatient prescription drug assistance to cover all "covered outpatient drugs" when those medicines are prescribed for an FDA-approved indication or an otherwise "medically accepted" use. *Id.* § 1396r-8(d)(1)(B)(i). The coverage requirement is subject only to narrow exceptions not applicable here. *Id.*

The MDRP establishes a covenant between the federal government, state governments, and drug manufacturers. Under the MDRP, drug manufacturers that enter into a Medicaid Prescription Drug Agreement with the Secretary of Health and Human Services must provide a statutory minimum 23.1% in rebates to the Medicaid program for "covered outpatient drugs." 42 U.S.C. § 1396r-8(c)(1)(B)(i)(VI). In exchange, to receive federal funding, state Medicaid agencies must follow the Social Security Act's requirements and must cover the manufacturers' covered outpatient drugs, subject to only narrow exceptions. *Id.* § 1396r-8(d)(1)(B)(i). *See Samantha A. v. Dep't of Soc. Servs. & Health Servs.*, 171 Wn.2d 623, 630, 256 P.3d 1138 (2011) ("As a voluntary participant in the federal Medicaid program, Washington State must comply with Medicaid statutes and related regulations."). The guarantee of coverage provides the financial incentive for manufacturers to sign rebate agreements, which leads to reduced costs for—and broader access to—prescription drugs for Medicaid patients across the country.

HCA's Violation of the Social Security Act. HCA has established a regulatory scheme that is contrary to federal law and disregards the incentives and compromises inherent in the MDRP. Under HCA's rules, it independently determines—even for FDA-approved prescription drugs—whether services are "medically necessary" before providing coverage, applying a "hierarchy of evidence" standard to evaluate the medical effectiveness and safety of a service. *See* WAC 182-501-0165(3); WAC 182-500-0070; WAC 182-501-0165(3), (4), (6). Using these rules, HCA has ceded to itself the authority to deny coverage for Exondys to Washington children afflicted with DMD, despite Sarepta having entered a Medicaid Prescription Drug Agreement and the patients' physicians having determined that Exondys was medically necessary. CP 146; 133; 136; 142. The effect of HCA's position is twofold: HCA can deny Washington children crucial medical care, and HCA can deny Sarepta the benefit of the bargain for participating in the MDRP.

Prior authorization regimes—whereby state Medicaid agencies can withhold coverage if, for example, a drug is not prescribed for an FDA-approved indication—are inarguably permitted under the Social Security Act. *See* 42 U.S.C. § 1396r-8(d)(1)(A). Federal law does not, however, allow state Medicaid agencies to apply a prior authorization threshold to deny coverage where a physician has determined that drug is medically necessary when prescribed for its FDA-approved indication for a particular patient. In other words, HCA's regulatory framework enables it to skirt its obligations under the Social Security Act by allowing it to determine—using its own criteria—that covered outpatient drugs are not medically necessary. This approach allows HCA to receive federal funding for Washington's Medicaid program without fulfilling its federally mandated obligation to pay for covered outpatient drugs, subject to a 23.1% rebate from a manufacturer. In short, HCA is benefiting from the bargain without upholding its end of the deal.

Violation of the Social Security Act in this manner threatens to reduce the availability of FDA-approved treatments to all Washingtonians by disincentivizing drug manufacturers to develop innovative medications and participate in the MDRP.

Procedural History. Sarepta filed its Petition for Judicial Review on July 12, 2019. The Superior Court found that Sarepta had standing but denied Sarepta's request for declaratory and other relief. Report of Proceedings, App. A, 47. Sarepta timely filed its Notice of Appeal on April 6, 2020.

On October 26, 2021, the Court of Appeals issued an opinion terminating review, holding that Sarepta lacked standing to file its petition for judicial review. Decision at 1. Applying an unduly exacting standard, the Court of Appeals concluded that because the state legislature did not specifically intend to protect a drug manufacture's financial interests when it established Washington's Medicaid program, Sarepta failed to satisfy the zone of interests test. Decision at 11. In so ruling, the Court of Appeals ignored this Court's precedent outlining the flexible

nature of the zone of interests test. Sarepta timely filed a motion for reconsideration on November 15, 2021, which was denied in a one-line order on September 28, 2022.

V. ARGUMENT

The Court of Appeals' Decision to terminate review on standing grounds means that HCA can deprive Washington children diagnosed with DMD access to a life-prolonging treatment. The Decision also eviscerates the incentive structure fundamental to the MDRP and threatens to reduce access to low-cost prescription drugs for Washingtonians on Medicaid. This Court should accept Sarepta's Petition in light of the substantial issues of public interest that this case raises with respect to Medicaid patients' access to prescription drugs.

Beyond that, in finding no standing, the Court of Appeals erred in three fundamental ways. ***First***, the Court of Appeals applied the incorrect standard under the zone of interests test. ***Second***, the Court of Appeals, had it interpreted the Social Security Act correctly, should have found that Sarepta easily

satisfies the zone of interests test. ***Third***, the Court of Appeals conflated its standing analysis with the merits of Sarepta's claim.

A. The Court of Appeals' Decision Implicates the Substantial Public Interest in Securing Medical Treatment for Washington Children with DMD.

This Court should grant Sarepta's petition because the Decision concerns the profound public interest in access to life-prolonging, FDA-approved medical treatments. *Cf. Matter of Recall of Inslee*, 199 Wn.2d 416, 430, 508 P.3d 635 (2022) ("Protecting public health is a substantial and compelling public interest."). The regulatory mechanisms erected by HCA allow the agency to circumvent federal law and deny low-income patients access to medical services, even after the FDA and a patient's doctor determine that such services are medically necessary. This Court should intervene to protect public health and ensure that HCA complies with the Social Security Act and MDRP.

Most immediately, the Decision permits HCA to restrict low-income Washington children diagnosed with DMD access to Exondys. Exondys is the only FDA-approved medication that

treats a particular cause of DMD, offering hope to patients facing an otherwise progressive and universally fatal disease. By denying Sarepta's right to petition for judicial review, the Court of Appeals has left in place a regime that permits HCA to unilaterally deny these children access to this innovative treatment. The public has a strong interest in preserving access to healthcare for all individuals receiving Medicaid benefits. *Cf. Matter of Recall of Inslee*, 199 Wn.2d at 430; *see also* RCW 70.01.010 (favoring statutory construction "most likely to satisfy federal laws entitling this state to receive federal funds for the various programs of public health").

More broadly, the Decision allows HCA to continue circumventing its obligations under the Social Security Act and MDRP with respect to other medications that it deems medically unnecessary. As a drug manufacturer with a rebate agreement, Sarepta is uniquely situated to challenge HCA's conduct on a statewide scale. The concomitant public benefit is that low-income Medicaid recipients in need of treatment will not be

forced to fight on a case-by-case basis HCA's determinations that contravene the judgment of the FDA and their doctors.

B. The Court of Appeals Applied the Incorrect Standard Under the Zone of Interests Test.

The zone of interests test is part of a three-pronged analysis to establish standing to challenge agency action. The Washington Administrative Procedure Act (the "APA") "delineates standing requirements that differ from the general standing test." *City of Burlington v. Wash. State Liquor Control Bd.*, 187 Wn. App. 853, 861, 351 P.3d 875 (2015), *as amended* (June 17, 2015). A petitioner has standing to obtain judicial review of an agency action if that person is "aggrieved or adversely affected by the agency action." RCW 34.05.530. A person is "aggrieved or adversely affected" under the APA under the following conditions:

> (1) The agency action has prejudiced or is likely to prejudice that person;
>
> (2) That person's asserted interests are among those that the agency was required to consider when it engaged in the agency action challenged; and

> (3) A judgment in favor of that person would substantially eliminate or redress the prejudice to that person caused or likely to be caused by the agency action.

Id.; *see also City of Burlington*, 187 Wn. App. at 862. The second prong is known as the "zone of interests" test. *Id.* (citing *Allan v. Univ. of Wash.*, 140 Wn.2d 323, 327, 997 P.2d 360 (2000)).

Washington courts routinely acknowledge that "although the zone of interests test serves as an additional filter limiting the group which can obtain judicial review of an agency decision, the 'test is not meant to be especially demanding.'" *Seattle Bldg. & Constr. Trades Council v. Apprenticeship & Training Council*, 129 Wn.2d 787, 797, 920 P.2d 581 (1996) (quoting *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399, 107 S. Ct. 750, 93 L. Ed. 2d 757 (1987)); *KS Tacoma Holdings, LLC v. Shorelines Hearings Bd.*, 166 Wn. App. 117, 128, 272 P.3d 876 (2012) (same). Despite

this, the Court of Appeals failed to apply the lenient standard required by this Court's precedent.[1]

St. Joseph Hospital & Health Care Center v. Department of Health—which the Court of Appeals cited but did not analyze—demonstrates an appropriate application of the lenient zone of interests test. *See* 125 Wn.2d 733, 740-42, 887 P.2d 891 (1995). There, this Court considered the test with respect to the competitive and economic interests of healthcare providers in a state health planning program developed in response to federal law. *See id.* at 735-37. The Department of Health argued that the provider plaintiff lacked standing by pointing to legislative

[1] Washington law directs that "courts should interpret provisions of [the APA] consistently with decisions of other courts interpreting similar provisions of ... the federal government." RCW 34.05.001. In addition to ignoring this Court's precedent, the Court of Appeals also ignored a host of other authorities, including numerous U.S. Supreme Court opinions, outlining the lenient and forgiving zone of interests inquiry. *See, e.g.*, *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130, 134 S. Ct. 1377, 188 L. Ed. 2d 392 (2014); *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225, 132 S. Ct. 2199, 183 L. Ed. 2d 211 (2012).

statements of purpose discussing the importance of access to cost-effective healthcare services for the public, claiming that the "economic and competitive interests of existing providers" were not considered. *Id.* at 740-41. The provider argued in response that the focus on cost control necessarily "require[d] its economic interests [to] be considered." *Id.* at 741. This Court agreed:

> While the Legislature clearly wanted to control health care costs to the public, equally clear is its intention to accomplish that control by limiting competition within the health care industry. The U.S. Congress and our Legislature made the judgment that competition had a tendency to drive health care costs up rather than down and government therefore needed to restrain marketplace forces. ***The means and end here are inextricably tied.*** Because the Legislature intended to regulate competition as well as control costs, we hold competing service providers to be within the statutory zone of interest.

Id. (emphasis added). By looking to the interests affected by the statutory framework, including those touched by the means to achieve the desired end, the Court in *St. Joseph* outlined the flexible standard for the zone of interests test that Washington courts must apply.

Washington State Housing Finance Commission v. National Homebuyers Fund, Inc., 193 Wn.2d 704, 445 P.3d 533 (2019), is similarly instructive. There, the Legislature had delegated authority to the Washington State Housing Finance Commission (the "Commission") to provide financial assistance for down payments to home buyers. *Id.* at 707. The Commission sought to prevent a private company from conducting the same type of business in Washington, arguing that "its activities impermissibly compete with the Commission's own activities." *Id.* The Court acknowledged that the Commission's enabling act did not contain an explicit prohibition on competition that would satisfy the zone of interests test. *Id.* at 715. But under the flexible test required by precedent, the Court found that it "must determine if one is nonetheless implied." *Id.* Looking to the "statute's purpose and operation," the Court concluded that "the Commission's interest against interference from competitors purporting to exercise such authority without authorization is implicit within its enabling act," thus satisfying the zone of interests test. *Id.* at 716; *see also Five*

Corners Fam. Farmers v. State, 173 Wn.2d 296, 304-05, 268 P.3d 892 (2011) ("In ascertaining the zone of interests protected by a statute, it is appropriate to look both to the operation of the statute, and to the statute's general purpose." (citations omitted)).

Contrary to this authority, the Court of Appeals applied an improper and significantly more exacting standard by searching for a specific and express congressional intent to benefit or safeguard the financial interests of drug manufacturers. *See Sarepta Therapeutics, Inc. v. Health Care Auth.*, 19 Wn. App. 2d 538, 552, 497 P.3d 454 (2021) ("Congress did not intend for prescription drug programs to protect the financial interests of drug manufacturers."); *id.* ("The legislative history of the MDRP does not establish Congress's intent to protect drug manufacturer's financial interests when establishing the MDRP."). This approach disregards the lenient and flexible standard employed by this Court and fails to consider the interests affected by the overall statutory framework, including those interests impliedly affected by the MDRP.

C. The Court of Appeals Erred by Concluding that Sarepta Fails to Satisfy the Zone of Interests Test.

Had the Court of Appeals considered the interests affected by the MDRP and carefully analyzed its text and purpose—as this Court's precedent requires—it would have concluded that Sarepta satisfies the zone of interests test. Instead, the Decision demonstrates a fundamental misunderstanding of the MDRP's statutory framework and incentive structure. This misunderstanding is most directly evidenced by the Court of Appeals' erroneous distinction between "coverage" and "payment" that strips all meaning from the coverage requirement. The Court of Appeals' treatment of the text and legislative history runs contrary to this Court's prior decisions.

1. The Purpose of the MDRP

The Court of Appeals failed to appreciate that the MDRP establishes a covenant between the federal government, state governments, and drug manufacturers that necessarily implicates the economic interests of companies like Sarepta. Established by the Social Security Act, Medicaid is a cooperative federal-state

program through which the federal government provides funding to support participating states in administering health benefits to qualifying low-income beneficiaries. 42 U.S.C. § 1396(b). To receive funding, participating states must follow the requirements of the Social Security Act. *See Samantha A.*, 171 Wn.2d at 630 ("As a voluntary participant in the federal Medicaid program, Washington State must comply with Medicaid statutes and related regulations."). Crucially for this case, when a state participating in the Medicaid program chooses to provide outpatient prescription drug assistance, that assistance is subject to all applicable requirements of the Social Security Act. 42 U.S.C. § 1396a(a)(54) ("a State plan that provides medical assistance for covered outpatient drugs ... [must] comply with the applicable requirements").

When drug manufacturers enter into a Medicaid Prescription Drug Agreement with the Secretary of Health and Human Services, they must provide a statutory minimum of 23.1% in rebates to the Medicaid program for Medicaid utilization

of the manufacturer's "covered outpatient drugs." 42 U.S.C. § 1396r-8(c)(1)(B)(i)(VI). In return, state Medicaid agencies must cover the manufacturers' covered outpatient drugs, subject to only narrow exceptions. *Id.* § 1396r-8(d)(1)(B)(i). The guarantee of coverage creates the incentive for drug manufacturers to participate. Without it, the system falls apart.

The legislative history of the MDRP supports this reading. The House Report explains that "the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide rebates." H. Rep. No. 101-881, at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110, 1990 WL 200617. Although Congress also intended "to control Medicaid costs by reducing the costs of prescription drugs" and "to ensure Medicaid patients have access to the same range of drugs as patients that do not require Medicaid," *see Sarepta*, 19 Wn. App. 2d at 552 (citing U.S.C.C.A.N. 2017, 2108), the means by which the MDRP achieves those ends are the rebate agreements that affect the

financial interests of manufacturers. In accordance with this legislative history, the U.S. Supreme Court has recognized the contractual nature of the MDRP's coverage requirements, explaining that "[t]o gain ***payment*** under Medicaid for covered drugs, a manufacturer must enter a standardized agreement with [the Department of Health and Human Services]; in the agreement, the manufacturer undertakes to provide rebates to States on their Medicaid drug purchases." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 114, 131 S. Ct. 1342, 179 L. Ed. 2d 457 (2011) (citing 42 U.S.C. § 1396r-8(a)) (emphasis added).

Under *St. Joseph* and *Washington State Housing Finance Commission*, Sarepta passes with flying colors the zone of interests test within this statutory framework. Just as in *St. Joseph*, the U.S. Congress and Washington Legislature made a judgment about how to control access to and costs for medical services. 125 Wn.2d at 741. "The means and end here are inextricably tied" in the same way. *Id.* Greater access to more

affordable medications is achieved through rebate agreements with drug manufacturers that necessarily impact their economic interests. If the framework is not explicit enough—and Sarepta contends it is—*Washington State Housing Finance Commission* dictates that the interests implicit in the statutory scheme must be considered. 193 Wn.2d at 716. Either way, Sarepta's economic interests are squarely at issue, thus easily satisfying the lenient zone of interests test.[2]

2. Coverage/Payment Distinction

In its analysis of standing, the Court of Appeals drew a distinction between "coverage" and "payment" that appears

[2] Any argument that the Court should evaluate the zone of interests based on the Washington Legislature's intent in fashioning the HCA regulatory framework misses the point. Sarepta's claim is not that HCA has violated its own rules; rather, Sarepta alleges that HCA's rules as applied to Sarepta violate federal law. Accordingly, it is the purposes of the federal statutes, not of HCA's rules, that are key to the zone of interests inquiry. *East Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 768 (9th Cir. 2018).

nowhere in the statutory text and threatens to undermine the important incentive structure of the MDRP described above.

While the Court of Appeals noted that "the definition of a 'covered outpatient drug' does not contain any language related to reimbursement or payment for a drug," *see Sarepta*, 19 Wn. App. 2d at 553, the title of the statutory provisions that creates the MDRP is "***Payment*** for covered outpatient drugs." 42 U.S.C. § 1396r-8 (emphasis added). The first sentence of the section reads: "In order for ***payment*** to be available … for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement…." *Id.* § 1396r-8(a) (emphasis added). As the title and first sentence make clear, the MDRP concerns payment for covered outpatient drugs, not merely coverage in name only. And as set forth above, when a drug is prescribed by a physician for its FDA-approved indication and no statutory exceptions are met, the Social Security Act requires that it be "covered"—i.e., paid for. *Id.* § 1396r-8(d)(1)(B)(i).

This makes sense because a coverage requirement that does not require payment as set forth in the statute would be no requirement at all. Under such a regime, a state could "cover" all covered outpatient drugs but universally refuse to pay by second-guessing judgments made by the FDA and prescribing physicians. The incentive to enter rebate agreements built into the MDRP would evaporate if manufacturers did not have any assurance of payment. And if coverage does not mean payment, there would be no need for a rebate. Such a regime would all but assure that Congress's goal "to ensure Medicaid patients have access to the same range of drugs as patients that do not require Medicaid," *Sarepta*, 19 Wn. App. 2d at 552, would never materialize. *See Astra USA*, 563 U.S. at 114 ("To gain ***payment*** under Medicaid for covered drugs, a manufacturer must enter a standardized agreement ….") (emphasis added). Sarepta sued HCA for precisely this reason—the FDA has approved Exondys for treatment of a debilitating disease, doctors have prescribed it for

that purpose, and HCA nevertheless believes it can deny patients access to the drug by refusing to pay for it.[3]

The Court of Appeals' misreading of the MDRP betrays a fundamental misunderstanding of our Medicaid system. This Court should grant Sarepta's petition to correct the error.[4]

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[3] The Court of Appeals cited two provisions to support the erroneous distinction between "coverage" and "payment" that have nothing to do with this case or the coverage requirement. *See Sarepta*, 19 Wn. App. 2d at 552-53. Both provisions deal with reimbursement limits for multiple-source drugs. *See* 42 U.S.C. § 1396r-8(e)(4); WAC 182-530-8100. Exondys is not a multiple-source drug—it has no therapeutic alternatives. These provisions simply have nothing to do with this case and do not support the Court of Appeals' analysis.

[4] Although not binding, the Court of Appeals also ignored directly on-point cases from other jurisdictions. *Edmonds v. Levine*, 417 F. Supp. 2d 1323 (S.D. Fla. 2006); *K-V. Pharm. Co. v. Cook*, 1:12-CV-2491-CAP, 2012 WL 3715276, at *2 (N.D. Ga. Aug. 9, 2012), *abrogated on other grounds by Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 135 S. Ct. 1378, 191 L. Ed. 2d 471 (2015); *Ark. Dep't of Hum. Servs. v. Sarepta Therapeutics, Inc.*, No. CV-20-253, 2021 WL 4186665 (Ark. Ct. App. Sep. 15, 2021).

D. The Court of Appeals Erroneously Conflated Standing with the Merits.

Courts must consider standing separate from questions on the merits. *See, e.g.*, *Magnolia Neighborhood Plan. Council v. City of Seattle*, 155 Wn. App. 305, 312, 230 P.3d 190 (2010), *as amended on reconsideration* (May 14, 2010) (rejecting "an argument directed to the merits … rather than an argument against standing"). The Court of Appeals ignored this general principle of standing, instead concluding that the MDRP does not guarantee payment for covered outpatient drugs. *See Sarepta*, 19 Wn. App. 2d at 552-53. That conclusion answers the merits question at the heart of Sarepta's petition for judicial review. This conflation of standing and the merits amounts to error under this Court's precedent and is an independent reason to grant Sarepta's petition.

VI. CONCLUSION

For the foregoing reasons, Sarepta respectfully asks this Court to grant review of the Court of Appeals' Decision.

This document contains 4,629 words, excluding the parts of the document exempted from the word count by RAP 18.17.

DATED this 28th day of October, 2022.

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CERTIFICATE OF SERVICE

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APPENDIX

IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON

IN AND FOR THE COUNTY OF THURSTON

SAREPTA THERAPEUTICS, INC.,	)	No. 19-2-03449-34
	)	Court of Appeals
Plaintiff,	)	No. 54870-4-II
vs.	)	
WASHINGTON HEALTH CARE AUTHORITY, et al.,	)	
Defendants.	)	

VERBATIM REPORT OF PROCEEDINGS

March 13, 2020

BE IT REMEMBERED that on March 13, 2020, the above-entitled matter came on for hearing before the HONORABLE ERIK PRICE, judge of Thurston County Superior Court.

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I N D E X

WITNESS	PAGE REFERENCE

E X H I B I T L I S T

NUMBER	PAGE

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*** March 13, 2020 ***

THE COURT: Good afternoon, everyone. We're here on the record with Sarepta, Sarepta. How do I pronounce that?

MS. HOWARD: Sarepta, Your Honor.

THE COURT: Sarepta Therapeutics versus the Health Care Authority, 19-2-03449-34. The matter comes before The Court today for an administrative law trial or hearing.

Who do I have? I know we have folks on the phone. Before I get to them, let's introduce ourselves for the record. Who is in the courtroom?

MR. RHEAUME: Your Honor, Warren Rheaume, Davis Wright Tremaine.

THE COURT: Mr. Rheaume, good morning.

MR ROBBINS: Ben Robbins, Davis Wright Tremaine.

THE COURT: Mr. Robbins, good morning -- good afternoon.

MS. HOWARD: Renee Howard, Davis Wright Tremaine.

THE COURT: Ms. Howard, good afternoon.

MS. IVERSEN: Nissa Iversen, Attorney General's Office.

THE COURT: Iversen?

MS. IVERSEN: Yes.

THE COURT: Good afternoon.

MR. BRADLEY: And Michael Bradley for the State.

THE COURT: Mr. Bradley, good afternoon.

All right. And who do I have on the phone?

MR. HANDWERKER: Your Honor, it's Jeff Handwerker and Paige Sharpe with Arnold & Porter Kaye Scholer in Washington, D.C.

(INTERRUPTION BY THE REPORTER.)

THE COURT: I'm sorry. Could you repeat your names for Madam Court Reporter? She indicated she could not hear your names.

MR. HANDWERKER: I'm sorry. I'm far from the phone. It's Jeff Handwerker, H-a-n-d-w-e-r-k-e-r, with Arnold & Porter Kaye Scholer, and with me is Paige Sharpe, S-h-a-r-p-e.

MS. HATFIELD: And Your Honor, this is Katy Hatfield from the Attorney General's Office also phoning in.

THE COURT: Ms. Hatfield, good afternoon to you.

And to those in Washington, D.C., good afternoon.

So before we get to the argument, I did want to make a bit of an announcement. I'm not sure it's relevant to this case. I know Mr. Robbins has heard my speech. But we have starting Monday significant changes in the way we are dealing with our cases here in Thurston County. This may be educational for some of our in-state folks.

But starting Monday until at least May 15 we will cease to be doing any civil trials, no bench or jury trials will

be conducted during that time period. We will also not be doing any administrative law appeals during that time, period. So this one got in just in under the wire, so to speak.

We will also only be considering emergent civil motions and non emergent civil motions that are filed will be struck at the discretion of the court. And any motions that are heard on civil motions calendars will likely be done entirely on the pleadings or with completely telephonic appearances.

We have some limited, and we're exploring our abilities to do video hearings. At this point, unless we have our civil litigants sitting in the jail, it's not easy to do telephonic hearings.

So that's, again, an announcement for what we're doing here in Thurston County. Obviously, a lot of changes with our criminal calendar as well which I won't get into apart from saying we are limiting ourselves to one jury trial at a time. And that's a significant impact on the system. We typically have three or four trials at a time. We have decided that only one trial can be conducted, well, while affording the jurors social distancing appropriately. We have shoeboxes for jury rooms and we'll have to spread people out and at that point we'll lose facilities. So that's the decisions we've made. Again, I'm not entirely

sure it's going to be applicable to this specific case.

I also want to make a preliminary comment about the initial motion regarding standing that was brought and the discussion we had some weeks ago regarding not combining that with this hearing. And one of my bases that I put on the record was my -- the value to The Court, meaning me specifically, of having -- I'm not sure the word I used -- but swimming in the issues for not one motion but two.

But then, of course, I was unable to hear that motion. And I apologize for that. It was unavoidable. It was unscheduled. I won't go into the details of why. It was a non-life threatening medical thing.

So in any event, back here I have prepared for this hearing, however, and ready to go. But I did want to explain the inconsistency with what I said on the record and, of course, what happened.

So, those are my preliminary comments. Is there any questions or comments before we get into the merits of the hearing from either side?

MR. BRADLEY: No, not for the State.

MS. HOWARD: No, Your Honor.

THE COURT: Hearing none, so let's move on to the hearing.

On these types of hearings, although our rules say ten minutes a side, I typically given 20 minutes a side. So

I'm assuming that that's not going to be problematic for the parties?

MR. BRADLEY: No.

MS. HOWARD: No, Your Honor.

THE COURT: So let's hear from the petitioner first and I'll have you present up here, or whomever is presenting.

MS. HOWARD: Great. I am, Your Honor.

Good afternoon, Your Honor. My name is Renee Howard. As previously indicated, I'm from Davis Wright Tremaine and I'm here on behalf of Sarepta Therapeutics. And I would just encourage Your Honor, if you have specific questions, and I'm sure you have many, please feel free to stop me and ask questions as I go along.

I had assumed coming into it, and your comments just confirmed, that I should address both the procedural issues that the State has raised with respect to standing in addition to the merits. So is that what you're expecting?

THE COURT: Well, that's a good question. Of course, I was not present for the result of the standing argument. My understanding from talking with the judicial officer who presided over that hearing, that it was essentially denied without prejudice to rebring should they choose. And it was unclear to me whether that was going to be a big part of what the State's response was today. So whatever you're

anticipating I suggest you address in your comments.

MS. HOWARD: Sure. I'm anticipating that they will reraise those issues, so I plan to address them now.

But first, before I do that, I just wanted to orient you a little bit to Sarepta because you're probably not familiar with Sarepta. They're from Cambridge, Massachusetts. But I think it's helpful to just understand a little bit about what this company is and what their product is and why we're here today.

So Sarepta is a biotechnology company and its mission is to develop novel therapies for extremely rare genetic diseases. And one of those rare genetic diseases is called Duchenne muscular dystrophy. And you're probably familiar with muscular dystrophy. Duchenne is a form of muscular dystrophy.

And it's really a terrible disease. It's one of the worst devastating forms of the disease. It affects almost exclusively young boys, and typically a Duchenne boy, once the symptoms are diagnosed at a young age, is wheelchair bound by the age of ten and life expectancy is I think the average age of 27. So it really is a cruel disease. And Sarepta's mission is to develop therapies for diseases like Duchenne.

The particular product that we're talking about today is called Exondys 51. Exondys is a very unique therapy and

what it does is it targets a subset of genetic mutations that are in DMD patients and the genetic mutation causes a muscle weakness because the mutation basically prevents the gene from expressing a code for something called dystrophin which is basically a muscle protein. So, you know, overly simplified what happens is, you know, the gene can't express the gene for dystrophin, the muscles then atrophy and are replaced with scar tissue or fat.

So what the therapy does it binds to a part of a gene and there's -- this is a very large gene and they're made up of parts called exons. And the reason it's called Exondys 51 is that this therapy binds to Exon 51 and basically reroutes the pathway of the gene to allow the gene to express the code for dystrophin.

So that means that the patient now, rather than being completely unable to produce any dystrophin, dystrophin can be produced. And as the FDA recognized, you know, that's a surrogate end point meaning that the fact that the medication can produce dystrophin is a benefit to the patient because that slows down the deterioration of the muscles.

Unfortunately, it's not a cure for DMD but it definitely improves the quality of life, it extends the patient's ability to ambulate on their own and overall just improves their quality of life. So it's really a wonderful,

wonderful therapy.

So about 13 patients with DMD have this genetic mutation which makes them amenable to Exondys 51. So the FDA approved Exondys on its accelerated approval pathway, recognizing that this was an extremely beneficial and novel therapy and that these children simply do not have the time to wait for the normal full clinical studies that would be conducted to prove exactly how much dystrophin is therapeutic but the FDA recognized that the dystrophin production itself is a surrogate endpoint such that it was appropriate to approve the drug through its accelerated approval pathway.

So that's a long way of saying that it's a unique therapy but it has been approved by the FDA. And although it's been approved by an accelerated approval pathway, it's just like any other drug that the FDA approves for coverage purposes. And we're here today to talk about Medicaid coverage and the circumstances under which Medicaid programs like the Health Care Authority can decide to not cover a particular drug.

So in terms of HCA's stance towards Exondys 51, it's important to understand two things: First, the Health Care Authority does not dispute that Exondys 51 is in fact a covered outpatient drug as defined by federal Medicaid law. It also doesn't dispute that Exondys 51 has been prescribed

for what are called medically accepted indications. And basically a medically accepted indication as defined by federal law is any indication that is approved by the FDA. It also includes certain off-label indications but that's not relevant here. So no dispute, it's a covered outpatient drug. It's for a medically accepted indication.

So but the reason we're here today is the Washington State Health Care Authority has ignored the mandates of federal Medicaid law which requires that all state Medicaid programs provide -- who decide to offer coverage for outpatient prescription drugs cover any drugs that are any covered outpatient drugs that are prescribed for a medically-accepted indication.

And I'll talk a little bit more about the specific statutory language in a minute and why there's limitations on states' abilities to provide -- or to impose any restrictions on the drugs that they're going to cover.

But before we get to that, I wanted to address the procedural issues. So Sarepta is bringing this challenge under the Washington Administrative Procedures Act. The specific provision that we're proceeding under allows the petitioner to challenge, quote, the validity of any rule when, quote, its threatened application interferes with or impairs or immediately threatens to interfere with or impair the legal rights or privileges of the petitioner.

That's RCW 34.05.570(b)(i).

So there's a couple aspects about this provision that I think is important to focus on here. One of them is the language the "threatened application."

HCA here has argued that we shouldn't be here today because since we initially filed this petition it decided to cover Exondys 51 for the three patients that we discussed in our petition. That absolutely is not an argument for mooting the case. It's not an argument that we don't have standing here.

And the reasons for that is that HCA has continued to maintain, despite covering at least for a limited period of time Exondys 51 for these patients, that it is still reserving to itself the right at any point to apply its medical necessity and hierarchy of evidence rules -- these are the State rules that the Health Care Authority has promulgated -- to second guess any prescriptions of Exondys and that are written by physicians for medically-accepted indications.

And as I'll talk about when I get to the merits, that is unlawful. And that is HCA's policy. It's their policy today, it will be their policy tomorrow, it will be their policy next month. So absolutely there is a threatened application of the agency's rules that is improper here.

And, you know, if you look to the various exceptions to

the mootness doctrine, for example, the voluntary cessation exception, to me this seems very much like situations where courts have said just because you temporarily corrected the problematic behavior, unless it's absolutely clear that you've corrected the issue going forward, the issue is not moot.

And we cited the Regal Cinemas case where the movie theater adopted closed captioning. That's a very good example of, you know, what seemed like an action that would take care of the discrimination claim. The court said no, it's not absolutely clear that you're going to fix this problematic conduct going forward. The issue is not moot.

In addition, this also seems like a case that is absolutely capable of repetition yet evading review. Just because HCA is at this moment covering Exondys for three patients doesn't mean that when those patients need new authorizations for their drug the HCA will continue to cover it. It doesn't mean that when another patient presents with a prescription for Exondys the HCA is going to cover it in accordance with federal law. So there's absolutely no reason why this issue shouldn't be decided today.

On the issue of standing, I expect the HCA is going to argue that Sarepta shouldn't be the entity to bring this challenge. They may argue that Medicaid beneficiaries

should be the ones who come here and argue that the State's denials are unlawful. And I have a couple responses to that:

Number one, just because there is a mechanism for beneficiaries to challenge coverage denials through a separate administrative process doesn't mean that there isn't a separate avenue for Sarepta under the APA to challenge this action based on its own injury that HCA's coverage denials have caused.

And second, the requirements for standing under the APA are clearly met here. As you are aware, I mean, there's three of them. Two of them are essentially injury in fact requirements and one of them is the zone of interests test. Zone of interests test the courts have concluded is a relatively minimal test. Courts are fairly lenient. So unless it appears as if the petitioner's interests have no relationship at all to the interests that are intended to be protected by the underlying statute, the zone of interests test is met.

And here I would submit that Sarepta's interests are absolutely congruent with any interests of a Medicaid beneficiary. We want the exact same thing. We want the coverage for necessary therapies that have been prescribed to Medicaid beneficiaries. We want the Health Care Authority to follow the law in determining whether those

therapies be covered or not. So there is absolute congruence.

And then in terms of injury in fact, Sarepta is absolutely injured by denials, in addition to denials also by the mere fact that HCA has this policy and will continue to impose this policy. The policy itself violates federal law. That injures Sarepta's commercial interests as a pharmaceutical manufacturer.

As recognized in the K-V Pharmaceutical case, economic loss stemming from a Medicaid agency's policy that allows the State to circumvent its payment obligations is an injury and that's absolutely what's happening here. Sarepta is injured by the Health Care Authority's improper denial of this drug which is actually the -- it used to be Sarepta's only product on the market and now it's -- they have another product, but it's their primary product. So if Medicaid agencies are just arbitrarily deciding not to cover, it obviously impacts Sarepta's commercial interests.

So because there is -- this case is not mooted and we clearly have standing, to the extent the State is renewing their motion to dismiss, we submit that it should be denied.

So this brings us to the merits. Sarepta's petition is asking this Court to declare the Health Care Authority may not apply its existing medical necessity and hierarchy of

evidence rules to Sarepta to determine coverage because doing so violates federal law.

And I want to make clear that there is an as-applied challenge to the agency's rules. This isn't a rule making challenge. We are saying that the medical necessity rule or the hierarchy of evidence rule can never be applied lawfully. We're not saying that the agency didn't properly promulgate the rule. So I think that's key to keep in mind because you may hear the agency try to argue, well, if Sarepta's position prevails then how can our agency exercise any control over expenditures in the Medicaid program, how can it be that whenever someone writes a prescription we always have to authorize it.

Well, the answer here is that this is not a slippery slope. This is a case involving a challenge for a specific prescription drug where there is a specific federal statute that dictates the parameters of the State's medical necessity review.

THE COURT: Ms. Howard, let me push back a little on that, though.

I get how the challenge, as I understand it, doesn't really affect -- or a decision in this case wouldn't affect some sort of judgment on the way the rules were promulgated. But how does a decision -- if The Court were to adopt petitioner's position, why doesn't that affect the

State's right or potentially affect the State's right to utilize the hierarchy of evidence rule and the medical necessity rule in the way they're applying it to almost anybody else?

MS. HOWARD: Sure. No, that's a great question.

Well, first of all, the relief that we would be seeking today would be to have a declaratory judgment that HCA cannot apply its medical necessity and hierarchy of evidence rule to determinations for Exondys 51. So that would be the ruling that we would seek, which is quite narrow.

But, you know, I appreciate your question because I think it's important. We're not saying that the agency could never use this rule. There's lots of services that the Medicaid program authorizes and has to review. You know, for example, someone is having back surgery. Maybe the agency is going to authorize that surgery and in so doing is going to look to see whether the surgery appears to be reasonable and necessary.

We're not arguing that the reasonable and necessary inquiry, which is basically the medical necessity standard, isn't relevant and that the agency can't consider it. What we're arguing is that for the narrow category of outpatient prescription drugs under the Medicaid program, the medical necessity review is circumscribed by the Medicaid Act.

THE COURT: But a decision from The Court would affect all those other outpatient prescription drugs that would fall outside of those -- the limitations that the federal law has; am I correct?

MS. HOWARD: I don't think the order would. But the implications -- that could be the implication. I think another pharmaceutical company might have to bring its own challenge if the agency continued to apply their rules to their products in the same way as to Sarepta.

I don't know what HCA is doing. It's possible that they haven't, you know, applied these rules to other companies in this way. We're only here because of Sarepta. So the order wouldn't affect that. But, you know, I would submit that the Medicaid Act applies to all outpatient prescription drugs. So that's why we're here.

And many of the cases that the State cites in their brief, you know, that talk about medical necessity, for example, the Moore case that was about skilled nursing hours and whether it was okay for a Medicaid program in addition to the physician to weigh in on how many hours of skilled nursing someone needs, that's a very different case because there the federal law at issue didn't dictate the parameters of that review. It just said that the underlying statute said that the State has to provide all necessary service but it didn't define the parameters of

what's necessary.

Here we have 1396r-8 which is the Medicare -- or sorry, Medicaid Act provision about outpatient prescription drugs. And the context for that statute is that the states have agreed to cover outpatient prescription drugs and to the extent... Well, excuse me. Let me back up. To the extent states decide to cover outpatient prescription drugs, they don't have to, but if they decide to do that, they have to follow federal law. And the manufacturers as a condition of having their drugs covered enter into Medicaid rebate agreements. So the bargain there is that by offering a minimum of 23.1 percent discounts on all of their products, the manufacturers can expect uniform coverage of their products in all states that have a prescription drug benefit.

So that's why this context is a little different. Congress has this system. I mean, this was a very intentional law with a bargain struck, basically, between the manufacturers and the states in order to expand access to prescription drugs, ensure uniformity of coverage, and ensure also, you know, as the House report that we quoted in our opening brief notes, to ensure that the states in administering their programs don't deny otherwise covered drugs. So that's the reason we have the 1396r-8.

THE COURT: So that's the quid pro quo, the states

are unable to apply a medical necessity and hierarchy of evidence rules to this subset of medications as part of the bargain that was the struck. That's the argument.

MS. HOWARD: Yes, that's the argument. 1386r-8 lays out the permissible restrictions. That's how -- that's one of the headings in the statute, permissible restrictions. So you have to refer to that statute to know what you can do.

And, you know, for example, formularies is a permissible restriction so the Health Care Authority can have a formulary. This isn't a formulary-type drug because there is no substitute, so we're not talking about a formulary situation here. But that's an example where the statute says, yes, you can control costs and utilizations, for example, through having a formulary.

The State can also have a prior authorization process. I think what HCA is going to argue today is that really what it's doing is using its prior authorization process to perform a medical necessity review. And our contention is that it cannot use that prior authorization process for a purpose that isn't consistent with federal law.

It can certainly use prior authorization to confirm that a medication is prescribed for a medically-indicated -- for a medically-approved indication, so to make sure, for example, that if it was Exondys that the patient's amenable

to exon 51 skipping. If the patient wasn't, then it's not an FDA-approved indication and certainly then HCA could deny prescription.

HCA can also make sure the drug isn't listed in the statute's list of categorically-excluded drugs, for example, hair loss drugs or fertility drugs. And as I mentioned earlier, it could look to see whether the requested medication is on formulary or not.

THE COURT: Okay.

MS. HOWARD: Does that answer your question?

THE COURT: Yes.

MS. HOWARD: Great.

So, yeah, so I think -- I mean, that really mainly captures the points I was going to make about the unlawfulness of the agency's actions. They're unlawful because, you know, when you examine the requirements of the statute, and I don't think HCA argues that the statute doesn't apply to it, I mean, they have to follow federal law because they receive matching funds from the federal government so that's not really in dispute.

What we're talking about here is whether the Health Care Authority can impose its own standards on whether something is covered or not, to deny coverage for a drug that is otherwise indisputably a covered outpatient drug that's prescribed for a medically-accepted indication.

And for guidance on that, you know, we cite a couple cases in our briefing that I think are really instructive. One of them is the K-V Pharmaceutical case which has very similar facts. The plaintiff there was a pharmaceutical company and what was happening is their product which is called Makena, it's a drug for women who are at risk for preterm labor, the state Medicaid program in Georgia was, instead of authorizing prescriptions for Makena, they were requiring there to be no availability of another product that had a similar active ingredient but was a compounded medication.

And the court there found that essentially the policy amounted to no coverage because, rather than just accepting and reimbursing the prescription for Makena, the court -- or the Medicaid agency was, no, we want to substitute this product instead. I'm guessing it was cheaper because it was a compounded medication and it was generic. And the court said, no, that's essentially noncoverage, you have to provide it if it's for an FDA-accepted indication and you can't use your prior authorization process to impose standards like that. So I think the courts that have considered it have come out exactly in favor of Sarepta's position.

The Edmonds vs. Levine case is similar. That was the Neurontin case where the state Medicaid program was trying

to impose additional restrictions to certain off label uses of Neurontin. And as I alluded to earlier, medically-accepted indications can include off-label indications in some cases, as long as they're recognized in certain drug compendia. And in that case I think it was the Georgia Medicaid program -- no, the Florida Medicaid program wanted to impose additional requirements. They wanted to say, well, yes, it's in the compendia but we think that there should be double blind placebo controlled studies and if there's not we're going to deny coverage. And the court said no, you're basically rewriting the definition of medically-accepted indication so because this is a medically-accepted indication it has to be covered.

So I think, you know, those authorities are pretty persuasive. And the Health Care Authority hasn't cited anything to the contrary. You know, the cases that they cite are for different types of services like skilled nursing services or, you know, services that don't involve prescription drugs so they're subject to a different set of -- a different statutory framework.

THE COURT: All right. Thank you, Ms. Howard.

MS. HOWARD: Thank you, Your Honor.

THE COURT: Ms. Howard you exceeded your time by a bit, which means I'm going to go liberal with the State's time. And I'll still permit Ms. Howard to have

five minutes for rebuttal.

MS. HOWARD: Thank you.

THE COURT: That means Mr...

MR. BRADLEY: Bradley.

THE COURT: Mr. Bradley. Mr. Bradley, you will have 25 minutes.

MR. BRADLEY: Thank you, Your Honor.

THE COURT: By the way, feel free not to use it all.

MR. BRADLEY: Okay. Fair enough.

Your Honor, Washington's medical necessity rules require the State to consider on an individualized case-by-case basis whether a particular covered service is safe and effective for a specific Medicaid client. These rules are not about coverage. They're about what actually works for an actual Medicaid client, a specific person. Washington has been applying these rules for 15 years to all covered services within Medicaid that require prior authorization, and a covered drug like Exondys 51 is no different.

Sarepta has not shown that our rules are inconsistent with federal law because it is not shown that a covered prescription drug should be treated any differently than any other covered service under the Medicaid program. And because we can apply a case-by-case medical necessity determination to covered services, our rules are valid as applied to Sarepta in this case.

I want to touch on three issues with my time today: The first is the drug rebate program that you have heard a lot about. That did not change the state of the law. We continue to be permitted to apply our prior authorization policies even after that legislation went into effect. Second, because there's no relevant distinction between covered prescription drugs and other covered services, the case that should govern this Court's decision is Moore vs. Reese from the 11th Circuit. And finally, because we are discussing a medical necessity which is in a case-by-case individualized determination, the bevy of cases Sarepta points to that deal with across-the-board exclusions from coverage are not relevant to this Court's decision making.

So I want to turn first to the rebate statute that we've been arguing about that is 1396r-8. The relevant language is in subsection (d)(1)(A). That subsection expressly provides the State with the right to continue to apply prior authorization programs.

Now, prior authorization policy simply means that that's a payment mechanism. It allows the State to enforce its rules before reimbursing for an admittedly covered service. So, again, there's no dispute here that Exondys 51 is covered. What the issue is, through our prior authorization program can we apply our case-by-case medical necessity rule. Subsection (d)(1)(A) says that we can.

Sarepta cites to the following provision: Subsection (d)(1)(B). And in its reply brief it had the bullet point list of the four restrictions that apply to states. But that only applies where the state is attempting to restrict or exclude drugs from coverage.

As part of that rebate program that Congress enacted, it ratcheted back the State's ability to exclude FDA drugs from coverage. But at the same time that it did that, it continued to allow the states to apply their prior authorization policies.

And we know that because of the Pharmaceutical Manufacturers vs. Walsh case the State has cited to. That was a Supreme Court case decided I believe in 2003. That case is relevant to this Court's decision making because The Court looks at the regime that existed both before and after the rebate program was put in place.

So prior to 1990 there was no rule or statute that governed those prior authorization policies and said the secretary of DHHS would approve the states who as a part of their Medicaid plans had those types of policies in place. As the Walsh court explains, post the legislation in 1991, Congress ratified that prior practice that allowed the states to continue to do that.

And let me quote directly the Supreme Court's decision on page 652. Quote, "Congress ratified the practice of

approving state plans containing prior authorization requirements when it created its rebate program." That's the language I've cited to in (d)(1)(A).

So there is no -- and the court also cites in that Walsh case to the Cowan vs. Myers case. That's out of California, decided in 1986. The Supreme Court cited to that case as an example of the type of prior authorization programs that existed and then were ratified into the rebate statute. So in that California case it discusses how California had the ability to apply its medical necessity definition on a case-by-case basis when a Medicaid beneficiary requested a covered drug. That's exactly what we are doing here with our case-by-case medical necessity rule.

At this point I'd like to turn to the case that should govern the outcome here and that is the Moore vs. Reese case from the 11th Circuit. So just to begin with why these are factually similar, in the Moore case, the court was discussing skilled nursing and that is a service that the federal government requires states to cover. So there was no dispute, just like there's no dispute here, that this service was required. The dispute instead was whether the state had the ability on a case-by-case basis to apply its medical necessity determination to that individual requesting those services.

So the treating physician says my patient should get these services and the State of Georgia, just like Washington is doing here, looked at the specific facts surrounding that particular medicaid client's request for those services. So, again, just like here, there was no across-the-board denial of coverage. The State of Georgia did not say for a class of beneficiaries you are not receiving skilled nursing. Instead, George focused in on the specific facts of that case in doing its medical necessity determination.

And its reasoning is persuasive. The court goes through both the statute, the regulation that applies, it goes through CMS's guidance, and it synthesizes case law related to this issue. So while obviously the 11th Circuit is not binding on this court, that provides the roadmap for this Court to decide this case and it's similar to the outcomes of the cases in Cowan vs. Myers out of California and also the Thie vs. Davis case from Indiana.

I want to turn now to some of the cases that Sarepta has been relying on. But to do that, it's important to be clear on the coverage versus medical necessity distinction. And I understand we've discussed that a lot in the briefing and I don't mean to put too fine a point on it. But even in today's argument, we're hearing how HCA is denying coverage and that is simply not true.

In that Cowan vs. Myers case they discuss coverage and medical necessity in terms of a macro-type decision and a micro decision. A macro decision is a decision that congress or the legislature makes that says we are going to cover this service, state plans as a general matter must cover this service. The next step is to have a micro level decision. That's where you look at the specific facts and determine is this admittedly covered service safe and effective for this individual.

So any case that looks to a state policy that's making exclusions across a class of beneficiaries is not relevant and is not dispositive here because it's unlike the rule that Washington is applying.

So, for example, the K-V Pharmaceutical case, the one out of Georgia, in that case the State had a blanket policy that applied to every single beneficiary where they would not pay for the drug that the Food and Drug Administration had approved and said they would only pay for the drug they wanted to pay for because it was generic and cheaper and was not approved by the Food and Drug Administration. And in that case the District Court said, well, you're turning the whole coverage -- the approval process on its head because you're discriminating essentially against the drug the Food and Drug Administration has approved for your drug.

But again, we don't have a rule specific to Exondys 51. We have a generic medical necessity rule that applies to all covered services, all covered drugs. This is not a blanket policy.

Similarly, in the Edmonds vs. Levine case out of Florida, there the State said we will only cover this approved drug if it's prescribed for one of four uses. So it doesn't matter if an individual Medicaid beneficiary says, well, it's an off-label use but it works for me, this is what my treating physician is saying. There was no case-by-case medical necessity determination. So once again, that goes to coverage and not to medical necessity.

Finally, just one more case that's relied on by Sarepta is their litigation in Arkansas. They cite to that case in their briefing as more evidence that states cannot apply their medical necessity rules to deny payment for this drug. But in that case Arkansas made a threshold determination that it would not pay for this drug.

And I'll quote the court's decision there. "The decision was not made upon the facts presented to it with respect to the specific prescription."

Arkansas was not looking at the facts with regard to the specific prescription for Exondys 51. And if a state is not looking at the specific facts, they are not applying a rule like we have in Washington. And because states are

allowed to apply medical necessity rules on a case-by-case basis, as is explained by Moore and as is set froth in the rule in the Center for Medicaid and Medicare Services Rule at 448 subpart 230(d) which expressly states to have these medical necessity determinations for coverage services, because all of those rules apply to covered drugs just as much as they do to any other coverage service, our rules are consistent with federal law.

Rules that are challenged are presumed to be valid. And Sarepta has not carried its burden in this case to prove that our rules are inconsistent with these federal law authorities.

I do want to mention briefly the standing argument. We are renewing that argument. My understanding of Judge Murphy's ruling was that the merits of the case were so tied up with the arguments that we were making on those standing issues that it made sense to consider them together.

There's been no shortage of briefing in this case so I don't want to belabor any points. Just to put the matter succinctly, because there is nothing unlawful about having a case-by-case medical necessity determination, there are no interests that are being harmed. Sarepta's interests are not being harmed when the State applies those rules. The party who could be aggrieved by that application are

Medicaid beneficiaries. But there are no Medicaid beneficiaries that are a part of this case. So that goes to the injury in fact portion.

On the zone of interests, how that zone of interests test works under Washington law is that the statute, you look at the statute that the legislature enacted to determine if the interests of the petitioning party were among those that the legislature was intending to protect.

As we've argued before, the purpose of Medicaid is to provide medical assistance for those who cannot afford it. It is not to guarantee a revenue stream to anyone who would like to provide products to them. And because Sarepta falls outside of the zone of interests, they don't have standing to raise this claim. But given Judge Murphy's ruling, I recognize that this is in fact tied into the merits of the issue. So I don't want to spend much more time discussing that.

THE COURT: So Mr. Bradley, before you move off of that, your argument with respect to the injury in fact, that seems to be circular, right? I mean, would you concede that if Sarepta is correct that Washington is violating a federal law with the State's application, that that would create an injury of fact, but if indeed there is no violation of law there is no injury of fact? So your argument that there is no injury of fact really does depend

on The Court not buying Sarepta's argument, correct?

MR. BRADLEY: With respect to one part -- with respect to whether there's a cognizable interest --

THE COURT: I recognize your zone of interests analysis is separate from that.

MR. BRADLEY: But I would also suggest that within the injury in fact test there's a cognizable injury but then there's an actual or imminent injury element to that. So you can have a cognizable injury but it could be too hypothetical or speculative for it to warrant review at this point. So that's the argument that we made earlier with regard to the economic injury.

If all of the beneficiaries who have requested this drug, if reimbursements are being made for all of them, there is no current injury, so you have to look to the threat of a future injury.

THE COURT: And the parties differ on their analysis of the imminent harm.

MR. BRADLEY: Right. So we have said this has been approved for at least a year so you're looking at at least a year out for any potential injury, so it's not imminent enough for it to satisfy the injury in fact test for standing.

THE COURT: Okay.

MR. BRADLEY: So those are the points I have, unless

Your Honor has any further questions.

THE COURT: No.

MR. BRADLEY: Thank you.

THE COURT: Ms. Howard, five minutes.

MS. HOWARD: Thank you.

To quickly address the injury in fact argument, I just want to reiterate that Sarepta's interests are absolutely congruent with interests of Medicaid beneficiaries. If you look to the purpose of the Medicaid program, as we noted in the Gresham case that we quoted in our briefs, the Medicaid program's purposes is to help those in need by providing healthcare coverage.

THE COURT: I'm sorry. I'm going to move you past standing. If you can just address --

MS. HOWARD: Sure.

THE COURT: -- the merits.

MS. HOWARD: So on the merits points, HCA is relying on the Walsh case. I wanted to point out that the Walsh case involves completely different facts.

In Walsh it involved restrictions that were being placed on manufacturers who did not participate in the main prescription drug program. So unlike the situation here where we're talking about a manufacturer like Sarepta that is part of a Medicaid rebate agreement and, therefore, has a certain expectation of coverage, the Walsh case involved

pharmaceutical companies that had not entered into that kind of agreement.

And also it just involved, you know, very different issues. I think it was a Dormant Commerce Clause case and the court's holding really said nothing to the issue here which is whether a state Medicaid program can use its prior authorization program or put limits on prescription drug coverage that violate federal law.

And I already mentioned the Moore case. But, you know, just to reiterate what I said earlier, I don't believe that Moore was wrongly decided but Moore just involves different facts in a different statutory regime. Moore involved skilled nursing services under a very particular Medicaid program with a different standard. It did not involve an interpretation of 1396r-8.

And I'd like to just make sure The Court is aware of the statutory structure of the 1396r-8 because I think it's very important. We just heard the State argue that (d)(1)(A) of that statute, which is the prior authorization section, is what gives the State the authority to do what it's done here which is perform a case-by-case analysis to determine whether it believes the prescriptions ought to be covered.

And our position is that that is absolutely not appropriate because the limits of a prior authorization

program are set forth in the statute. The limits of what a Medicaid program can do generally in making decisions about prescription drugs are in the statute.

Section (d) is entitled Limitations on Coverage of Drugs. (d)(1) is titled Permissible Restrictions. So just as a pure statutory construction matter, if these are the permissible restrictions, all other restrictions are impermissible. And nowhere in this list which includes prior authorization program and also the other circumstances that we talked about such as formularies or categorically-excluded drugs, nowhere in here has Congress given state Medicaid programs the authority to do case-by-case medical necessity reviews based on their own standards. And, you know, doing so would be inconsistent with the purpose of the Medicaid Drug Rebate Agreement and the Medicaid Act.

THE COURT: Ms. Howard, doesn't the fact that (d)(1)(A) stands alone within the context of the statutory provision indicate or doesn't it arguably indicate that that is not modified by the limitations that are subsequent in the layout of the statute?

MS. HOWARD: Well, (d)(1)(A) is listed under permissible restrictions. And I'm not disputing that the state Medicaid program can have a prior authorization program and it can use that program to impose permissible

limits and restrictions on drugs. So, for example, it can use that process to decide -- to make sure that the drug is being prescribed for a medically-created purpose.

You know, a lot of drugs don't go through prior authorization. They're prescribed and they're filled. So the purpose of that program is for the agency to have a chance to review the prescription and make sure that there's no reason for it to exclude it from coverage.

Probably the most common use of it is formulary drugs to determine whether the physician's, say, brand name drug that's being prescribed is something the State can cover when they have a generic drug on their formulary. I think that's the more typical application prior authorization process.

THE COURT: So is the argument that since (d)(1) is a limitations chapter, the fact that (d)(1)(A) exists referencing prior authorization means that that prior authorization, perhaps unfettered in other contexts, is still limited in this context as otherwise outlined in the statute? Is that the argument?

MS. HOWARD: Yes, that's correct.

And finally, well, it sounds like you're satisfied on the mootness point. But I just wanted to point out that there could be a prescription tomorrow, so the fact that they're covering three patients for a year, you know,

certainly doesn't mean that we don't have injury and continue to have injury because of the unlawful policy.

Thank you.

THE COURT: I'm smiling, Ms. Howard, because any time you assume I'm satisfied on anything, its at your peril.

All right. So first of all --

MS. HOWARD: Your Honor, sorry. Did you have more questions? I figured I ran way over my five minutes.

THE COURT: Actually, you didn't. But no, I'm fine.

First of all, let me... I appreciate the oral argument of both sides. Perhaps the parties don't have an appreciation for this, but we judges see an awful lot of bad oral argument and this was not that.

I also would under normal circumstances more seriously consider taking it under advisement because of the significance and complexity of the issues. I'm not going to do that, though, because some of the -- in part because of what's happening in our world today and I understand that this decision is not likely to stop here. I also understand that this decision, when it is reviewed, will be reviewed without caring much about what I say. And so to accelerate that process -- not accelerate the process, I don't want to make it seem like it's being moved along too quickly, but I think it's useful to both sides if I issue a decision today. I'm not prepared to do that right this

minute.

So what I'm going to do is take a break and digest some of the arguments here today, refer back to some of the cases I have collected in my chambers, and come back with an oral ruling. And, of course, the prevailing party will be tasked with an order. Again, these types of cases' orders, you know, Court's rationale has varying degrees of relevance upstairs.

So I will take a break. I'm going to ask that the parties be prepared to be here in 30 minutes, that would be at 3 o'clock. I'm not promising to be back at 3 o'clock, but I am asking that the parties be prepared for a decision or be here in the courtroom by at least 3 o'clock.

With respect to our folks on the telephone, I expect that folks don't want to sit on hold for 30 minutes. I also don't necessarily relish asking Madam Clerk to coordinate call-ins again. But I'm curious whether the parties on the phone would want to... Well, let me ask Madam Clerk her preference first.

THE CLERK: If they want to call back, they can connect again.

THE COURT: So Madam Clerk is suggesting that the parties on the phone call the Bridge Line back at 3 o'clock. Is that acceptable to those on the phone?

MS. SHARPE: That's fine with me.

MR. HANDWERKER: That's fine with us. We're happy to leave it on hold, whatever is more convenient for The Court.

THE COURT: Madam Clerk has no preference, so I guess we'll just see what people do. I don't certainly have any preference.

I'm going to be leaving the bench now. I will be coming back at some point 3 o'clock or after and we'll see where we go. We are in recess.

(BRIEF RECESS.)

THE COURT: We are back on the record with Sarepta vs. Washington State Health Care Authority, cause number 19-2-03449-34.

I trust we have our folks successfully listening in by phone?

MS. HATFIELD: I'm here, Your Honor, Katy Hatfield.

MS. SHARPE: Yes, Your Honor. This is Jeff Handwerker and Paige Sharpe from Arnold & Porter Kaye Scholer.

THE COURT: All right. That sounds like everybody we needed.

And let me... I'm a little late from what I had hoped. I appreciate the patience of the parties. Again, let me restate my appreciation for the parties tolerating the shift in judicial officers as well on this matter.

I want to start just by making some introductory comments. I was struck as I was listening to Ms. Howard talk generally speaking about the product involved here that, you know, lots of times we in the justice system get rolled in to the legal nuances and legal arguments and focus on that when obviously the background of this is sick individuals that are suffering, and certainly considering legal arguments doesn't -- you know, I try not to lose sight of that.

I was also struck with the complexity of the rhetoric out there about pharmaceutical companies. Depending on what or whom you're listening to, they get demonized, yet there's work being done by pharmaceutical companies to develop products and medications that are helpful to people, and certainly sometimes that creates complexity when the world sees things more simply.

But that being said, let me get to what The Court has to decide here today and that is the decision on Sarepta's petition for administrative review of these rules by the Washington State Health Care Authority, the rules specifically related to medical necessity of the drug Exondys.

MS. HOWARD: Exondys.

THE COURT: Exondys 51 drug.

There was some difference of status of the individuals

that had been prescribed this medication from the beginning of this case to now. That in part drives some of the standing arguments that the State has. As I understand it, the State has moved to dismiss based on a lack of standing. And in part that's, as I understand it, based upon the facts that some of these individuals are now provided the medications, when initially perhaps they were denied.

That standing argument was brought earlier and a previous judicial officer made a decision of sorts but that decision left it sort of punted to today. So I'm going to address that issue first and then I'll, if necessary, address the merits.

On the standing, the State has argued that Sarepta does not fall within either the zone of interests or the injury in fact. The injury in fact I think we discussed in oral arguments sort of intertwine with the merits of the issue. I'm not sure the zone of interests is.

The State has argued that the pharmaceutical company is not within the zone of interests of these Medicaid regulations but that these are designed for recipients, not companies, and that economic damage of a company based upon decisions under these regulations is not something that would be appropriately in the zone of interests. That's an interesting question, one I suppose I have to resolve. I'm going to... Let me just be quick about it.

I'm going to deny the State's motion on standing. And I would imagine that particular issue will be looked at by folks who grade my homework because I think it is an interesting question. But my view of the zone of interests test, if I were cynical, I'd say, you know it when you see it and there's not a lot of tight standards on what it means. And then I can see arguments that the economic interests of the pharmaceutical company is not appropriately within the zone of interests of these regulations.

On the other hand, especially when you have a circumstance where the financial incentive for any given recipient is -- or financial wherewithal to make a challenge by an individual recipient is difficult and there is some overlap with the interests of a pharmaceutical company in providing that medication, that the concept of zone of interests broadens a little bit. Otherwise, it would be difficult for this question to be answered by the courts.

That's not an appropriate -- probably not an appropriate legal determination in terms of how to characterize zone of interests, but I think you can read between the lines on some of the cases in which the concept is broadened under some circumstances. And I think here I'll make a similar decision and if only because proceeding onto the next step,

should someone again in an appellate capacity decide that The Court's decision should find that there was standing, there would be no record made on the merits and I think it's prudent to continue on with the Court's analysis.

So I suppose, a long way of saying, The Court's going to deny the motion on standing.

Now, with respect to the merits, again, I want to repeat my appreciation for the oral arguments here as well as the briefing, frankly. The briefing was well done. I can always tell when a brief is well done when I'm reading through 25 pages and it doesn't feel like 25 pages and I can tell a poorly written brief when I read through 7 pages and it feels like 50, and I think both sets of briefing were excellent. But the oral argument helped The Court immensely as well.

I went back in the break and not only refreshed myself with the arguments made within the briefing but I actually reread the Walsh case, the Reese case, Moore vs. Reese, and I also re-read Edmonds case and then, of course, re-read the synopsis by the parties as well as the distinguishing arguments about those cases.

Principally the State is arguing that those cases that restricts states from departing from approvals made by doctors is based on a coverage decision, not an as-applied prior authorization decision.

Let me just say 42 U.S.C. 1396r-8(d)(1)(A) says, quote, "A state may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." And then (d)(1)(B) has a specific -- well, it says, quote, "A state may exclude or otherwise restrict coverage of a covered outpatient drug if," and then it has some limitations.

So the argument between the parties, as I understand it, is that the State says what we're doing is perfectly permissible under these regulations under the first part, this is just a prior authorization program that we're applying with our medical necessity decisions; whereas, petitioner is saying no, this language very clearly restricts your ability to deny coverage to only these examples or these exceptions, this isn't one of those, you're denying coverage for those recipients in violation of this law.

So you read the cases cites by the petitioner and you see clearly a concern by the courts in those cases of states overreaching in their coverage decisions. And then you read the cases cited by the State and you see the courts discussing the need for states, even in the context of this regulatory scheme with outpatient prescription medication, to have the ability to have some sort of

medical necessity prior authorization program. Therein lies the conflict.

It is somewhat relevant that the burden here is on the petitioner to establish that these rules are -- or that the courts -- I'm sorry, the State's application of its Medicaid rules are invalid as applied to this petitioner. And I find that that burden wasn't met.

I recognize that this is a close -- I guess I recognize the legitimacy of the position of both parties. I guess I won't call it a "close call." I do that way too much. I think judges use that as a crutch, frankly, say this is a "close call." But I do see the legitimate argument that's being met by the petitioners here.

But ultimately I'm persuaded that the prior authorization program is specifically permitted within the context of (d)(1)(A) and I am unpersuaded that what happened here was a coverage decision under (d)(1)(B) or outside of the permission of (d)(1)(B) and was an appropriate prior authorization of (d)(1)(A).

I'll finish where I started, which was the tragedy of the specifics. I am heartened to hear when a physician says this drug will be helpful to a patient that there was the ability of and successful ability of that physician to convince the State in those particular cases to permit coverage.

I'm obviously not a medical professional. Ms. Howard lost me when she talked about the specifics of what this drug did. But at least in the cases that were filed now, the patients are getting the coverage. I recognize that has nothing to do with The Court's decision here today and perhaps The Court's decision makes it problematic for the next one, but at least they're getting covered now.

So questions, Ms. Howard?

MS. HOWARD: No, Your Honor. I think I understand The Court's ruling.

THE COURT: I'll have you stand.

MS. HOWARD: Sure. I mean, I'll just say, you know, in case it wasn't clear before, I mean, our argument is that what the State was doing, you know, they're talking about a case-by-case analysis but really what it is was a threshold determination that they're making that they get to take a covered drug and apply a criteria to it that's not found anywhere and permitted by the federal statutes.

So, you know, we accept that there are prior authorization programs, we accept they get to use their prior authorization program, but it has to be for a permissible purpose which is what the cases we cited in K-V Pharmaceutical [unintelligible]. The State other -- I mean, because the -- what would happen otherwise is that states could come up with whatever medical necessity policy

they want which would swallow the rule of coverage.

But I know you -- I'm sure you've already thought about that and taken that into account in your ruling. But that's where we're coming from is, you know, we're talking about one drug that thankfully is being paid for right now but it can be used and the courts recognize that it could be used -- that authorization process could be used in improper ways and we believe this is one of those improper ways.

THE COURT: Well, Ms. Howard, that sounds like paragraph 1 of your notice of appeal rather than a question to me about my ruling.

MS. HOWARD: Understood, Your Honor.

THE COURT: Mr. Bradley, any questions?

MR. BRADLEY: Your Honor, my preference today would not to be to enter an order but to receive a transcript of your ruling and then prepare an order that opposing counsel has an opportunity to review and then have that entered, unless you prefer that we enter the order now.

THE COURT: My typical response to that question or its variance that I get at this stage is to say that the non prevailing party should have a healthy role in what they want the order to look like, given that that's what they are likely going to be running up to somebody else.

So there are different sides to the idea of whether,

again, what I said was relevant to anybody who's looking at this. But I'm fine with whatever the parties decide they want to do with respect to a proposed order. So that will be a discussion between the parties. I'm not gleaning that Ms. Howard has a position right now.

Or do you?

MS. HOWARD: I'm fine with the State's proposal to get -- wait for the transcript. That's fine with us.

THE COURT: Okay. A transcript obviously takes a little more time. So you can work with Madam Court Reporter about getting that put together.

Anything else on this matter at this point, Mr. Bradley?

MR. BRADLEY: No. Thank you.

THE COURT: Ms. Howard?

MS. HOWARD: No. Thank you.

THE COURT: There being nothing further, we shall go off the record.

To those on the phone, good day to you.

I hope everyone stays safe. Again, this may be the last in-person argument this courtroom is going to have in some time. Everybody keep your distance.

We'll be in recess.

C E R T I F I C A T E.

STATE OF WASHINGTON)
) ss
COUNTY OF THURSTON)

I, CHERYL HENDRICKS, CCR, Official Reporter of the Superior Court of the State of Washington in and for the County of Thurston do hereby certify:

1. I reported the proceedings stenographically;
2. This transcript is a true and correct record of the proceedings to the best of my ability, except for any changes made by the trial judge reviewing the transcript;
3. I am in no way related to or employed by any party in this matter, nor any counsel in the matter; and
4. I have no financial interest in the litigation.

Dated this 18th day of March, 2020.

_____
Cheryl L. Hendricks,
CCR NO. 2274

June 08, 2020 - 5:30 PM

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Washington State
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Division Two

October 26, 2021

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

SAREPTA THERAPEUTICS, INC., Appellant/Cross-Respondent v. STATE OF WASHINGTON, HEALTH CARE AUTHORITY, and MARYANNE LINDEBALD, in her official capacity as Director of Washington State Health Care Authority, Respondent/Cross-Appellant.	No. 54870-4-II PUBLISHED OPINION

LEE, C.J. — Sarepta Therapeutics, Inc., appeals the superior court's order denying its petition for judicial review under the Washington Administrative Procedure Act (APA), chapter 34.05 RCW, wherein Sarepta challenged the Washington Health Care Authority's (HCA) application of its prior authorization rules to Sarepta's drug, EXONDYS 51 (Exondys). The HCA cross-appeals the superior court's order denying its motion to dismiss Sarepta's petition for lack of standing. We hold that Sarepta lacks standing to file its petition for judicial review. Therefore, the superior court erred by denying the HCA's motion to dismiss. Accordingly, we reverse the superior court's order denying Sarepta's motion to dismiss for lack of standing and dismiss Sarepta's appeal.

FACTS

A. BACKGROUND—APPROVAL OF EXONDYS

Duchenne Muscular Dystrophy (DMD) is a "genetic disorder characterized by the progressive loss of skeletal muscle and degeneration." Clerk's Papers (CP) at 131. DMD primarily affects young boys. "The primary symptoms of [DMD] are caused by a lack of dystrophin in the muscle. Children with [DMD] lose the ability to walk independently and most become reliant on wheelchairs for mobility by the age of 13." CP at 131.

On September 19, 2016, the Food and Drug Administration (FDA) approved Sarepta's new drug application for Exondys pursuant to its accelerated approval regulations. Exondys is a drug that treats patients with specific mutations of DMD. "The provision of EXONDYS 51 has been shown to result in the production of truncated dystrophin, which hopes to have a positive effect on muscle degeneration [by] slowing or halting the progression of [DMD]." CP at 131 (boldface omitted). Only 13 percent of all DMD patients have the specific mutation which Exondys treats.

B. MEDICAID DRUG REBATE PROGRAM AND HCA'S PRIOR AUTHORIZATION REQUIREMENT

"Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act." *Pharmaceutical Research & Mfrs. of America v. Walsh*, 538 U.S. 644, 650, 123 S. Ct. 1855, 155 L. Ed. 2d 889 (2003). However, before 1990, Medicaid did not specifically address outpatient prescription drug coverage. *Id*. at 651. Instead, the Secretary of the Health and Human Services would approve individual State plans regulating the coverage of outpatient prescription drugs as part of controlling Medicaid costs. *Id*. These individual state plans controlled the coverage of outpatient prescription drugs through the use of formularies excluding specific drugs from coverage or through prior authorization requirements. *Id*. at 651-52.

In 1990, Congress included the Medicaid Drug Rebate Program (MDRP) in the Omnibus Reconciliation Act of 1990. 42 U.S.C. § 1396r-8; *Walsh*, 538 U.S. at 652. Under the MDRP, drug manufacturers must enter into rebate agreements in order for their drugs to be eligible for coverage by Medicaid. 42 U.S.C. § 1396r-8(a)(1). Once a drug manufacturer enters into a rebate agreement with either the Secretary or a state, their drugs are considered "covered outpatient drugs" and are reimbursable under State Medicaid programs. 42 U.S.C. § 1396r-8(a)(1), (k)(2). Reimbursement for covered outpatient drugs is subject to various limitations. 42 U.S.C. § 1396r-8(d). Congress specifically included the use of formularies under certain circumstances and the use of prior authorization programs. 42 U.S.C. § 1396r-8(d)(1), (4), (5).

"A State may subject to prior authorization any covered outpatient drug." 42 U.S.C. § 1396r-8(d)(1)(A). 42 U.S.C. § 1396r-8(d)(5) provides:

> A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug . . . the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—
>
> (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
>
> (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

The purpose of creating the MDRP was to reduce the cost of prescription drugs to the Medicaid program and to ensure that Medicaid recipients had access to a variety of prescription drug choices:

> The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order

> to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.

H.R. REP. NO. 101-881 at 96-97 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09. The House Bill report states, "[T]he bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs." 1990 U.S.C.C.A.N. 2017, 2110. The report further explained,

> States that elect to offer prescription drug coverage under their Medicaid programs would be required to cover all of the drugs of any manufacturer entering into and complying with such an agreement with the Secretary. This requirement would take effect April 1, 1991. As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs *in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care*. However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e., *assuring access by Medical beneficiaries to prescription drugs where medically necessary*.

1990 U.S.C.C.A.N. 2017, 2110. "Congress effectively ratified the Secretary's practice of approving state plans containing prior authorization requirements when it created its rebate program." *Walsh*, 583 U.S. at 652.

The legislature has delegated the authority of administering Washington's Medicaid program to the HCA. RCW 74.09.530(1)(a). As a part of its administration, the HCA is required to "take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs." RCW 70.14.050(1). To further this purpose, the legislature

requires the HCA to establish "an evidence-based prescription drug program." RCW 70.14.050(1).

The HCA has implemented regulations in the Washington Administrative Code (WACs) establishing an evidence-based prior authorization program for health care services and equipment, including prescription drugs.[1] WAC 182-501-0165(3). Prior authorization determinations are based on findings of medical necessity. WAC 182-501-0165(3). Specifically, WAC 182-501-0165(3) provides that "[t]he [HCA] authorizes, on a case-by-case basis, [prescription drug requests] when [the HCA] determines the service or equipment is medically necessary as defined in WAC 182-500-[0]070." "Medically necessary" is defined as

> a term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. There is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service. For the purposes of this section, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all.

WAC 182-500-0070 (medical necessity rule).

Medical necessity determinations are based on submitted medical evidence[2] and an evidence-based rating system. WAC 182-501-0165(3). The evidence-based rating system is

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[1] Prescription drugs are considered health care services. WAC 182-501-0050 ("For the purposes of this section, health care services includes treatment, equipment, related supplies, and drugs.").

[2] The HCA considers the following medical evidence:

> (4) The agency reviews available evidence relevant to a medical, dental, or behavioral health service or equipment to:
> (a) Determine its efficacy, effectiveness, and safety;
> (b) Determine its impact on health outcomes;

codified under WAC 182-501-0165(6) (hierarchy of evidence rule). Under the hierarchy of evidence rule, "[t]he [HCA] uses a hierarchy of evidence to determine the weight given to available data." WAC 182-501-0165(6)(a). And "[b]ased on the quality of available evidence, the [HCA] determines if the requested service is effective and safe for the client by classifying it as an **'A,' 'B,' 'C,'** or **'D'** level of evidence." WAC 182-501-0165(6)(b).

An "A" level classification "[s]hows the requested service or equipment is a proven benefit to the client's condition." WAC 182-501-0165(6)(b)(i). A "B" level classification "[s]hows the requested service or equipment has some proven benefit." WAC 182-501-0165(6)(b)(ii). A "C" level classification "[s]hows only weak and inconclusive evidence regarding safety, or efficacy, or both." WAC 182-501-0165(6)(b)(iii). And a "D" level classification "[i]s not supported by any

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> (c) Identify indications for use;
> (d) Evaluate pertinent client information;
> (e) Compare to alternative technologies; and
> (f) Identify sources of credible evidence that use and report evidence-based information.
>
> (5) The agency considers and evaluates all available clinical information and credible evidence relevant to the client's condition. The provider responsible for the client's diagnosis, or treatment, or both, must submit with the request credible evidence specifically related to the client's condition including, but not limited to:
> (a) A physiological description of the client's disease, injury, impairment, or other ailment;
> (b) Pertinent laboratory findings;
> (c) Pertinent X-ray and/or imaging reports;
> (d) Individual patient records pertinent to the case or request;
> (e) Photographs, or videos, or both, if requested; and
> (f) Objective medical/dental/behavioral health information such as medically/dentally acceptable clinical findings and diagnoses resulting from physical or behavioral health examinations.

WAC 182-501-0165(4), (5).

evidence regarding its safety and efficacy, for example that which is considered investigational or experimental." WAC 182-501-0165(6)(b)(iv). Based on the evidence classification, the agency:

> (i) Approves **"A"** and **"B"** rated requests if the service or equipment:
> (A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment; and
> (B) Is not more costly than an equally effective alternative treatment.
> (ii) Approves a **"C"** rated request only if the provider shows the requested service is the optimal intervention for meeting the client's specific condition or treatment needs, and:
> (A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment;
> (B) Is less costly to the agency than an equally effective alternative treatment; and
> (C) Is the next reasonable step for the client in a well-documented tried-and-failed attempt at evidence-based care.
> (iii) Denies **"D"** rated requests unless:
> (A) The requested service or equipment has a humanitarian device exemption from the [FDA]; or
> (B) There is a local institutional review board (IRB) protocol addressing issues of efficacy and safety of the requested service that satisfies both the agency and the requesting provider.

WAC 182-501-0165(6)(c).

C. HCA'S MEDICAL NECESSITY DETERMINATIONS FOR EXONDYS

In May and June 2019, the HCA received requests for prior authorization for Exondys from three Medicaid patients with DMD. In June 2019, the HCA denied each of the requests for prior authorization because it determined that Exondys was not medically necessary for the three patients. The HCA concluded that Exondys had a level "D" evidence rating and that "[g]iven the lack of effectiveness noted in the FDA label, the low quality of the clinical trials, an unchanged trajectory of change for the 6MWT, and continued significant functional decline in multiple functional domains, the best available evidence does not support the efficacy of and therefore medical necessity of [Exondys]." CP at 147. In other words, because each of the three Medicaid

patients failed to show clinical responsiveness to Exondys, and because they continued to decline while taking the drug, the HCA concluded that Exondys was not medically necessary.

On August 27, 2019, the HCA amended its earlier denial letters by changing the evidence rating of Exondys to "C." The HCA also explained that the denials were based on each patient's failure to show clinical responsiveness to Exondys.

In October 2019, the Medicaid patients' treating physician requested a peer-to-peer consultation with the HCA's medical officer who made the initial medical necessity determinations. The treating physician provided new information demonstrating that the Medicaid patients were obtaining minor therapeutic benefits from using Exondys. Based on this information, the HCA's medical officer determined that Exondys was medically necessary for the three patients and provided instructions to the HCA to approve the requests for prior authorization.

D. PROCEDURAL HISTORY

On July 12, 2019, Sarepta filed a petition for judicial review under the APA. Specifically, Sarepta sought declaratory judgment invalidating the HCA's hierarchy of evidence rule as it applies to reimbursement for Exondys.[3] Later, Sarepta amended the petition to also include a challenge to the validity of the medical necessity rule.

The HCA filed a motion to dismiss Sarepta's petition for judicial review, arguing that Sarepta lacked standing under the APA. The superior court denied the HCA's motion to dismiss for lack of standing. The superior court also denied Sarepta's petition for judicial review on the merits.

[3] RCW 34.05.570(2)(a) provides, "A rule may be reviewed by petition for declaratory judgment filed pursuant to this subsection."

Sarepta appeals and the HCA cross-appeals.

ANALYSIS

The HCA cross-appeals the superior court's order on the amended petition,[4] arguing that the superior court erred by denying the HCA's motion to dismiss because Sarepta lacked standing to bring its petition for judicial review under the APA. We agree.

A. LEGAL PRINCIPLES

We review standing de novo. *Center for Biological Diversity v. Dep't of Fish & Wildlife*, 14 Wn. App. 2d 945, 981, 474 P.3d 1107 (2020). The petitioner bears the burden of establishing standing. *KS Tacoma Holdings, LLC v. Shorelines Hr'gs Bd.*, 166 Wn. App. 117, 127, 272 P.3d 876, *review denied*, 174 Wn.2d 1007 (2012).

Judicial review of an agency action is governed by the APA. *Patterson v. Segale*, 171 Wn. App. 251, 257-58, 289 P.3d 657 (2012). A party has standing to obtain judicial review of an agency action if that person is aggrieved or adversely affected by the agency action. RCW 34.05.530. A party is aggrieved or adversely affected when three conditions are present:

> (1) The agency action has prejudiced or is likely to prejudice that person;
> (2) That person's asserted interests are among those that the agency was required to consider when it engaged in the agency action challenged; and
> (3) A judgment in favor of that person would substantially eliminate or redress the prejudice to that person caused or likely to be caused by the agency action.

[4] The HCA's cross-appeal alleges that the superior court erred by denying its motion to dismiss of lack of standing. Because standing is required for a party to obtain judicial review under the APA, we address the HCA's cross-appeal before Sarepta's appeal on the merits of the petition. *See* RCW 34.05.530.

RCW 34.05.530(1)-(3).[5] All three requirements must be established for a person to have standing. *Allan v. Univ. of Wash.*, 140 Wn.2d 323, 326-27, 997 P.2d 360 (2000).

The first and third requirements of this standing test are collectively referred to as the "'injury-in-fact' test." *Patterson*, 171 Wn. App. at 258 (quoting *Allan*, 140 Wn.2d at 327). Under the "injury-in-fact" test, the petitioner must show that the agency decision caused some specific and perceptible harm. *Freedom Found. v. Bethel School Dist.*, 14 Wn. App. 2d 75, 86, 469 P.3d 364 (2020), *review denied*, 196 Wn.2d 1033 (2021). In other words, there must be an invasion of a legally protected interest. *Snohomish County Pub. Transp. Benefit Area v. Pub. Emp't Relations Comm'n*, 173 Wn. App. 504, 513, 294 P.3d 803 (2013).

Where "a party alleges a threatened injury, 'as opposed to an existing injury,' the party must prove that the threatened injury is 'immediate, concrete, and specific'" in order to have standing under the APA. *City of Burlington v. Liquor Control Bd*., 187 Wn. App. 853, 869, 351 P.3d 875, *review denied*, 184 Wn.2d 1014 (2015) (quoting *Trepanier v. City of Everett*, 64 Wn. App. 380, 383, 824 P.2d 524 (1992)). "Conjectural or hypothetical injuries are insufficient to confer standing." *Freedom Found.*, 14 Wn. App. 2d at 86. Finally, the petitioner must show that

[5] In addition to the standing requirements under RCW 34.05.530, RCW 34.05.570(2)(b)(i) requires a person challenging an agency rule to show that the rule or its threatened application "interferes with or impairs or immediately threatens to interfere with or impair the legal rights or privileges of the petitioner." Furthermore, challenges to agency rules are brought through a declaratory judgment action. RCW 34.05.570(2)(a). A justiciable controversy is required to bring a declaratory judgment action. *To-Ro Trade Shows v. Collins*, 144 Wn.2d 403, 410-11, 27 P.3d 1149 (2001), *cert. denied*, 535 U.S. 931 (2002). A justiciable controversy requires (1) an actual, present, and existing dispute, (2) between parties with opposing interests, (3) involving direct and substantial interests, and (4) for which a judicial determination will be final and conclusive. *Id.* at 411. Neither party argues these additional standards should apply or that they would compel a different result. And under any of the applicable standards, Sarepta has failed to establish standing to bring this action challenging the HCA's rules.

a favorable decision will likely—not merely speculatively—redress the injury. *Patterson*, 171 Wn. App. at 259.

The second requirement is referred to as the "zone of interests" test. *Allan,* 140 Wn.2d at 327. "The zone of interest test limits judicial review of an agency action to litigants with a viable interest at stake, rather than individuals with only an attenuated interest in the agency action." *City of Burlington*, 187 Wn. App. at 862. In order to satisfy the "zone of interests" test, the party seeking standing must demonstrate that "the Legislature intended the agency to protect the party's interests when taking the action at issue." *St. Joseph Hosp. and Health Care Ctr. v. Dep't of Health*, 125 Wn.2d 733, 739-40, 887 P.2d 891 (1995); *City of Burlington*, 187 Wn. App. at 863.

B. SAREPTA'S STANDING—ZONE OF INTERESTS

The HCA argues that Sarepta fails to establish standing because Sarepta has not met its burden to show that the zone of interests test is satisfied. Specifically, the HCA contends that the legislature did not intend to protect a drug manufacturer's financial interests in establishing the administration of Washington's Medicaid program. Sarepta argues that because it has entered a Medicaid Drug Rebate Agreement under the MDRP, its interest in having its drugs reimbursed by the HCA is established under the terms of the MDRP. We agree with the HCA.

As an initial matter, the Washington legislature clearly did not intend to protect the interests of drug manufacturers when it directed the HCA to establish an evidence-based prescription drug program under RCW 70.14.050. The legislature directed the HCA to "take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs." RCW 70.14.050(1). Based on the plain language of the statute, the legislature's intent was for the HCA to balance controlling costs with ensuring quality of care. The legislature did not intend for

the HCA to protect Sarepta's financial interests when making rules to administer the prescription drug program. Therefore, Sarepta has failed to satisfy the zone of interests test under the Washington statutes. *See St. Joseph Hosp.*, 125 Wn.2d at 739-40.

However, Sarepta argues that its standing derives from the MDRP, not the Washington statutes. Sarepta contends that the MDRP guarantees coverage when a drug manufacturer enters into a rebate agreement under the terms of the MDRP. Because the HCA is responsible for ensuring the state Medicaid program complies with federal Medicaid requirements, Sarepta asserts that the HCA was required to protect Sarepta's interests under the MDRP when administering its prescription drug program.

Sarepta misinterprets the effect of an agreement under the MDRP and conflates coverage of drugs with reimbursement of drugs. And Sarepta's argument fails to acknowledge Congress's legislative intent when establishing the MDRP. Sarepta's financial interests are no more protected under the MDRP than they are under RCW 70.14.050. Because Congress did not intend for prescription drug programs to protect the financial interests of drug manufacturers, Sarepta is not within the zone of interests protected by the MDRP.

First, Sarepta's argument fails to acknowledge Congress's legislative intent when establishing the MDRP. The text of the MDRP does not contain an explicit statement of purpose or intent like that contained in RCW 70.14.050. Therefore, the plain language of the statute is ambiguous in establishing Congress's intent in passing the legislation. However, the legislative history is not ambiguous. The house bill report clearly shows that Congress's intent in establishing the MDRP was to control Medicaid costs by reducing the costs of prescription drugs. 1990 U.S.C.C.A.N. 2017, 2108 ("The Committee believes that Medicaid, the means-tested entitlement

program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy."). Congress further intended to ensure Medicaid patients have access to the same range of drugs as patients that do not require Medicaid. 1990 U.S.C.C.A.N. 2017, 2108-09. The legislative history of the MDRP does not establish Congress's intent to protect the drug manufacturer's financial interests when establishing the MDRP.

Second, despite Congressional intent, Sarepta argues that agreements under the MDRP entitle Sarepta to reimbursement for its drugs, which creates a protected interest for drug companies who have agreements under the MDRP. Sarepta's argument conflates the concepts of coverage and reimbursement under the MDRP. Furthermore, Sarepta's argument misrepresents the effect of a rebate agreement under the MDRP.

Sarepta's argument is that because state prescription drug programs are required to *cover* all of a drug manufacturer's prescription drugs, the state prescription drug program is required to *pay* for all covered drugs prescribed for its intended use. This is an incorrect reading of the MDRP.

The MDRP does not specifically define the meaning of "covered" and the definition of a "covered outpatient drug" does not contain any language related to reimbursement or payment for a drug. *See* 42 U.S.C. § 1396r-8(k)(2). However, reading the MDRP as a whole shows there is a difference between coverage of a drug and reimbursement/payment for a drug. For example, 42 U.S.C. § 1396 r-8(d)(5) references prior authorization as a condition of "coverage or payment," indicating that there is a difference between coverage of a drug and payment for a drug. Sections of the MDRP also reference "upper payment limits" and "maximum allowable cost limitation" established by State programs, implying that there is a point at which the State would not be

required to pay for covered drugs. *See* 42 U.S.C. § 1396r-8(e)(3) ("This section shall not supersede or affect provisions . . . relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation."); *see also* 42 U.S.C. § 1396r-8(e)(4), (e)(5).

The language of the MDRP does not establish that coverage for prescription drugs requires payment for prescription drugs. The MDRP only establishes that the covered prescription drugs are *eligible* for reimbursement or payment under Medicaid programs. Therefore, Sarepta has incorrectly interpreted the MDRP to guarantee payment for prescription drugs; the MDRP only allows coverage for prescription drugs.

Third, Sarepta argues that its agreement under the MDRP creates an interest that must be protected because drug manufacturers agree to provide rebates in exchange for a guarantee that that State Medicaid programs cover their drugs. As explained above, coverage is not the same as payment. And rebate agreements under the MDRP are not the equivalent of negotiated contracts as Sarepta implies. Rebate agreements under the MDRP are a mandatory prerequisite for prescription drugs to be eligible for Medicaid coverage. 42 U.S.C. § 1396r-8(a)(1). In other words, to the extent that a rebate agreement is akin to a contract, drug manufacturers enter into rebate agreements in exchange for their drugs being eligible for Medicaid coverage, not to guarantee payment for their drugs.

Because the MDRP only makes the drugs covered and does not guarantee drug manufacturers payment for their drugs under Medicaid, the MDRP does not establish that Sarepta has an interest that the HCA was required to protect when it established rules for the administration

of its Medicaid prescription drug program. Therefore, Sarepta has failed to establish that the MDRP places Sarepta's financial interests within the zone of interests required to be considered by the HCA.

Sarepta's MDRP agreement does not establish standing to petition for judicial review under the APA. Therefore, Sarepta has failed to establish standing under the APA to bring its petition for judicial review of the HCA's application of its hierarchy of evidence rule in determining reimbursement for Exondys.

CONCLUSION

Sarepta does not have standing to petition for judicial review of HCA's prior authorization rules under the APA because Sarepta has failed to satisfy the zone of interests requirement. Therefore, the superior court erred by denying the HCA's motion to dismiss for lack of standing. Accordingly, we reverse the superior court's order denying the HCA's motion to dismiss for lack of standing and dismiss Sarepta's appeal.

Lee, C.J.

We concur:

Maxa, J.

Cruser, J.

DAVIS WRIGHT TREMAINE LLP

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