NO. 101414-7

SUPREME COURT OF THE STATE OF WASHINGTON

SAREPTA THERAPEUTICS, INC.,

v.

WASHINGTON STATE HEALTH CARE AUTHORITY

ANSWER TO PETITION FOR REVIEW

ROBERT. W. FERGUSON
Attorney General

KATY HATFIELD, WSBA NO. 39906
NISSA IVERSEN, WSBA NO. 46708
Assistant Attorneys General

Office of the Attorney General
7141 Cleanwater Drive SW
PO Box 40124
Olympia, WA 98504-0124
(360) 586-6565
Katy.Hatfield@atg.wa.gov
Nissa.Iversen@atg.wa.gov
OID No. 91021

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I. INTRODUCTION

Sarepta Therapeutics, Inc. (Sarepta) does not have standing under the Washington Administrative Procedure Act (APA) to challenge the application of the Washington Health Care Authority's (HCA's) medical necessity rules to individual Medicaid clients because Sarepta is not within the "zone of interest" that either the Washington Legislature or Congress were trying to protect.

Sarepta manufactures EXONDYS 51 (Exondys), a covered outpatient drug in Washington's Medicaid program that HCA pays for if a Medicaid client has Duchenne Muscular Dystrophy and the drug is medically necessary for the client under HCA's medical necessity rules. Sarepta's claim that HCA's medical necessity rules violate federal law "as applied" to Medicaid clients who have requested prior authorization for Exondys is wrong on the merits, as found by Thurston County Superior Court. The Court of Appeals correctly held Sarepta does not have standing to bring this claim.

Sarepta's Petition for Review is merely a re-argument of how to interpret federal statutes, which the Court of Appeals properly rejected below. In ruling that Sarepta did not have standing, the Court of Appeals conformed to applicable precedent and did not create a conflict with an opinion of this Court. And Sarepta fails to establish that the decision raises an issue of substantial public interest. As none of the criteria in RAP 13.4(b) apply, this Court should deny review.

II. IDENTITY OF RESPONDENT

Respondent is the Washington State Health Care Authority.

III. DECISION BELOW

Sarepta Therapeutics, Inc. seeks review of the October 26, 2021, opinion issued by Division II of the Court of Appeals, *Sarepta Therapeutics, Inc. v. Health Care Authority*, 19 Wn. App. 2d 538, 497 P.3d 454 (2021), which held that Sarepta lacks standing under the Washington APA to challenge the application of HCA's medical necessity rules to individual

Medicaid clients. The Court of Appeals denied Sarepta's motion for reconsideration on September 28, 2022.

IV. COUNTER STATEMENT OF ISSUES PRESENTED FOR REVIEW

1) By failing to satisfy the zone of interest requirement, does Sarepta lack standing under the Washington APA to challenge HCA's application of its medical necessity rules to individual Medicaid clients who have requested prior authorization for Exondys?

V. COUNTER-STATEMENT OF THE CASE

Washington's Medicaid program is designed to balance two interests: providing safe and effective health care to Washington Medicaid clients and safeguarding against unnecessary waste. *See, e.g.*, RCW 41.05.013(1) (HCA must ensure "prudent, cost-effective health services purchasing" by using "the best available scientific evidence and medical evidence" to develop a "definition of medical necessity"); RCW 70.14.050 (state agencies must take necessary actions to

control costs without reducing the quality of care). When a Washington Medicaid client's provider requests prior authorization for payment of a service or drug on a client's behalf, HCA conducts a two-step inquiry for determining whether it will be paid for by Medicaid: (1) HCA determines if the service or drug is "covered" under the state's program for medically accepted indications; and, if yes, then (2) HCA determines if the covered service or drug is "medically necessary" for the specific individual Medicaid client. WAC 182-501-0165. If HCA denies any service or drug to a Medicaid client, federal and state law protect the Medicaid client's right to appeal. 42 U.S.C. § 1396a(a)(3); 42 C.F.R. § 431.200; RCW 74.09.741(1). Whenever there is a prior authorization request for Exondys for an individual Medicaid client with Duchenne Muscular Dystrophy, the request automatically moves to step two, where HCA determines whether the drug is medically necessary for that particular Medicaid client. Clerk's Papers (CP) at 357, 363. HCA evaluates

medical necessity on a case-by-case basis by applying two program rules to the individual Medicaid client requesting the drug: WAC 182-500-0070 (definition of "medically necessary") and WAC 182-501-0165 (hierarchy of evidence).

The Washington Medicaid program's evidence-based approach to evaluating medical necessity was developed partly in response to legislative mandates during the 2003 legislative session requiring the State to use evidence in the administration of state-purchased health care programs. *See* Laws of 2003, 1st Spec. Sess., ch. 29 (the State must establish an "evidence-based prescription drug program" because the "inappropriate use of prescription drugs can result in unnecessary expenditures and lead to serious health consequences"); Laws of 2003, ch. 276 (the State's policies should be based "upon the best available scientific and medical evidence"). The hierarchy of evidence rule applies when a provider requests prior authorization seeking Medicaid to pay for a medical service or drug for an individual Medicaid recipient.

WAC 182-501-0165(1); WAC 182-530-1000(2)(e). Under the rule, HCA evaluates the evidence that the provider submits in support of the request by assigning weight to various types of data according to their objective validity and reliability and then designating a level of evidence. WAC 182-501-0165(3)–(5); WAC 182-501-0165(6)(b). Although the evidence level partially informs HCA's medical necessity analysis, under the hierarchy of evidence rule HCA still evaluates "on a case-by-case basis" whether the requested service "is medically necessary as defined in WAC 182-500-[0]070." WAC 182-501-0165(3).

Administrative appeal rights are available for all Medicaid clients aggrieved by HCA's medical necessity determinations. *See* 42 U.S.C. § 1396a(a)(3); 42 C.F.R. § 431.200; RCW 74.09.741(1). The Medicaid client's adjudicative proceeding is governed by the Washington APA. RCW 74.09.741(5)(a). When a Medicaid client is dissatisfied with the result of the administrative hearing, HCA's medical

necessity denials are reviewable by the courts. RCW 34.05.570(3).

In this case, no Medicaid clients challenged HCA's rules or their application. Rather Sarepta, a pharmaceutical company, sought a declaration under the Washington APA that HCA's medically necessary definition and HCA's hierarchy of evidence rule violate federal law when applied to individual Medicaid clients who have requested Exondys.

HCA filed a motion to dismiss for lack of standing. Thurston County Superior Court denied HCA's motion to dismiss "if only because proceeding onto the next step, should someone again in the appellate capacity decide 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 [of the merits]." Report of Proceedings (RP) (Mar. 13, 2020) at 44-45. Thurston County Superior Court then denied Sarepta's Petition for Judicial Review on the merits, finding that the State's medical necessity prior authorization program is permitted within the

context of 42 U.S.C. § 1396r-8(d)(1)(A). CP at 319-20; RP (Mar. 13, 2020) at 47.

Sarepta appealed the merits denial. HCA cross-appealed the denial of its motion to dismiss for lack on standing. The Court of Appeals determined that Sarepta lacked standing to file its Petition and that the superior court erred by denying HCA's motion to dismiss. *Sarepta*, 19 Wn. App.2d at 555. The Court of Appeals denied Sarepta's motion for reconsideration. Sarepta now petitions this Court to accept review of the Court of Appeals' decision.

VI. REASONS WHY REVIEW SHOULD BE DENIED

This Court should deny review because none of the criteria in RAP 13.4(b) has been satisfied.

Sarepta's main argument, that the Court of Appeals misunderstood the Medicaid Drug Rebate Program and that this Court should accept review "to correct the error," is nothing more than an attempt to re-litigate the merits of the legal issues decided by the Court of Appeals, and has no basis in the grounds

articulated under RAP 13.4. Petition at 27. Additionally, although Sarepta also argues that the Court of Appeals' decision regarding standing conflicts with two opinions of this Court, an analysis of those two cases reveals no conflict. Finally, Sarepta attempts to argue that this case implicates issues of substantial public interest, but Sarepta's interests here are purely financial. Sarepta's interest in profiting from medically *un*necessary products is not within the zone of interest HCA was required to consider when promulgating rules under the Medicaid program. Because none of the criteria in RAP 13.4 are met, this Court should deny review.

A. The Court of Appeals Correctly Determined That Sarepta Is Not Within the Zone of Interest as Required for Standing Under Washington's APA

Sarepta brought its as applied rule challenge under the Washington State APA. In passing the APA, the Washington Legislature "did not confer standing on simply anyone who is dissatisfied with the outcome of the rule-making process." *Allan v. Univ. of Wash.*, 92 Wn. App. 31, 35–36, 959 P.2d 1184 (1998),

aff'd, 140 Wn.2d 323, 997 P.2d 360 (2000). To have standing under the APA, one must meet each of three 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.

RCW 34.05.530.

The first and third prongs compose the "injury-in-fact" requirements, while the second prong is called the "zone of interest" test. *Seattle Bldg. & Const. Trades Council v. Apprenticeship & Training Council*, 129 Wn.2d 787, 793-94, 920 P.2d 581 (1996). The petitioner bears the burden of proving that both tests are satisfied. *Allan v. Univ. of Washington*, 140 Wn.2d 323, 332, 997 P.2d 360 (2000).

The zone of interest test requires the petitioning party to demonstrate that its "asserted interests are among those that the

agency was required to consider when it engaged in the agency action challenged." *Seattle Bldg. & Const. Trades Council*, 129 Wn.2d. at 793. The zone-of-interests test "serves as a filter to limit review to those for whom it is most appropriate." *Id.* at 797 (citing William R. Andersen, *The 1988 Washington Administrative Procedure Act—An Introduction*, 64 Wn. L. Rev. 781, 824-25 (1989). "'The test focuses on whether the Legislature intended the agency to protect the party's interests when taking the action at issue.'" *Id.* (quoting *St. Joseph Hosp. & Health Care Ctr. v. Dep't of Health*, 125 Wn.2d 733, 739-40, 887 P.2d 891 (1995)). To make that determination, the court looks "to the statute's purpose and operation." *Hous. Fin. Comm'n v. Nat'l Homebuyers Fund, Inc.*, 193 Wn.2d 704, 715, 445 P.3d 533 (2019) (citing *Five Corners Family Farmers v. State*, 173 Wn.2d 296, 304-05, 268 P.3d 892 (2011)). "If the statute in question was not designed to protect a party's interests, it is not within the zone of interest and its assertion of standing fails." *Tacoma Auto Mall, Inc. v. Nissan N. Am., Inc.*,

169 Wn. App. 111, 119, 279 P.3d 487 (2012) (citing *Grant Cty. Fire Prot. Dist. No. 5 v. Moses Lake*, 150 Wn.2d 791, 803, 83 P.3d 419 (2004)). As the Court of Appeals correctly determined after analyzing the pertinent laws, Sarepta does not meet the zone of interest test because neither the Washington Legislature nor Congress intended to protect drug manufacturers' financial interests in selling drugs.

Here, the Court of Appeals analyzed the Washington statutes and found that the Legislature clearly did not intend to protect the interests of a drug manufacturer when it directed HCA to establish an evidence-based prescription drug program. *Sarepta*, 19 Wn. App. at 551. Rather, the Legislature's interests were only in controlling costs and ensuring quality care to Medicaid clients. *Id.* In analyzing federal law, the Court of Appeals determined that the "legislative history is not ambiguous" that Congress's intent in establishing the Medicaid Drug Rebate Program was to control costs, not to protect the financial interests of drug manufacturers, and that Sarepta does

not have a legally protected interest that HCA was required to protect when it established rules for the administration of Washington's Medicaid program. *Id.* at 552-54.

1. Washington State's interests in implementing the Medicaid program are to provide safe and effective care to its citizens and avoid waste from unnecessary expenditures

For decades, the Washington Legislature has directed Washington's Medicaid agency to protect two interests: the individual Washington citizen's interest in receiving safe and effective care and the State's interest in providing that care while avoiding waste via unnecessary expenditures. *See, e.g.*, RCW 70.14.050 (state must "take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs").

Consistent with federal law, Washington's Legislature has granted an administrative hearing right only to "any [Medicaid] applicant or [Medicaid] recipient" who is aggrieved by HCA's actions. RCW 74.09.741(1)(a); *see* 42 U.S.C. § 1396a(a) (a state's Medicaid plan must grant an opportunity for a fair hearing

before the state agency to any individual whose claim for medical assistance under the plan is denied). Often in disputes between a state and the Medicaid client, "material questions of fact arise as to whether a treatment is medically necessary." *Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1252 (11th Cir. 2011). The purpose of a medical necessity administrative hearing is to resolve these disputed facts regarding whether or not a service is medically necessary for that particular Medicaid client.

The Court of Appeals analyzed the Washington statutes and correctly determined that the two interests the Legislature wanted to protect—the individual Medicaid client's interest in receiving safe and effective care and the State's interest in providing precisely that type of care without waste—do not include a drug manufacturer's financial interest in selling products. *Sarepta*, 19 Wn. App. at 551-52. Sarepta appears to concede that it is not within the zone of interest established by the Washington State Legislature by only arguing that the Court of Appeals failed to consider the interests affected by the *federal*

Medicaid Drug Rebate Program. Petition at 20. However, this reliance on federal law is in error as well.

2. Congress's interest in passing the prescription drug rebate program was to save money by ensuring Medicaid got the best price on drugs

The purpose of the Medicaid program is to benefit individual Medicaid recipients, not the providers who serve them. *Armstrong v. Exceptional Child Center, Inc.*, 575 U.S. 320, 332, 135 S. Ct. 1378, 191 L. Ed. 2d 471 (2015) (Medicaid was created "for the benefit of the infirm whom the providers were to serve, rather than for the benefit of the providers themselves"). Like other federal Spending Clause legislation, federal dollars are provided to states in exchange for the states' agreement to spend the money in accordance with congressionally imposed conditions. *Id.* at 323, 328, 332 (providers have no cause of action to challenge how a state applies Medicaid law because the "sole remedy" that Congress provided for a state's violation is "the withholding of [federal] Medicaid funds").

Federal law allows states to take steps "necessary to safeguard against unnecessary utilization" to "assure that payments are consistent with efficiency, economy, and quality of care." 42 U.S.C. § 1396a(a)(30)(A). States can also "place appropriate limits" on covered services "based on such criteria as medical necessity." 42 C.F.R. § 440.230(d).

Although Sarepta criticizes the Court of Appeals for conflating standing with the merits, the crux of Sarepta's standing argument is that Medicaid Drug Rebate Program provides Sarepta with a legally protected interest in payment for Exondys any time a doctor prescribes it. *E.g.*, Petition at 20. Therefore, it was necessary for the Court of Appeals to consider the substantive law in evaluating standing. Sarepta has a fundamental misunderstanding of federal law.

In 1990, Congress determined that Medicaid was routinely paying more for prescription drugs than other large drug purchasers. H.R. Rep. No. 101-881 (1990), *as reprinted in* 1990 U.S.C.C.A.N 2017, 2108. Therefore Congress decided to

"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." *Id.*

As the United States Supreme Court has explained, pre-1990, states utilized two different methods to control payment for prescription drugs: (1) coverage restrictions (i.e., a list of non-covered drugs), and (2) prior authorization programs "that required approval by a state agency to qualify a doctor's prescription for reimbursement." *Pharm. Rsch & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 651, 123 S. Ct. 1855, 155 L. Ed. 2d 889 (2003). In passing the Medicaid Drug Rebate Program, Congress prohibited the first (coverage restrictions such as non-covered lists), and ratified the second (prior authorization programs). *Id.* at 651-53. As an example of the type of existing prior authorization program that Congress ratified, the Supreme Court cited to California's prior authorization program. *Id.* at 651 (citing *Cowan v. Myers*, 187 Cal.App.3d 968, 974-75, 232 Cal.Rptr. 299 (1986)). In California's prior authorization

program, the type that was being ratified by Congress, California's Medicaid program evaluated the medical necessity of a physician's prescription. *Cowan*, 187 Cal.App.3d at 976 ("plaintiffs are in error when they assert the physician is the sole arbiter of what constitutes a medical necessity"). When Congress authorized states to "subject to prior authorization any covered outpatient drug," 42 U.S.C. § 1396r-8(d)(1)(A), Congress recognized this would continue to give states the ability to "safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." 1990 U.S.C.C.A.N 2017, 2110. In other words, under the Medicaid Drug Rebate Program, a state still retains "broad discretion to subject covered drugs to prior authorization in order to achieve cost saving for the Medicaid program, even though a prior authorization requirement may burden the ability of the Medicaid recipients to obtain prescription drugs." Brief for the United States of America as Amicus Curiae Supporting Reversal,

Pharm. Rsrch. and Mfrs. of Am., 538 U.S. 644 (2003) (No. 01-188), 2002 WL 31156279 at *15.

Here, it was necessary for the Court of Appeals to understand the purpose and mechanics of the Medicaid Drug Rebate Program to determine if Sarepta was in Congress's zone of interest. After carefully considering the federal law, the Court of Appeals correctly determined that Congress's intent in passing the Medicaid Drug Rebate Program was to reduce costs and that federal law does not establish that Sarepta has an interest that HCA was required to protect when it established rules for the administration of Washington's Medicaid program. *Sarepta*, 19 Wn. App. at 552-55.

Sarepta's arguments to this Court disputing the Court of Appeals' legal conclusions are nothing more than an attempt to re-litigate the legal question of Congress's intent in passing the Medicaid Drug Rebate Program. But the Court of Appeals' analysis of this issue does not conflict with precedent from this

Court and has no basis in the grounds articulated under RAP 13.4.

B. The Court of Appeals' Decision in This Case Does Not Conflict with any Decisions From This Court

Sarepta's claim that the Court of Appeals' analysis of the zone of interest test is in conflict with two of this Court's decisions is not well-founded. Petition at 16-18. These cases support the Court of Appeals' analysis, rather than conflict with it.

The first case Sarepta incorrectly claims is in conflict involves the certificate of need program, where health care providers wishing to establish or expand certain medical facilities are required to obtain a "certificate of need" from the Department of Health. *St. Joseph Hosp.*, 125 Wn.2d at 736. When Care Inc. filed a certificate of need application for a new kidney dialysis center in Lakewood, the Department of Health gave St. Joseph Hospital required notice as an "affected person" and notified the hospital of its right to request a public hearing. *Id.* at 737. St. Joseph's requested a public hearing and testified at

it, after which the Department of Health denied Care Inc.'s application on the basis that there was not a need for additional dialysis stations in that geographical area. *Id.* But after Care Inc. utilized an administrative appeal process that did not include St. Joseph's participation, the Department of Health granted Care Inc.'s application subject to the condition that Care Inc. obtain agreement with St. Joseph Hospital for patient referral and treatment coordination. *Id*. When the Department of Health refused to consider St. Joseph's objection, St. Joseph's filed a petition for judicial review, and the superior court found the Department of Health's approval of Care Inc.'s application unconstitutional, outside the agency's authority, and arbitrary and capricious. *Id.* at 738. The Department of Health argued that St. Joseph's was not in the "zone of interest" required for standing. This Court analyzed the statute and determined the Legislature's intent was not only to control costs to the public, but also "to accomplish that control by limiting competition within the health care industry." *Id*. at 741. Because the

Legislature intended to "regulate competition," and because appeals of a certificate of need approval "can only be achieved if competitors have standing," this Court found competing service providers to be within the statutory zone of interest. *Id.* at 741-42.

Sarepta argues that the *St. Joseph* case demonstrates the appropriate application of the "lenient" zone of interest test. Petition at 16. But in the *St. Joseph* case, this Court found that the test "focuses on whether the Legislature intended the agency to protect the party's interests when taking the action at issue." *St. Joseph Hosp.*, 125 Wn.2d at 739-40. Although HCA acknowledges that this test "is not meant to be especially demanding," it does serve as "an additional filter limiting the group that can obtain judicial review." *Seattle Bldg. & Const. Trades Council*, 129 Wn.2d. at 797. Thus, the court's task is to determine whether the Legislature intended the party's interests to be protected by the agency. *Id.*

In *St. Joseph*, this Court conducted a thorough analysis of the certificate of need statute and the Legislature's intent for that particular program. And a thorough analysis of the applicable laws and intent of Medicaid law is exactly what the Court of Appeals did here. The Court of Appeals' conclusion that Sarepta is not within the zone of interest does not conflict with a decision of this Court merely because the outcome of the fact-specific analysis turns out differently when different facts are presented. Also, unlike in the certificate of need program where competitors had a right to notice and the ability to request a public hearing, and where there would no ability for anyone to challenge an approval if competitors didn't have standing, a Medicaid client who is denied any particular service or drug has appeal rights.

There is also no conflict with the second case that Sarepta raises, which involves standing under the Uniform Declaratory Judgment Act, not the APA. *Hous. Fin. Comm'n,* 193 Wn.2d at 704. In that case, the Washington State Housing Finance Commission, an instrumentality of the state exercising

essential governmental functions, brought a declaratory judgment action under the Uniform Declaratory Judgment Act arguing that the National Homebuyers Fund was unlawfully invoking governmental authority in Washington and thus interfering with the Commission's work. *Id.* at 709-10. To determine if the Commission was within the zone of interest protected by the statute, this Court looked to the statute's purpose and operation. *Id.* at 715. In looking at the particular statute at issue in that case, this Court found that the statute authorized the Commission to act in a restricted area and that implicit with the enabling act was the Commission's interest in excluding unauthorized actors from that space. *Id.* at 716.

Again, a thorough analysis of the Medicaid laws' purpose and intent is exactly what the Court of Appeals did here. The Court of Appeals' conclusion that Sarepta is not within the zone of interest does not conflict with a decision of this Court merely because the outcome of the fact-specific analysis turns out differently.

C. The Petition Does Not Involve an Issue of Substantial Public Interest

Sarepta's Petition fails to raise an interest of substantial public interest warranting review of this Court. As argued above, Sarepta's interest in profiting from medically *un*necessary products is not an issue of public interest. Likewise, it is not a matter of public interest for Medicaid to pay for medically *un*necessary drugs.

Furthermore, access to medically necessary drugs for Medicaid clients is protected by HCA's current processes. If a Medicaid client disputes a denial based on medical necessity, administrative appeal rights are available under the APA. *See* 42 U.S.C. § 1396a(a)(3); 42 C.F.R. § 431.200; RCW 74.09.741(1). If a Medicaid client is dissatisfied with the result of the administrative hearing, HCA's medical necessity denials are reviewable by the courts. RCW 34.05.570(3). Here, where the Petitioner is a pharmaceutical company with a financial profit motive, rather than a Medicaid client seeking to

overturn a medical necessity determination, there is no substantial public interest at issue.

VII. CONCLUSION

None of the arguments raised by Sarepta demonstrates that the standards for review under RAP 13.4(b) have been met. There is no conflict with a decision of this Court, Sarepta's claims do not raise any issues of substantial public interest, and the remainder of Sarepta's Petition for Review is merely a re-argument of how the federal Medicaid statutes should be interpreted. This Court should deny review.

This document contains 4,151 words, excluding the parts of the document exempted from the word count by RAP 18.17.

RESPECTFULLY SUBMITTED this 28th day of November 2022.

ROBERT. W. FERGUSON
Attorney General

KATY HATFIELD, WSBA NO. 39906
NISSA IVERSEN, WSBA NO. 46708
Assistant Attorneys General

Office of the Attorney General
7141 Cleanwater Drive SW

PO Box 40124
Olympia, WA 98504-0124
(360) 586-6565
Katy.Hatfield@atg.wa.gov
Nissa.Iversen@atg.wa.gov
OID No. 91021

CERTIFICATE OF SERVICE

I certify that I caused to be served a copy of this Answer To Petition For Review on all parties or their counsel of record on the date below as follows:

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TO:

WARREN RHEAUME - Warrenrheaume@dwt.com
BENJAMIN J. ROBBINS - Benrobbins@dwt.com
MARGARET WYKOWSKI – Maggiewykowski@dwt.com
DAVIS WRIGHT TREMAINE LLP

JEFFREY L. HANDWERKER – Jeffrey.Handwerker@arnoldporter.com
PAIGE H. SHARPE - Paige.Sharpe@arnoldporter.com
ALLISON P. GARDNER - Allison.Gardner@arnoldporter.com
ARNOLD & PORTER KAYE SCHOLER LLP

I certify under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.

DATED this 28th day of November, 2022, at Olympia, Washington.

Katy Hatfield

KATY HATFIELD
Assistant Attorney General

SOCIAL AND HEALTH SERVICES DIVISION, ATTORNEY GENERALS OFFICE

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