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No. 1025734

SUPREME COURT OF THE STATE OF WASHINGTON

RCCH TRIOS HEALTH, LLC, a Delaware Limited Liability Company,

Petitioner,

v.

DEPARTMENT OF HEALTH OF THE STATE OF WASHINGTON and KADLEC REGIONAL MEDICAL CENTER,

Respondents.

KADLEC'S ANSWER TO PETITION FOR DISCRETIONARY REVIEW

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I. INTRODUCTION

The Department of Health (the "Department") denied the Certificate of Need ("CN") application of Trios Health, LLC ("Trios") provide elective percutaneous coronary interventions ("PCIs") because the Department did not project a sufficient number of PCIs in the planning area for Trios to meet the Department's volume standard to ensure quality and safety. This decision is consistent with the plain language of the relevant regulations, the Department's application of those regulations, and the underlying legislative intent that for a tertiary health service—defined in RCW 70.38.025(14) as "a specialized service that meets complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care" (emphasis added)—the Department should not approve additional providers unless it determines that appropriate volume standards will be met.

The Department's denial of Trios's application is neither in conflict with a decision of the Supreme Court nor an issue of substantial public interest that should be determined by the Supreme Court, the two grounds for discretionary review asserted by Trios. It is instead a routine and straightforward application of the Department's CN rules. Trios's real complaint is not that the Department's need methodology was applied incorrectly; its argument instead is that, according to Trios, the methodology itself is flawed. But that is a policy argument for rulemaking or legislation that should be addressed to the Department or the Legislature, not a legal issue to be resolved by this Court.

II. IDENTITY OF RESPONDENT

Respondent is Kadlec Regional Medical Center ("Kadlec").

III. COURT OF APPEALS DECISION

Trios petitions for review of the published opinion terminating review entered on October 17, 2023, by Division II of the Court of Appeals (the "Opinion").

IV. ISSUE PRESENTED FOR REVIEW

Whether the Department's Final Order on Summary Judgment and Cross-Motion for Summary Judgment, dated January 6, 2021 (the "Final Order")—affirmed by the Thurston County Superior Court on September 7, 2022, and by the Court of Appeals on October 27, 2023—should be affirmed because the Department correctly interpreted and applied WAC 246-310-745(4).¹

¹ Trios does not seek review of the Department's interpretation of WAC 246-310-745(9), relating to the data sources that may be used in the PCI need methodology. *See* Petition for Discretionary Review ("Pet."), Nov. 16, 2023, at 16, n.5; *see also* Opinion at 12-14 (affirming Department's interpretation of §745(9)).

V. COUNTERSTATEMENT OF THE CASE

A. Washington's CN laws govern new tertiary health services.

It is the public policy of Washington to regulate the operation of certain new healthcare facilities and services, through CN laws. See RCW 70.38.015; WAC 246-310-001. Tertiary health services are among those new services that require CN approval. See RCW 70.38.105(4)(f); WAC 246-310-020(1)(d). This refers to "specialized service[s] that meet[] complicated medical needs of people and require[] sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." RCW 70.38.025(14); WAC 246-310-010(58). It includes PCIs, which are a set of procedures used by cardiologists for the revascularization of obstructed coronary arteries. See WAC 246-310-700; WAC 246-310-745(4).

B. Trios may not establish an elective PCI program without a CN.

The Department allows hospitals without on-site cardiac surgery to provide elective PCIs, but only with CN approval. See WAC 246-310-700. The applicable CN rules are designed to ensure that PCI programs perform at least 200 PCIs annually. See WAC 246-310-720(1) ("Hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter"); WAC 246-310-720(2)(b) (a new program will not be approved unless "[a]ll existing PCI programs in that planning area are meeting or exceeding the minimum volume standard"); WAC 246-310-715(1) (requiring CN applicant to "[s]ubmit a detailed analysis" showing how it will achieve the 200-PCI standard).

These regulations "are predicated on a safety-related purpose." *Yakima Valley Mem. Hosp. v. Wash. State Dep't of Health*, 731 F.3d 843, 848 (9th Cir. 2013) (affirming constitutionality of Washington's PCI rules). Specifically, the

link between "minimum [volume] requirements" and "safety and quality" and medical literature that recommends "closing facilities that [fall] below the 200 procedure threshold." *Id.* at 849; *see also* WAC 246-310-715(2) ("If an applicant hospital fails to meet annual volume standards, the department may conduct a review of certificate of need approval for the program under WAC 246-310-755."); WAC 246-310-755 ("Failure to meet the standards may be grounds for revocation or suspension of a hospital's CON, or other appropriate licensing or certification actions.")²

C. A CN cannot be issued for a new PCI program unless the Department projects another 200 PCIs in the planning area.

The Department has divided the state into fourteen PCI planning areas. *See* WAC 246-310-705(5). Because a PCI program must perform 200 PCIs annually, "the department *will*

² The Ninth Circuit was addressing Washington's 300-PCI minimum in effect at the time of its decision. In 2018, the threshold was reduced to the 200-PCI requirement in the current rule. *See* WAC 246-310-720(1). Therefore, the Ninth Circuit upheld an even higher volume standard, on safety grounds, than the one Trios now seeks to circumvent.

not approve a new program" in a planning area "[i]f the net need for procedures is less than two hundred[.]" WAC 246-310-745(10) (emphasis added). There are no exceptions.

To determine net need, the Department first calculates demand, by multiplying the planning area's current PCI use rate ("step 1") by the planning area's projected population in five years ("step 2"). The Department next calculates supply, by adding up the number of PCIs being performed by existing providers ("step 3"). The Department then calculates net need, by subtracting supply from demand ("step 4"). *See* WAC 246-310-745(10).

D. The Department publishes its PCI need calculations for the 2019 concurrent review cycle, showing no need in planning area no. 2.

PCI applications are evaluated on an annual, concurrent-review schedule. *See* WAC 246-310-710. At the beginning of each year, the Department calculates net need in each of the state's PCI planning areas. If net need exceeds 200 in a

planning area, hospitals may apply to establish a new PCI program there.

The Department published its 2018-2019 PCI numeric need methodology in January 2019. For PCI planning area no. 2, which consists of Benton, Columbia, Franklin, Garfield, and Walla Walla counties, the methodology showed net need of only 182 PCIs. AR 610. Because this was below the 200-PCI threshold, an additional PCI program could not be approved. *See* WAC 246-310-745(10).

E. Trios applies for a CN, while acknowledging that the Department's regulatory methodology does not project need for Trios's proposed PCI program.

On February 28, 2019, Trios applied for a CN to establish a PCI program at Trios Southridge Hospital in Kennewick, Washington, within PCI planning area no. 2. In its application, Trios acknowledged that the need methodology, WAC 246-310-745, requires a projected "net need" of at least 200 cases for a new PCI program to be approved; that the Department's application of the methodology to planning area

no. 2 only showed "need for 182 additional PCIs"; and that this "is short of the 200-case requirement." AR 610. Trios asserted that the Department's need methodology understated the "real" need, because, according to Trios, the Department's projection did not capture all relevant cases. AR 610.

F. The Program reiterates in screening that the need methodology it is required to use does not project need for another PCI program in planning area no. 2.

Following receipt of a CN application, the Department's CN Program (the "Program"), the departmental unit that evaluates CN applications, conducts a screening process to ensure that the application is complete. *See* WAC 246-310-090(2); WAC 246-310-120; WAC 246-310-710. The Program may request supplemental information from the applicant during this process. *See* WAC 246-310-090(2)(a).

The Program requested supplemental information from Trios on March 29, 2019. AR 667-85 (Trios's responses). In its request, the Program reminded Trios that "the 'state need forecasting methodology' referenced in rule was published on

the Department of Health website in February 2019"; that "[t]his is the methodology that will be used in the 2019 concurrent review cycle"; that under the Department's methodology, "there is no numeric need in the planning area"; and that "[t]he rule does not include any provisions for an exception to this standard." Apparently surprised by the fact that Trios applied for a CN despite the documented lack of need, the Program asked Trios to "confirm [its] understanding of this section of the rule." AR 669 (emphasis added).

Trios responded on June 21, 2019. It refused to acknowledge that the Department's published need projection should be used, and asked the Department to modify the projection for Trios's application. AR 669. Specifically, Trios asked the Department to adjust its need methodology to incorporate: (1) "raw data" from "[t]he Oregon Association of Hospital and Health Systems" regarding PCI procedures performed in Oregon for residents of planning area no. 2; (2) data relating to Walla Walla General Hospital identified in "a

letter from LifePoint Health" generated "from the Trilliant database, which is accurate at the 95% confidence level" as well as additional "outpatient and inpatient data for Oregon hospitals serving PCI Planning Area #2 residents"; and (3) "data . . . for St. Joseph Medical Center in Lewiston, Idaho," another Trios hospital. AR 669.

The Department's methodology requires it to use data from three data sources: (1) the comprehensive hospital abstract reporting system ("CHARS"), (2) the clinical outcomes assessment program ("COAP"); and (3) the Department's survey of PCI providers. WAC 246-310-745(9) ("The data used for evaluating applications submitted during the concurrent review cycle *must be* the most recent year end data as reported by CHARS or the most recent survey data available through the department or COAP data for the appropriate application year.") (emphasis added). Therefore, Trios effectively was asking the Department to violate its regulation by relying on data sources other than the three data sources allowed by rule.

G. The Department publishes an updated need methodology, which continues to show no need for Trios's proposed program.

In October 2019, the Department published an updated projection. It showed net need for 188 PCIs in the planning area, still below the 200-PCI threshold for approval of an additional program. AR 426.

H. Kadlec and others explain during the public comment period why Trios's application does not satisfy the Department's standards.

After a CN application has been screened by the Program, a public comment process is conducted regarding the application. *See* WAC 246-310-710. The Program accepted public comments on Trios's application through December 9, 2019. Kadlec submitted comments. AR 755-794. Kadlec asserted that Trios's application should be denied because the Department's need forecast does not show need for Trios's proposed program. AR 757-58, 760-68, 779-794. Kadlec noted that the departmental standard "unequivocally states that 'the Department will not approve a new program' if the net need for

PCI procedures is less than 200" and that the net need is for "only 182 adult PCI procedures in the Planning Area, which is less than the 200-procedure minimum volume standard." AR 760 (quoting WAC 246-310-745(10)). Kadlec also asserted that Trios's application should be denied under the Department's access, financial feasibility, structure and process of care, and cost containment criteria. AR 758-59, 768-77.

I. Trios attempts to supplement the record with additional data outside the regulatory methodology.

Under the Department's regulations, "[t]he department shall not accept responses to the department's screening letters later than ten days after the department has given 'notification of the beginning of review." WAC 246-310-090(2)(d). Here, the Department's notice of review was issued on November 1, and the deadline for Trios to supplement its screening responses was November 12. AR 752.

Trios attempted to use the public-comment period to supplement its application after the deadline to do so—*i.e.*, it submitted "public" comments on its own application. AR 846-

56; see also AR 896 (Kadlec's rebuttal, observing that "Trios' self-styled 'public comments' are an attempt to improperly supplement its application"). Trios asserted that it had found 31 cases in the CHARS databases of procedures "outside of DRGs 246-251" (i.e., the Diagnosis Related Groups for PCIs) that Trios believed were PCIs. And it argued that if these 31 cases are counted in the October 2019 updated need calculation, there will be an additional 205 PCIs in the planning area by 2022, meeting—just barely—the threshold for approval of a new program. AR 851.

The Program accepted rebuttal comments through December 23, 2019. Kadlec submitted rebuttal comments, in which it explained that the alleged PCI cases identified in Trios's public comments could not be considered because, under the Department's regulations, only cases "defined by diagnosis related groups (DRGs)" as PCIs may be included in the need methodology. AR 894-903.

J. The Program denies Trios's application.

The Program denied Trios's application on February 6, 2020. AR 11-76. The Program determined that due to the lack of need for Trios's proposed PCI program, the application failed to satisfy several CN requirements relating to need, financial feasibility, structure and process of care, and cost containment. AR 29-34, 48-51, 69, 70-71 (application failed WAC 246-310-210(1), 220(1), 230(4), 240(1), and 240(3)).

K. The Presiding Officer affirms the Program's denial of Trios's application.

A denied CN applicant may request a departmental adjudicative proceeding, in which one of the Department's administrative law judges (referred to as "Health Law Judges" or "HLJs") is assigned to serve as the Presiding Officer and reviews the Program's evaluation. *See* RCW 70.38.115(10)(a). Trios requested such an adjudicative proceeding here. AR 2-7. The Presiding Officer, HLJ Matthew Herington, permitted Kadlec, which operates a PCI program in the same planning area as Trios's proposed program, to intervene. AR 183. Kadlec

filed a motion for summary judgment, in which it asked the Presiding Officer to affirm the Program's denial of Trios's application because the Department's regulatory need methodology does not project need for Trios's proposed program. The Program supported Kadlec's motion. Trios opposed Kadlec's motion. AR 421-36.

The Presiding Officer granted Kadlec's summary judgment motion. AR 421-36. The Presiding Officer determined that the Department cannot, as a matter of law, modify its need methodology as Trios proposes; that the need methodology accordingly was applied correctly; and that Trios's application therefore does not satisfy the need requirement set forth in WAC 246-310-210(1) and must be denied for that reason. AR 432-33.³

³ If Trios's application had not been denied on summary judgment based on lack of need, a hearing would have had to be conducted, at which Trios would have had the burden to prove that its application satisfied all CN requirements. *See* WAC 246-10-606(2); *DaVita, Inc. v. Wash. State Dep't of Health*, 137 Wn. App. 174, 151 P.3d 1095 (2007).

L. The Department's Review Officer affirms the Presiding Officer's denial of Trios's application.

A CN applicant whose application is denied by the Presiding Officer in a departmental adjudicative proceeding may seek administrative review of that order by the Department's Review Officer, appointed by the Secretary of Health to act as the Department's final decisionmaker. *See* WAC 246-10-701(1). Trios sought such administrative review here. AR 438-47. The Program and Kadlec opposed Trios's petition. AR 584. The Department's Review Officer, Michael Ellsworth, affirmed the Presiding Officer's order. AR 580-89. The Review Officer's decision was the Department's final order in this matter. *See* RCW 35.05.464.

M. The Superior Court affirms the Department's final order.

Trios sought judicial review of the Department's final order in Thurston County Superior Court. CP 1-20. The Honorable Mary Sue Wilson determined that the Department's interpretation of its applicable regulations was not erroneous.

CP 33, 35. Judge Wilson accordingly denied Trios's petition and affirmed the Department's final order. CP 24.

N. The Court of Appeals affirms the Department's final order.

Trios sought judicial review of the Department's final order in the Court of Appeals. In a published decision entered on October 17, 2023, the Court of Appeals affirmed the Department's final order. *See* Opinion at 15.

VI. ARGUMENT

A. If the Court were to accept review, the Department's final order would be reviewed under the APA judicial review standards.

In a judicial review proceeding under the Administrative Procedure Act ("APA"), the Court reviews the final decision of the agency, except to the extent the final decision adopts a subordinate officer's order. *See Providence Physician Servs.*Co. v. Wash. State Dep't of Health, 196 Wn. App. 709, 716, 384 P.3d 658 (2016); see also RCW 34.05.570(3) (judicial review of agency order in adjudicative proceeding); RCW 34.05.510(11)(a) (defining "order").

Under the APA, "[t]he burden of demonstrating the invalidity of agency action is on the party asserting invalidity." RCW 34.05.570(1)(a). In CN cases, "the agency decision is presumed correct and . . . the challengers have the burden of overcoming that presumption." *Overlake Hosp. Ass'n v. Dep't of Health of the State of Wash.*, 170 Wn.2d 43, 49-50, 239 P.3d 1095 (2010). Therefore, if the Court were to accept review, it should begin with the presumption that the Department's final order was correct, and Trios would bear the burden of demonstrating otherwise.

Judicial relief from agency adjudicative decision-making is available "only in limited circumstances." *DaVita*, 137 Wn. App. at 181; *see also* RCW 34.05.570(3) (identifying the circumstances in which a court may grant relief from an agency order in an adjudicative proceeding). These include when "[t]he agency has erroneously interpreted or applied the law." RCW 34.05.570(3)(d). However, when interpreting ambiguous regulatory language, the Court "accord[s] substantial deference

to the agency's interpretation, particularly in regard to the law involving the agency's special knowledge and expertise." *Univ. of Wash. Med. Ctr. v. Wash. State Dep't of Health*, 164 Wn.2d 95, 102, 187 P.3d 243 (2008). The Court should "uphold an agency's interpretation of a regulation if it reflects a plausible construction of the language of the [regulation] and is not contrary to legislative intent." *Cobra Roofing Serv. Inc. v. Dep't of Labor & Indus.*, 122 Wn. App. 402, 409, 97 P.3d 17 (2004) (quotation marks omitted).

- B. The Department's final order should be affirmed under the APA judicial review standards.
 - 1. The Department is required to use its regulatory need methodology to evaluate CN applications for PCI programs.

The Department must use its regulatory methodology to determine need for an additional PCI program in a planning area. *See* WAC 246-310-745(10). And the Department may "only grant a certificate of need to new programs within the identified planning area if . . . [t]he state need forecasting methodology projects unmet volumes sufficient to establish one

or more programs within a planning area[.]" WAC 246-310-720 (2)(a) (emphasis added). Therefore, the Department was required to deny Trios's application if the methodology did not project net need for 200 PCIs.

2. The Department cannot use cases not defined as PCIs by the applicable DRGs to modify its need forecast.

As discussed above, demand is calculated within the need methodology by dividing "the total number of PCIs performed on" planning-area residents by the planning area population (the "use rate"), and then multiplying this by the planning area's projected population. WAC 246-310-745(10). The PCIs to be counted are "cases as defined *by diagnosis related groups* (*DRGs*) as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest." WAC 246-310-745(4) (emphasis added). The CMS-designated DRGs that describe PCIs are DRGs 246-251.

Trios asserts that although the procedures it asked the Department to include were not coded as PCIs, they still should be included because they were PCIs. As the Program pointed out below, Trios's approach is suspect, and at minimum such a "laborious reckoning of which cases identified by procedure code to include provides insight into why the Department and its stakeholders at the time of rulemaking may have considered use of PCI DRGs preferable to procedure code"—*i.e.*, to allow for a practical and transparent CN application process. AR 323.

More importantly, even if Trios were correct that these patients obtained PCIs, it is irrelevant because these cases were not PCI "cases as defined by diagnosis related groups (DRGs)" and accordingly may not be counted. WAC 246-310-745(4). If "cases as defined by . . . DRGs" does not refer to DRG coding, the regulation's reference to DRGs becomes meaningless; the very point of DRGs is to classify patients for payment purposes.

See 42 U.S.C. § 1395ww(d)(4) (establishing "classification of inpatient hospital discharges by diagnosis-related groups").

Trios argues that the Department's approach is flawed. But as the Program explained below, there are good reasons for the regulation to rely upon the well-defined DRG data rather than on ad hoc, applicant-advocated alternatives: i.e., "[t]he methodology conducted by the Department helps assure that competitors receive fair and evenhanded treatment in their applications"; "[a]llowing competitors to introduce alternative estimates of unmet PCI need during the application process thwarts fairness"; and considering different data for an individual application would "alter[] the regulatory scheme with the result of the Department conducting a separate methodology for each planning area instead of conducting a state methodology as required by the rule." AR 322. As the Review Officer explained, "[t]he methodology in WAC 246-310-745 does not count every PCI performed." AR 586 (Final Order). But it allows the Department to follow a consistent, rules-based approach to forecast need and evaluate CN applications to establish new PCI programs.

Finally, as noted by the Court of Appeals, the Department included a general definition of PCIs in its regulations, which would encompass all PCIs performed. *See* WAC 246-310-704(4). But for purposes of the need methodology, to determine whether another provider should be approved, the Department chose to use the more restrictive definition in WAC 246-310-745(4), counting only those PCIs "as defined by" the relevant DRGs. Therefore, it is clear from the regulatory language as a whole that the Department did not intend for *all* PCIs to be counted in the need methodology. *See* Opinion at 11.

Pursuant to WAC 246-310-745(4), the PCIs to be included in the need methodology are those defined as PCIs by DRG. Accordingly, the Department cannot, as a matter of law, include in its need methodology the alleged additional PCIs identified by Trios. If Trios believes that a different methodology would yield more accurate need forecasts and better serve the Department's policy goals, Trios may petition

the Department to conduct a rulemaking process to change the methodology. But under the regulations in place, the Department was required to deny Trios's CN application.

C. The Court should deny Trios's request for discretionary review.

Trios asserts that the Court should grant review under RAP 13.4(b)(1) or 13.4(b)(4). Neither of those grounds for review is present here.

1. The Court of Appeals' opinion is not in conflict with any decision of the Supreme Court.

Trios cites three Supreme Court decisions in its petition—Overlake; Bostain v. Food Express, Inc., 159 Wn.2d 700, 153 P.3d 846 (2007); and Kenmore MHP LLC v. City of Kenmore, 1 Wn.3d 513, 528, P.3d 815 (2023). The Court of Appeals' opinion is not in conflict with any of these decisions.

Overlake, involving a challenge to the Department's CN need methodology for ambulatory surgical facilities ("ASFs"), is instructive here for two reasons.

First, although the Overlake appellants' interpretation of the ASF need methodology was "reasonable," 170 Wn.2d at 54, this Court affirmed the Department's interpretation, noting that it "must accord the Department's interpretation of the ambiguous regulatory language great deference, as the agency has expertise and insight gained from administering the regulation that the reviewing court does not possess[.]" Id. at 56. Overlake therefore underscores the deference that must be given to the Department's interpretation of WAC 246-310-745(4) here, should that regulation be found to be ambiguous.

Second, ASFs are not a tertiary service. The Department's need methodology for ASFs at issue in *Overlake* was essentially a supply-and-demand calculation, without the safety- and quality-based volume requirements at issue with respect to PCIs. Thus, Trios's reliance on the "access" analysis in *Overlake*, see Pet. at 26, is misplaced because the Department's calculation of how many operating rooms will be needed in a planning area is fundamentally different from the

Department's determination of whether another hospital should be approved for a tertiary service for which a certain volume of procedures is needed to maintain quality of care.

Bostain involved the interpretation of Washington's Minimum Wage Act. Trios cites the case for the Court's statement of the general principle that courts should not defer to an agency's interpretation of a statute "that conflicts with a statutory mandate." Pet. at 18; see also Bostain, 159 Wn.2d at 716. Trios also cites Overlake for this principle. See Pet. at 18-19. But the Department's interpretation of its PCI regulation does not conflict with a statutory mandate. To the contrary, it is consistent with the underlying statute, which recognizes that "tertiary health services" like PCIs require "sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." RCW 70.38.025(14).

Kenmore involved the interpretation of Washington's Growth Management Act. Trios cites this case for the general principle that the Court should not defer to the agency's

Pet. at 18; see also Kenmore, 1 Wn.3d at 522. Trios also cites Overlake for this principle. See Pet. at 17. But the Court of Appeals' opinion here is not in conflict with this principle. The Court of Appeals affirmed the Department's interpretation of WAC 246-310-745(4) based on its plain language. See Opinion at 10. The Court of Appeals then stated that "[e]ven if the language of WAC 246-310-745(4) was ambiguous, we would give deference to DOH's position because the regulation falls within its area of expertise." Opinion at 11 (emphasis added).

Because the Court of Appeals' opinion does not conflict with any Supreme Court decisions cited in Trios's petition, Trios has failed to demonstrate that the Court should accept discretionary review under RAP 13.4(b)(1).

2. The Court of Appeals' decision does not involve an issue of substantial public interest that should be resolved by the Supreme Court.

The Department's denial of Trios's CN application is not an issue of substantial public interest—unless *every* dispute regarding the CN regulations would be considered as such. Instead, the Department's action here was a routine CN decision, and has been reviewed by four tribunals which all reached the same conclusion, *i.e.*, the hearing officer, review officer, Superior Court, and Court of Appeals all affirmed the Department's denial of Trios's application.

Moreover, there are at least four factors present here which would make Supreme Court review even *less* warranted for Trios's denial than it may be for other CN denials.

First, unlike a case involving hospital beds, or operating rooms, or dialysis stations, or other physical limits on healthcare capacity, this planning area has a PCI provider, Kadlec, which is available to provide needed PCIs. Therefore, there is less of a public interest here than there may be for a CN

denial which might physically limit the healthcare capacity of a planning area and the number of patients who can receive care.

Second, Trios may provide emergency PCIs without CN approval; it is only prohibited from providing elective PCIs. Therefore, there is less of a public interest here than there may be for a CN decision which entirely prohibited the applicant from providing the type of service at issue.

Third, there is no geographic access issue here. Trios is proposing to provide elective PCIs at 3810 Plaza Way, Kennewick, Washington, which is a short distance from where Kadlec provides PCIs, at 888 Swift Boulevard, Richland, Washington. AR 603 (Trios address), 755 (Kadlec address). Therefore, there is less of a public interest here than there may be for a CN decision which could limit access to care for a large geographic area or patient population.

Fourth, Trios's argument is not really that the Department has misinterpreted its methodology. Instead, Trios is arguing that the Department's methodology is overly

conservative, and that the Department should use a more permissive methodology that would result in approval of more PCI providers. Whatever the merits of Trios's argument, they relate to a *policy* issue to be resolved by the Legislature, or by the Department in rulemaking, not to a *legal* issue, *i.e.*, not to an issue "that should be determined by the Supreme Court." RAP 13.4(b)(4).

VII. CONCLUSION

The Department's interpretation of WAC 246-310-745(4) is correct based on the plain language of the regulation. And even if the language is ambiguous, the Department's interpretation is at minimum a plausible construction of the regulatory language and not contrary to legislative intent. It also serves the legitimate policy goal of limiting the number of PCI programs to ensure that each program is performing a sufficient volume of procedures to ensure program quality. Because Trios has failed to demonstrate that the Court of Appeals' opinion conflicts with a decision of this Court or involves a substantial

public interest that should be determined by this Court, Trios's petition for discretionary review should be denied.

Respectfully submitted.

December 18, 2023

I certify that this brief contains 4,829 words, in compliance with RAP 18.17(c)(2).

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CERTIFICATE OF SERVICE

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