No. 102573-4

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

(Court of Appeals No. 57403-9-II)

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.

PETITION FOR DISCRETIONARY REVIEW

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I. INTRODUCTION

Washington's certificate of need (CN) requirements for health services and facilities are intended "to promote, maintain and assure the health of all citizens in the state, provide accessible health services, health manpower, health facilities and other resources while controlling increases in costs, and recognize prevention as a high priority in health programs." RCW 70.38.015(1); *Overlake Hosp. Ass'n. v. Dep't of Health of the State of Washington*, 170 Wn.2d 43, 50, 239 P.3d 1095 (2010). Implementing these standards, the Department of Health (DOH) has issued regulations providing for its evaluation of CN applications including review of need for the services in question. WAC 246-310-210.

Petitioner RCCH Trios Health, LLC, now Lifepoint Health,[1] operates Trios Southridge Hospital in Kennewick, Washington (Trios). It provides comprehensive health care

[1] RCCH HealthCare Partners merged with Lifepoint Health after the CN application at issue in this appeal.

services including cardiology care. Based on unmet need,[2] Trios applied for a CN to provide procedures known as elective percutaneous coronary interventions (PCIs). DOH denied its requested CN based on an erroneous determination that Trios had not established need as required by WAC 246-310-210 and WAC 246-310-745. We explain herein that this was error. The reviewing courts' failure to correct it conflicts with this Court's jurisprudence on review of agency action and the public interest expressed in the CN law and requires reversal.

DOH erred in applying the regulatory definition of PCIs used to determine unmet need and consequently undercounted need in the planning area. WAC 246-310-745(4) states, "[PCIs] means 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 of the chest." Relying on this

[2] The region has only one current provider of elective PCIs—Kadlec Regional Medical Center (Kadlec), an intervenor in this action.

"defined by diagnosis related groups" language and the definitions in the relevant DRGs, Trios identified sufficient PCIs to satisfy the need standard, but DOH insisted that "defined by DRGs" actually meant "coded with" certain DRGs and concluded that need was not proved because not all PCIs, including those identified by Trios, are *coded with* the relevant DRGs. This parsimonious calculation of need excluding PCIs meeting the regulation's definition cannot be squared with the legislature's intention that the CN process would enhance the health care of all citizens. Counting all PCIs meeting the DRG definitions allows for accurate identification of need, but DOH insists that the regulation does not require it to count all conforming PCIs and it may instead use DRG coding to determine need. In effect, reducing DOH workload trumps providing available health care for Washington residents.

In affirming DOH's decision, the lower courts made two errors applying this Court's cases and both meet the Rule 13.4 standard for review by this Court. At all levels, the reviewing

tribunals did not construe the plain language of the applicable regulation and instead substituted DOH's self-serving theory that it need not count all PCIs. And the lower courts did not apply the legislature's and this Court's clear and emphatic direction identifying the goals of the CN process to advance health care and reduce costs of such care.

II. IDENTITY OF PETITIONER

The petitioner is RCCH Trios Health, LLC, now Lifepoint Health, parent of Trios Health (Trios), the applicant in the administrative proceeding and appellant in the court of appeals.

III. CITATION TO COURT OF APPEALS DECISION

Trios petitions for review of the published decision terminating review entered on October 17, 2023, by Division II of the Court of Appeals (the "Decision"). A copy of the Decision is attached hereto.

IV. ISSUES PRESENTED FOR REVIEW

Whether PCIs meeting the definitions in relevant DRGs but not coded with those DRGs must be included in DOH's assessment of need for PCI services, in order to give effect to the plain text of WAC 246-310-745(4) and intent of the CN process to promote, maintain, and assure the "health of all citizens in the state…provide accessible health services…while controlling increases in costs…"

V. STATEMENT OF THE CASE

A. Trios operates a hospital in southeastern Washington with an established cardiac care program.

Trios Southridge Hospital is an acute care hospital in Kennewick, Washington. Administrative Record (AR) 603. The hospital has two cardiac catheterization labs where a variety of diagnostic and therapeutic services are performed by contracted interventional cardiologists. AR 604-605, 620-621.

PCIs are invasive but nonsurgical procedures performed by cardiologists to revascularize (restore blood flow) within

obstructed arteries of the heart. WAC 246-310-705(4).[3] PCIs are currently performed at Trios only in emergent circumstances. AR 87; *see also* WAC 246-310-705(3) (defining emergent PCIs as those required immediately in the treating physician's judgment). Trios does not have DOH approval to provide elective PCIs, performed on patients whose cardiac function is stable before the procedure. WAC 246-310-705(2). When an elective PCI is appropriate for a Trios patient, the patient must be transferred to a different facility, resulting in transport costs and delays in treatment. AR 612, 631.

B. CN requirements are intended to assure the health of citizens in the state and provide accessible health services and facilities. CN requirements include proof of need for new PCI providers based on a methodology described in WAC 246-310-745.

A CN is written authorization issued by the DOH CN program to implement a proposal for a particular undertaking.

[3] The CN regulations contain two definitions of PCI. One is a general definition found in WAC 246-310-705(4): PCIs are "invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries." The other definition, found in WAC 246-310-745(4), must be used for the PCI need methodology.

WAC 246-310-010(11). The CN program is "a component of a health planning regulatory process" established in the CN law, Ch. 70.38 RCW. CNs are required for certain healthcare facilities and services, including elective PCIs at hospitals that do not perform on-site cardiac surgery. RCW 70.38.128. The CN regulations, Ch. 246-310 WAC, set forth general standards for issuance of a CN (see WAC 246-310-200), as well as requirements specific to PCIs. *See generally* WAC 246-310-700 to WAC 246-310-755. The criteria for approval include whether there is need for elective PCI services in the applicant's region, described in the regulations as their "planning area." WAC 246-310-210(1); WAC 246-310-705(5).

The CN regulations contain a five-step methodology to forecast need for elective PCI services. WAC 246-310-745(10). The first step requires computation of a planning area's historical "use rate" by dividing the "total number of PCIs" performed in a certain time period by a segment of the population. WAC 246-310-745(10), Step 1. PCIs may be inpatient or outpatient

procedures and the use rate must include both. *Id.* The use rate is applied in later steps of the methodology to project future need. WAC 246-310-745(10), Steps 2-5. The methodology must demonstrate numeric need of at least 200 before a CN may issue. WAC 246-310-745(10), Steps 4 and 5; *see also* WAC 246-310-720(2)(a). Undercounting the total number of PCIs in Step 1 results in a use rate that is too low and ultimately causes underestimation of need, preventing approval of a CN. DOH agrees that the purpose of the methodology is to identify whether there are "shortfalls in PCI availability." AR 232-233 (deposition testimony of DOH analyst Elizabeth Harlow, who evaluated Trios's application).

C. Trios applied for a CN and provided evidence of need for PCI services exceeding the regulatory threshold.

Trios is located in Planning Area 2, consisting of Benton, Columbia, Franklin, Garfield, and Walla Walla counties. AR 603; WAC 246-310-705(5). The Benton/Franklin area, including Kennewick, has a rapidly growing population, and more than 80

percent of all PCIs in 2017 were performed on residents of one of these two counties. AR 611. Kadlec is the only hospital with a CN to provide elective PCIs in Planning Area 2. AR 603.

In 2019, Trios applied for a CN to provide elective PCI services. AR 595. During the application review process, Trios provided data to DOH that was not incorporated in a projection of need previously published by DOH but was necessary for accurate forecasting of need in Planning Area 2.[4] Trios identified 31 PCIs provided to hospital inpatients in 2017, the year from which data was used for DOH's need projection. AR 848-851. These additional PCIs met the definition of PCIs for purposes of the methodology: "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

[4] The CN regulations state that DOH shall only grant a PCI CN if the "state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area." The "state need forecasting methodology" must conform to WAC 246-310-745. Nothing in the CN regulations prevents DOH from altering its initial projection of need.

the chest." WAC 246-310-745(4). DOH does not contend otherwise, and yet it refused to alter its need calculation or even consider the data, as further explained below. AR 251 (Harlow testimony that she did not consider the 31 PCIs).

D. DRGs are used to define PCIs and generally for hospital billing.

DRG codes are used for hospital billing purposes. Each DRG code corresponds to a definition in a manual published by CMS. AR 345; *see also* AR 353-358 (excerpt from CMS manual). At the time of Trios's application, the DRGs associated with PCIs were DRGs 246 through 251, each of which defines a type of PCI. *See* AR 353-358 (excerpt from CMS manual); *see also* AR 291 (deposition testimony of DOH analyst Randall Huyck that DRGs 246-251 are used by DOH to identify PCIs). For example, DRG 246 is a "Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents," whereas DRG 247 is a "Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without

MCC." AR 353, 356. Each of the DRG definitions include a list of associated ICD-10 codes indicating procedures that may be part of the services provided to the patient. *See generally* AR 352-358 (CMS manual excerpt).

Only one DRG is assigned per hospital admission based on the patient's principal diagnosis and other factors. AR 344. Each procedure is also separately coded using the ICD-10 system. *See* AR 344-345. If a patient receives multiple procedures during the same hospital stay, a DRG code is not assigned for all procedures. AR 344. DRGs 246–251 are typically assigned to patients who receive a PCI unless a different DRG is more appropriate based on factors related to the patient's hospital stay. AR 344; *see also* AR 850 ("the patient could have been admitted for an unrelated issue, and then began displaying symptoms such as chest pain and elevated cardiac enzyme values that resulted in a cardiology consultation and determination that a coronary intervention was necessary" or "the patient could also have had co-morbidities or another diagnosis that resulted in

them being assigned to a higher-weighted DRG."). This means that whether a patient who received a PCI is assigned a corresponding DRG code depends on the timing of the PCI in relation to other procedures performed, the cause of admission, and other factors.

WAC 246-310-745(10) requires that outpatient PCIs be counted in the need calculation, as well. DRG codes are not assigned for outpatient PCIs because the patient is not admitted to or discharged from the hospital. *See* AR 344 ("DRGs are a scheme of classifying inpatient diagnoses"); *see also* DOH Response Brief in the Court of Appeals, Division II (hereafter, "DOH Brief") at 19 (DRGs are used to "classify inpatient discharges" for reimbursement purposes). To comply with its obligation to include outpatient data in the PCI need methodology, DOH obtains such data from hospital survey responses and the Clinical Outcomes Assessment Program (COAP), as required by WAC 246-310-745(7) and (9). The

survey form that DOH distributes to hospitals directs hospitals to use ICD-10 codes to identify outpatient PCIs. AR 871.

The 31 PCIs identified by Trios met one or more of the definitions in DRGs 246 through 251 but were coded with a different DRG based on other factors related to each patient's hospital stay and not the PCI itself. AR 345 (declaration of Trios consultant explaining that in each of the 31 cases, the patient received a procedure with an ICD-10 code corresponding to one or more of DRGs 246-251). Trios located the 31 PCIs within the Comprehensive Hospital Abstract Reporting System (CHARS). AR 849. CHARS is a DOH system containing data on inpatient PCIs. WAC 246-310-745(7)(a), (9); *see also* AR 235 (deposition testimony from DOH analyst that CHARS contains data on inpatient PCI volume but not outpatient PCI volume). Nothing prevented other hospitals or DOH from obtaining or reviewing the data that Trios reviewed. *See* AR 288 (Huyck deposition testimony that ICD-10 codes are visible within CHARS and that

he has looked at such data "to understand what DRGs certain PCI procedure codes might fall into").

Trios demonstrated that when the 31 PCIs described above were included in an assessment of need, need in Planning Area 2 was established. AR 851.

E. DOH refused to consider the omitted PCIs and denied Trios's application.

DOH's refusal to consider the 31 PCIs not coded with DRGs 246-251 was not based on a disagreement over whether the PCIs met the relevant DRG definitions. DOH's analyst who reviewed Trios's application testified that she did not consider the additional 31 PCIs because she believed (incorrectly) that the data was not publicly available, and she did not know if the PCIs met the relevant definitions. AR 251-254. DOH has since conceded that "discharged patients with cases classified by DRGs other than 246-251 may have received a PCI while in the hospital." DOH Brief at 20; Decision at 10. DOH does not deny that such PCIs meet the definitions of DRGs 246-251.

DOH denied Trios's application in a written evaluation issued in February 2020. AR 9-71. DOH erroneously concluded that there was insufficient need for a new PCI provider in Planning Area 2 and therefore, WAC 246-310-210(1) was not satisfied. AR 34. Based solely on this conclusion, DOH concluded that Trios's application also did not satisfy other CN criteria. AR 51, 59, and 70-71 (finding certain requirements under WAC 246-310-220, 230, and 240 not satisfied based on the application's alleged failure to satisfy WAC 246-310-210); *see also* AR 914-918 (analysis by DOH that Trios would meet various criteria "contingent upon a demonstration of need").

F. DOH's erroneous calculation of need and refusal of a CN was endorsed and affirmed in the administrative review process.

Applicants who are denied a CN have the right to a proceeding before DOH's Adjudicative Service Unit. WAC 246-310-610(1). Trios timely initiated such a proceeding. AR 2-7. The parties to the proceeding were Trios, DOH, and Kadlec as a permitted intervenor. AR 172-174. Before the scheduled hearing,

Kadlec moved for summary judgment against Trios, arguing that DOH was barred from considering the omitted PCIs on grounds described below. AR 180-195. DOH joined in Kadlec's motion on the basis that its calculation of need did not justify a new provider of elective PCIs in Planning Area 2. AR 317. A Health Law Judge granted Kadlec's motion in Findings of Fact, Conclusions of Law, and Initial Order on Summary Judgment (the "Initial Order"). AR 529-544. On further administrative review requested by Trios under WAC 246-310-701(1), the Initial Order was affirmed by a Final Order on Summary Judgment and Cross-Motion for Summary Judgment dated October 22, 2021 (the "Final Order"). AR 582-589. The Final Order was affirmed in Thurston County Superior Court by order dated September 7, 2022. Trios timely appealed. The Court of Appeals affirmed in an opinion dated October 17, 2023.[5]

[5] In addition to the issue presented for review in this Petition, the court of appeals also decided a separate issue related to permissible data sources for the methodology. The court affirmed DOH's decision to exclude additional data of PCI use introduced by Trios (other than the 31 PCIs) because the data did not come from one of three listed in WAC 246-310-745(7). Decision at 12-14. Trios does not agree with, but does not seek review of, the court's determination on this issue.

VI. ARGUMENT WHY REVIEW SHOULD BE GRANTED

A. Standard of Review.

The party challenging agency action has the burden of proof, but this Court must make a de novo judgment whether DOH adhered to the methodology in WAC 246-310-745, a copy of which is attached hereto. *Cobra Roofing Serv. v. Dep't of Labor and Indus.,* 122 Wn. App. 402, 409, 97 P.3d 17 (2004). "If the meaning of a rule is plain and unambiguous on its face the court should give effect to that plain meaning." *Davita Healthcare Partners, Inc. v. Washington State Dep't of Health,* 192 Wn. App. 102, 114, 365 P.3d 1283 (2015); *see also Overlake,* 170 Wn.2d at 52. Only when there is more than one reasonable interpretation does ambiguity exist and then the court "may resort to statutory construction, legislative history, and relevant case law in order to resolve the ambiguity." *Overlake,* 170 Wn.2d at 52.

This Court has granted deference to agency interpretation of its rules in carrying out its administrative function, but only

when the "agency's interpretation is plausible and consistent with the legislative intent." *Alpine Lakes Prot. Soc'y v. Dep't of Nat. Res.*, 102 Wn. App. 1, 14, 979 P.2d 929 (1999). Thus, the Court must first determine whether WAC 246-310-745(4) is ambiguous before turning to DOH's explanation. *Kenmore MHP LLC v. City of Kenmore,* 1 Wn. 3d 513, 522, 528 P.3d 815 (2023). On the question of legislative intent, the Court's "paramount concern is to ensure that the regulation is interpreted in a manner that is consistent with the underlying policy of the statute." *Overlake,* 170 Wn.2d at 52; *see also Bostain v. Food Exp., Inc.*, 159 Wn.2d 700, 716, 153 P.3d 846 (2007) ("deference to an agency's interpretation is never appropriate when the agency's interpretation conflicts with a statutory mandate"); *Cobra*, 122 Wn. App. at 409 (courts must "ensure that the agency applies and interprets its regulations consistently with the enabling statute.").

Rules of statutory construction apply to administrative regulations. *Overlake,* 170 Wn.2d at 51-52. A regulation's plain meaning must be enforced. *Id.* at 52. "A term in a regulation

should not be read in isolation but rather in the context of the regulatory and statutory scheme as a whole." *Id.* (internal quotations omitted). And, the Court "should not construe a regulation in a manner that is strained or leads to absurd results." *Id.*

Finally, in this case the agency's final action was an order on summary judgment. Consequently, the Court must overlay the error of law standard with the summary judgment standard, and review the agency's interpretation or application of the law de novo while viewing the facts in the light most favorable to the nonmoving party. *State Dep't. of Revenue v. Bi-Mor, Inc.*, 171 Wn. App. 197, 202, 286 P.3d 417 (2012).

Rule on Appeal 13.4 governs whether this Court will accept review. We explain below that review should be accepted under subpart (b)(1) because the court of appeals' application of agency deference principles conflicts with this Court's cases. Review should also be accepted under subpart (b)(4) because the

lower court decisions have frustrated legislative intent to ensure important health care for Washington residents.

B. Plain meaning of the regulation.

The crux of the error by the tribunals below is their failure to construe WAC 246-310-745(4) and deference to DOH's practices in applying the regulation. The following facts are not disputed. The WAC defines PCIs as "cases as defined by" DRGs that "describe catheter-based interventions involving the coronary arteries and great arteries of the chest…" DRG codes are generally used to define services for the purpose of hospital billing and each DRG code corresponds to a definition in a manual published by CMS which contains associated ICD-10 codes. AR 345. The 31 PCIs identified by Trios met one or more of the definitions in DRGs 246–251, but were coded with a different DRG based on other factors related to each patient's hospital stay and not the PCI itself. *Id.*

If every PCI at issue received a corresponding DRG code, there would no dispute here as DOH concedes that Trios

identified a sufficient number of PCIs to exceed the regulatory need threshold. DOH insists, however, that "defined by" really means "coded by" and consequently, it may limit its calculation of PCIs to a list derived from DRG coding, even though it concedes that PCIs not coded with applicable DRGs will be excluded. DOH Brief at 21-22 ("DRGs that do not describe a PCI, but in which the patient may have received a PCI as indicated by procedure code are not on the list and are not counted."). "Defined by" is not synonymous with "coded by" and DOH could have used the latter phrase in WAC 246-310-745(4). It did not and cannot now ignore the distinction.

The decision on review—the Final Order from the Health Law judge—does not attempt to parse the regulation and merely agrees with DOH's interpretation:

> The methodology in WAC 246-310-745 does not count every PCI performed. When this application was submitted, the [CN] Program could only include PCI cases defined by DRGs 246-251 [sic] described catheter-based interventions involving the coronary arteries and great arteries of the chest pursuant to the definition in WAC 246-310-745(4).

> Therefore the Program cannot consider the additional PCI proposed by Trios.

Final Order at 5. This does not persuade or even engage the issue. Trios, not DOH, counted all PCIs defined by the relevant DRGs. DOH counted only those coded with DRGs 246–251. The Health Law Judge had nothing to say about the distinction. The court of appeals had more to say and we turn to its analysis next.

The DOH brief in the court of appeals made no attempt at parsing the language in the regulation. That is, it did not explain why "defined by" means "coded by." *See* DOH Brief at 21 (claiming that Trios's argument distinguishing "defined by" from "coded by" is a "distraction."). Instead, DOH stated its own preferred outcome. The centerpiece of DOH's argument is this: that WAC 246-310-745 does "not count every PCI performed…the methodology instead counts a specific subset of PCIs defined by DRGs under the CMS classification system" and the "explicit text of the rule—'[PCIs] means cases as defined by [DRGs]'—makes this plain." DOH Brief at 21. This merely

repeats the regulation without giving effect to its key language and does more to prove Trios's point than DOH's.

In seeking to bolster its position, the DOH Brief reveals that DOH is actually rewriting the regulation to serve its purposes. This is what it says:

> The Department's rule expressly limits the PCI cases counted in the methodology to a certain list of DRGS that describe a PCI. DRGS that do not describe a PCI, but in which the patient may have received a PCI as indicated by the procedure code are not on the list and are not counted.

DOH Brief at 21-22. DOH is saying here that the regulation allows it to create a list based on DRG codes and it need not count any PCI that was not coded with the specified DRGs. DOH acknowledges that other PCIs may have met the DRG definitions, but they do not go on the list to be counted. This approach illustrates DOH's labor saving goal of using codes to locate PCIs, but it does not parse the regulation and cannot be squared with the directive that PCIs mean "cases defined by diagnosis related groups." WAC 246-310-745(4).

The court of appeals also did not attempt a construction of the key language. At page 10 of its Decision, the court of appeals recapped DOH's concession that use of DRG coding may not identify all patients who received a PCI while in a hospital, but it then simply restates the conclusion that all PCIs are not counted—without any explanation of why. Decision at 10. What is entirely lacking is any parsing of the actual language of the regulation or explanation of the choice of "defined by" instead of "coded by." Nor did either DOH or the court of appeals explain why PCIs meeting the DRG definition should be excluded in calculating need.

Thus, the court of appeals starts by conceding that DOH's approach undercounts PCIs, which on its face is an impermissible "strained or absurd" result because the purpose of the regulation is to count PCIs, but then simply adopts a conclusion about the outcome of the regulation tracking DOH's position. This does not address Trios's analysis of the plain

meaning of the regulation and it does not qualify for any form of deference.

Any regulatory construction must also consider the remainder of the regulations as they bear on plain meaning. Of importance here, WAC 246-310-745 requires DOH to count both inpatient and outpatient PCIs. WAC 246-310-745(10), Step 1 ("Compute each planning area's PCI use rate calculated for persons fifteen years of age or older, including inpatient and outpatient PCI case counts."); *see also* WAC 246-310-745(7) (data sources for the methodology include survey data collected from hospitals indicating "whether the PCI was performed on an inpatient or outpatient basis"); WAC 246-310-745(9) (hospital survey data is intended to "bridge the current outpatient patient origin-specific data shortfall" in other data sources). Because DRG codes are only applied to inpatient care, limiting the count of PCIs to those coded with a DRG will exclude outpatient PCIs in direct contravention of the regulation. Both DOH and the court of appeals ignored this point. Deference to agency interpretation

does not countenance this refusal to apply the relevant provisions of the regulation.

C. Legislative intent.

All statutory or regulatory analysis must target the intent of the legislature. *Overlake,* 170 Wn.2d at 51. The starting point for analysis is this Court's counsel that the "overriding purpose" of the CN program is to "promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower [and] health facilities." *Overlake,* 170 Wn.2d at 55.

Judging the parties' positions with this in mind, Trios's construction of the "defined by" language in WAC 246-310-745(4) results in counting all eligible PCIs in the need determination and is easily squared with the intent of the legislature to promote "the health of all citizens of the state" while "controlling increases in costs." Counting all PCIs allows a comprehensive need forecast. Grant of a CN for needed PCI services gives the public more access to health care and choice

in providers. More supply also protects against increased prices, also a goal of the CN statute.

It is much harder to see how DOH's "coded by" approach with conceded undercounting of PCIs helps the public in any way. The only obvious beneficiary is Kadlec, which will avoid competition and maximize profit based on limited supply of PCI services. DOH also seems to suggest that it will benefit because the CN process will be easier for it and more transparent for applicants.

The Health Law Judge's Final Order did not discuss legislative intent. DOH's briefing has taken on the issue. Responding to Kadlec's summary judgment motion, DOH claimed that its methodology helped assure that competitors receive fair and evenhanded treatment. AR 322. This does not persuade because the record is clear that all applicants have access to the data used by Trios and obtained from CHARS, a publicly available source maintained by DOH. Moreover, making life easier for applicants is not a stated legislative

purpose. DOH also argued that Trios's method of counting using procedure codes to locate qualifying PCIs was "laborious", AR 586, but did not explain why saving labor for applicants and DOH was a legislative goal that might compete with providing available health care for all Washington residents.

In the court of appeals, DOH reframed its legislative intent argument to acknowledge that one purpose of the need forecast is to "optimize provider effectiveness, quality of service, and improved outcomes of care," citing the definition of tertiary services in RCW 70.38.025(14) and argued that adherence to the patient volume threshold is consistent with the statute's purpose. This is certainly accurate but it undermines DOH's claim. If adherence to volume standards is important, then all qualifying PCIs should be counted. DOH's statement elsewhere that not all PCIs should be counted (see DOH Brief at 22) cannot be squared with its argument on legislative intent nor the actual intent of the legislature.

The court of appeals adopted DOH's view on legislative intent almost verbatim, Decision at 11-12, reasoning that adherence to volume requirements helps protect competitors such as Kadlec by ensuring sufficient patient volume, and keeping accurate need projections is necessary for health planning and resource development. Both of these arguments depend on the false premise that Trios's supplemental PCI data is unreliable in any respect. As DOH has conceded the accuracy of Trios's identification of additional PCIs and does not contest its availability in public resources (CHARS), there is no accuracy concern that might support a different construction. This is no help on the question at issue here: does counting all PCIs meeting the DRGs definition advance the legislative intent to enhance health care for residents. The court of appeals did not take this Court's counsel that the "overriding purpose" of the CN program is to "promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower [and] health facilities." *Overlake,* 170 Wn.2d at 55. Counting all

eligible PCIs advances that purpose. Deferring to DOH's preference to work off a list based on coding does not.

VII. CONCLUSION

This Court should grant review to address the important issues identified above and to ensure the CN law is applied in a manner consistent with its purpose.

RESPECTFULLY SUBMITTED this 16th day of November, 2023.

I certify that the foregoing memorandum contains 4,982 words, excluding words contained in the title sheet, tables of contents and authorities, certificate of service, signature blocks, any pictorial images or appendices, and this certificate.

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CERTIFICATE OF SERVICE

On said day below I electronically served a true and accurate copy of the Petition for Review in Division II, Cause No. 57403-9-II to the following parties:

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I declare under penalty of perjury under the laws of the State of Washington and the United States that the foregoing is true and correct.

Dated this 16th day of November, 2023 at Seattle, Washington.

/s/Chris Hoover
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Exhibit A

Filed
Washington State
Court of Appeals
Division Two

October 17, 2023

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

RCCH TRIOS HEALTH, LLC, a Delaware Limited Liability Company, Appellant, v. DEPARTMENT OF HEALTH OF THE STATE OF WASHINGTON and KADLEC REGIONAL MEDICAL CENTER, Respondents.	No. 57403-9-II PUBLISHED OPINION

MAXA, P.J. – RCCH Trios Health LLC (Trios) appeals an administrative final order in which the Department of Health (DOH) denied Trios a certificate of need (CN) to perform elective percutaneous coronary interventions (PCIs).

Health care facilities without on-site cardiac services are allowed to perform elective PCIs only after obtaining a CN from DOH, which requires a showing of projected net need of at least 200 PCIs a year. For purposes of need forecasting, the definition of PCIs in the CN regulation is "cases as defined by diagnosis related groups (DRGs)" that involve certain cardiac procedures. WAC 246-310-745(4). To calculate net need, DOH gathers data from three sources: (1) the comprehensive hospital abstract reporting system (CHARS), (2) surveys DOH

sends out to PCI providers, and (3) clinical outcomes assessment program (COAP) data. WAC 246-310-745(7).

DOH released a methodology that showed the net need for PCIs in each of 14 PCI planning areas using DRGs 246-251. DOH calculated that the net need for PCIs in Trios's planning area would be 182, less than the 200 procedure threshold.

Trios, located in planning area 2, decided to apply to DOH for a CN in 2019 to perform elective PCIs. At the time, Kadlec Regional Medical Center (Kadlec) was the only other hospital in planning area 2 that was performing elective PCIs.

Trios attempted to introduce data from sources other than DOH used as a part of its application to demonstrate that the net need for PCIs was over the 200 procedure threshold. Specifically, Trios identified 31 cases where PCIs had been performed but had not been coded under DRGs 246-251. And Trios claimed that DOH should count PCIs performed on residents of planning area 2 in Oregon, Idaho, and a closed Walla Walla hospital that had not reported to DOH. But DOH concluded that it could not consider Trios's sources and denied Trios's application.

Trios initiated a review procedure before an administrative health law judge (HLJ). Kadlec was allowed to intervene and filed a motion for summary judgment. The HLJ granted summary judgment and affirmed DOH's CN denial in an initial order. Trios appealed, and the review officer affirmed in a final order. Trios then appealed the final decision to superior court, which denied Trios's petition for judicial review.

We hold that (1) the 31 PCIs not coded under DRGs 246-251 did not fall within the definition of PCIs in WAC 246-310-745(4) and therefore could not have been counted in the

determination of need, and (2) DOH's refusal to consider Trios's proffered data was not contrary to law because it was based on a reasonable interpretation of WAC 246-310-745(7) and WAC 246-310-745(9). Accordingly, we affirm the review officer's final order.

FACTS

Background

A medical provider can operate certain facilities and perform certain procedures in Washington only after obtaining a CN. RCW 70.38.105(3)-(4). Procedures requiring a CN include new tertiary health services. RCW 70.38.105(4)(f). Elective PCIs are tertiary services. WAC 246-310-700. The legislature directed DOH to adopt rules establishing criteria for the issuance of CNs for elective PCIs at hospitals that do not otherwise provide on-site cardiac surgery. RCW 70.38.128. DOH adopted such rules in WAC 246-310-700, et seq.

The definition of PCIs in the CN regulation, for purposes of need forecasting, is "cases as defined by [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). DRGs are codes assigned to patients who are hospitalized. DOH identified the relevant DRGs for 2019 as DRGs 246-251, which typically are assigned to patients who receive PCIs. However, a different DRG might be assigned even if the patient received a PCI if another procedure outweighs the PCI or other factors make a different DRG more appropriate.

Hospitals with an elective PCI program must perform at least 200 adult PCIs per year by the end of the third year of operation. WAC 246-310-720(1). DOH will issue a CN for elective

PCIs to a new program only if projected unmet need within the relevant planning area meets or exceeds the minimum volume standard of 200 procedures. WAC 246-310-720(2).

WAC 246-310-745(7) states that the data sources for determining adult elective PCI volumes "include":

> (a) The comprehensive hospital abstract reporting system (CHARS) data from the department, office of hospital and patient data;
> (b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and
> (c) Clinical outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department.

In addition, WAC 246-310-745(9) states that the data used for evaluating CN applications "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."

CN Application

Trios is a hospital in Kennewick. Trios is located in planning area 2, which includes Benton, Columbia, Franklin, Garfield, and Walla Walla counties. Trios began providing emergent PCI services in 2012 but does not employ interventional cardiologists.

DOH published a methodology that showed the projected need for PCIs in each planning area. DOH calculated that the net need for PCIs in planning area 2 would be 182.

Trios applied for a CN for elective PCIs in 2019. Trios acknowledged that DOH's assessment of 182 was below the 200 case requirement, but stated that it had identified a number of areas in which the methodology had missed data. First, Trios highlighted that there was no count or attempt to count residents of planning area 2 who received PCIs in either Oregon or Idaho. Second, Trios noted that a Walla Walla hospital closed in 2017 and did not report any

outpatient data in 2016 or 2017, which meant the hospital underreported PCIs. Including data from those sources, Trios believed that the patient net need for PCIs would exceed 200.

During the review of Trios's application, DOH was able to access Oregon's inpatient database and updated the methodology to include these publicly accessible PCIs. DOH's updated methodology increased the projected need from 182 to 188.

DOH opened the application for public comment. DOH received comments from those opposing Trios's application, including Kadlec, the only facility in planning area 2 that could perform elective PCIs.

Trios also submitted comments. Trios again commented that DOH should be able to consider the additional data from Idaho and the Walla Walla hospital that Trios submitted because although WAC 246-310-745(7) lists CHARS, survey data and COAP as data sources, it does not say that DOH is limited to only those three sources. Trios also commented that it had located an additional 31 PCIs in the CHARS database identified by their ICD-10 procedure code that were not coded under DRGs 246-251. Trios commented that DOH should include these PCIs in the projected need calculation.[1]

In February 2020, DOH denied Trios's CN application. DOH did not consider Trios's additional data. Therefore, Trios was unable to meet the 200-procedure threshold. DOH stated that "[t]o accept novel data sources that could not have been [publicly] available prior to the concurrent review cycle changes the process and removes the element of transparency, fairness, and predictability in a Certificate of Need review." Admin. Rec. (AR) at 32.

[1] Trios initially identified an additional 52 PCIs, but reduced that number to 31. The excluded PCIs included the ones from the Walla Walla hospital.

Procedural History

Trios requested an administrative hearing with a HLJ to contest the denial of the CN. The presiding officer allowed Kadlec to join as an intervenor.

Before the scheduled hearing, Kadlec moved for summary judgment, arguing that Trios's CN denial should be affirmed because DOH's methodology did not project a need for the PCI program. In response, Trios submitted a declaration from Jody Carona, the principal of Health Facilities Planning and Development. She stated in her declaration that the 31 PCIs they identified were coded with a different DRG than DRGs 246-251, but they could have been coded with DRGs 246-251 if a different DRG had not taken precedence based on the patient's condition.

The HLJ granted Kadlec's motion for summary judgment and issued an initial order with findings of fact and conclusions of law. The HLJ rejected Trios's argument that the additional 31 PCIs identified using the ICD-10 procedure code should be included in the need projections. The HLJ concluded that "WAC 246-310-745(4) is clear in requiring that PCIs be defined by DRGs – not procedure codes – when calculating need for new PCI programs." AR at 433. Regarding Trios's argument that data from other sources – like Oregon and Idaho – should be used, the HLJ rejected the argument that the word "include" in WAC 246-310-745(7) allowed considerations of other sources besides the three listed. AR at 432. Trios petitioned for administrative review of the initial order. The review officer issued findings of fact and conclusions of law in a final order that adopted and affirmed the initial order.

In addressing WAC 246-310-745(4), the review officer stated, "The methodology in WAC 246-310-745 does not count every PCI performed. When this application was submitted,

[DOH] could only include PCI cases defined by DRGs 246-251. . . . Therefore, [DOH] cannot consider the additional PCIs proposed by Trios." AR at 586.

Regarding the data sources DOH could consider, the review officer concluded,

> The word 'include' may be either exhaustive or nonexhaustive depending on the context. Whereas, use of 'including, but not limited to' has consistently been interpreted by the courts as an illustrative, not exhaustive, list. The context of WAC 246-310-745 point towards interpreting 'include' in subsection (7) as indicating an exhaustive list of data sources because subsection (9) states the data used 'must' be from three specific data sources. WAC 246-310-745(7) only identifies these three specific state data sources and does not open the door to equivalent data sources . . . this Reviewing Officer finds the data sources identified are the exhaustive list.

AR at 585 (citations omitted).

Trios then petitioned for judicial review of the final order. The superior court affirmed the final order and denied Trios's petition for judicial review.

Trios appeals the superior court's denial of judicial review of the review officer's final order.

ANALYSIS

A. STANDARD OF REVIEW

Under the Administrative Procedure Act (APA), chapter 34.05 RCW, we consider the record before the agency and sit in the same position as the superior court. *Kenmore MHP LLC v. City of Kenmore*, 1 Wn.3d 513, 519-520, 528 P.3d 815 (2023).

The APA provides nine grounds for reversing an administrative order. RCW 34.05.570(3). Three grounds potentially are applicable here: (1) the agency erroneously interpreted or applied the law, RCW 34.05.570(3)(d); (2) the order is inconsistent with a rule of the agency, RCW 34.05.570(3)(h); and (3) the order is arbitrary and capricious, RCW

34.05.570(3)(i). The party challenging the agency's decision has the burden of demonstrating the invalidity of that decision. RCW 34.05.570(1)(a).

When an administrative decision is decided on summary judgment, we overlay the APA and summary judgment standards of review. *Waste Mgmt. of Wash., Inc. v. Wash. Util. and Transp. Comm'n*, 24 Wn. App. 2d 338, 344, 519 P.3d 963 (2022), *rev. denied*, 1 Wn. 3d 1003 (2023). We review the ruling de novo and construe the facts and all reasonable inferences in the light most favorable to the nonmoving party. *Id.* Summary judgment can be determined as a matter of law if the material facts are not in dispute. *Antio LLC v. Dep't of Revenue*, 26 Wn. App. 2d 129, 134, 527 P.3d 164 (2023).

We review an agency's legal conclusions de novo and give substantial deference to the agency's interpretation of its own regulations when that subject area falls within its area of expertise. *Waste Mgmt. of Wash.*, 24 Wn. App. 2d at 344. We may substitute our own interpretation of the law for that of the agency. *Id.* But we generally will uphold an agency's "interpretation of ambiguous regulatory language as long as the agency's interpretation is plausible and consistent with the legislative intent." *Kenmore MHP*, 1 Wn.3d at 520. " 'An agency acting within the ambit of its administrative functions normally is best qualified to interpret its own rules, and its interpretation is entitled to considerable deference by the courts.' " *Id.* (quoting *D.W. Close Co. v. Dep't of Lab. & Indus.*, 143 Wn. App. 118, 129, 177 P.3d 143 (2008)).

B. DEFINITION OF PCI

Trios argues that DOH erroneously refused to include in its projected need calculation the 31 additional PCIs it identified that were not coded under DRGs 246-251 because those PCIs fell within the definition of "PCI" in WAC 246-310-745(4). We disagree.

For purposes of need forecasting, WAC 246-310-745(4) defines PCIs to mean

> 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. . . . . The department will update the list of DRGs administratively to reflect future revisions made by CMS to the DRG to be considered in certificate of need definitions, analyses, and decisions.

(Emphasis added.) At the time of Trios's application, the DRGs to be considered were DRGs 246-251.

The additional 31 PCIs Trios identified were not coded under DRGs 246-251. However, Trios emphasizes that the 31 PCIs *could* have been coded under DRGs 246-251 and therefore would have been considered by DOH if a different DRG had not taken precedence. Trios states,

> Putting the case in concrete terms, if you go to the hospital with chest pain and receive a PCI and your visit is assigned a DRG code on that basis, [DOH] will count your PCI for its need calculation. If you go to the hospital for a different reason and your care is coded on that basis, and the doctor determines you also need a PCI, [DOH] will not count that PCI for need purposes even though the same procedure was performed.

Br. of Appellant at 22-23.

Resolution of this issue depends on the interpretation of the phrase "cases as defined by [DRGs]" in WAC 246-310-745(4). Trios argues that "as defined by" means that a procedure meets the definition of PCI if it is *capable of* being coded under DRGs 246-251, even though they were not actually coded under those DRGs. Trios emphasizes that if the drafters of WAC

246-310-745(4) had wanted to limit the definition of PCI to only those procedures *actually* coded under DRGs 246-251, they easily could have done so. But the drafters used "defined by" instead of "coded as," thereby negating such a limitation. And according to Trios, DOH's interpretation has the effect of undercounting PCIs and preventing the issuance of a CN when there is a need.

DOH does not dispute that patients with cases classified with DRGs other than DRGs 246-251 may have received a PCI while in the hospital. But DOH emphasizes that WAC 246-310-745(4) deliberately does not count every PCI performed. Instead, to forecast projected need the regulation counts a specific subset of PCIs – those defined by DRGs under the CMS classification system. Patients that may have received a PCI as indicated by a procedure code but were discharged under a different DRG code simply are not counted. DOH notes that if "defined by [DRGs]" does not mean that it must use DRGs in its need projections, the reference to DRGs in WAC 246-310-745(4) would be meaningless. Kadlec argues that the use of well-defined DRG data rather than other alternatives helps assure that applicants are treated evenhandedly and fairly.

We conclude that the plain language of WAC 246-310-745(4) supports DOH's position. For purposes of need forecasting, WAC 246-310-745(4) expressly defines PCIs with reference to DRGs, not ICD-10 procedure codes. In drafting this regulation, DOH could have defined PCI more generally as *any* "catheter-based interventions involving the coronary arteries and great arteries of the chest." Or DOH could have defined PCIs with reference to ICD-10 procedure codes. Instead, the regulation limits the definition to those procedures classified under certain DRG codes. The fact that certain procedures *could* have been coded under DRGs 246-251 is immaterial.

Significantly, the CN regulation contains a general definition of PCIs that does not reference DRG codes. WAC 246-310-705(4). But WAC 246-310-745 contains more specific definitions "[f]or the purposes of the need forecasting method." As noted, the specific definition of PCIs in WAC 246-310-745(4) references DRG codes. If the PCIs included in the need calculation were not defined with reference to DRG codes, DOH could simply have used the general WAC 246-310-705(4) definition.

Even 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. *Waste Mgmt. of Wash.*, 24 Wn. App. 2d at 344. DOH is best qualified to interpret its own rules. *See Kenmore MHP*, 1 Wn.3d at 520.

Trios argues that we should not give deference to DOH's interpretation of WAC 246-310-745(4) because DOH's position is contrary to legislative intent. One public policy underlying the CN program is to "promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower, health facilities, and other resources while controlling increases in costs." RCW 70.38.015(1). Trios argues that counting all PCIs and not only those PCIs coded under DRGs 246-251 promotes this policy because such an approach provides a more accurate assessment of need.

DOH relies on the definition of "tertiary health service" in RCW 70.38.025(14), which states that such service "requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." DOH asserts that strictly adhering to the mandatory patient volume threshold is consistent with "promot[ing], maintain[ing], and assur[ing] the health of all citizens in the state," a stated public policy underlying the CN

program. RCW 70.38.015(1). And adherence to the volume threshold helps ensure that other CN providers like Kadlec have sufficient patient volume to "optimize provider effectiveness, quality of service, and improved outcomes of care." RCW 70.38.025(14).

In addition, another public policy of the CN program is that "the development and maintenance of adequate health care information, statistics, and projections of need for health facilities and services is essential to effective health planning and resources development." RCW 70.38.015(3). DOH has implemented this policy by relying on DRG codes to project need for PCI services.

We conclude that DOH's interpretation of WAC 246-310-745(4) is consistent with legislative intent and we give deference to that interpretation. *See Kenmore MHP*, 1 Wn.3d at 520.

We hold that DOH's refusal to consider the 31 additional PCIs identified by Trios was not based on an erroneous interpretation of WAC 246-310-745(4). Therefore, we affirm the review officer's final order on this issue.

C. APPLICABLE DATA SOURCES

Trios argues that DOH erroneously refused to consider data from sources other than the three sources listed in WAC 246-310-745(7). We disagree.

WAC 246-310-745(7) states,

> (7) The data sources for adult elective PCI case volumes *include*:
>
> (a) The comprehensive hospital abstract reporting system (CHARS) data from the department, office of hospital and patient data;
>
> (b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient

> origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and
>
> (c) Clinical outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department.

(Emphasis added.) Trios argues that the word "include" in WAC 246-310-745(7) means that the three sources listed are examples, not an exclusive list. Therefore, DOH can consider other data sources as well.

The cases support Trios's position. The word "include" generally indicates that the following list is illustrative, not exclusive. *City of Edmonds v. Bass*, 16 Wn. App. 2d 488, 499, 481 P.3d 596 (2021), *aff'd*, 199 Wn.2d 403, 414, 508 P.3d 172 (2022). "[O]ur Supreme Court generally recognizes that a statute that uses the term 'including' is one of enlargement, not restriction." *Id.* (citing *Queets Band of Indians v. State*, 102 Wn.2d 1, 4, 682 P.2d 909 (1984)); *see also Brown v. Scott Paper Worldwide Co.*, 143 Wn.2d 349, 359, 20 P.3d 921 (2001); *Wheeler v. Dept. of Licensing*, 86 Wn. App. 83, 88, 936 P.2d 17 (1997).

However, DOH and Kadlec argue – and the HLJ and the review officer ruled – that WAC 246-310-745(7) must be read in context with WAC 246-310-745(9). WAC 246-310-745(9) states, "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.)

DOH's argument is that WAC 246-310-745(9) states that the data used in evaluating CN applications "must be" from the three sources listed in WAC 246-310-745(7). DOH claims that

harmonizing subsections (7) and (9) compels the interpretation that the three sources listed in WAC 246-310-745(7) are exhaustive.

Trios argues that WAC 246-310-745(9) relates to the time frames to be used when data is collected from the listed sources rather than restricting the available data sources. This interpretation is not unreasonable. The term "must be" in WAC 246-310-745(9) appears right before the phrase "the most recent end year data." Arguably, the term is directing DOH to use the most recently available end year data, not to only use those three sources of data. Trios also points out that DOH used data from Oregon hospitals in this case and on other prior occasions, even though that data was not from the sources listed in WAC 246-310-745(7).

But DOH's position also is reasonable. WAC 246-310-745(9) can be interpreted as stating that the data used for evaluating CN applications "must be" from the three listed data sources. And the fact that WAC 246-310-745(9) only lists out the same three sources of data contained in subsection (7) suggests that the drafter only contemplated the use of those sources and not some other sources. That subsection could have – but did not – refer generically to "data sources" rather than specifying the sources listed in WAC 246-310-745(7).

Because the language of WAC 246-310-745(9) is ambiguous, we give deference to DOH's position because the regulation falls within its area of expertise. *Waste Mgmt. of Wash.*, 24 Wn. App. 2d at 344. DOH is best qualified to interpret its own rules. *See Kenmore MHP*, 1 Wn.3d at 520.

We hold that WAC 246-310-745(7) is an exhaustive list and that DOH could not consider other sources. Therefore, we affirm the review officer's final order on this issue.

CONCLUSION

We affirm the review officer's final order.

MAXA, P.J.

We concur:

LEE, J.

CHE, J.

Exhibit B

WAC 246-310-745 Need forecasting methodology. For the purposes of the need forecasting method in this section, the following terms have the following specific meanings:

(1) "Base year" means the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the department's CHARS reports or successor reports.

(2) "Current capacity" means the sum of all PCIs performed on people (aged fifteen years of age and older) by all certificate of need approved adult elective PCI programs, or department grandfathered programs within the planning area. To determine the current capacity for those planning areas where a new program has operated less than three years, the department will measure the volume of that hospital as the greater of:

(a) The actual volume; or

(b) The minimum volume standard for an elective PCI program established in WAC 246-310-720.

(3) "Forecast year" means the fifth year after the base year.

(4) "Percutaneous coronary interventions" means 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. The department will exclude all pediatric catheter-based therapeutic and diagnostic interventions performed on persons fourteen years of age and younger are excluded. The department will update the list of DRGs administratively to reflect future revisions made by CMS to the DRG to be considered in certificate of need definitions, analyses, and decisions. The DRGs for calendar year 2008 applications will be DRGs reported in 2007, which include DRGs 518, 555, 556, 557 and 558.

(5) "Use rate" or "PCI use rate," equals the number of PCIs performed on the residents of a planning area (aged fifteen years of age and older), per one thousand persons.

(6) "Grandfathered programs" means those hospitals operating a certificate of need approved interventional cardiac catheterization program or heart surgery program prior to the effective date of these rules, that continue to operate a heart surgery program. For hospitals with jointly operated programs, only the hospital where the program's procedures were approved to be performed may be grandfathered.

(7) The data sources for adult elective PCI case volumes include:

(a) The comprehensive hospital abstract reporting system (CHARS) data from the department, office of hospital and patient data;

(b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and

(c) Clinical outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department.

(8) The data source for population estimates and forecasts is the office of financial management medium growth series population trend reports or if not available for the planning area, other population data published by well-recognized demographic firms.

(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. The

forecasts for demand and supply will be for five years following the base year. The base year is the latest year that full calendar year data is available from CHARS. In recognition that CHARS does not currently provide outpatient volume statistics but is patient origin-specific and COAP does provide outpatient PCI case volumes by hospitals but is not currently patient origin-specific, the department will make available PCI statistics from its hospital survey data, as necessary, to bridge the current outpatient patient origin-specific data shortfall with CHARS and COAP.

(10) Numeric methodology:

Step 1. Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient PCI case counts.

(a) Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.

(b) Divide the total number of PCIs performed on the planning area residents over fifteen years of age by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Step 2. Forecasting the demand for PCIs to be performed on the residents of the planning area.

(a) Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.

Step 3. Compute the planning area's current capacity.

(a) Identify all inpatient procedures at certificate of need approved hospitals within the planning area using CHARS data;

(b) Identify all outpatient procedures at certificate of need approved hospitals within the planning area using department survey data; or

(c) Calculate the difference between total PCI procedures by certificate of need approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.

(d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.

Step 4. Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than two hundred, the department will not approve a new program.

Step 5. If Step 4 is greater than two hundred, calculate the need for additional programs.

(a) Divide the number of projected procedures from Step 4 by two hundred.

(b) Round the results down to identify the number of needed programs. (For example: 375/200 = 1.875 or 1 program.)

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-745, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-745, filed 12/19/08, effective 12/19/08.]

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