



## BACKGROUND

The material facts are not disputed.

### Certificate of Need Program

In 1979, Washington State began to regulate the number of providers entering the healthcare market. Univ. of Wash. Med. Ctr. v. Dep't of Health, 164 Wn.2d 95, 99, 187 P.3d 243 (2008). The legislature enacted the State Health Planning and Resources Development Act, creating the certificate of need (CN) program. RCW 70.38.015(2). The Department of Health administers the CN program. RCW 70.38.105(1). Designed to effectuate the goals and principles of the Act, the CN program controls the number and type of healthcare services that are provided in a specific planning area. The program ensures that services and facilities are developed in a manner consistent with the department priorities and avoids unnecessary duplication. Overlake Hosp. Ass'n v. Dep't of Health, 170 Wn.2d 43, 47, 239 P.3d 1095 (2010). Healthcare providers must obtain a CN before establishing certain healthcare facilities or providing certain procedures such as the elective percutaneous coronary intervention<sup>1</sup> (PCI) program at issue here. The need for a particular healthcare service or facility in that planning area must be demonstrated by a healthcare provider. Specific criteria in the statute and rules govern the evaluation of CN applications. Chapter 70.38 RCW; WAC 246-310.

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<sup>1</sup> A percutaneous coronary intervention is an invasive nonsurgical procedure performed by a cardiologist for the revascularization of obstructed coronary arteries. See WAC 246-310-754(4).

During 2007 and 2008, the department solicited feedback from stakeholders and the public as it sought to draft new rules that governed requirements for hospitals seeking to perform elective PCI procedures. The department enacted new PCI rules that established the minimum volume standard of 300 PCI procedures per year for each CN approved program. Each licensed program must meet or exceed this minimum volume standard or otherwise no new PCI programs may be approved under this standard.

Swedish's Certificate of Need Application

The department granted CNs for elective PCI programs to Overlake Hospital Medical Center, Valley Medical Center, EvergreenHealth, Auburn Regional Medical Center and St. Francis Hospital, all located in the King East planning area. These are the only programs authorized by the department to perform elective PCI procedures in the King East planning area. Valley, Evergreen, Auburn and St. Francis performed fewer than 300 PCI procedures per year in February 2011 when Swedish Health Services submitted its CN application to perform elective PCIs at its Issaquah campus.<sup>2</sup> These four programs also had not yet been open for three years.

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<sup>2</sup> The parties disagree on the number of PCI procedures performed by each program. It also appears the Health Law Judge's findings of fact on the number might be incorrect. But for purposes of this appeal, the parties agree on the main fact—four of the programs in the King East planning area did not meet the 300 PCI minimum volume standard. Auburn and St. Francis operate a joint PCI program. This accounts for why the Health Law Judge's conclusion of law 2.3 refers to "four PCI programs" performing less than 300 PCIs per year but parties refer to three PCI programs.

The department denied Swedish's CN application on several grounds including its failure to establish that all existing King East planning area providers met or exceeded the 300 PCI per year minimum volume standard spelled out in WAC 246-310-720.<sup>3</sup>

Swedish challenged the denial in an adjudicative proceeding presided over by a Health Law Judge.

As statutory intervener, Overlake moved for summary judgment opposing Swedish's interpretation of WAC 246-310-720's minimum volume standard and application of WAC 246-310-745's need forecasting methodology. Swedish cross moved for partial summary judgment arguing its interpretation should prevail. The Health Law Judge upheld the department's denial of Swedish's CN application on the grounds WAC 246-310-720's minimum volume standard plainly requires that all existing programs meet or exceed the 300 PCI procedure minimum volume threshold.<sup>4</sup> He found that four PCI programs in the planning area were performing fewer than 300 procedures per year.

2.3 With four PCI programs in the planning area performing less than 300 PCIs per year (the minimum number of procedures required by WAC 246-310-720(1)), Swedish's application for a new [CN] program failed to satisfy the requirement in WAC 246-310-720(2)(b) that all programs be meeting or exceeding the threshold. Thus, the Program properly denied Swedish's application.

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<sup>3</sup> The only ground relevant to the present appeal involves the minimum volume standard.

<sup>4</sup> The Health Law Judge declined to address WAC 246-310-745's need assessment issue because the failure to meet the minimum volume standard was dispositive of the CN application question.

2.4 Swedish failed to show the existence of a genuine issue of material fact. The facts are not in dispute. The conflict is in the interpretation of WAC 246-310-720.

AR 1341 (CL 2.3, 2.4).

He therefore concluded that Swedish's application under RCW 246-310-720(2)(b) must be denied.

The superior court affirmed the department's denial. The court reasoned that the statute's purpose is to promote patient safety by ensuring that new programs have the opportunity to "get up to speed." RP (October 7, 2013) at 42. It concluded that policy and WAC 246-310-720's plain text, supports the department's denial of the CN application. Swedish appealed.

## ANALYSIS

### Standards of Review

The Administrative Procedure Act (APA), RCW 34.05 standard of review applies to CN cases. RCW 70.38.115(10)(a); Providence Hosp. of Everett v. Dep't of Soc. & Health Servs., 112 Wn.2d 353, 355, 770 P.2d 1040 (1989). On a petition for review under the APA, this court sits in the same position as the superior court and reviews the validity of the contested administrative order. Wenatchee Sportsman Ass'n v. Chelan County, 141 Wn.2d 169, 176, 4 P.3d 123 (2000). The party seeking judicial review has the burden of demonstrating the invalidity of the contested administrative order. RCW 34.05.570(1)(a). In CN cases, the agency decision is presumed correct and the challenger bears the burden of overcoming the presumption. Overlake Hosp., 170 Wn.2d at 49-50.

We grant relief from an agency order in an adjudicative proceeding if the agency erroneously interpreted or applied the law, or the order is inconsistent with a rule of the agency unless the agency explains the inconsistency by stating facts and reasons to demonstrate a rational basis for the inconsistency. RCW 34.05.570(3)(d); RCW 34.05.570(3)(h). Courts must grant “substantial deference” to the department’s interpretation of the regulatory language given the agency’s “expertise and insight gained from administering the regulation that the reviewing court does not possess.” Overlake Hosp., 170 Wn.2d at 56.

Courts apply the rules of statutory construction in interpreting regulatory language. Overlake Hosp., 170 Wn.2d at 51-52. When construing the meaning of the law, the plain language of the law controls. Koenig v. City of Des Moines, 158 Wn.2d 173, 181, 142 P.3d 162 (2006). Courts cannot rewrite or modify the language of the statute under the guise of statutory interpretation or construction. Graham Thrift Grp., Inc. v. Pierce County, 75 Wn. App. 263, 267, 877 P.2d 228 (1994) (citing State v. McAlpin, 108 Wn.2d 458, 465, 740 P.2d 824 (1987)). “Our fundamental purpose in construing statutes is to ascertain and carry out the intent of the legislature. We determine the intent of the legislature primarily from the statutory language.” In re Marriage of Schneider, 173 Wn.2d 353, 363, 268 P.3d 215 (2011) (citations omitted).

Swedish assigns no error to any factual findings. Unchallenged factual findings are verities on appeal. Postema v. Pollution Control Hr’gs Bd., 142 Wn.2d 68, 100, 11 P.3d 726 (2000).

Swedish challenges the Health Law Judge's interpretation of WAC 246-310-720.

That regulation provides:

Hospital Volume Standards.

- (1) Hospitals with an elective PCI program must perform a minimum of three hundred adult PCIs per year by the end of the third year of operation and each year thereafter.
- (2) The department shall only grant a certificate of need to new programs within the identified planning area if:
  - (a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and
  - (b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.

We must decide whether the Health Law Judge properly interpreted this rule.

Swedish interprets WAC 246-310-720(2)(b) to mean that only those programs that have existed longer than three years must meet the 300 procedure minimum. In other words, a new program may be approved if all programs, except programs in existence for less than three years, meet or exceed the minimum volume standard. We disagree. Swedish's interpretation contradicts the plain text of this rule, contravenes the rule's intent, and rewrites the rule contrary to well settled principles of statutory interpretation.

The parties agree that WAC 246-310-720 is not ambiguous. There is only one reasonable interpretation of this rule that makes sense and avoids an illogical result.

WAC 246-310-720(1) establishes a 300 minimum volume standard for PCI programs. The choice of a 300 minimum standard was the result of a comprehensive study and extensive public vetting with stakeholders. See Yakima Valley Memorial Hosp. v. Washington State Dep't of Health, 731 F.3d 843 (9th Cir. 2013). The 300 PCI

minimum standard enhances patient safety by assuring that physicians and staff of a facility have sufficient patient volume to maintain their skill and competence. Yakima Valley, 731 F.3d at 849. By its terms, WAC 246-310-720(1) allows newly established programs three years to meet the minimum volume standard. This “ramp-up” period makes sense because it recognizes that new programs need time to develop a volume of patients.

WAC 246-310-720(2) governs the requirements that must be met by existing programs before a new program can be approved. WAC 246-310-720(2)(b) plainly states that no new program may be approved unless “all” existing programs meet or exceed the minimum volume standard. The use of the unambiguous term, “all” leaves no doubt that it includes all programs regardless of how long they have existed. We conclude the rule’s plain language means that all programs including those in existence for less than three years must be operating at the 300 minimum volume standard before the department may approve a new PCI program.

This interpretation is also consistent with the rule’s intent noted above. A newly established PCI program inevitably attracts new patients who otherwise would have sought services from an existing program. This negative consequence to the existing programs is the reason WAC 246-310-720(2)(b) prohibits approval of a new program unless all existing programs, including programs in existence for less than three years, are performing at least 300 procedures per year. Including all programs is logical since a program’s ability to meet the 300 PCI standard is critical to ensure patient safety no matter how long the program has existed. Yakima Valley, 731 F.3d at 849.

Swedish also contends that the Health Law Judge's order denying its CN application is erroneous because it "requires existing providers to perform at least 300 PCIs per year even during their first three years..." Br. of Appellant at 15. That assertion is not supported by the record. It is evident that the Health Law Judge recognized that new programs are permitted three years to meet the 300 standard.

Swedish also relies on WAC 246-310-745's need forecasting methodology to override WAC 246-301-720(2)(b)'s unambiguous prohibition against approval of new programs if existing programs are below the 300 minimum volume standard. Swedish focuses on one methodology provision to argue that WAC 246-310-720's minimum volume standard should be measured by the definition of "current capacity" in WAC 246-310-745's need forecasting methodology. We disagree. The "current capacity" definition has no bearing on the proper interpretation of WAC 246-310-720's requirement that "all" programs including those in existence for less than three years must be operating at the 300 minimum volume standard before the department may approve a new PCI program.

The definition of "current capacity" has a "specific meaning" "for the purposes of the need forecasting method..." WAC 246-310-745. Swedish attempts to combine two distinct procedures and concepts—WAC 246-310-720's minimum volume standard and WAC 246-310-745's need forecasting methodology—to make its point. The minimum volume standard addresses the number of procedures actually performed while the need forecasting methodology addresses the number of procedures that could be performed or that there is capacity to perform. WAC 246-310-745 is a planning tool that

asks if the current capacity in the planning area can meet the demand. In other words, the current capacity definition seeks to establish the procedures that could be performed in order to forecast patient need. The plain reading of the regulations require that all existing programs perform more than 300 PCI procedures. Because it is undisputed that St. Francis, Auburn, Valley and Evergreen are not performing 300 PCI procedures, we conclude the superior court properly affirmed the department's denial of Swedish's CN application.

Jan, J.

WE CONCUR:

Trickey, J

Becker, J.

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