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No. 71122-9-I

COURT OF APPEALS, DIVISION I
OF THE STATE OF WASHINGTON

SWEDISH HEALTH SERVICES,
a Washington nonprofit corporation,

Petitioner,

v.

DEPARTMENT OF HEALTH OF THE STATE OF
WASHINGTON,

Respondent.

OPENING BRIEF OF SWEDISH HEALTH SERVICES

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I. INTRODUCTION

This appeal relates to the Certificate of Need (“CON”) application of Swedish Health Services (“Swedish”) to provide elective percutaneous coronary interventions (“PCIs”) at its hospital campus in Issaquah. Swedish is a leading provider of cardiac care and performs more PCIs at its Cherry Hill hospital campus in central Seattle than are performed at any other hospital in western Washington. The proposed Issaquah program would be an extension of the world-class program at Cherry Hill, and both programs would be staffed by the same highly-regarded interventional cardiologists.

The final decision-maker for the Department of Health (the “Department”) on Swedish’s CON application, Health Law Judge John F. Kuntz (the “HLJ”), denied Swedish’s application based upon a misinterpretation of one of the regulations relating to CON approval of an elective PCI program, WAC 246-310-720(2)(b). Because the HLJ denied Swedish’s application on this ground, the HLJ did not determine whether Swedish’s application satisfies any of the other applicable requirements.

Swedish respectfully requests that the Court determine the correct interpretation of WAC 246-310-720(2)(b). If Swedish’s interpretation of this regulation is correct, it is undisputed that Swedish’s application satisfies it. The Court accordingly should set aside the HLJ’s denial of

Swedish's application and remand to the HLJ to determine whether or not Swedish's CON application satisfies the other applicable requirements for approval.

II. ASSIGNMENT OF ERROR

The HLJ erred by granting the motion for summary judgment brought by Overlake Hospital Medical Center ("Overlake") in the adjudicative proceeding relating to Swedish's CON application, which was the Department's final decision on Swedish's application.¹

III. ISSUE PERTAINING TO ASSIGNMENT OF ERROR

Whether WAC 246-310-720 requires that before the Department will approve a new PCI program, existing programs in the relevant planning area must be performing a minimum of 300 PCIs per year by the end of the third year of operation (Swedish's interpretation) or that existing programs in the relevant planning area must be performing a minimum of 300 PCIs per year even during the first three years of operation (the HLJ's interpretation).

¹ As discussed below, this Court reviews the decision of the agency, not the decision of the Superior Court. As a corollary matter, the HLJ also erred by denying Swedish's cross-motion for summary judgment, at minimum with respect to the legal issue on which the HLJ granted Overlake's motion.

IV. STATEMENT OF THE CASE

A. Percutaneous Coronary Intervention.

PCI refers to certain procedures performed by cardiologists for the revascularization of obstructed coronary arteries. *See* WAC 246-310-705(4). These include bare and drug-eluting stent implantation; percutaneous transluminal coronary angioplasty; cutting balloon atherectomy; rotational atherectomy; directional atherectomy; excimer laser angioplasty; and extractional thrombectomy. *See id.* PCIs are “invasive” procedures, but are not considered to be “surgery.” *See id.* These important medical procedures are required by many Washington residents. Annually, more than 13,000 such procedures are performed statewide. *See* Administrative Record (“AR”) 1360-61.

B. Swedish’s Cardiac Program.

Swedish offers a world-class cardiology program with the expertise to provide every procedure related to interventional cardiology. AR 1577. Swedish’s cardiology program is the largest in western Washington, whether measured in terms of cardiac surgery, invasive cardiac procedures, or PCIs specifically. AR 1360-61. Swedish’s cardiac program is based at its Cherry Hill campus in central Seattle. AR 1360-61.

C. Certificate of Need Requirements.

In Washington, healthcare providers must obtain CON approval from the Department before establishing certain types of healthcare facilities or providing certain types of healthcare services. *See* RCW 70.38.105(4); WAC 246-310-020(1). The Department generally will issue a CON only if it determines that the proposed facility or service is needed by the population to be served and satisfies certain cost and other criteria. *See* RCW 70.38.115(2); WAC 246-310-200.²

The Department's initial decisions on CON applications are made by the Department's CON Program. If an application is denied, the unsuccessful applicant may obtain review of the decision in an adjudicative proceeding, in which a Health Law Judge, an administrative law judge employed by the Department, serves as the presiding officer. *See* RCW 70.38.115(10)(a); WAC 246-310-610(1).³

² The Department may be able to approve a CON application even if the applicable regulations are not satisfied, based on "special circumstances," but that is not relevant to the issue before the Court in this appeal. *See King County Pub. Hosp. Dist. No. 2 v. Dep't of Health*, 178 Wn.2d 363, 374, 309 P.3d 416 (2013).

³ At the time of the Department's decision at issue here, the HLJs were the Department's final decision-makers in CON matters. *See DaVita, Inc. v. Dep't of Health*, 137 Wn. App. 174, 181, 151 P.3d 1095 (2007) ("HLJ is the Secretary's designee with the authority to make final decisions and issue a final order for CON applications."). A third level of agency review has since been created which applies to CON decisions. However, it did not exist at the time of the Department's decision at issue here. *See* Engrossed Substitute House Bill 1381, 63rd Leg., Reg. Sess. (Wash. 2013) (effective July 28, 2013).

For purposes of CON review, the Department divides PCIs into two categories: “emergent” and “elective.” The Department defines “emergent” to mean those situations in which “a patient needs immediate PCI because, in the treating physician’s best clinical judgment, delay would result in undue harm or risk to the patient.” WAC 246-310-705(3). The Department defines “elective” to mean “a PCI performed on a patient with cardiac function that has been stable in the days or weeks prior to the operation.” WAC 246-310-705(2).

Hospitals with on-site cardiac surgery programs, like Swedish/Cherry Hill, are permitted to perform both emergent and elective PCIs. Hospitals without on-site cardiac surgery programs, like Swedish/Issaquah, are permitted to perform emergent PCIs, but are not permitted to perform elective PCIs unless they obtain CON approval to do so. *See* WAC 246-310-700.

The Department evaluates “need” for new elective PCI programs on a “planning area” basis. It divides King County into two planning areas for this purpose: “King West” and “King East.” Swedish/Cherry Hill is located in King West. Swedish/Issaquah is located in King East. *See* WAC 246-310-705(5). King East has more than a million residents and covers a large geographic area. AR 1367 (population statistics); 1397

(map). The Department's PCI need forecasting methodology is discussed in detail below.

D. History of PCI services on the Eastside.

Historically, only hospitals with on-site cardiac surgery programs were permitted to perform elective PCIs. In 2008, the Department's rules were changed to allow hospitals without on-site cardiac surgery programs to perform elective PCIs, so long as they first obtained CON approval to do so, based on the regulatory criteria. *See* WAC 246-310-700.

Prior to this change of policy, Overlake, which operates a cardiac surgery program at its Bellevue hospital, was the only hospital in the King East planning area permitted to perform elective PCIs. In 2009, Overlake performed 43% of the PCIs required by planning-area residents. AR 1365. Swedish was the second-largest provider of PCIs for King East residents, performing 14% of the total. AR 1365. Of course, planning-area residents who chose Overlake-affiliated cardiologists were able to obtain this care within the planning area, whereas planning-area residents who chose Swedish-affiliated cardiologists had to leave the planning area to obtain this care in Seattle.

Immediately after the Department's change in policy, which allowed hospitals without on-site cardiac surgery programs to obtain CON approval to provide elective PCIs, the other hospitals in the planning

area—Evergreen Hospital Medical Center (Kirkland), Valley Medical Center (Renton), St. Francis Hospital (Federal Way), and Auburn Regional Medical Center (Auburn)—applied for such approval. AR 22. In 2009, the Department approved three additional elective PCI programs in King East: a program at Evergreen, a program at Valley, and a program jointly operated by St. Francis and Auburn. AR 22.⁴

E. Swedish/Issaquah.

In November 2011, Swedish opened its new hospital in Issaquah. The hospital was built with a cardiac catheterization laboratory (“cath lab”) in which emergent PCIs may be provided. AR 1360.⁵

F. Swedish’s Certificate of Need Application.

Following the Department’s change of policy regarding elective PCIs, and in anticipation of the opening of the new hospital, Swedish applied for CON approval to provide elective PCIs at Swedish/Issaquah. AR 1346-1522 (February 28, 2011, application); *see also* 1533-47 (supplemental information requested by Department); 1552-68 (additional supplemental information requested by Department); 1605-09 (response to

⁴ The planning area also has two critical-access (25-bed) hospitals in rural areas, St. Elizabeth’s (Enumclaw) and Snoqualmie Valley (Snoqualmie), which did not apply. AR 22.

⁵ Swedish was required to obtain CON approval to build the hospital itself. That application, filed in 2004, also was opposed by Overlake and Evergreen, and was the subject of extensive administrative and judicial proceedings that lasted until 2009. However, Swedish ultimately prevailed and obtained CON approval to build the hospital.

public comments). Because the cath lab already was being built out to provide emergent PCIs, approval to provide elective PCIs in the same space, with the same equipment, would require no additional capital expense. AR 1360.

Swedish explained in its application materials that the Issaquah program essentially would be an extension of the well-established program at Cherry Hill. AR 1361. Importantly, the Issaquah program would be staffed by the same highly-regarded interventional cardiologists as the Cherry Hill program. AR 1361; *see also* AR 1493-98, 1577 (support letters from cardiologists). The CON Program denied Swedish's application. AR 1624-66.⁶

G. Department's Final Decision on Swedish's Application.

Swedish exercised its right to administrative review of the CON Program's decision and, on June 6, 2012, commenced an adjudicative proceeding. AR 1-12. The HLJ was designated by the Secretary of Health to serve as the presiding officer in the adjudicative proceeding and make the Department's final decision on Swedish's application. AR 59-

⁶ The CON Program did not issue its decision until after an extraordinary delay. The record on Swedish's application closed on August 4, 2011. AR 1570. Under the Department's regulations, this meant that the CON Program's evaluation was due by September 19, 2011. *See* WAC 246-310-160(1)(b); WAC 246-310-010(17). The CON Program did not issue its evaluation until May 10, 2012, nearly fifteen months after Swedish filed its application and more than nine months after the application record closed. AR 1624-59.

62. A hearing was scheduled for February 14-15, 2013. AR 59-62. The HLJ permitted Overlake and Evergreen, which oppose Swedish's application, to intervene in the adjudicative proceeding. AR 293-97; AR 726-30.⁷

Overlake and Swedish filed cross-motions for summary judgment. AR 326-41; 547-77; 795-808; 879-901. The CON Program supported Overlake's motion. AR 732-42.

The HLJ granted Overlake's motion and denied Swedish's motion, based upon his determination that Swedish's application does not satisfy WAC 246-310-720(2)(b). The parties' dispute regarding the interpretation of this regulation is discussed in detail below. Because the HLJ denied Swedish's application on this ground, he did not determine whether or not Swedish's CON application satisfies the other applicable requirements for approval. AR 1337-42. This was the Department's final decision on Swedish's application.

⁷ Overlake and Evergreen similarly have opposed other Swedish CON applications to provide healthcare services on the Eastside. *See Overlake Hosp. Ass'n v. Dep't of Health*, 170 Wn.2d 43, 55, 239 P.3d 1095 (2010) (resulting in approval of Swedish's CON application to establish ambulatory surgical facility in Bellevue, over objections of Overlake and Evergreen); *Swedish Health Servs. v. Dep't of Health*, King County Superior Court, No. 06-2-14401-5 SEA, Order Reversing the Department of Health's Final Order Denying Swedish's Application for a Certificate of Need to Establish a Hospital in Issaquah and Remanding Swedish's Application to the Department, February 15, 2007 (resulting in approval of Swedish's CON application to establish hospital in Issaquah, over objections of Overlake and Evergreen); *Swedish Health Servs. v. Dep't of Health*, Washington Court of Appeals, Division I, No. 71258-6-1 (pending) (relating to Swedish's CON application to relocate ambulatory surgical facility from Issaquah to Redmond, opposed by Evergreen).

H. Judicial Review.

Swedish sought judicial review in King County Superior Court. The Superior Court affirmed the HLJ's decision. CP 20-23. Swedish now seeks judicial review by this Court. CP 24-31.

V. STANDARD OF REVIEW

The Court reviews the Department's decision pursuant to the judicial review standards set forth in the Administrative Procedure Act (the "APA"). The Court reviews the Department's decision directly, not the Superior Court's order. *See Postema v. Pollution Control Hearings Bd.*, 142 Wn.2d 68, 77, 11 P.3d 726 (2000).

Because the Department's decision was an agency order in an adjudicative proceeding, the Court reviews it pursuant to RCW 34.05.570(3). Under that statute, the Court should reverse the Department's decision if the Court determines, *inter alia*, that "[t]he agency has erroneously interpreted or applied the law" (RCW 34.05.570(3)(d)) or the agency's "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 inconsistency" (RCW 34.05.570(3)(h)).

This judicial review proceeding relates to the correct interpretation of WAC 246-310-720. The Court applies "the rules of statutory

construction” in interpreting regulatory language. *Overlake Hosp. Ass’n*, 170 Wn.2d at 51. “Statutory construction is a question of law[.]” *Cockle v. Dep’t of Labor and Indus.*, 142 Wn.2d 801, 807, 16 P.3d 583 (2001).

Under the APA, if the Court determines that relief should be granted from the Department’s decision, the Court may, *inter alia*, “enter a declaratory judgment order”; “set aside [the] agency action”; and/or “remand the matter for further proceedings[.]” *See* RCW 34.05.574(1)(b).

VI. RELIEF REQUESTED

Swedish respectfully requests that the Court determine the correct interpretation of WAC 246-310-720; set aside the HLJ’s summary judgment order, which was based on an incorrect interpretation of the regulation; and remand to the HLJ to determine whether or not Swedish’s CON application satisfies the other applicable requirements for approval.

VII. ARGUMENT

A. **The Department’s regulations require existing PCI programs to meet a minimum volume standard before a new PCI program will be approved.**

The regulation which the Department determined Swedish did not satisfy, WAC 246-310-720, provides as follows:

- (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.

WAC 246-310-720.

Thus, under subsection (2)(b), a new PCI program will be approved only if existing PCI programs in the relevant planning area “are meeting or exceeding the minimum volume standard.” That standard is defined in subsection (1) as “three hundred adult PCIs per year by the end of the third year of operation and each year thereafter.”

B. The parties dispute the correct interpretation of WAC 246-310-720.

Swedish interprets the “minimum volume standard,” referenced in WAC 246-310-720(2)(b), to be “a minimum of three hundred adult PCIs per year by the end of the third year of operation and each year thereafter.” In other words, Swedish interprets it to mean the standard referenced in the previous sub-part, WAC 246-310-720(1). The HLJ, on the other hand, interpreted the “minimum volume standard” to be a minimum of three hundred adult PCIs per year irrespective of how long an existing program has been in operation. AR 1341. In other words, the HLJ interpreted it to

mean the standard referenced in the previous sub-part with the last thirteen words omitted. The reasons why Swedish's interpretation is correct are discussed in detail below.

C. The interpretation of the regulation is dispositive of whether Swedish's application satisfies the regulation.

When Swedish applied to establish a PCI program in Issaquah, Overlake operated the only PCI program in the King East planning area that had been in operation for more than three years. AR 1375. During the most recent year for which data was available, Overlake performed 1,064 PCIs, well above the 300 PCIs required. AR 1632. Evergreen, Valley, and St. Francis/Auburn operated PCI programs in the planning area that, unlike Overlake's program, had been in operation for less than three years. AR 1375. They performed 198, 148, and 172 PCIs respectively. AR 1632.⁸

If Swedish's interpretation of WAC 246-310-720(2)(b) is correct the regulation is satisfied because the only program in operation more than three years was performing more than 300 PCIs per year. If the HLJ's interpretation of WAC 246-310-720(2)(b) is correct the regulation is not satisfied because the programs in operation less than three years were not

⁸ The HLJ misstated these volumes in the summary judgment order. AR 1340.

performing more than 300 PCIs per year. Therefore, the interpretation of the regulation is dispositive of whether Swedish's application satisfies it.

D. Swedish's interpretation of the regulation is correct based on its plain language.

"If the meaning of a rule is plain and unambiguous on its face" the Court should "give effect to that plain meaning." *Overlake Hosp. Ass'n*, 170 Wn.2d at 52. On its face, WAC 246-310-720 requires that existing PCI programs perform more than 300 PCIs per year only after three years in operation:

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.

WAC 246-310-720(1) (emphasis added); *see also* WAC 246-310-720(2)(b) (requiring standard to be met before a new program may be approved). The Court should give effect to this plain meaning and determine that Swedish's application satisfied this regulation. Overlake was in compliance with WAC 246-310-720(1) because it was performing more than 300 PCIs per year; the other existing programs were in compliance with the regulation because they each had been in operation for less than three years.

E. Swedish’s interpretation of the regulation is correct under the principles of statutory construction.

If the Court determines that the regulation is ambiguous, i.e., that there is more than one reasonable interpretation of the regulation, the Court may rely upon the principles of statutory construction to resolve the ambiguity. *See Overlake Hosp. Ass’n*, 170 Wn.2d at 52. At least three such principles are applicable here: consistency with the legislative intent underlying the enabling legislation; giving effect to all words in the regulation; and reading the specific regulation in the context of the regulatory scheme as a whole.

1. Swedish’s interpretation is consistent with the intent of the CON statute.

The Court’s “paramount concern” when interpreting a regulation “is to ensure that the regulation is interpreted in a manner that is consistent with the underlying policy” of the enabling statute. *Overlake Hosp. Ass’n*, 170 Wn.2d at 52. The Supreme Court has held that the “overriding purpose of the [CON] program” is “promotion and maintenance of access to health care services for all citizens.” *Id.* at 55 (emphasis added) (interpreting ambulatory surgical facility CON regulations).

Swedish’s interpretation promotes access to PCI services by permitting approval of new programs where there are existing programs in the planning area which have been in operation less than three years and

are not yet performing 300 PCIs per year but the need forecasting methodology projects need for an additional program even after assuming that all such programs will achieve this volume. In other words, it means that planning-area residents will not be deprived of access to an additional PCI program which is projected to be needed, in addition to the planning area's nascent programs, based on the Department's own need forecasting methodology.

In contrast, the HLJ's interpretation reduces access to PCI services by effectively creating a moratorium on additional programs, even if they are projected to be needed under the Department's need forecasting methodology, if any of the planning area's nascent programs are not yet performing 300 PCIs per year. Only Swedish's interpretation is consistent with the underlying purpose of the CON program.

2. Swedish's interpretation gives effect to all of the language in the regulation.

When interpreting a regulation, the Court should "give effect to every word, clause, and sentence whenever possible[.]" *Conway v. Dep't of Social and Health Servs.*, 131 Wn. App. 406, 416, 120 P.3d 130 (2005). Swedish's interpretation of the regulation gives effect to all words in the minimum-volume standard: i.e., that "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.” WAC 246-310-720(1) (emphasis added). By contrast, the HLJ’s interpretation of the regulation ignores the last thirteen words and requires existing providers to perform at least 300 PCIs per year even during their first three years of operation. Only Swedish’s interpretation gives effect to all words in the regulation.

3. Swedish’s interpretation harmonizes the PCI regulations.

Finally, in addition to giving effect to all of the language of a regulation, the Court should interpret a regulation in a way which “harmoniz[es] all provisions.” *D.W. Close Co., Inc. v. Dep’t of Labor and Indus.*, 143 Wn. App. 118, 126, 177 P.3d 143 (2008). Swedish’s interpretation of the regulation harmonizes all of the PCI regulations, whereas the HLJ’s interpretation does not.

Specifically, the minimum-volume standard set forth in WAC 246-310-720 works in tandem with the need forecasting methodology set forth in WAC 246-310-745. Indeed, the need forecasting methodology is specifically referenced in WAC 246-310-720(2)(a).

The Department’s need forecasting methodology compares the number of PCIs forecasted to be needed by planning-area residents with the “current capacity” of the existing programs to meet this demand. If

forecasted demand exceeds current capacity by at least 300 PCIs, a new program may be approved. WAC 246-310-745.

For existing programs in operation for more than three years, their “current capacity” is defined to be their actual volume. For existing programs in operation for less than three years, their “current capacity” is defined to be the greater of their actual volume or 300 PCIs. *See* WAC 246-310-745(2). In other words, the need forecasting methodology effectively reserves at least 300 of the planning area’s future PCIs for each of the nascent programs, and only permits approval of a new program if there are an additional 300 PCIs projected to be needed by planning-area residents even after assuming all existing programs will have the capacity to perform at least 300 PCIs.⁹

The HLJ interprets WAC 246-310-720 to mean that whenever there is an existing program in operation less than three years that is performing fewer than 300 PCIs, no new program may be approved in the planning area. This interpretation would render superfluous the language in WAC 246-310-745 which governs how need for a new program should be evaluated precisely when there is an existing program in operation less

⁹ The parties dispute whether current capacity should be based on the volume of procedures performed on the residents of the planning area or on residents of the planning area and other planning areas. However, the Court need not resolve this issue for purposes of the pending appeal.

than three years which is performing fewer than 300 PCIs. Only Swedish's interpretation of WAC 246-310-720 harmonizes it with the other PCI regulations, including the need forecasting regulation.

VIII. CONCLUSION

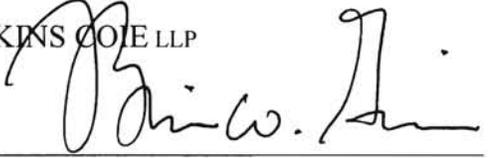
For a new PCI program to be approved, the existing PCI programs in the planning area that have been in operation for at least three years must be performing at least 300 PCIs per year. Existing PCI programs in the planning area which have been in operation for less than three years need not be performing this volume, but the need forecasting methodology assumes they will be doing so in future years, and allows for approval of a new program only if there is still a projected need for an additional program after making this assumption.

When Swedish applied to provide elective PCIs at its Issaquah campus, the only existing PCI program in the planning area in operation for more than three years was at Overlake, which performs more than 300 PCIs per year. The HLJ erred by ruling that WAC 246-310-720 required that the planning area's PCI programs in operation for less than three years also had to be performing this number of PCIs before Swedish could be approved. Swedish respectfully requests that the Court determine the correct interpretation of the regulation; set aside the Department's denial of Swedish's application on this ground; and remand to the HLJ to

determine whether or not Swedish's CON application satisfies the other applicable requirements for approval.

Respectfully submitted this 10th day of March 2014.¹⁰

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¹⁰ Swedish's opening brief originally was filed on March 10, 2014. This corrected opening brief was filed on April 24, 2014. Nothing has been changed except the spacing of the text, the Table of Contents and Table of Authorities, and the addition of this footnote.