

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

In the Matter of

CERTIFICATE OF NEED
APPLICATION OF SWEDISH HEALTH
SERVICES TO ESTABLISH AN
ELECTIVE PCI PROGRAM AT
SWEDISH MEDICAL CENTER/FIRST
HILL,

SWEDISH HEALTH SERVICES, a
Washington non-profit corporation,

Petitioner.

No. M2013-615

FINAL ORDER ON
SUMMARY JUDGMENT

This matter has come before the Review Officer on delegation by the Secretary of Health for administrative review of Swedish Health Services' (Swedish) Petition for Administrative Review (Petition) of Health Law Judge John F. Kuntz's Prehearing Order No. 1: Initial Order on Summary Judgment (Initial Order) dated September 24, 2013.

The Initial Order granted the Certificate of Need Program's (Program) Summary Judgment Motion and denied Swedish's application for an elective percutaneous coronary intervention program at Swedish Medical Center/First Hill.

The Program filed a Memorandum Opposing Swedish's Petition for Administrative Review (Response) requesting that the Review Officer deny Swedish's Certificate of Need (CN) application and supporting the adoption of the Initial Order as the Final Order in this case.

Based on a review of the record,¹ the Review Officer grants the Program's Motion for Summary Judgment, denies Swedish's CN application for an elective percutaneous coronary intervention program at Swedish Medical Center/First Hill, and adopts the Initial Order as the Final Order with the additional conclusions of law in paragraphs 2.9 and 2.10.

I. PROCEDURAL HISTORY AND FINDINGS OF FACT

Application

1.1 On or about February 29, 2012, Swedish submitted an application for a CN to establish an elective percutaneous coronary intervention (PCI) program at the Swedish Medical Center/First Hill facility.² A "PCI" means an invasive but nonsurgical mechanical procedure and/or device used by cardiologists for the revascularization of obstructed coronary arteries. See WAC 246-310-705(4). A PCI procedure is where a catheter is placed within the coronary artery to study them or open them when they are obstructed. See Taber's Cyclopedic Medical Dictionary, 21st Edition (2009), page 1740-1741. PCI procedures are "tertiary health services" or specialized services meeting complicated medical needs that require sufficient patient volumes to optimize provider effectiveness, quality of service, and improved outcomes of care. See WAC 246-310-010(58).

1.2 On April 4, 2013, the Program issued its evaluation and denied the Swedish application. The Program's denial decision was based on a number of factors. First, the Program determined that there was insufficient need for a new PCI program in the planning area (King West), as there was not sufficient additional volume to justify a new

¹ Including Swedish's Petition, Program's Response, the Program's Summary Judgment Motion, Swedish's Opposition to the Program's Summary Judgment Motion, the Program's Reply, Swedish's CN application, and the Program's evaluation of Swedish's CN application.

² "Elective" refers to PCI procedures performed on a stable patient. WAC 246-310-705(2). No CN is required to perform "emergency" PCI procedures (urgently scheduled procedures within 24 hours due to a patient's conditions.) WAC 246-310-705(3).

PCI program (300 PCI procedures by the third year of operation). Additionally, the Program found that the existing two PCI programs (University of Washington Medical Center [UWMC] and Northwest Hospital) within the planning area were performing less than 300 PCI procedures per year. Before a new PCI program can be granted a CN, WAC 246-310-720(2) requires that all PCI programs in the planning area must perform 300 procedures per year after the first three years. Finally, the Program determined that the new PCI program proposed by Swedish would have a negative impact on the UWMC (in violation of a requirement of WAC 246-310-715) by reducing (or potentially reducing) the number of elective PCI procedures available to be performed at the UWMC Interventional Cardiology Fellowship training program.

1.3 On April 24, 2013, Swedish filed an Application for Adjudicative Proceeding with the Adjudicative Clerk Office. Swedish argued that the Program erred in performing the need calculation methodology by including PCI procedures performed on residents who lived in other planning areas in the King West need calculation of existing capacity. Swedish also argued that its proposed PCI program would not have any impact on University of Washington training programs because the Swedish proposal would only allocate patients between the two Swedish downtown campuses (Swedish First Hill and Swedish Cherry Hill).³ These two campuses are about eight blocks from each other. See Swedish's Opposition to Program's Summary Judgment Motion, page 4, lines 36-37.

1.4 On July 11, 2013, the Program filed a Summary Judgment Motion with the Adjudicative Clerk Office. The Program argued that the Swedish application was properly denied because: (1) not all of the existing PCI programs in the King West planning area

³ Swedish provided a map of the Swedish and UWMC PCI locations as a part of its Opposition to the Program's Summary Judgment. See page 11, which is incorporated into this Order.

are performing 300 PCI procedures a year as required; and (2) the WAC 246-310-745 methodology shows no need for the Swedish program.

The 300 minimum rule:

1.5 WAC 246-310-720(2) states that the Program shall only grant a CN to a new program if: (1) the state need forecasting methodology projects unmet volume sufficient to establish a program within the planning area; and (2) all existing PCI programs in the planning area are meeting or exceeding the minimum volume standard.

1.6 WAC 246-310-720(1) sets a minimum volume threshold of PCI procedures that existing facilities must perform per year in a planning area before a CN can be granted to an applicant for another facility in the same planning area. The minimum volume standard is 300 adult PCI procedures per year by the third year of operation and every year thereafter. WAC 246-310-720(1). The King West planning area contains three other PCI programs, one at Northwest Hospital, one at UWMC, and one at Virginia Mason Medical Center.

1.7 As of February 2012, when Swedish applied for its CN, using the 2010 data, Swedish/Cherry Hill and Virginia Mason were meeting the minimum volume threshold of 300 PCI procedures per year. Swedish/Cherry Hill performed 1170 procedures and Virginia Mason performed 568 procedures. However, UWMC performed only 272 procedures per year and Northwest Hospital performed only 244 procedures per year. These levels are both below the 300 per year minimum volume threshold set by WAC 246-310-720(1).

1.8 Swedish argues that because UWMC and Northwest are affiliated, they should be counted as one provider and therefore the 272 performed by UWMC and the 244

performed by Northwest should be added together to total 516, which would exceed the 300 procedure level requirement. Swedish provides no legal authority in support of its interpretation of WAC 246-310-720 (that affiliated programs are counted as one hospital or program).

Calculating Need:

1.9 WAC 246-310-745(10) sets out a four step process for calculating need for a new PCI program. Under Step 3 of the Need Forecasting Methodology, the regulation sets forth the following:

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

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

(b) Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data;

(c) Calculate the difference between total PCI procedures in CON approved hospitals within the planning area reported to COAP or CHARS. The difference represents total outpatient procedures; or

(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.

"CHARS" is the Department of Health's Comprehensive Abstract Reporting System; "COAP" is the Washington State Clinical Outcomes Assessment Program. These programs/systems provide statistical data used by PCI applicants.

1.10 In its application, Swedish calculated need by counting only patients who resided in the planning area. (A significant percentage of the patients who obtained PCIs reside outside of the planning area). Swedish found there was a net projected need of 321 PCI procedures, which was sufficient to support and to establish its requested PCI program. See Program Summary Judgment Motion, Attachment 1, pages 7-11. The Program

counted all patients regardless of their residence because the WAC specifies that all procedures are to be counted — not just those on patients residing in the planning area. Calculated in this manner, there is no need for an additional PCI program. See Program Summary Judgment Motion, Attachment 1, pages 11-13.

The "Allocation" argument:

1.11 Swedish argues its application would not result in a new choice of provider within the planning area because it is simply seeking to allocate its patients between its Cherry Hill facility and a First Hill facility. Therefore, Swedish argues, the WAC requiring all other programs to be operating at 300 procedures per year does not apply. Swedish describes this as an internal allocation of resources, a distribution of patients between the two Swedish downtown Seattle campuses. However, these two campuses are separately licensed hospitals. The First Hill facility is not currently providing PCI care and has not provided it since 2006 when Swedish's cardiac care was consolidated in the Cherry Hill location. The establishment of a new PCI program in a new location is not an "allocation." Swedish's argument ignores the fact that a new program will potentially attract new patients.

II. CONCLUSIONS OF LAW

2.1 The Secretary has jurisdiction over the subject matter of this case. Chapter 70.38 RCW.

2.2 Swedish's Petition for Review of the Initial Order, and the Program's Response, were timely filed. WAC 246-10-701.

2.3 The Secretary is authorized to designate a Review Officer to enter final orders. Chapter 109, Laws of 2013. The Review Officer has all the decision-making power that

the Review Officer would have had to decide and enter the final order had the Review Officer presided over the hearing. RCW 34.05.464(4).

2.4 The Presiding Officer shall rule on motions. WAC 246-10-403(1). An administrative agency may employ summary procedures, and may enter an order summarily disposing of a matter if there is no genuine issue of material fact. *Asarco v. Air Quality Coalition*, 92 Wn.2d 685, 697, 601 P.2d 501 (1979).

2.5 Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." CR 56(c). See also *State Farm General Ins. Co. v. Emerson*, 102 Wn.2d 477 (1984). In a summary judgment motion, the moving party bears the initial burden of demonstrating there is no genuine dispute as to any material fact. *Young v. Key Pharmaceuticals*, 112 Wn.2d 216, 225, 770 P.2d 182 (1989). If the moving party meets its initial burden, the burden shifts to the non-moving party to set forth specific facts showing the existence of a genuine issue of material fact. *Id.* All facts submitted and all reasonable inferences from them must be viewed in the light most favorable to the nonmoving party. *Id.* at 226.

2.6 The facts in the present case are not in dispute. The moving party (the Program) presents evidence that there are two King West programs (University of Washington Medical Center and Northwest Hospital) that are below the 300 volume standard set forth in WAC 246-310-720(1). The non-moving party (Swedish) does not present evidence that disputes these figures. What Swedish does present is an argument that the two affiliated hospitals can be joined together to meet the 300 volume standard. It does not provide any

legal authority in support of that argument and, in fact, this interpretation conflicts with the clear language in WAC 246-310-720 and WAC 246-310-745. The intent behind using the term hospital in WAC 246-310-720 was to ensure that the specific hospital location did over 300 PCI procedures a year to ensure that quality of procedure. Interpreting the rule in the way Swedish argues conflicts with that intent. There is no genuine issue of material fact and summary judgment is granted for that reason.

2.7 Swedish further contends that only the patients and procedures that reside within the planning area should be used in calculating need. The plain language of Step 3 of WAC 246-310-745(10) requires the counting of all patients regardless of whether they reside in the planning area and by counting all procedures that take place in the planning area regardless of the residence of the patient. The rule is unambiguous and not subject to statutory construction. See *Agrilink Foods v. Department of Revenue*, 153 Wn. 2d 392 (2005). Thus, summary judgment is also appropriate on this basis.⁴

2.8 Swedish argues that the Presiding Officer can override CN rules in this situation given the unique circumstances in this matter. See Swedish's Opposition to Program's Summary Judgment Motion, at 12-13. This argument is not persuasive. Overriding a rule under the guise of interpreting it would essentially act to find the rule invalid, and the Presiding Officer has no such authority. See WAC 246-10-602(3)(c). A PCI program must withstand a CN review regardless of whether the applicant already has a program in the planning area.

⁴ In its evaluation the Program found the Swedish application failed to address the impact of the proposed Swedish program on the University of Washington training program under WAC 246-310-715(1). See the Program evaluation, pages 14-15. The Program did not raise this issue in its Motion. Given the Presiding Officer's summary judgment ruling above, this issue need not be addressed further.

2.9 As discussed above, the plain language of the department's CN rules prevent approval of Swedish's application for an elective PCI program at Swedish/First Hill. The plain language of a statute must be enforced. *State v. Armendariz*, 160 Wash.2d 106, 110, 156 P.3d 201 (2007). The rules of statutory construction apply to agency rules and regulations. *Overlake Hosp. Ass'n v. Dep't of Health*, 170 Wn.2d 43, 52, 239 P.3d 1095 (2010).

In the present case, Swedish, citing the recent state Supreme Court decision in *Odyssey*,⁵ asserts that the Review Officer has discretion to grant its CN application based on "special circumstances",⁶ irrespective of whether its application satisfies the criteria plainly stated in the CN rules. See Swedish's Petition, pages 10-12. This is a misreading of *Odyssey*. In *Odyssey*, the Program denied Odyssey a hospice application for a lack of "need" under the methodology using data available at the time of application. Odyssey requested an adjudicative proceeding to contest the denial. Subsequently, updated data became available showing need under the methodology and the Program reversed its position and supported approval of the application. The Health Law Judge (HLJ) considered the updated data in deciding the case in Odyssey's favor (the HLJ approved the proposed settlement) and two opposing hospice agencies appealed. The court held that the HLJ did not abuse his discretion in considering the updated need calculation given the special circumstances in the case. *King County Pub. Hosp. Dist. No. 2 v. Wash. State Dep't of Health*, 178 Wash.2d. 363, 373, 309 P.3d 416 (2013).

⁵ *King County Pub. Hosp. Dist. No. 2 v. Wash. State Dep't of Health*, 178 Wash.2d. 363, 309 P.3d 416 (2013).

⁶ Swedish reasons that its application presents special circumstances because a PCI program at Swedish/First Hill will not establish a new provider of PCI services and will merely allow Swedish to internally reallocate resources and distribute patients between its First Hill and Cherry Hill locations. The "allocation" argument is addressed in paragraph 1.11.

Unlike this case, the applicant in *Odyssey* did, in fact, qualify for a CN based on the CN criteria; the special circumstances in *Odyssey* referred primarily to the CN application process and the timing of the updated need data. *Odyssey* does not stand for the proposition that the Program may disregard applicable CN criteria when evaluating an application due to "special circumstances".

2.10 Finally, Swedish interprets a provision of the Administrative Procedure Act, RCW 34.05.570(3)(h), as giving the Review Officer the authority to disregard the department's CN rules in deciding this case. See Swedish's Petition, page 12, n.3. RCW 34.05.570(3)(h) sets out a judicial review standard granting relief from an agency order that is inconsistent with an agency rule unless the order states "facts and reasons to demonstrate a rational basis for inconsistency". Conversely, Swedish reads this statute to mean that the department may issue an order that is inconsistent with the CN rules so long as it states a rational basis for doing so. Swedish does not cite any case law supporting its interpretation. Regardless, the decision to deny Swedish's application is based on the applicable CN rules and does not implicate RCW 34.05.570(3)(h) because the decision is not inconsistent with a prior agency rule or order.

III. ORDER

Based on the foregoing Procedural History and Findings of Fact, and Conclusions of Law, it is ORDERED:

The Program's Motion for Summary Judgment is GRANTED. Swedish's application for an elective PCI program is DENIED.

Dated this 3 day of January, 2014

JOHN WIESMAN, DrPH, MPH
SECRETARY OF HEALTH



By Kristin Peterson
REVIEW OFFICER

NOTICE TO PARTIES:

Either Party may file a petition for reconsideration. RCW 34.05.461(3); RCW 34.05.470.

The petition must be filed within ten (10) days of service of this Order with:

Adjudicative Clerk Office
Adjudicative Service Unit
PO Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

State of Washington
Department of Health
Office of Legal Services
P.O. Box 47873
Olympia, WA 98504-7873

The petition must state the specific grounds upon which reconsideration is requested and the relief requested. WAC 246-10-704. The petition for reconsideration is considered denied twenty (20) days after the petition is filed if the Adjudicative Clerk Office has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A petition for judicial review must be filed and served within thirty (30) days after service of this Order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, the thirty

(30) day period for requesting judicial review does not start until the petition is resolved.
RCW 34.05.470(3).

The Order remains in effect even if a petition for reconsideration or petition for judicial review is filed. "Filing" means actual receipt of the document by the Adjudicative Clerk Office. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).

Final Orders will be reported to the National Practitioner Data Bank (45 CFR Part 60) and elsewhere as provided by law. Final orders will be placed on the Department of Health's website, otherwise disseminated as required by the Public Records Act, (chapter 42.56 RCW) and the Uniform Disciplinary Act. RCW 18.130.10. All orders are public documents and may be released.