

NO. 72612-9

**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.

**DEPARTMENT OF HEALTH'S RESPONSE TO THE
OPENING BRIEF OF SWEDISH HEALTH SERVICES**

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TABLE OF CONTENTS

I. INTRODUCTION.....1

II. ISSUE.....1

III. STATEMENT OF CASE.....2

IV. STANDARD OF REVIEW.....3

V. ARGUMENT4

 A. WAC 246-310-720(2)(b) Prohibits Approval Of
 Swedish’s PCI Application.....4

 B. Swedish’s Application Cannot Be Approved Based on
 Alleged “Special Circumstances”6

 1. WAC 246-310-720(2)(b) Contains No Special-
 Circumstance Exception And No Such Exception
 May Be Read Into The Rule.....6

 2. Case Law Cited By Swedish Does Not Support Its
 Special-Circumstances Argument8

 3. RCW 34.05.570(3)(h) Does Not Support Swedish’s
 Special-Circumstances Argument11

VI. CONCLUSION13

TABLE OF AUTHORITIES

Cases

<i>Anderson v. City of Seattle</i> , 78 Wn.2d 201, 471 P.2d 87 (1970).....	7
<i>Green v. Dep't of Soc. & Health Servs.</i> , 163 Wn. App. 494, 260 P.3d 254 (2011).....	12
<i>In re Detention of Sheldon Martin</i> , 163 Wn.2d 501, 182 P.3d 951 (2008).....	6
<i>King County Pub. Hosp. Dist. No. 2 v. Dep't of Health</i> , 178 Wn.2d 363, 309 P.3d 416 (2013).....	3, 4, 8, 9
<i>Kittitas County v. E. Wash. Growth Management Hearings Bd.</i> , 172 Wn.2d 144, 256 P.3d 1193 (2011).....	12
<i>Manary v. Anderson</i> , 176 Wn.2d 342, 292 P.3d 96 (2013).....	7
<i>Marion Hosp. Corp. v. Illinois Health Fac. Planning Bd.</i> , 324 Ill.App.3d 451, 753 N.E.2d 1104 (2001).....	10
<i>Odyssey Healthcare v. Dep't of Health</i> , 145 Wn. App. 131, 185 P.3d 652 (2008).....	4, 9
<i>Overlake Hosp. Ass'n v. Dep't of Health</i> , 170 Wn.2d 43, 239 P.3d 1095 (2010).....	4, 6
<i>State v. Gray</i> , 174 Wn.2d 920, 280 P.3d 1110 (2012).....	6
<i>State v. Kincaid</i> , 103 Wn.2d 304, 692 P.2d 823 (1985).....	8
<i>Tesoro Ref. & Mktg. Co. v. Dep't of Rev.</i> , 173 Wn.2d 551, 269 P.3d 1013 (2012).....	6

<i>Univ. Community Hosp. v. Dep't of Health & Rehab. Servs.</i> , 472 So.2d 756 (Fla. Dist. Ct. App. 1985)	11
<i>Univ. of Wash. Med. Ctr. v. Dep't of Health</i> , 164 Wn.2d 95, 187 P.3d 243 (2008).....	4, 9, 11
<i>Yakima Valley Mem. Hosp. v. Dep't of Health</i> , 731 F.3d 843 (9th Cir. 2013)	5

Statutes

RCW 34.05	3
RCW 34.05.570(1)(a)	4
RCW 34.05.570(3).....	12
RCW 34.05.570(3)(d)	4
RCW 34.05.570(3)(h)	11, 12, 13
RCW 34.05.574(1)(a)	13
RCW 70.38	1, 2
RCW 70.38.128	2, 4

Regulations

WAC 10-08-135.....	3
WAC 246-10-602(2)(e)	3
WAC 246-310.....	2
WAC 246-310-210.....	2
WAC 246-310-220.....	2
WAC 246-310-230.....	2

WAC 246-310-240..... 2

WAC 246-310-270..... 13

WAC 246-310-270(2)(b) 7

WAC 246-310-700..... 2

WAC 246-310-705(3)..... 2

WAC 246-310-705(4)..... 2

WAC 246-310-705(5)..... 5

WAC 246-310-720..... 5, 12

WAC 246-310-720(1)..... 4

WAC 246-310-720(2)(b) passim

I. INTRODUCTION

Petitioner Swedish Health Services (Swedish) applied to the Respondent Department of Health (Department) under RCW 70.38 for a Certificate of Need to establish an elective percutaneous coronary intervention (PCI) program at its First Hill hospital in Seattle. At the time, two existing PCI programs in Swedish's planning area performed fewer than 300 PCI procedures per year. Under such circumstance, WAC 246-310-720(2)(b) prohibits approval of a new program. Accordingly, the Department denied Swedish's application.

Swedish contends that the WAC 246-310-720(2)(b) prohibition against approval of a new PCI program should not apply to Swedish because of alleged "special circumstances" surrounding its application. This contention should be rejected because no statute or rule allows for a special-circumstance exception to the prohibition. This Court should uphold the denial of Swedish's PCI application.

II. ISSUE

WAC 246-310-720(2)(b) prohibits the Department from approving a Certificate of Need application for a PCI program when an existing program in the planning area performs fewer than 300 PCI procedures per year. When the WAC 246-310-720(2)(b) prohibition applies, may an PCI

applicant nevertheless be approved by showing “special circumstances” surrounding its application?

III. STATEMENT OF CASE

To establish certain types of health care facilities and services, an entity must first obtain a Certificate of Need from the Department of Health (Department) under RCW 70.38 and WAC 246-310. For approval, an applicant must satisfy four general criteria: Need (WAC 246-310-210); Financial Feasibility (WAC 246-310-220); Structure and Process of Care (WAC 246-310-230); and Cost Containment (WAC 246-310-240).

One type of service that requires a Certificate of Need is elective¹ PCI. RCW 70.38.128; WAC 246-310-700. PCI includes a range of invasive but non-surgical mechanical procedures for the revascularization of coronary arteries. WAC 246-310-705(4).

In February 2012, Swedish filed a Certificate of Need application for a PCI program at its First Hill hospital in Seattle. Administrative Record (AR) at 422-465. WAC 246-310-720(2)(b) prohibits approval of an application whenever an existing program in the planning area performs fewer than 300 PCI procedures per year. Because two existing

¹ “Elective” PCI, requiring a Certificate of Need, is performed on a stable patient. WAC 246-310-705(2). By contrast, no certificate is required for a hospital to perform an “emergent” PCI, which are those that must be scheduled within 24 hours due to a patient’s unstable condition. WAC 246-310-705(3).

programs in Swedish's planning area were below the 300 standard, the Department denied the application. AR at 772-808.

Swedish requested an adjudicative proceeding to contest the denial. The Department moved for summary judgment to uphold the denial.² A Department Health Law Judge granted the motion. AR at 246-255. Swedish filed for administrative review. A Department Review Officer issued a final order upholding denial of the application. AR at 409-420. Swedish petitioned under RCW 34.05 for judicial review of the Review Officer's denial. Clerk's Papers (CP) at 1-38. King County Superior Judge Jean Rietchel upheld the denial. CP at 40-41. Swedish further appeals to this Court. CP at 40-46.

IV. STANDARD OF REVIEW

Swedish challenges the Department's decision to deny its PCI Certificate of Need application for failure to meet the requirement of WAC 246-310-720(2)(b). On review, this Court sits in the same position as the superior court, and applies the standards of the Administrative Procedures Act (RCW 34.05) directly to the agency record. *King County Pub. Hosp. Dist. No. 2 v. Dep't of Health*, 178 Wn.2d 363, 372, 309 P.3d 416 (2013).

² Motions may be made in adjudicative proceedings before the Department. WAC 246-10-602(2)(e). A summary judgment motion may be granted "if the written record shows that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." WAC 10-08-135.

Swedish bears the burden of demonstrating the invalidity of the Department's decision. RCW 34.05.570(1)(a). An agency order may be overturned if the agency has erroneously interpreted or applied the law. RCW 34.05.570(3)(d). However, the reviewing court must accord "substantial deference" to the Department's interpretation of the Certificate of Need law. *King County Pub. Hosp. Dist. No. 2*, 178 Wn.2d at 372; *Overlake Hosp. Ass'n v. Dep't of Health*, 170 Wn.2d 43, 56, 239 P.3d 1095 (2010); *Univ. of Wash. Med. Ctr. v. Dep't of Health*, 164 Wn.2d 95, 102, 187 P.3d 243 (2008); *Odyssey Healthcare v. Dep't of Health*, 145 Wn. App. 131, 142, 185 P.3d 652 (2008).

V. ARGUMENT

A. WAC 246-310-720(2)(b) Prohibits Approval Of Swedish's PCI Application

RCW 70.38.128 directs the Department to adopt rules on the issuance of a Certificate of Need for an elective PCI program, including rules addressing "patient safety and quality outcomes." In response, the Department adopted WAC 246-310-720(1) which requires PCI programs to perform 300 PCI procedures per year by the third year of operation. This 300 minimum volume standard assures that practitioners, through repetition, maintain skills and competence, thereby promoting patient safety. *Yakima Valley Mem. Hosp. v. Dep't of Health*, 731 F.3d 843, 849

(9th Cir. 2013) (upholding constitutionality of 300 standard under the dormant commerce clause). WAC 246-310-720(2)(b) further states:

The department shall only grant a certificate of need to new [elective PCI] programs if . . .

(b) All existing PCI programs in the planning area are meeting or exceeding the [300 procedure per year] minimum volume standard.

The two material facts, necessary to decide this case, are not in dispute. First, Swedish's First Hill Hospital, where it seeks to establish a PCI program, is in "Planning Area # 10", also known as "King [County] West". WAC 246-310-705(5); AR at 785. Second, when Swedish applied, two existing PCI programs in King West – the University of Washington Medical Center (UWMC) (272 procedures) and Northwest Hospital (244 procedures) – were performing fewer than 300 procedures per year. AR at 785.

Based on these facts, the Review Officer applied WAC 246-310-720, and correctly denied Swedish's application to establish a PCI program at First Hill because two programs in the King West planning area perform fewer than 300 procedures per year. AR at 415-16, ¶ 2.6. This Court should uphold the denial.

B. Swedish's Application Cannot Be Approved Based on Alleged "Special Circumstances"

1. WAC 246-310-720(2)(b) Contains No Special-Circumstance Exception And No Such Exception May Be Read Into The Rule

Based on alleged "special circumstances," Swedish contends that WAC 246-310-720(2)(b) does not bar approval of its proposed PCI program.³ Swedish Brief at 24-27. Swedish's contention should be rejected under rules of statutory construction. These rules apply to construing agency rules. *Overlake Hosp. Ass'n*, 170 Wn.2d at 52.

First, the plain meaning of a law must be given effect by the court. *State v. Gray*, 174 Wn.2d 920, 927, 280 P.3d 1110 (2012); *Tesoro Ref. & Mktg. Co. v. Dep't of Rev.*, 173 Wn.2d 551, 269 P.3d 1013 (2012). When the language of a law is subject to only one interpretation, the court's "inquiry is at an end." *In re Detention of Sheldon Martin*, 163 Wn.2d 501, 508, 182 P.3d 951 (2008). WAC 246-310-720(2)(b) states that a new

³ One alleged special circumstance is that a First Hill program would be just eight blocks from Swedish existing program at its Cherry Hill Hospital located outside the King West planning area. Swedish Br. at 23. However, Swedish does not deny that First Hill would be a *new* program *inside* King West where two existing programs are below the 300 standard.

The other alleged special circumstance is that the two programs below the 300 standard (UWMC and Northwest) are both affiliated with UW Medicine, and *combined* perform over 300 procedures per year. However, Swedish does not deny that the two programs are *separate* programs and both must *separately* achieve a 300 volume in order to protect patient safety.

program may be approved “only” when all existing PCI programs in the planning area meet the 300 volume standard. Since two programs are below the standard, the plain language of WAC 246-310-720(2)(b) mandates the denial of Swedish’s application.

Moreover, WAC 246-310-270(2)(b) makes no exceptions to the prohibition of approval of new PCI programs when existing programs are below the 300 volume standard. A judicially-created special- circumstance exception to WAC 246-310-720(2)(b), as requested by Swedish, would modify the rule. Modification of a law is neither the “function nor the prerogative” of the court. *Anderson v. City of Seattle*, 78 Wn.2d 201, 202, 471 P.2d 87 (1970). Nor may a court read omitted language into a law. *Manary v. Anderson*, 176 Wn.2d 342, 357, 292 P.3d 96 (2013). A special-circumstance exemption may not be read into WAC 246-310-720(2)(b).

Finally, Swedish concedes that no statute or rule permits approval of its application when it cannot meet the requirement of WAC 246-310-270(2)(b). Swedish Br. at 18. In support of its argument, Swedish cites several non-PCI rules that contain exemptions from Certificate of Need requirements. *Id.* at 18-19. These non-PCI rules are not relevant to Swedish’s PCI case. They actually underscore that, in

adopting the PCI rules, the Department chose not to make any exception to the WAC 246-310-720(2)(b) requirement.

In summary, the WAC 246-310-720(2)(b) requirement mandates denial of Swedish's application. When a law is "clear," a court must "respect" and enforce it. *State v. Kincaid*, 103 Wn.2d 304, 313, 692 P.2d 823 (1985).

2. Case Law Cited By Swedish Does Not Support Its Special-Circumstances Argument

Swedish wrongly relies on three cases to support the judicial creation of a special-circumstance exception to the WAC 246-310-720(2)(b) requirement.

Swedish cites *King County Public Hosp. Dis't No. 2 v. Dep't of Health*, 178 Wn.2d 363, 309 P.3d 416 (2013). Swedish Br. at 18-19, 20-23.⁴ The Review Officer properly rejected Swedish's interpretation of this case. AR at 417-38 ¶ 2.9.

In *King County Public Hosp. Dis't*, the Department denied Odyssey's Certificate of Need hospice application for lack of "need" under a methodology based on data available *at the time of the application*. *Id.* at 368. Odyssey requested an adjudicative proceeding to contest the denial. *Id.* Ordinarily, in an adjudicative proceeding, the

⁴ Swedish refers to this case as "*Odyssey*".

Department does not consider data coming into existence *after* its review of the application. *Id.* at 420; *Univ. of Wash. Med. Ctr.*, 164 Wn.2d at 104. However, the Health Law Judge admitted updated data based on several “special circumstances.” *Id.* at 420. The court held that the Health Law Judge did not abuse his discretion by admitting the updated data into evidence. *Id.* at 422. The updated data showed “need” for Odyssey’s proposed hospice, leading the court to uphold the Department’s approval of Odyssey’s application. *Id.*

Swedish fails to recognize that the special-circumstance holding in *King County Public Hosp. Dis’t* relates solely to an evidentiary ruling on the admissibility of updated data. The updated data showed that Odyssey met the criteria for Certificate of Need approval. Swedish misreads the case, as the court certainly did not hold that an application may be approved based on special circumstances even if the application otherwise fails to meet the criteria for approval.

Finally, it should be understood that the special-circumstance holding of *King County Public Hospital Dist.* could have come into play if, during an adjudicative proceeding, Swedish had attempted to introduce *updated* data showing that existing programs were no longer below the 300 volume standard. The holding would have given the Health Law Judge discretion to admit the updated data and to possibly approve

Swedish's application. However, because Swedish made no attempt to introduce updated data, the holding is simply inapplicable to its case.

Swedish also cites two out-of-state cases. In *Marion Hosp. Corp. v. Illinois Health Fac. Planning Bd.*, 324 Ill.App.3d 451, 753 N.E.2d 1104 (2001), a statute required an open heart surgery program applicant to show that, if approved, it could perform a certain minimum number of surgeries. *Id.* at 453. Although the applicant could not satisfy the minimum-volume requirement, the court upheld approval because a *different* statute allowed for approval of an application even when an applicant could not meet all criteria for approval. *Id.* at 482. Absent that statute, the court no doubt would have denied the application for failure to meet the minimum volume standard.

The *Marion Hospital* decision actually supports the Department's position. As stated, Illinois law included a provision allowing for an override of the minimum-volume requirement in approving an application. By contrast, as Swedish admits, no Washington statute or rule allows for an override of the minimum-volume requirement in WAC 246-310-720(2)(b). Swedish Br. at 18. Hence, the Department correctly denied Swedish's application under WAC 246-310-720(2)(b), and did not consider whether special circumstances justified approval.

Univ. Community Hosp. v. Dep't of Health & Rehab. Servs., 472 So.2d 756, 758 (Fla. Dist. Ct. App. 1985), involved an existing open heart surgery program that had been approved based on the “special circumstance” of proposing to serve people from Latin America. The decision contains no explanation of the Florida law allowing for approval of the program under special circumstances. That is because the approval was not at issue. Instead, the issue was whether the approval of the existing program blocked the plaintiff – a subsequent applicant – from also being approved for an open heart surgery program. *Id.* This case does not remotely support Swedish’s special-circumstance argument.

In summary, no case law would support this Court creating a special-circumstance exception to WAC 246-310-720(2)(b) and allowing approval a new PCI program at Swedish even though two existing programs in the King West planning area are not meeting the 300 per-year minimum volume requirement.

3. RCW 34.05.570(3)(h) Does Not Support Swedish’s Special-Circumstances Argument

RCW 34.05.570(3)(h) states that a court may overturn an agency order if 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 inconsistency.” Swedish contends that

this judicial-review statute allows a court to require an agency, in deciding a case, to consider whether a rational basis exists for ignoring its own rules. Swedish Br. at 23-24. For two reasons, this contention has no merit.

First, judicial review under RCW 34.05.570(3)(h) is inapplicable here because, as Swedish admits, the Review Officer's order is not "inconsistent" with WAC 246-310-720. To the contrary, Swedish acknowledges that the order is consistent with WAC 246-310-720. RCW 34.05.570(3)(h) review does not apply when, as in Swedish's case, the challenge is simply to an agency's interpretation or application of a rule. *Green v. Dep't of Soc. & Health Servs.*, 163 Wn. App. 494, 507, n.11, 260 P.3d 254 (2011).

Secondly, judicial review under RCW 34.05.570(3)(h) requires an agency give a rational basis whenever the agency has not applied its rules in a consistent manner. *Kittitas County v. E. Wash. Growth Management Hearings Bd.*, 172 Wn.2d 144, 174, 256 P.3d 1193 (2011). Swedish makes no allegation that the Department has ever approved a PCI applicant when the WAC 246-310-720(2)(b) requirement was not satisfied. No inconsistency in the Department's application of the rule invites judicial review under RCW 34.05.570(3).

In summary, RCW 34.05.570(3)(h) does not require an agency, in reaching a decision, to consider whether a rational basis exists for ignoring the requirements of its own rules. The contrary result urged by Swedish would have far-reaching implications for all state agencies. It would jeopardize the enforceability of every agency rule by allowing litigants to argue that a rule should be disregarded under the particular circumstances of their case. Swedish cites no support for its novel interpretation of RCW 34.05.570(3)(h).

VI. CONCLUSION

Based on the foregoing, the Department of Health respectfully requests this Court under RCW 34.05.574(1)(a) affirm its decision to deny Swedish's Certificate of Need application to establish an elective PCI program at its First Hill Hospital. Under WAC 246-310-270, Swedish's

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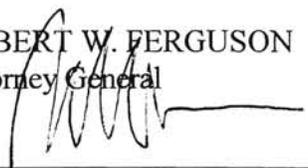
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PCI application cannot be approved because two programs in the King West planning area perform fewer than 300 PCI procedures per year.

RESPECTFULLY SUBMITTED this 26 day of January, 2015.

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CERTIFICATE OF SERVICE

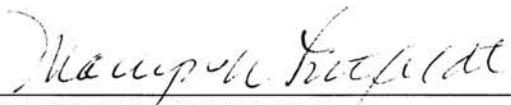
I, MARILYN WHITFELDT, certify that I served a copy of this document, *Department of Health's Response to the Opening Brief of Swedish Health Services*, on all parties or their counsel of record on the date below as follows:

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DATED this 31st day of January, 2015, at Olympia, Washington.



MARILYN WHITFELDT
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