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DIVISION I
COURT OF APPEALS
STATE OF WASHINGTON
2001 DEC 20 AM 10:26

NO. 60554-2-I

**COURT OF APPEALS, DIVISION I
OF THE STATE OF WASHINGTON**

OVERLAKE HOSPITAL ASSOCIATE and OVERLAKE HOSPITAL
MEDICAL CENTER, a Washington nonprofit corporation; and KING
COUNTY PUBLIC HOSPITAL DISTRICT NO. 2 d/b/a EVERGREEN
HEALTHCARE, a Washington Public Hospital District,

Appellants,

v.

WASHINGTON STATE DEPARTMENT OF HEALTH,

Respondent.

**RESPONDENT DEPARTMENT OF HEALTH'S BRIEF
OPPOSING PETITION FOR JUDICIAL REVIEW**

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I. STATEMENT OF CASE

A. Overview Of Certificate Of Need Law

The Department of Health (Department) administers the Certificate of Need law under RCW 70.38 and WAC 246-310. The law requires providers to obtain a Certificate of Need prior to establishing a new “health care facility” in the state. RCW 70.38.105(4)(a). That term includes an “ambulatory surgery center (ASC).” RCW 70.38.025(6). An ASC is a facility with operating rooms where physicians perform surgeries on patients not requiring hospitalization. WAC 246-310-010(5). An ASC Certificate of Need application seeks approval to establish a certain number of operating rooms within the proposed ASC facility.

The Department reviews an ASC Certificate of Need application under five criteria: WAC 246-310-270 (Need Methodology); WAC 246-310-210 (Need); WAC 246-310-220 (Financial Feasibility); WAC 246-310-230 (Structure and Process of Care); and WAC 246-310-240 (Cost Containment).

Whether to approve an application is initially decided by the Department’s Certificate of Need Program (Program). When an application is denied, the applicant may request an adjudicative hearing under RCW 70.38.115(10)(a) to contest the denial. On the other hand, when an application is approved, a competitor of the applicant may

request an adjudicative proceeding under RCW 34.05.422(1)(b) to contest the approval. Adjudicative proceedings are conducted by a Department Health Law Judge (HLJ) who has authority to make the final administrative decision for the Department. WAC 246-10-102 (defining “presiding officer”).

B. Procedural History Of Case

In November 2002, Swedish Health Services applied to the Department for a Certificate of Need to establish an ASC with two operating rooms in Bellevue. CP 60-211. Overlake Hospital Association and Evergreen Healthcare (Overlake/Evergreen), which already have operating rooms in East King County, opposed the application. In May 2003, the Program approved the application. CP 42. Overlake/Evergreen requested an adjudicative proceeding to contest the approval. CP 42. The HLJ reversed the Program’s approval and denied the Swedish application. Swedish petitioned for judicial review; the superior court granted the petition and remanded the case to the Department for further review. CP 42-43.¹

On remand, in November 2006, the HLJ approved the Swedish application. AR at 491-509; Appendix (App.) at 1-19. Overlake/Evergreen petitioned for judicial review (CP 1-35), and the

¹ Reasons for the HLJ’s and trial court’s earlier decisions are no longer relevant to this case, but are explained in the Overlake/Evergreen brief at page 14.

superior court denied the petition. CP 402-03. Overlake/Evergreen filed the Notice of Appeal to this Court.

II. ISSUE

1. Should this Court uphold the November 2006 decision by the Department's Health Law Judge to approve Swedish's Certificate of Need application to establish an ambulatory surgery center with five operating rooms in Bellevue?

2. Did Overlake/Evergreen meet its burden to show that the Health Law Judge's interpretation of the Methodology in WAC 246-310-270 was arbitrary and capricious?

III. STANDARD OF REVIEW

This judicial review involves Overlake/Evergreen's challenge to the Department's interpretation of its own rule, WAC 246-310-270. The court's ability to overturn the Department's interpretation is constrained. Given the Department's expertise, its interpretation of the Certificate of Need law is entitled to "considerable weight" by the reviewing court. St. Joseph v. Department of Health, 125 Wn.2d 733, 743, 887 P.2d 891 (1995).

Overlake/Evergreen correctly argues that the HLJ's interpretation of WAC 247-310-270 should be reviewed under the "arbitrary and capricious" standard. Brief at 20, 31, 34. This standard has been applied

by the court in reviewing the Department's interpretation of the Certificate of Need law. Children's Hospital v. Department of Health, 95 Wn. App. 858, 871, 975 P.2d 567 (1999). A court reverses under this standard only if the agency action was "willful and unreasoning, without regard to the attending facts or circumstances." ITT Rayonier v. Dalman, 122 Wn.2d 801, 809, 863 P.2d 64 (1993). An agency's action is not arbitrary and capricious if there is "room for two opinions," even if the reviewing court disagrees with the action. Rios v. Department of Labor and Industries, 145 Wn.2d 483, 39 P.2d 961 (2002).

The party challenging the validity of an agency action – Overlake/Evergreen in this case – bears the burden of proving the invalidity of the action. RCW 34.05.570(1)(a).

IV. ARGUMENT

A. Overlake/Evergreen Fails To Show That The Health Law Judge's Interpretation Of The Methodology In WAC 246-310-270, Leading To Approval Of Swedish Application, Was In Error And Was Arbitrary And Capricious

This appeal involves the application of the Methodology in WAC 246-310-270 (App. at 20-21), a numeric equation used by the Department to determine "need" for additional operating rooms in the "planning area" where a proposed ASC would be located. The Methodology is a calculation of whether the number of existing operating

rooms in the planning area is sufficient to meet the need, or whether additional new operating rooms are needed.

WAC 246-310-270(2) states that the “need” calculation is performed in certain defined “secondary health services planning areas.” The proposed Swedish facility in Bellevue would be located in the “East King County” (East King) planning area. WAC 246-310-270(8) states that the need for additional operating rooms in a planning area “will be determined using the method” set forth in WAC 246-310-270(9). WAC 246-310-270(9)(a) determines “existing [operating room] capacity” in the planning area. WAC 246-310-270(9)(b) determines the “future [operating room] need” in the planning area. WAC 246-310-270(9)(c) determines “net [operating room] need” in the planning area based on the future need for operating rooms minus the existing operating room capacity. While the Methodology is complex, the disagreement between the parties over its proper application, as discussed below, is relatively narrow and straightforward.

1. Overlake/Evergreen Fails To Show That The Health Law Judge Should Be Reversed In His Determination Of Existing Capacity Under WAC 246-310-070(9)(a)

An “ASC” subject to Certificate of Need regulation does not include those outpatient surgery facilities that are located:

[I]n the offices of private physicians . . . whether for individual or group practice, if the privilege of using the facility is not extended to physicians . . . outside the individual or group practice.

WAC 246-310-010(5) (App. at 22). Thus, in-office operating rooms, which are not open to use by outside physicians, are exempt from Certificate of Need review under RCW 70.38 and WAC 246-310. (These facilities are referred to below as “closed exempt facilities.”)

WAC 246-310-270(9)(a)(iii) of the Methodology instructs the Department to calculate the “total annual capacity (in numbers of surgeries) of all dedicated outpatient operating rooms in the area.” These operating rooms are those used only for outpatient surgeries (as opposed to “inpatient” hospital surgeries). In performing the Methodology, the Department counted 19 dedicated operating rooms in East King. CP at 334; App. at 23.

WAC 246-310-270(9)(a)(iv) then instructs the Department to calculate the “total annual capacity of inpatient and outpatient [mixed use] operating rooms in the area.” In performing the Methodology, the Department counted 14 mixed use operating rooms in East King. Id.

This 19/14 operating-room count included only the operating rooms in East King hospital operating rooms and ASC operating rooms subject to Certificate of Need regulation. The count did not include

operating rooms located in closed exempt facilities because these facilities, as stated, are not regulated by the Department, given the definition of “ASC” in WAC 246-310-010(5). Thus, the Department reasonably concluded that operating rooms in closed exempt facilities should not be considered “operating rooms” within the meaning of WAC 246-310-270(9)(a)(iii)-(iv). This conclusion is entitled to considerable weight, is not arbitrary and capricious, and should be upheld by the Court.

2. Overlake/Evergreen Fail To Show That The Health Law Judge Should Be Reversed In His Decision To Apply A 82/1000 “Use Rate” Under WAC 246-310-270(9)(b).

Next, following the above existing-capacity calculation, WAC 246-310-270(9)(b) (Section 9(b)) states that in order to calculate “future need, the Department must”:

Project the number of inpatient and outpatient surgeries within . . . the planning area for the third year of operation [of the proposed new facility].

(Emphasis added.)

This Section 9(b) projection requires the Department to estimate the percentage of East King residents who use ASC services every year in order to project future need. The projection requires the Department to determine an ASC “use rate” for the planning area. A use rate is based on

the historical number of surgeries and the population in the planning area. In performing the Methodology for the Swedish application, the Department used an 82 surgeries per 1,000 population use rate for East King. CP at 334; App. at 23 (top left corner of worksheet). As noted by the HLJ, 82/1000 was the use rate utilized by the Department earlier in reviewing the Northwest Nasal Sinus Center (NWNSC) East King County application. AR 499-500; App. at 9-10 (¶1.13).

In the NWNSC evaluation, in calculating the 82/1000 use rate under Section 9(b), the Department included in the East King historical volume a number of surgeries that were performed at closed exempt facilities (as well as at facilities open to use by all physicians.)² Overlake/Evergreen argues that counting closed exempt facility surgery volume in calculating the use rate under Section 9(b) was illogical – and incorrectly inflated the use rate – because under WAC 246-310-270(9)(a) the number of closed exempt operating rooms was not counted in existing operating room supply. Brief at 21-24.

The HJL correctly rejected Overlake/Evergreen’s argument. As stated, in calculating future need, Section 9(b) requires a determination of the surgeries to be performed “within” the planning area. The HLJ found

² In the NWNSC evaluation, the CN Program surveyed known closed exempt facilities in East King County, and received volume data from seven of 21 facilities, and counted that data in calculating the 82/1000 use rate. CP 301. Thus, the rate is understated in that it includes volume from only one-third of the closed exempt facilities.

that this Section 9(b) language is “all inclusive.” AR at 507; App. at 17 (¶2.8). Hence, Section 9(b) required the Department to project future need based on the number of surgeries performed at all East King operating rooms, including those at closed exempt facilities.

Besides relying on the plain wording of Section 9(b), the HLJ noted that, under RCW 70.38.015(1), the purpose of the Certificate of Need law to assure that Washington citizens have “accessible” health care services. AR at 507-08; App. at 17-18 (¶2.9). The HLJ further noted that the closed exempt facilities are “not available to many of the individuals within the planning area,” since these facilities are used only to operate on the patients of physicians who own the facilities (whether individually or in group practice). *Id.* Thus, in determining future need, the Department’s Section 9(b) approach assures a sufficient number of operating rooms open to use by all physicians; that is, the Department’s approach does not rely on closed exempt facilities to meet part of the public demand for the service. The HLJ’s conclusion is supported by the following testimony on direct at the adjudicative hearing from Program Analyst Randall Huyck:

Q: So what is the rationale for counting the volumes in an exempt facility but not counting the facility itself?

A: That’s a longstanding rationale that the department has used for a number of years. The rationale behind that is that operating rooms that are approved by certificate of need or are included in community hospitals are available

to the general surgical public if they are properly credentialed to use the rooms for treatment of their patients, whoever their patients may be.

The facilities that are described as exempt facilities, the use of those facilities is limited only to members of those group practices. And very frequently, we see that the use of these facilities is limited to one, sometimes two, different specialties of medicine, such as ENT surgery, oral surgery, or something like that. So those operating rooms are not really analogous to a generally available ambulatory surgery center, operating room, where a multitude of various services could be performed by a number of different physicians . . .

Q: So are you attempting to make sure that the [total] number of surgeries can be met by the facilities that are open and generally available to everyone.

A: Right. That's exactly what we're attempting to do . . .

CP 333 and 335. Overlake/Evergreen failed to shake Mr. Huyck's testimony, as he further testified on cross-examination:

[The] reason is that these are surgeries that are presumed to be needed by the population in the future. The department is charged with, at least, facilitating access to care in such a way that we would like to see that adequate capacity is available to these patients in the future to obtain the surgeries . . . [T]hat's . . . longstanding policy of the program . . .

CP 336. Assuring that a sufficient number of operating rooms are available to use by all physicians is in the public interest, and certainly is not an "unnecessary duplication" of services as contended by Overlake/Evergreen. Brief at 26.

In summary, the Department interprets WAC 246-310-270(9)(b) to allow calculation of the use rate based the total number of surgeries performed within the planning area. The interpretation is consistent with the plain language of the rule, and fulfills the legislative mandate for the Department to assure sufficient public “access” to health care services, including ASC services. The interpretation is not in error, and certainly is not arbitrary and capricious, as there is a rationale for the interpretation, even if the court should happen to disagree with the rationale. Thus, the Department’s interpretation should not be overturned by the court.

B. If The Department’s Approach To Performing The Methodology Is Correct, Swedish’s Application Should Be Approved.

The WAC 246-310-270 Need Methodology – using the Department’s approach, as explained above – shows need for 5.3 additional ASC operating rooms in East King County.³ CP at 334; App. at 23. Thus, the HLJ correctly found that, under the Methodology, need exists for the two new East King operating rooms proposed in the Swedish application. AR at 501; App. at 11 (¶1.18). This finding of need led the HLJ to approve the application. AR at 508; App. at 18 (¶¶ 3.1-3.2). If the Court accepts the Department’s approach to performing the Methodology,

³ This limited showing of need for 5.3 operating rooms exposes the fallacy of Overlake/Evergreen’s argument that the Department’s approach to performing the Methodology will “virtually guarantee” approval of any ASC application. Brief at 27.

it should uphold approval of Swedish's application, because Overlake/
Evergreen does not otherwise challenge the decision to approve the
application.

V. CONCLUSION

The Department's interpretation of the WAC 246-310-270 Need
Methodology – leading to a finding of “need” and to approval of
Swedish's ASC application – is entitled to considerable weight by the
Court. The interpretation is reasonable, and Overlake/Evergreen failed to
meet their burden to show that the Department's interpretation is arbitrary
and capricious. Accordingly, the Department respectfully requests that the
Court affirm the Department's approval of the Swedish application.

RESPECTFULLY SUBMITTED this 19 day of December,
2007.

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Attorneys for State of Washington

APPENDIX

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In the Matter of:)

OVERLAKE HOSPITAL MEDICAL)
CENTER, a Washington non-profit)
corporation; and KING COUNTY)
PUBLIC HOSPITAL DISTRICT NO. 2,)
dba EVERGREEN HEALTHCARE,)
a Washington public hospital district,)

Petitioners.)
_____)

Docket No. 03-06-C-2001CN

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CONCLUSIONS OF LAW
AND FINAL ORDER ON
REMAND

APPEARANCES:

Petitioner, Overlake Hospital Medical Center, by
Ogden Murphy Wallace PLLC, per
Donald W. Black, Attorney at Law

Petitioner, King County Public Health District No. 2,
dba Evergreen Healthcare, by
Livengood, Fitzgerald, & Alskog, PLLC, per
James S. Fitzgerald, Attorney at Law

Intervenor, Swedish Health Services,
dba Swedish Medical Center, by
Bennett Bigelow & Leedom, P.S. per
Stephen I. Pentz, Attorney at Law

Department of Health Certificate of Need Program, by
Office of the Attorney General, per
Richard A. McCartan, Assistant Attorney General

PRESIDING OFFICER: John F. Kuntz, Health Law Judge

Following the issuance of the Amended Findings of Fact, Conclusions of Law
and Final Order, Swedish Health Services (Swedish) filed a petition in King County

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Superior Court appealing the order. The Superior Court remanded the matter for further action.

ISSUES

1. Whether Swedish correctly included the number of surgeries performed at exempt ambulatory surgery center operating rooms in its WAC 246-310-270 calculation of the surgical procedure, use rate, and correctly excluded the number of exempt ambulatory surgery center operating rooms in its calculation of the existing operating room capacity determination?
2. Whether the Program's decision to grant the Swedish certificate of need application should be granted?

SUMMARY OF THE EVIDENCE

Randall Huyck, Robin Edward MacStravic, and Jody Carona testified at the hearing. The following thirteen exhibits were admitted at the hearing:

- Exhibit 1: The Swedish Certificate of Need Application Record.
- Exhibit 2: Health Service Area Map showing Southeast (yellow) and East (blue) King County Service Areas.
- Exhibit A: Program analysis in the Northwest Nasal Sinus Center application (Certificate of Need No. 1250).
- Exhibit B: Resume of Robin Edward MacStravic, Ph.D.
- Exhibit C: Deposition of Program Analyst Randy Huyck, taken August 27, 2003 (pages 58 through 95).
- Exhibit D: Facsimile dated August 20, 2003, with Program work sheets used in the original analysis date of August 15, 2003.

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- Exhibit E: Four ambulatory surgery center need methodology worksheets prepared by Jody Carona, Health Service Planning & Development, based on the Program's worksheets and data in the record, demonstrating the numerical need:
- E-1: In the Swedish defined planning area if all exempt ambulatory surgery center operating rooms are included in the available supply;
 - E-2: In the Swedish planning area if all surgeries performed in all exempt ambulatory surgery center operating rooms are excluded from the use rate;
 - E-3: In the East King County planning area if all exempt ambulatory surgery center operating rooms are included in the available supply; and
 - E-4: In the East King County planning area if all surgeries performed in all exempt ambulatory surgery center operating rooms are excluded from the use rate.
- Exhibit F: Oversized Map of Proposed Service Area for Swedish ambulatory surgery center (Exhibit 7 from the Huyck deposition).
- Exhibit G: Swedish Defined Service Area (actual Swedish defined service area facilities per Department of Health directory of certified ambulatory surgery centers and Swedish application).
- Exhibit H: Summary of East King Surgery 2001 Utilization Data and Use Rate Calculations corrected Calculation of Need – Northwest Nasal Surgery Center.
- Exhibit I: 2006 East King Secondary Health Service Area – Excluding Exempt Facilities.
- Exhibit J: Swedish Bellevue Ambulatory Surgery Center Need Methodology:
- J-1: Methodology using 102/1000 use rate.
 - J-2: Methodology using 82/1000 use rate.
 - J-3: Methodology using 57/1000 use rate.

- J-4: Methodology using 76/1000 use rate.
- Exhibit K: November 27, 2002 letter to Lori Aoyama, Health Facilities Planning & Development, from Randy Huyck (with attached copies of the Program's application of the ambulatory surgery center numeric need methodology contained in WAC 246-310-270:
- K-1: Program methodology.
 - K-2: Methodology using Evergreen/Overlake number of surgeries (prepared November 27, 2002).
 - K-3: Methodology using Northwest Nasal Sinus Center projected surgeries (prepared November 27, 2002).
 - K-4: Methodology as prepared by applicant Northwest Nasal Sinus Center (prepared November 27, 2002).
 - K-5: East King Ambulatory Surgery Center Survey CN Facilities (prepared November 27, 2002).
 - K-6: East King Ambulatory Surgery Center Survey All Responding (prepared November 27, 2002).

Based on the evidence and exhibits in this matter, the Presiding Officer enters the following:

I. FINDINGS OF FACT

A. Background

1.1 The Certificate of Need Program (the Program) granted Swedish Health Services (Swedish) Certificate of Need No. 1264 to establish an ambulatory surgical facility in Bellevue, Washington. Overlake Hospital Medical Center and Evergreen Healthcare (the Petitioners) appealed the Program's decision. Swedish was permitted to intervene in the appeal.

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1.2 On July 8, 2005, the Presiding Officer issued an Amended Findings of Fact, Conclusions of Law and Final Order (the Final Order). The Final Order reversed the Program's decision that granted the certificate of need to Swedish.

1.3 On August 9, 2005, Swedish filed a Petition for Judicial Review in King County Superior Court pursuant to RCW 34.05.530. On April 19, 2006, King County Superior Court Judge Douglas North issued an Order Reversing the Presiding Officer's Amended Findings of Fact, Conclusions of Law and Final Order, and Remanding to the Presiding Officer for Further Proceedings (the Remand Order). Judge North ruled, in relevant part:

Accordingly, the Presiding Officer's Final Order is affirmed in part and reversed in part. The case is remanded to the Presiding Officer, based on the evidence presented by the parties to the Department of Health during the application process and the adjudicative proceeding, to (i) determine whether Swedish's proposed ASC satisfies the certificate of need criteria, using the East King County planning area; and (ii) address any other issues raised by the parties in the prior adjudicative proceeding and not previously addressed in the Final Order or this order.

The Remand Order at 2.

1.4 Surgery can be performed on an inpatient or outpatient basis.¹ Inpatient surgery is when a person's surgery requires board and room in a health care facility (i.e., a hospital) on a continuous twenty-four-hour-a-day basis.² Therefore, outpatient surgery is when a person's surgery requires less than twenty-four hour care. When a

¹ "Surgery" means that "branch of medicine dealing with the manual and operative procedures for correction of deformities and defects, repair of injuries, and diagnosis and cure of certain diseases." Taber's Cyclopedic Medical Dictionary (14th Edition, 1981), at 1395.

² See WAC 246-310-010.

need exists for additional outpatient operating room capacity, preference is given to dedicated outpatient operating rooms.³

1.5 When a person receives surgery on an outpatient basis, that surgery can be performed in an ambulatory surgical facility. An "ambulatory surgical facility" is a free standing entity that operates primarily for the purpose of performing outpatient surgical procedures, that is surgery for patients who do not require hospitalization.⁴ To qualify as an ambulatory surgical facility, the facility must have a minimum of two operating rooms.⁵ The facility can be located in a private physician or dentist office. When the use of the facility is not restricted to a specific individual or group practice, the facility can qualify as an ambulatory surgical facility. When a facility's use is restricted to a specific individual or group practice, by definition, it is not an ambulatory surgical facility.⁶ These exempt facilities can be referred to as ambulatory surgical centers.⁷

1.6 Characterizing a facility as an ambulatory surgical facility or an ambulatory surgical center is important under the law. An ambulatory surgical facility must obtain a certificate of need to operate in the state of Washington.⁸ An ambulatory surgical center is exempt from the certificate of need requirement.

³ WAC 246-310-270(5).

⁴ WAC 246-310-010.

⁵ WAC 246-310-270(6) and WAC 246-310-010. To "operate" is "to perform an incision or to make a suture on the body or any of its organs or parts to restore health." Taber's Cyclopedic Medical Dictionary (Edition 14, 1981), at 990.

⁶ See WAC 246-310-010.

⁷ The term ambulatory surgical center is not defined in chapter 246-310 WAC. The term is being used to help to differentiate between exempt and non-exempt facilities.

⁸ WAC 246-310-270(1).

1.7 The decision whether to grant or deny an ambulatory surgical facility certificate of need application is determined by using a mathematical formula or methodology to determine whether there is a "need" for an additional facility (that is, a requirement for additional operating room capacity).⁹ To determine whether need for an additional facility exists requires the identification of a geographic region known as a secondary health services planning area (the health planning area).¹⁰ If the applicant can show there is a net need for dedicated outpatient operating rooms in the relevant health planning area in the future (three years after the applicant anticipates starting the operation of the facility) the application is granted. If no need exists, the application is denied.

1.8 Need exists if more operating room capacity is required in the project year. Capacity speaks to the number of surgeries that can be performed in an operating room. The surgery information is obtained from information derived from surveys provided by facilities in the health planning area or by use of a default figure provided in the regulation. Facilities in a health planning area are not required to complete the surveys regarding surgical capacity at their respective facilities. Thus, the capacity calculations in any given application are affected by the number of facilities that reply to the submitted surveys.¹¹

⁹ WAC 246-310-270(9).

¹⁰ WAC 246-310-270(3).

¹¹ The Program analyst acknowledged at hearing that an issue exists with any use rate calculations, as the figure is calculated without receiving complete surgical statistics.

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1.9 Deciding whether future operating room capacity is necessary requires the calculation of a figure known as a "use rate." The use rate means a projection of the number of inpatient and outpatient surgeries within the applicant's health planning area for the applicant's target year (the third year of operation).¹² The projection is based on the current number of surgeries adjusted for the forecasted growth in the population served, and may be adjusted for trends in surgeries per capita (that is, surgeries according to the number of individuals). The use rate is represented by a percentage of surgeries required per each one thousand population (for example, 100 surgeries per each 1000 individuals, or 100/1000).

1.10 When calculating the use rate for a health planning area, it is necessary to include the surgical volume or number of surgeries that have been performed both in ambulatory surgical centers (that is, surgical centers that are exempt from the requirement of obtaining a certificate of need) and ambulatory surgical facilities (non-exempt facilities which are required to obtain a certificate of need). When calculating the number of existing facilities in a health service area, it is necessary to exclude from that count the number of operating rooms from ambulatory surgical centers (exempt facilities). The calculation performed under this regulation requires a comparison of separate concepts: (1) The total volume or number of inpatient and outpatient surgeries which have been performed in the planning area; and (2) the amount of capacity or facilities needed to accommodate the number of anticipated future surgeries (based on the anticipated increase in the population) in the health planning area.

¹² See WAC 246-310-270(9)(b)(i).

1.11 The number of anticipated future surgeries can be calculated by applying the use rate to the anticipated future population. Determining whether an individual will obtain that future surgery, in an ambulatory surgical center (an exempt facility) or an ambulatory surgical facility (a non-exempt facility) cannot be reduced to a mathematical formula. The first concept (anticipated future surgeries) is a numerical value. The second concept (the location of the future surgery) cannot be determined with mathematical certainty. For example, a patient who may qualify for surgery at an exempt ambulatory surgical center in the present may not qualify for surgery in the future at the same exempt facility. Another example is a surgeon who holds surgical privileges at an exempt ambulatory surgical center in the present, may not hold surgical privileges at the same facility in future. Finally, the exempt ambulatory surgical center may no longer exist.

B. Need.

1.12 What does this mean for calculating the need methodology? It means capturing all current surgical capacity statistics from ambulatory surgical facilities (non-exempt facilities) and ambulatory surgical centers (exempt facilities) in calculating existing capacity, but calculating future need considering only ambulatory surgical facilities to ensure that the patients have access to surgical facilities in the future.

1.13 Swedish submitted its application to establish the free-standing ambulatory surgical facility in November 2002. Under its application, the third year of operation would be 2006. Swedish provided need calculation information as a part of its application. The Swedish information shows that with a use rate of 102/1000 (based on

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National Center for Health Statistics data) and a population of 533,055 in 2004 (based on the Northwest Nasal Sinus Center application) there existed a net need for 5.9 outpatient operating rooms. PR 316-317. With a use rate of 82/100 (obtained from the Northwest Nasal Sinus Center application) and using the same 2004 population figure, there existed a net need for 1.0 outpatient operating rooms. PR 319.

1.14 The Swedish need calculations under WAC 246-310-270(9) included all surgery data, whether those surgeries were performed in an ambulatory surgery center (an exempt facility) or an ambulatory surgical facility (a non-exempt facility). When calculating whether need existed, Swedish performed those calculations using only ambulatory surgical facility operating rooms to show the existence of a surplus or shortage of dedicated outpatient operating rooms.

1.15 The Program submitted need figures at hearing based on information contained in the Swedish application records. With a use rate of 82/1000 and a 2006 population figure of 546,288, there existed a net need for 5.39 dedicated outpatient operating rooms. Exhibit J-2.

1.16 The Program need calculations under WAC 246-310-270(9) included all surgery data, whether those surgeries were performed in an ambulatory surgical center (an exempt facility) or an ambulatory surgical facility (a non-exempt facility). When calculating whether need existed, the Program performed those calculations using only ambulatory surgical facility operating rooms to show the existence of a surplus or shortage of dedicated outpatient rooms.

1.17 Information in both the Swedish application and the Program's certificate of need analysis show need exists. However, Swedish used 2004 population information as opposed to 2006 population figures (the third year of operation) as required under WAC 246-310-270(9)((b)(i). The Northwest Nasal Sinus Center use rate (82/1000) was based on state population information as opposed to national population figures from the National Center for Health Statistics (102/1000).

1.18 In calculating whether operating room need exists, the appropriate use rate is 82/1000, as this figure is derived from state population information and the appropriate health planning area. The appropriate population information is the 2006 population information from the East King County health planning area. That population figure is 546,288. See Exhibit J-2. The calculations show a net need for an additional 5.39 dedicated outpatient operating rooms. Therefore, need exists.

1.19 All surgery data (the total number of surgeries performed) was included in the calculations in Finding of Fact 1.18 above, whether those surgeries were performed in an ambulatory surgical center (an exempt facility) or an ambulatory surgical facility (a non-exempt facility). When calculating whether need existed in Finding of Fact 1.18, calculations were performed using only ambulatory surgical facility outpatient operating rooms to show a shortage of dedicated outpatient operating rooms in the East King County health planning area.

C. Remaining Certificate of Need Criteria.

1.20 Swedish provided financial information to show that the immediate and long range capital and operating costs for its proposed ambulatory surgical facility

project could be met. The Program considered whether the Swedish project was financially feasible by using a financial ratio analysis to assess the financial impact of the project on the overall facility operation. PR 563-564. The Program also compared costs of the project and determined the Swedish project would not result in an unreasonable impact on the costs and charges for health services within the service area. PR 565. Swedish provided sufficient information to show that it could finance the project from available cash reserves. PR 566.

1.21 Swedish provided information to show that it could meet the structure and process (quality) of care for the project. Swedish provided sufficient information in its application to show that it could meet staffing requirements, establish sufficient ancillary and support services and would conform to any applicable legal requirements. PR 566-568.

1.22 Swedish provided information in its application to show that it could meet the cost containment requirements of the project. Swedish provided information to show it had considered whether there were any superior alternatives to its proposal to establish an ambulatory surgical facility, and that the project would not have an impact on the costs and charges to the public. PR 566-568.

II. CONCLUSIONS OF LAW

2.1 The certificate of need program is regulated pursuant to chapter 70.38 RCW and chapter 246-310 WAC. The development of health services and resources should be accomplished in a planned, orderly fashion, consistent with identified priorities and without unnecessary duplication or fragmentation.

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RCW 70.38.015(2).

2.2 In all license application cases, the burden shall be on the applicant to establish that the application meets all applicable criteria. WAC 246-10-606.¹³ The Program then decides whether to grant or deny a certificate of need application. The Program's written decision must contain sufficient information to support the Program's decision granting or denying the application. See WAC 246-310-200(2)(a); see also *In re Auburn Regional Medical Center*, Docket No. 01-05-C-1052CN (February 20, 2003). Evidence is admissible in certificate of need hearings if it is the kind of evidence on which reasonably prudent persons are accustomed to rely on in the conduct of their affairs. RCW 34.04.452; WAC 246-10-606.

2.3 In general a certificate of need hearing does not supplant the certificate of need application review process. Rather, the hearing assures that the procedural and substantive rights of the parties have been observed and factual record supports the Program's decision and analysis. *In re Ear, Nose, Throat*, Docket No. 00-09-C-1037CN (April 17, 2001) (Prehearing Order No. 6). While the hearing does not supplant the certificate of need review process under normal circumstances, the King County Superior Court remanded the proceeding to the Presiding Officer in this case to determine whether the application should be granted using information contained in the application record regarding the East King County planning area. The remand order also required the Presiding Officer to address any other issues raised by the parties in the prior

¹³ Certificate of need proceedings are governed by the Administrative Procedure Act (chapter 34.05 RCW), chapter 246-310 WAC and chapter 246-08 WAC. WAC 246-310-610. The relevant sections in chapter 246-08 WAC were replaced in 1993 by chapter 246-10 WAC. WAC 246-10-101

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(9) Operating room need in a planning area shall be determined using the following method:

(a) Existing capacity.

(iii) Calculate the total annual capacity (in number of surgeries) of all dedicated outpatient operating rooms in the area.

(iv) Calculate the total annual capacity (in number of minutes) of the remaining inpatient and outpatient operating rooms in the area, including dedicated specialized rooms except for twenty-four hour dedicated emergency rooms. When dedicated emergency operating rooms are excluded, emergency or minutes should also be excluded when calculating the need in the area. Exclude cystoscopic and other special purpose rooms (e.g. open heart surgery) and delivery rooms.

(b) Future need.

(i) Project number of inpatient and outpatient surgeries performed within the third year of operation. This shall be based on current number of surgeries adjusted for forecasted growth in the population served and may be adjusted for trends in surgeries per capita.

(ii) Subtract the capacity of dedicated outpatient operating rooms from the forecasted number of outpatient surgeries. The difference continues into the calculations of (b)(iv) of this subsection.

(iii) Determine the average time per inpatient and outpatient surgery in the planning area. Where data are unavailable, assume one hundred minutes per inpatient and fifty minutes per outpatient surgery. This excludes preparation and cleanup time and is comparable to "billing minutes".

(iv) Calculate the sum of inpatient and remaining outpatient (from (b)(ii) of this subsection) operating room time needed in the third year of operation.

(c) Net Need.

adjudicative proceeding and not previously addressed in the Final Order or this order.

See the Remand Order, page 2.

A. First Remand Issue: Need.

2.4 There is sufficient information in the Swedish application file to answer the first issue identified in the Remand Order, specifically to determine whether the ambulatory surgical facility proposed by Swedish satisfied the certificate of need criteria using the East King County planning area. See Findings of Fact 1.13 through 1.18. Regarding the 2006 project year, there is need for an additional 5.39 operating rooms in the East King County planning area. See Finding of Fact 1.18.

B. Second Remand Issue: Issue Not Previously Addressed in Earlier Final Order.

2.5 Answering the first issue (determining if need exists in the East King County planning area) requires answering another issue that was not addressed in the Amended Final Order. That issue is whether, when calculating operating room need under WAC 246-310-270(9), the applicant can include the number of surgeries performed at an exempt ambulatory surgical center when determining the surgical procedure use rate, but exclude the number of operating rooms in an exempt ambulatory surgical center from the count in existing capacity. The Certificate of Need Program has historically used this approach in reviewing ambulatory surgical facility applications.

2.6 The rule which is applied is WAC 246-310-270. That rule provides, in pertinent part:

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(i) If (b)(iv) of this subsection is less than (a)(iv) of this subsection, divide their difference by ninety-four thousand two hundred fifty minutes to obtain the area's surplus of operating rooms used for both inpatient and outpatient surgery.

(ii) If (b)(iv) of this subsection is greater than (a)(iv) of this subsection, subtract (a)(iv) of this subsection from the inpatient component of (b)(iv) of this subsection and divide by ninety-four thousand two hundred fifty minutes to obtain the area's shortage of inpatient operating rooms. Divide the outpatient component of (b)(iv) of this subsection by sixty-eight thousand eight hundred fifty to obtain the area's shortage of dedicated outpatient operating rooms.

WAC 246-310-270(9) (emphasis added).

2.7 When capturing outpatient surgery data (the number of surgeries) for use in calculating future need, all outpatient surgery data should be included in the final data figure. All outpatient surgery data means data from both exempt and non-exempt facilities. The plain language of WAC 246-310-270(9)(a)(iii) requires that operating room need shall be determined using the total annual capacity (in number of surgeries) of all dedicated outpatient operating rooms in the area. The plain language of the rule does not differentiate between exempt (ambulatory surgical centers) and non-exempt (ambulatory surgical facilities). Rules of statutory construction apply to administrative rules and regulations, particularly where they are adopted pursuant to express legislative authority. See *State v. Burke*, 92 Wn.2d 474, 478 (1979). Where the meaning of a provision is plain on its face, the court must give effect to that plain meaning as an expression of legislative intent. *City of Olympia v. Drebeck*, 156 Wn.2d 289, 295 (2006) (citing *Department of Ecology v. Campbell & Gwinn LLC*, 146 Wn.2d 1, 9-10 (2002)).

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2.8 The next question is whether the WAC 246-310-270(9)(b) and (c) language is equally clear regarding the calculation of operating room need? In other words is the operating room need calculation restricted to only the number of non-exempt (ambulatory surgical facility) operating rooms, or all operating rooms consistent with the reading of WAC 246-310-270(9)(a). A reading of the regulatory language in WAC 246-310-270(9)(b) speaks to projecting the number of inpatient and outpatient surgeries performed in the planning area. This language appears to be all inclusive, similar to a reading of the capacity language set forth in WAC 246-310-270(9)(a).

2.9 However, the language of WAC 246-310-270(9)(b) and (c) cannot be read in isolation. A provision's plain meaning may be ascertained by an examination of the statute in which the provision at issue is found, as well as related statutes or other provisions of the same act in which the provision is found. *City of Olympia v. Drebeck*, 156 Wn.2d at 295 (internal citations omitted). The legislative declaration of public policy states that health planning should promote, maintain, and assure that all citizens have accessible health services. See RCW 70.38.015(1). If the more inclusive approach were followed, the calculation of available operating rooms would include ambulatory surgery center (exempt) operating rooms that would not be available to many of the individuals within the health planning area. See Findings of Fact 1.11 and 1.12. For this reason, while all surgeries from whatever source should be included in the existing capacity calculations under WAC 246-310-270(9)(a), that inclusive approach should not

be used in determining the future need/net need calculation under WAC 246-310-270(9)
(b) and (c).

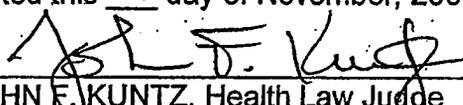
III. ORDER

Based on the foregoing Findings of Fact and Conclusions of Law of the Amended Final Order, and the above Findings of Fact and Conclusions of Law following the King County Superior Court remand order, it is ORDERED:

3.1 There is a net need for 5.39 additional dedicated outpatient operating rooms in the East King County planning area in the 2006 project year.

3.2 Certificate of Need No. 1264 for Swedish Health Services to establish an ambulatory surgical facility in Bellevue, Washington, is GRANTED.

Dated this 9th day of November, 2006.


JOHN F. KUNTZ, Health Law Judge
Presiding Officer

NOTICE TO PARTIES

Either party may file a petition for reconsideration. RCW 34.05.461(3); . RCW 34.05.470. The petition for reconsideration must be filed within 10 days of service of this Order with:

Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

And a copy must be sent to:

Certificate of Need Program
P.O. Box 47852
Olympia, WA 95204-7852

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The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Service Unit 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 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, however, the 30-day period will begin to run upon the resolution of that petition.

This order remains in effect even if a petition for reconsideration or petition for judicial reviewed is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. 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).

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246-310-263 << 246-310-270 >> 246-310-280

WAC 246-310-270

Ambulatory surgery.

(1) To receive approval, an ambulatory surgical facility must meet the following standards in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(2) The area to be used to plan for operating rooms and ambulatory surgical facilities is the secondary health services planning area.

(3) Secondary health services planning areas are: San Juan, Whatcom, East Skagit, Whidbey-Fidalgo, Western North Olympic, East Clallam, East Jefferson, North Snohomish, Central Snohomish, East Snohomish, Southwest Snohomish, Kitsap, North King, East King, Central King, Southwest King, Southeast King, Central Pierce, West Pierce, East Pierce, Mason, West Grays Harbor, Southeast Grays Harbor, Thurston, North Pacific, South Pacific, West Lewis, East Lewis, Cowlitz-Wahkiakum-Skamania, Clark, West Klickitat, East Klickitat, Okanogan, Chelan-Douglas, Grant, Kittitas, Yakima, Benton-Franklin, Ferry, North Stevens, North Pend Oreille, South Stevens, South Pend Oreille, Southwest Lincoln, Central Lincoln, Spokane, Southwest Adams, Central Adams, Central Whitman, East Whitman, Walla Walla, Columbia, Garfield, and Asotin.

(4) Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need.

(5) When a need exists in planning areas for additional outpatient operating room capacity, preference shall be given to dedicated outpatient operating rooms.

(6) An ambulatory surgical facility shall have a minimum of two operating rooms.

(7) Ambulatory surgical facilities shall document and provide assurances of implementation of policies to provide access to individuals unable to pay consistent with charity care levels provided by hospitals affected by the proposed ambulatory surgical facility. The amount of an ambulatory surgical facility's annual revenue utilized to finance charity care shall be at least equal to or greater than the average percentage of total patient revenue, other than medicare or medicaid, that affected hospitals in the planning area utilized to provide charity care in the last available reporting year.

(8) The need for operating rooms will be determined using the method identified in subsection (9) of this section.

(9) Operating room need in a planning area shall be determined using the following method:

(a) Existing capacity.

(i) Assume the annual capacity of one operating room located in a hospital and not dedicated to outpatient surgery is ninety-four thousand two hundred fifty minutes. This is derived from scheduling forty-four hours per week, fifty-one weeks per year (allowing for five weekday holidays), a fifteen percent loss for preparation and clean-up time, and fifteen percent time loss to allow schedule flexibility. The resulting seventy percent productive time is comparable to the previously operating hospital commission's last definition of "billing minutes" which is the time lapse from administration of anesthesia until surgery is completed.

(ii) Assume the annual capacity of one operating room dedicated to ambulatory surgery is sixty-eight thousand eight hundred fifty minutes. The derivation is the same as (a)(i) of this subsection except for twenty-five percent loss for prep/clean-up time and scheduling is for a thirty-seven and one-half hour week. Divide the capacity minutes by the average minutes per outpatient surgery (see (a)(vii) of this subsection). Where survey data are unavailable, assume fifty minutes per outpatient surgery, resulting in a capacity for one thousand three hundred seventy-seven outpatient surgeries per room per year.

(iii) Calculate the total annual capacity (in number of surgeries) of all dedicated outpatient operating rooms in the area.

(iv) Calculate the total annual capacity (in number of minutes) of the remaining inpatient and outpatient operating rooms in the area, including dedicated specialized rooms except for twenty-four hour dedicated emergency rooms. When dedicated emergency operating rooms are excluded, emergency or minutes should also be excluded when calculating the need in an area. Exclude cystoscopic and other special purpose rooms (e.g., open heart surgery) and delivery rooms.

(b) Future need.

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(i) Project number of inpatient and outpatient surgeries performed within the hospital planning area for the third year of operation. This shall be based on the current number of surgeries adjusted for forecasted growth in the population served and may be adjusted for trends in surgeries per capita.

(ii) Subtract the capacity of dedicated outpatient operating rooms from the forecasted number of outpatient surgeries. The difference continues into the calculation of (b)(iv) of this subsection.

(iii) Determine the average time per inpatient and outpatient surgery in the planning area. Where data are unavailable, assume one hundred minutes per inpatient and fifty minutes per outpatient surgery. This excludes preparation and cleanup time and is comparable to "billing minutes."

(iv) Calculate the sum of inpatient and remaining outpatient (from (b)(ii) of this subsection) operating room time needed in the third year of operation.

(c) Net need.

(i) If (b)(iv) of this subsection is less than (a)(iv) of this subsection, divide their difference by ninety-four thousand two hundred fifty minutes to obtain the area's surplus of operating rooms used for both inpatient and outpatient surgery.

(ii) If (b)(iv) of this subsection is greater than (a)(iv) of this subsection, subtract (a)(iv) of this subsection from the inpatient component of (b)(iv) of this subsection and divide by ninety-four thousand two hundred fifty minutes to obtain the area's shortage of inpatient operating rooms. Divide the outpatient component of (b)(iv) of this subsection by sixty-eight thousand eight hundred fifty to obtain the area's shortage of dedicated outpatient operating rooms.

[Statutory Authority: RCW 70.38.135 and 70.38.919, 92-02-018 (Order 224), § 246-310-270, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040, 91-02-049 (Order 121), recodified as § 246-310-270, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919, 90-16-058 (Order 073), § 248-19-700, filed 7/27/90, effective 8/27/90.]

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246-310-001 << 246-310-010 >> 246-310-020

WAC 246-310-010

Definitions.

For the purposes of chapter 246-310 WAC, the following words and phrases have the following meanings unless the context clearly indicates otherwise.

- (1) "Acute care facilities" means hospitals and ambulatory surgical facilities.
- (2) "Affected person" means an interested person who:
 - (a) Is located or resides in the applicant's health service area;
 - (b) Testified at a public hearing or submitted written evidence; and
 - (c) Requested in writing to be informed of the department's decision.
- (3) "Alterations," see "construction, renovation, or alteration."
- (4) "Ambulatory care facility" means any place, building, institution, or distinct part thereof not a health care facility as defined in this section and operated for the purpose of providing health services to individuals without providing such services with board and room on a continuous twenty-four-hour basis. The term "ambulatory care facility" includes the offices of private physicians, whether for individual or group practice.
- (5) "Ambulatory surgical facility" means any free-standing entity, including an ambulatory surgery center that operates primarily for the purpose of performing surgical procedures to treat patients not requiring hospitalization. This term does not include a facility in the offices of private physicians or dentists, whether for individual or group practice, if the privilege of using the facility is not extended to physicians or dentists outside the individual or group practice.
- (6) "Applicant," means:
 - (a) Any person proposing to engage in any undertaking subject to review under chapter 70.38 RCW; or
 - (b) Any person or individual with a ten percent or greater financial interest in a partnership or corporation or other comparable legal entity engaging in any undertaking subject to review under chapter 70.38 RCW.
- (7) "Bed banking" means the process of retaining the rights to nursing home bed allocations which are not licensed as outlined in WAC 246-310-395.
- (8) "Bed supply" means within a geographic area the total number of:
 - (a) Nursing home beds which are licensed or certificate of need approved but not yet licensed or beds banked under RCW 70.38.111 (8)(a) or where the need is deemed met under RCW 70.38.115 (13)(b), excluding:
 - (i) Those nursing home beds certified as intermediate care facility for the mentally retarded (ICF-MR) the operators of which have not signed an agreement on or before July 1, 1990, with the department of social and health services department of social and health services to give appropriate notice prior to termination of the ICF-MR service;
 - (ii) New or existing nursing home beds within a CCRC which are approved under WAC 246-310-380(5); or
 - (iii) Nursing home beds within a CCRC which is excluded from the definition of a health care facility per RCW 70.38.025(6); and
 - (iv) Beds banked under RCW 70.38.115 (13)(b) where the need is not deemed met.
 - (b) Licensed hospital beds used for long-term care or certificate of need approved hospital beds to be used for long-term care not yet in use, excluding swing-beds.
- (9) "Bed-to-population ratio" means the nursing home bed supply per one thousand persons of the estimated or forecasted resident population age sixty-five and older.
- (10) "Capital expenditure": Except for WAC 246-310-280, capital expenditure means an expenditure, including a force account expenditure (i.e., an expenditure for a construction project undertaken by a nursing home facility as its own contractor), which, under generally accepted accounting principles, is not properly chargeable as an expense of

Service Area Population: 546,288
 Surgeries @ 82/1,000: 44,796

5-2

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a.i. 94,250 minutes/year/mixed-use OR

a.ii. 68,850 minutes/year/dedicated outpatient OR

a.iii. 19 dedicated outpatient OR's x 68,850 minutes = 1,308,150 minutes dedicated OR capacity

a.iv. 14 mixed-use OR's x 94,250 minutes = 1,319,500 minutes mixed-use OR capacity

b.i. projected inpatient surgeries = 16,574 = 1,947,489 minutes inpatient surgeries

projected outpatient surgeries = 28,221 = 1,679,164 minutes outpatient surgeries

b.ii. Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's

28,221 - 21,986 = 6,236 outpatient surgeries

b.iii. average time of inpatient surgeries = 117.5 minutes

average time of outpatient surgeries = 60 minutes

b.iv. inpatient surgeries*average time = 1,947,489 minutes

remaining outpatient surgeries(b.ii.)*ave time = 371,014 minutes

2,318,503 minutes

c.i. if b.iv. < a.iv., divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's

Not Applicable - Go to c.11. and ignore any value here.

1,319,500

2,318,503

-999,003 / 94,250 = -10.60

c.ii. if b.iv. > a.iv., divide (inpatient part of b.iv - a.iv.) by 94250 to determine shortage of inpatient OR's

USE THESE VALUES

1,947,489

1,319,500

627,989 / 94,250 = 6.66

divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's

371,014 / 68,850 = 5.39