STATE OF WASHINGTON
DEPARTMENT OF HEALTH
OFFICE OF PROFESSIONAL STANDARDS

In Re the Appeal of PACIFIC RIM OUTPATIENT SURGERY CENTER Certificate of Need BELLINGHAM SURGERY CENTER, Petitioner, Pacific Rim Outpatient Surgery Center, Respondent.	)	Docket No. 02-08-C-1003CN FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

APPEARANCES:

Petitioner, Bellingham Surgery Center, by
Thomas H. Grimm and John F. Sullivan

Respondent, Pacific Rim Outpatient Surgery Center, by
Greg E. Montgomery

Intervenor, PeaceHealth, dba St. Joseph Hospital, by
Stuart P. Hennessey

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

PRESIDING OFFICER: John F. Kuntz, Health Law Judge

The Presiding Officer, on authority delegated by the Secretary of Health, conducted a hearing on December 18-20, 2002, in Kent, Washington. Certificate of Need upheld.

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ISSUES

Did the Program base Certificate of Need No. 1246 to Pacific Rim Outpatient Surgery Center on the applicable criteria, set forth in chapters 70.38 RCW and 246-310 WAC, for the establishment of an ambulatory surgical facility?

SUMMARY OF DECISION

The Program decision to issue Certificate of Need No. 1246 to Pacific Rim Outpatient Surgery Center showed the applicant met the applicable criteria set forth in chapters 70.38 RCW and 246-310 WAC. More specifically, the applicant showed a need for additional dedicated outpatient operating rooms, following the Program's application of the need formula set forth in WAC 246-310-270(9). The application met the criteria in WAC 246-310-210 through 246-310-240.

PROCEDURAL HISTORY

On December 13, 2000, Pacific Rim Outpatient Surgery Center (the Respondent) applied for a certificate of need to establish a Medicare certified ambulatory surgery center, with five operating suites, in Bellingham, Washington. The Certificate of Need Program (the Program) notified all interested parties of the Respondent's application, conducted a public hearing to allow input by the interested parties, and created the 713 page application file.[1]

On August 7, 2002, following its review process, the Program notified the Respondent that its certificate of need application met the applicable criteria. The Program advised the Respondent the certificate would be issued following the Respondent's acceptance of certain conditions. The Respondent accepted the specified conditions, and the Program issued Certificate of Need No. 1246 to the Respondent on August 23, 2002.

[1] At hearing the application file was amended to include 4 additional pages. The additional pages included Respondent's acceptance letter, and a copy of Certificate of Need No. 1246.

On August 12, 2002, Bellingham Surgery Center (the Petitioner) filed a request for an adjudicative proceeding to appeal the Program's decision. PeaceHealth, dba St. Joseph Hospital (the Intervenor) intervened in the case. Prehearing Order No. 1.

Prior to the hearing, the parties raised two procedural issues:

1. The Petitioner moved to remand the proceeding, following notification from the Program on December 17, 2002 that it had made a mathematical error in its operating room need calculation in the analysis awarding the certificate of need to the Respondent.

2. The Program moved to limit evidence to that received no later than the issuance of the certificate of need, consistent with the ruling in ENT & Plastic Surgery Associates, Docket No. 00-09-C-1037CN.

In response to the procedural issues raised by the parties, the Presiding Officer:

1. Denied the Petitioner's motion to remand on the basis that the Program's proposed change to the numbers contained in Exhibit 7, page 713 were the result of a scrivener's error. 12/18/02 RP at 15. In addition the cost factor of the hearing (the presence of the attorneys and witnesses) was considered. 12/18/02 RP at 20 – 21.

2. Granted the Program's motion to limit evidence. Factors in granting the motion included: (A) the substantial regulatory process in place regarding certificate of need applications; and (B) the Program's motion to limit evidence was an interpretation of existing rules rather than an impermissible creation of a rule. 12/18/02 RP at 38-39. *See* Budget Rent A Car v. Department of Licensing, 144 Wn.2d 889 (2001).

The parties submitted closing briefs in lieu of closing argument, following the receipt of the hearing transcript. Posthearing Order No. 1. The time for the issuance of the final order was extended to September 4, 2003. Posthearing Order No. 2. The time for issuance of the final order was extended to October 20, 2003, to allow the Program to specify which WAC 246-310-270(9) calculation was the basis of its decision to award

Certificate of Need No. 1246, and to allow the other parties to submit responsive pleadings. Posthearing Order No. 3.

On September 11, 2003, the Program identified the calculation on Exhibit 10, page 9, as the preferred calculation of methodology. 12/20/02 RP 3 at 61 – 62. The Respondent agreed with the Program's position by letter dated September 12, 2003. The Petitioner disagreed with the Program's calculation on procedural and substantive ground by letter dated October 3, 2003.

The evidentiary record consisted of the 717-page certificate of need application record (Exhibit 7), and other exhibits derived from the application record (Exhibits 1 – 6, and 8 – 14).[2] *See also* ENT & Plastic Surgery Associates, Docket No. 00-09-C-1037CN (April 17, 2001) at 8.

HEARING

Janis Sigman, Certificate of Need Program Manager, reviewed the Respondent's certificate of need application for a 5 operating room ambulatory surgery center. Based upon her written analysis, the Program issued Certificate of Need No. 1246. Exhibit 7, pages 699-713.[3] Within the application file, the terms "ambulatory surgery center" and "ambulatory surgical facility"[4] are used interchangeably. 12/18/02 RP at 68.

The Respondent filed its certificate of need application on December 13, 2000. The Respondent described the project as:

[2] Exhibit 1 is the resume of Certificate of Need Program Manager Janis Sigman. While not created from information contained in the application record, the parties did not oppose its admission.
[3] The application file was supplemented, without objection, at hearing. Exhibit 7, pages 714 – 717.
[4] By definition, an "ambulatory surgical facility" may include an ambulatory surgery center. See WAC 246-310-010.

> A limited liability company formed by the Respondent and Physicians Surgery Centers, Inc proposed to establish a Medicare certified ambulatory surgery center with 5 operating suites.
>
> Physicians Surgery Center would act as the managing partner.
>
> The primary goal of serving as much as 80% of the outpatient surgeries being scheduled by the hospital in its mixed use operating rooms.
>
> The Respondent anticipated representing close to 80% of the Whatcom county surgeons and anesthesiologists described itself as a limited liability company.

Exhibit 7, page 16.

The Program screened and processed the application using the regular review process. WAC 246-310-110(2)(c). As part of the process the Program conducted a public hearing in Whatcom County, and allowed a public comment period for issues raised at that hearing. The public comment period ended on May 15, 2001.

The Program declared a pivotal unresolved issue on February 15, 2002, following notification that Physicians Surgery Center, the managing partner/minority owner in the Respondent's original proposal, had withdrawn as part of the Respondent's application. Exhibit 7, page 384. The Program requested the Respondent provide specific information regarding changes in the project as a result of the withdrawal of Physicians Surgery Center, including:

A. Who would perform the role and responsibilities as managing partner;

B. Any changes in the FTEs;

C. Submitting revised financial statements;

D. Any changes in the financing of the project;

E. An explanation of why moving ahead alone (an option originally rejected by the Respondent) was acceptable now;

F. Any other relevant changes.

On March 8, 2002, the Respondent responded and explained it would hire in-house staff to manage the project, provided updated financials, and provided updated letters of credit to show it could finance the project alone. Exhibit 7, pages 387-404.

The Program forwarded the response material to the affected parties for further comment. Exhibit 7, pages 405-408. The Petitioner submitted detailed rebuttal comments to the pivotal unresolved issue material on April 2, 2002, and identified the following problems:

A. Increased but incomplete recognition of costs and serious underestimation of the costs of the project;

B. Lack of identification of where the replacement expertise will come;

C. No identification of investors who will put in the increased funds necessary to build and equip the larger space;

D. No identification of the management or accounting personnel and the consultants;

E. Very vague as to how the effects of the departure of Physician Surgery Centers, Inc. from the project will be dealt with;

F. Issues are raised as to the need for and the financial viability of the project where one of the biggest investors and the management company pulls out of the project.

Exhibit 7, pages 409-410.

In the project rationale portion of its application (Exhibit 7, pages 52 – 61), the Respondent provided utilization forecasts for outpatient surgeries for the period 2002 through 2006. The Respondent calculated existing capacity using the operating rooms available at the Intervenor's hospital (7 operating rooms), the Petitioners surgery center

(4 rooms), and NW Ambulatory Surgery Center (2 rooms). Exhibit 7, page 54. The Intervenor hospital has 9 mixed-use rooms, but the Respondent excluded two of those rooms (dedicated to open heart surgery and cesarean section patients) in calculating capacity. Exhibit 7, page 54.

The Respondent notified the Program of a calculation error. *Compare* FY 2000 use rate in Exhibit 7, page 55 *and contrast* FY 2000 use rate in Exhibit 7, page 377. After making the adjustment, the Respondent's calculated net outpatient operating room need changed from 5.2 to 4.53. *Compare* Exhibit 7, page 58 *and contrast* Exhibit 7, page 379.

In analyzing the Respondent's application, Ms. Sigman applied the formula provided in WAC 246-310-270(9) to determine whether "need" existed for the Respondent's proposed ambulatory surgical facility. Exhibit 7, page 713. RCW 246-310-270(9) breaks down into three parts: existing capacity; future need; and net need. Ms. Sigman calculated operating room need based on the responses she received to Program surveys mailed to facilities in the same secondary health service planning area as the Respondent. Exhibit 3 at 4.

Ms. Sigman determined there were 8 dedicated outpatient operating rooms (1 at Northwest Surgical; 4 at the Petitioner's facility; 2 at Northwest Ambulatory Surgery Center (NASS); and 1 at Whatcom Surgery Center) in the area. 12/18/02 RP at 91. She did not include 2 of those operating rooms in her calculation because the two facilities (Northwest Surgical and Whatcom Surgery Center) were not, by definition, ambulatory surgery facilities. 12/18/02 RP at 92; WAC 246-310-010. Using the 6 dedicated operating room number, and 7 mixed-use operating rooms identified by the

Intervenor's hospital, Ms. Sigman determined there was a shortage of 3.4 outpatient operating rooms in the planning area. Exhibit 7, page 713. The calculation was based, in part, on figures submitted by the Respondent in its original submission. Exhibit 7, pages 55-56.

At hearing Ms. Sigman acknowledged making several errors in the calculation she used to support her analysis. These errors included: (1) using the incorrect projected outpatient surgery number (using 7,845 rather than 9,921) in step b.ii of the calculation; and (2) incorrectly adding preparation and cleanup time in its average minutes per surgery to calculate the overall need for surgeries. 12/18/02 RP at 93 – 96, 99; 12/20/02 RP at 9, 13-14. Using the correct data, Ms. Sigman's updated calculations showed a shortage of 5.9 dedicated outpatient operating rooms in the relevant health service planning area.[5] 12/19/02 RP at 221 – 223; Exhibit 3, page 1.

Ms. Sigman examined the Respondent's application against the other required criteria (need; financial feasibility; structure and process; and cost containment). In determining that the Respondent's project was consistent with the other applicable criteria, Ms. Sigman found:

A. Need. The Respondent established need, both by its operating room net need calculations under WAC 246-310-270, and by complying with the requirements set forth in WAC 246-310-210(1) and (2).[6] Exhibit 7, pages 701-705.

   i. The Program concluded the Respondent's assumptions that there would be no shift of volumes to the Respondent's facility from NW Ambulatory Surgery Center and the Petitioner's facility to be reasonable. Exhibit 7, pages 703-704.

[5] Using the Program practice of rounding up partial numbers, this would result in 6 outpatient operating rooms. This is an increase over the 5 operating rooms approved in the analysis.
[6] In its analysis the Program found subcriteria in WAC 246-310-210(3) – (6) did not apply because they were considered not relevant to the project. This was not disputed at hearing.

ii. The Program accepted as reasonable the Respondent's assumption that the Intervenor's hospital would shift 80% of its outpatient capacity to the Respondent. Exhibit 7, page 703. The Program found this assumption supportable, given that the Petitioner's facility reported operating at or above capacity for the preceding three-year period. Exhibit 7, page 704.

iii. The Program also reviewed the capacity of NW Ambulatory Surgery Center (which was recently awarded a certificate of need for its own ambulatory surgical facility). Given the type of services provided (pain management) and the projected percentage of utilization by 2004, the Program concluded that facility would not be available or accessible to meet the needs of the patient population proposed to be served by the Respondent. Exhibit 7, page 705.

iv. A private ambulatory surgery center (Hines/James) would be closing and shifting its surgeries to the Respondent's facilities. This would create a need for an additional outpatient surgery room by 2005. Exhibit 7, page 703.

v. The Program reviewed the average minutes per case reported by the Petitioner and the Intervenor. Based on findings that the Intervenor hospital reported higher average minutes per case, and the differences in CPT codes for the 10 most frequent surgeries performed at the two facilities, the Program determined it was reasonable that the Respondent's facility (which would be absorbing the majority of the Intervenor's outpatient surgeries) would be more capable of meeting the complex outpatient surgeries (that is, the 23 hour/59 minute surgeries). Exhibit 7, page 704.

vi. The Respondent's admission policy provided for low-income, racial and ethnic minorities, women, handicapped persons and other underserved groups and the elderly as required under WAC 246-310-210(2). Exhibit 7, pages 705-706.

B. Financial feasibility. The Program determined the project's financial ratios favorably exceeded the Program's ratio guidelines with the exception of the project's debt service. The Respondent's revenue and expense projections, given in current dollars, compared favorable to other like projects. The Program found the Respondent's costs for 10 identified procedures compared favorably to the Intervenor's hospital and other

previous ambulatory surgical facility applications.[7] The project was found to be appropriately financed. Exhibit 7, pages 707-708.

C. Structure and process of care. Based on the Respondent's offer of competitive and attractive wage and benefit package, the Program believed the project would be able to recruit sufficient personnel. While acknowledging a health care worker shortage both in Washington and nationally, the Program determined that fact, by itself, was not grounds for denial of the project. Exhibit 7, page 708-709.

D. Cost containment. The Program considered several alternatives in terms of cost, efficiency and effectiveness. The Program determined that the Respondent would absorb the duties originally managed by Physician Surgery Centers, Inc. by hiring its own staff to manage the facility. The Program analyzed options that could be considered less costly (the Petitioner's intended expansion of its facilities/NW Ambulatory Surgical Center accepting patients in addition to its pain management cliental). Absent any documentation to support these options, the Program had no reliable basis to make a cost comparison.

Nancy Bitting is the regional chief executive officer for St. Joseph Hospital, a Level II Trauma center located in Bellingham, Washington. The hospital determined it had too few outpatient operating rooms available, given that its mixed operating rooms were operating at or near capacity. It did not foresee a sufficient increase in operating room capacity in Whatcom County. 12/19/02 RP at 10. The hospital initially planned to address its increased need by expanding its facility to include ambulatory outpatient services at a different site, and not in the existing mixed operating rooms. The hospital then began discussions with the Respondent, with the goal of transferring at least 80% of its outpatient cases to the Respondent's facility. Exhibit 7, page 448. The hospital anticipated shifting outpatient cases to the Respondent's facility would address its capacity problem without adding operating room suites. 12/19/02 RP at 14; Exhibit 7, page 448. No written agreement existed regarding the 80% shift of outpatient surgeries

[7] The Program does not identify the number or location of the other ambulatory surgical facility applications reviewed in its analysis (other than the Northwest Ambulatory Surgery Services).

at the time of the completion of the Program's survey. 12/19/02 RP at 14; see also Exhibit 7, pages 445-448. Ms. Bitting anticipated the issue would be addressed in the final lease between the parties. 12/19/02 RP at 22. The hospital had not made any effort to shift the overload to any other operating rooms in the county. 12/19/02 RP at 61.

The hospital will continue to allow physicians to schedule outpatient surgeries. 12/19/02 RP at 23. However, Ms. Bitting believes scheduling flexibility and staffing issues at the hospital will encourage surgeons to schedule outpatient surgeries at the Respondent's facility. In the event the certificate of need application is denied, the hospital will "do something", which could include starting the project in the ambulatory services building. 12/19/02 RP at 58.

Charles Neal is president of the multi-speciality group for Symbion Healthcare, Inc. (Symbion), the owner of the Petitioner's facility. Symbion had concerns regarding the Respondent's application, as it would affect Symbion's ability to obtain staffing, the duplication of services and the financial viability of its surgical center. 12/19/02 RP at 64-65, 67. Symbion previously opposed the Northwest Ambulatory Surgical Services (NASS) Certificate of Need application and analysis issued by the Program. Exhibit 7, pages 470-481.

Symbion considered an increased need might exist if the hospital intended to "remove" two mixed operating rooms by dedicating the two rooms to cardiac and C-section rooms. 12/19/02 RP at 73. Mr. Neal concluded there might be need for an additional operating room following the Northwest Ambulatory Surgery Services application. 12/19/02 RP at 95. 12/19/02 RP at 94 – 95. Mr. Neal investigated the

possible expansion of the Petitioner's facility by this two-room need, but Symbion did not do so. This decision was based on a slight drop of the facility caseload starting in 1999, a consideration of the changing demographics in the area and a concern that Northwest Ambulatory Surgical Services might expand its 2-room center. Mr. Neal testified that at least one additional operation room would be needed to replace the Hines/James facility closure, and an excess operating room need that was identified during the Northwest Ambulatory Surgery Services certificate of need application.

Kenneth Kloehn, M.D., an anesthesiologist, is the executive manager of the board of managers, and an investor in, the Respondent's surgical center. Two entities, Pacific Rim Anesthesia & Surgical Consultants (the Respondent) and Physician Surgery Center (PSC) initially filed the certificate of need application. The certificate of need application was submitted, at least in part, to allow the physicians involved to have a direct say in how the surgery center was run. 12/19/02 RP at 142-143. PSC was hired to provide management expertise to the project. During the application process the Respondent and PSC experienced problems in their professional relationship. 12/19/02 RP at 133. When the two entities could not resolve these problems, they entered a settlement agreement which allowed the Respondent to go forward alone.

When the parties separated, the Program declared a pivotal unresolved issue. Exhibit 7, page 384. The Program asked the Respondent to explain or clarify changes in the management services, financing of the project and any other relevant changes to the project. The Respondent responded to the Program's questions. Exhibit 7, pages 387-404.

Dr. Kloehn identified a new group of individuals to provide management services during the development of the project (Linda Williams, Nia Kihayes, Kay Allen and Allen Knutson, CPA). 12/19/02 RP at 134-135, 151-152. Once the project was up and running, the Respondent would hire additional full-time management employees. 12/19/02 RP at 152.

Susan K. Sharpe is self-employed as a health care consultant. Ms. Sharpe calculated the use rate used in the Respondent's application. Exhibit 7, page 55. She later corrected the use rate to remove the preparation and clean-up time. Exhibit 7, page 377. Ms. Sharp notified the Program of the corrected use rate.

Lynne Oliver, R.N., is the administrator for the Petitioner's surgical center. Ms. Oliver notes there is currently a shortage of operating room nurses both at her facility and the other facilities in the region. Any loss of surgical staff would impact the Petitioner's ability to provide care, and could require a cutback of procedures being scheduled. 12/20/02 RP at 121 – 122. The Petitioner had provided 23 hour, 59 minute outpatient surgery care at their facility, but it was not cost effective. 12/20/02 RP at 123 – 124. The Petitioner arranged with a local nursing home to provide care for subsequent 23 hour, 59 minute cases. 12/20/02 RP at 124. After listening to the testimony at hearing, Ms. Oliver believed some amount of need existed for additional outpatient operating rooms. 12/20/02 RP at 126.

The Petitioner set forth several arguments, including:

A. the Program failed to fully count all of the operating rooms in Whatcom County in making its calculation. The Petitioner argues the Program took just such an approach in its earlier certificate of need analysis of Northwest Ambulatory Surgery Services. Exhibit 7, page 475. The Petitioner contends there is no future operating room need in the service area after analyzing the

data using the WAC 246-310-270(9) formula. Exhibit 11. The Program interprets "total number of operating rooms" in conjunction with the definition of "ambulatory surgery facility" in WAC 246-310-010. By so doing the Program finds a shortage or need in this case. Exhibit 7, page 713; Exhibit 10 at 9.

B. The Program did not meet the need requirement set forth in WAC 246-310-210(1)(b) by not determining "the efficiency and appropriateness of the use of existing services and facilities similar to those proposed." The Petitioner contends the Program failed to consider: (1) that the Petitioner considered adding two more operation rooms (12/19/02 RP at 73) and (2) the changes in the local economy (12/19/02 RP at 74, 81 – 83).

C. The Respondent's project did not meet the financial feasibility requirement in WAC 246-310-220. The Petitioner argued that the Respondent's project fails the debt service guideline criteria, which indicate the facility will not generate enough revenue to comfortably cover the debt service over the three-year period. The Petitioner contends the operating net profits considered by the Program did not meet the WAC 246-310-220(2) criteria, in that the analysis does not show how it will impact costs and charges for health services.

D. The Respondent's project fails to meet the structure and process of care criteria in WAC 246-310-230(1), as it did not identify the source of the additional staff needed to run the facility. By failing to meet this criterion, the Program fails to show how the project will promote continuity in providing health care. The Petitioner further argues the Respondent's project may take the Petitioner's staff. The Program contends WAC 246-310-230(4) does not allow a denial of the application base on the "possibility" there will not be sufficient professional staff available.

E. Addressing the issue of cost containment, the Petitioner points to the withdrawal of the Physician's Surgery Center from the project as a warning sign that the project is not feasible. The Program did not inquire why the Respondent broke up its partnership, which the Petitioner believes is absolutely necessary to determine whether the Respondent's project can succeed. Additionally, the Program failed to resolve the pivotal unresolved issue that resulted from that breakup.

In its reply brief, the Petitioner contends physician preference or control is not part of the need methodology and is not a valid basis on which to approve the project. Petitioner's Reply Memorandum at 9, *citing* Providence Hospital v. DSHS, 112 Wn.2d 353, 361 (1989). The Respondent contends the Petitioner is raising a new issue for the

first time in its reply memorandum, and at no time did the Respondent suggest that the Program should approve the project because the physicians wanted control over their work environment. Pacific Rim Outpatient Surgery Center's Memorandum Addressing Newly Raised Issue at 1-2. Given the conclusion that the Program provided sufficient evidence to support its decision, except for the limited issue of showing what is the "actual" shortage of dedicated outpatient operating rooms under WAC 246-310-270(9), the Presiding Officer did not address this issue.

The matter was remanded to the Program to specify which of the WAC 246-310-270(9) calculations presented at hearing it was relying on as the basis of its decision. Posthearing Order No. 3. The Program stated that Ms. Sigman identified at hearing the Program's preferred application of the methodology, that being Exhibit 10, page 9. See 12/20/02 RP at 61 –62. That calculation included the volume/anticipated volume of the Northwest Ambulatory Surgery Center. 12/20/02 RP at 61. That method of calculation determined a shortage of 6.4 dedicated outpatient operating rooms for 2005.

The Respondent agreed Ms. Sigman's testimony regarding Exhibit 10, page 9, was the most realistic calculation of need. Additionally, the Respondent noted that Petitioner's counsel was able to cross-examine Ms. Sigman regarding this calculation. See 12/20/03 RP at 78 – 90.

The Petitioner disagreed with the Program's new rationale, contending it failed both procedurally and substantively under WAC 246-310-270. The Petitioner noted that certificate of need appeals more closely resemble a superior court review that a de novo hearing, and therefore requests the Program's attempt to change the basis for its

decision be rejected. See Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988) (deference to what appears to be nothing more than an agency's litigation positilon is entirely appropriate) and Burlington Truck Lines Inc. v. United States, 371 U.S. 156 (1962) (courts may not accept appellate counsel's post hoc rationalizations for agency orders). The additional twenty-five versions of WAC 246-310-270(9) calculations were either prepared for litigation or were not considered by the Program as part of its analysis process. The Program should not be allowed to correct its faulty analysis on appeal, consistent with previous Office of Professional Standards decisions on the issue. See ENT & Plastic Surgery Center, OPS Docket No. 00-09-C-1037CN.

Based on a careful review of the record, the Presiding Officer enters the following:

I. FINDINGS OF FACT

1.1 The Petitioner filed a request for an adjudicative proceeding within the time limit required under chapters 34.05 RCW and 246-10 WAC.

1.2 The Respondent filed a certificate of need application on December 13, 2000. On August 8, 2002, the Program issued its analysis of the Respondent's application and found project was consistent with the certificate of need criteria. The Program approved the Respondent's application subject to the Respondent meeting certain specified conditions.

1.3 The Respondent agreed to the conditions, the Program issued Certificate of Need No. 1246 (authorizing the establishment of a freestanding ambulatory surgery center with 5 operating suites) on August 23, 2002.

1.4 At the time the Program issued Certificate of Need No. 1246, the Petitioner took no steps to increase the number of outpatient operating rooms at its facility. The Petitioner eventually decided against expansion of its facility by two outpatient operating rooms.

1.5 While indicating in its survey response that it had available capacity, Northwest Ambulatory Surgery Center had taken no concrete steps at the time the Respondent filed its application to make its two operating rooms available for outpatient surgical procedures, in addition to the chronic pain management procedures, authorized under Certificate of Need No. 1213. The Program was not informed of any additional capacity prior to the Respondent filing its certificate of need application.

1.6 The Program established additional need for dedicated outpatient operating rooms in the applicable secondary health service planning area (Whatcom County) under WAC 246-310-270(9). This additional need was established without using the major assumptions utilized by the Respondent in support of its application. In using the correct formula, the Program committed several calculation errors. The errors included the use of an incorrect use rate (81.38) even after notification of the correct figure (75) by the Respondent. *Compare* Exhibit 7 pages 55 – 56 and *contrast* Exhibit 7 pages 375 – 379. The Program representative also incorrectly included preparation and clean up time in calculating the surgical minute figures used in step b.ii (regarding future need) of the WAC 246-310-270(9) formula.

1.7 The Program established a projected shortage of 3.4 dedicated outpatient operating rooms in the relevant service area by 2005. In calculating this figure, the Program noted the Intervenor hospital dedicated two of its nine mixed use rooms for

cardiac and c-section procedures, and removed them from the pool of available operating rooms. See WAC 246-310-270(9)(a)(iv).

1.8 At hearing, the Program submitted twenty-five different WAC 246-310-270(9) calculations based on information contained in the certificate of need application file. Following the interim order of remand, the Program indicated the preferred application of the WAC 246-310-270(9) methodology (as testified to at hearing by Program Manager Janis Sigman) calculated a shortage of 6.4 dedicated outpatient operating rooms by 2005. This method was preferred because it utilized the use rate of 75 (reported in fiscal 2000 year) and included the volume or anticipate volume of Northwest Ambulatory Surgery Center (NASS). The NASS volume was not reported as available prior to the filing of the applicatiion.

1.9 The Program initially performed its net need operating room calculations, and found additional need existed, without considering any of the assumptions used by the Respondent in its application. Following its initial need calculation, the Program did consider the Respondent's assumptions and determined that additional need existed. These assumptions (adopted by the Program in its analysis) included the Intervenor hospital's assertion that it would shift 80% of its outpatient capacity to the Respondent, and the closing of a private ambulatory surgical facility identified as the Hines/James facility.

1.10 The Program conducted a need analysis, in addition to its calculations under WAC 246-310-270(9), pursuant to WAC 246-310-210. The Program determined it was reasonable that outpatient operating room services would not be available, at least in part, because:

A. All relevant facilities under consideration (the Intervenor hospital, Northwest Ambulatory Surgery Services and Petitioner's ambulatory surgical facility) were operating near or at full capacity.

B. There was need for an ambulatory surgery facility that could offer additional 23 hour/59 minute services in the Whatcom County area. The Petitioner did provide 23 hour/59 minute services, but the procedures to performed at the Respondent's facility were different than those being performed at the Petitioner's facility

C. There was additional need for adequate access to outpatient surgeries for low-income and other underserved groups, given the current facilities being at, or near full capacity.

1.11 The project is financially feasible pursuant to WAC 246-310-220:

A. The Respondent met three of the four financial ratios used by the Program over the three year projected period. The four financial ratios are not contained as a part of WAC 246-310-220(1).

B. The Respondent provided the Program with a projected revenue and expense figures for the project. The Program relied upon, and therefore adopted, the Respondent's projected revenues and expenses projections over the three-year project period. The expenses are based upon current dollars. These costs do not appear to result in an unreasonable impact on the cost and charges for health services in Whatcom County. WAC 246-310-220(2).

C. The Respondent provided evidence it obtained financing for the project. Exhibit 7, pages 401 – 402. WAC 246-310-220(3).

1.12 The project meets the structure and process requirements of care pursuant to WAC 246-310-230:

A. The Respondent indicates it will recruit on a regional and national basis. It is reasonable to believe that employment pool can meet the Respondent's employee needs. The Petitioner did not provide sufficient evidence to indicate that the Respondent cannot fill its facility positions from an employee pool of that size.

B. The Respondent is developing agreements with outside providers to supply ancillary and support services.

C. The was no evidence submitted that the Respondent's facility, or the Respondent's employees, would not be in conformance with applicable state licensing requirements, or applicable Medicaid or Medicare program requirements.

D. The Respondent's application shows the proposed facility will not result in any fragmentation of services to the community. The anticipated patient pool will not be taken from either the Petitioner or Northwest Ambulatory Surgical Services.

1.13 The project meets the cost containment criteria of WAC 246-310-240:

A. There are no superior alternatives. The Petitioner considered, but did not expand its facility, to the increased need in the service area. After receiving Certificate of Need No. 1213, Northwest Ambulatory Surgery Services was not accepting patients, outside of the pain management population addressed in its certificate of need application, at its facility. Additionally, the existing facilities were being utilized at, or near, capacity.

B. The Respondent addressed the Program's concerns as raised in the pivotal unresolved issue.

C. The Respondent's revenue and cost projections compared favorably to other like projects.

II. CONCLUSIONS OF LAW

2.1 The Petitioner argues that, assuming WAC 246-310-610 governs the proceeding, the procedure in chapter 246-08 applies. WAC 246-310-610 applies when an applicant's certificate application is denied, or a certificate holder whose certificate is suspended or revoked. It does not apply in the present case.

2.2 An agency may commence an adjudicative proceeding at any time with respect to a matter within the agency's jurisdiction. RCW 34.05.413(1). When required by law or constitutional rights, and upon timely application of any person, an agency shall commence an adjudicative proceeding. RCW 34.05.413(2). The Department of

Health is responsible for managing the certificate of need program under chapter 70.38 RCW. WAC 246-310-010. Applications for licenses that are contested by a person having standing to contest under the law shall be conducted as an adjudicative proceeding. RCW 34.05.422(1)(b). *See* St. Joseph Hospital and Health Care Center v. Department of Health, 125 Wn.2d 733 (1995).

2.3 Final orders shall be based upon the kind of evidence upon which reasonably prudent persons are accustomed to rely in the conduct of their affairs. WAC 246-10-606. *See* RCW 34.05.452. In all cases involving an application for license the burden shall be on the applicant to establish that the application meets all applicable criteria, and in all other cases the burden is on the department to prove the alleged factual basis set forth in the initiating document. WAC 246-10-606. The burden of proof is a preponderance of the evidence. WAC 246-10-606. Here the applicant (the Respondent) applied for and received a certificate of need (the initiating document) following the Program's conclusion that the Respondent's application was consistent with applicable criteria of the certificate of need program. Exhibit 7, page 697.

2.4 The findings of the Program's review of certificate of need applications and the actions of the secretary's designee on such applications shall be based on whether the proposed project:

(a) Is needed.

(b) Will foster containment of costs of health care.

(c) Is financially feasible.

(d) Will meet the criteria for structure and process of care identified in WAC 246-310-230.

WAC 246-310-200(1); WAC 246-310-210 through 246-310-240. The criteria contained in the rules shall be used by the program in making the required determinations. WAC 246-310-200(2).

A. To receive approval, an ambulatory surgical facility must meet additional standards under WAC 246-310-270. WAC 246-310-270(1). "Ambulatory surgical facility" is defined as:

> 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, and does not include a facility in the office of a private physician or dentist, whether for individual or group practice, if the privilege of using such facility is not extended to physicians or dentists outside the individual or group practice.

WAC 246-310-010. An ambulatory surgical facility shall have a minimum of two operating rooms. WAC 246-310-270(6). The need for operating rooms will be determined using the method identified in WAC 246-310-270(9). WAC 246-310-270(8).

B. Unlike the formula set forth in WAC 246-310-270(9), the other need criteria are not set forth with mathematical precision. Examining the criteria found in WAC 246-310-210 – WAC 246-310-240 is based on a "reasonableness" test. *See* Providence Hospital v. DSHS, 112 Wn.2d 353, 362 (1989).

2.5 Neither chapter 70.38 RCW nor chapter 246-310 WAC defines the term "operating room".

A. The Petitioner argued the term should be given its usual and ordinary meaning: a room where a surgeon performs "some manual act or series of acts with instruments upon the body of a patient to remedy or remove deformity, injury, or

disease". Webster's Unabridged Dictionary (1989). Petitioner's Post-Hearing Memorandum at 17 – 18. WAC 246-310-270(4) states:

> 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.

The Petitioner interpreted "total number of operating rooms" to include all available operating rooms in the service planning area, even operating rooms not found in ambulatory surgical facilities.

B. Rules of statutory construction apply to administrative rules and regulations where they are adopted pursuant to express legislative authority. Burke v. State, 92 Wn.2d 474, 478 (1979). (Citations omitted). Undefined regulatory terms, like undefined statutory terms, are given their usual and ordinary meaning. Hertzke v. Washington State Department of Retirement Systems, 104 Wn.App 920, 928 (2001). If the words of the WAC provision are plain and unambiguous, the decision-maker need look no further than the regulation. Labor and Industries v. Delozier, 100 Wn.App 73, 76 (2000). The agency must also give effect to every word, clause, and sentence. Labor and Industries v. Delozier, at 76. Courts do not engage in statutory interpretation of a statute that is not ambiguous. State v. Keller, 143 Wn.2d 267, 276 (2001). If a statute is plain and unambiguous, its meaning must be derived from the wording of the statute itself. State v. Keller, at 276. The plain meaning of an agency rule is discerned from the language of the rule and from all that the legislature has said in the enabling statute and related statutes that disclose legislative intent about the provisions in question. Mader v. Health Care Authority, 149 Wn.2d 458, 473 (2003). A statute is ambiguous if it can be reasonably interpreted in more than one way. State v. Keller,

143 Wn.2d at 276; Western Telepage, Inc. v. City of Tacoma, 140 Wn.2d 599, 608, (2000). A statute must be construed consistently with its purpose. Shoop v. Kittitas County, 149 Wn.2d 29 (2003).

C. The parties each define operating room differently, and this ambiguity raises a statutory interpretation issue. What is important is the characterization or type of "operating room". The question is not "what is an operating room". The issue is "what type of outpatient operating room" is included in the WAC 246-310-270(9) calculation? Viewed in this manner, the Presiding Officer concludes the term "operating room" must be read in conjunction with the definition of "ambulatory surgical facilities".[8] Counting all operating rooms in the service area is inconsistent with the other subsections contained in WAC 246-310-270:

i. An ambulatory surgical facility must meet the methodology in addition to the other certificate of need requirements. Exempt facilities need not meet these requirements. WAC 246-310-270(1).

ii. The health service planning area defines the area used to plan for operating rooms and ambulatory surgical facilities. Exempt facilities are not considered in this planning. WAC 246-310-270(2).

iii. Ambulatory surgical facilities must have at least 2 operating rooms. WAC 246-310-270(6).

iv. Ambulatory surgical facilities must document and provide assurances of implementing policies to provide access to individuals unable to pay, consistent with charity care levels provided by hospitals affected by the proposed ambulatory surgical facility. Exempt facilities are not. WAC 246-310-270(7).

This reading is supported by the public policy of health planning set forth by the Legislature. RCW 70.38.015.

[8] In its post-hearing brief the Program argues that additional operating rooms may be approved, pursuant to the language in WAC 246-310-270(4), even where the WAC 246-310-270(9) calculation shows a surplus. In light of Conclusion of Law 2.4, the Presiding Officer need not address this issue.

D. The Program's analysis in the Northwest Ambulatory Surgery Services application is consistent with its position in the present case. "Of the total 19 ORs available, only the 9 ORs located within Bellingham Surgery Center and St. Joseph Hospital could be available for use by physicians outside of a specific group practice." Exhibit 7, page 475. Even though the Program *considered* the total number of operating rooms in the service area, it only *counted* the ones available to the "public", those operating rooms in which any surgeon could schedule an outpatient surgery.

2.6 The Program's need calculations in analyzing the Respondent's application were based on erroneous information. That error does not foreclose the Program from approving or making a decision on the Respondent's application.

A. The Program admitted at hearing that the need calculation contained in the analysis was incorrect, because it failed to use corrected data provided by the Respondent. The Program stresses it followed the correct calculation process under WAC 246-310-270(9). Calculating future need using the corrected use rates shows a shortage of dedicated outpatient operation rooms by 2005 of 5.9 operating rooms. Exhibit 3, page 1. The Program submitted additional calculations, any of which (the Program argues) shows an increased need of dedicated outpatient operating rooms in the service area. Exhibits 8, 9 and 10. Using the "correct" use rate figures, and including the availability of the operating rooms Northwest Ambulatory Surgery Services, Ms. Sigman testified at hearing that the preferred method of calculation using the WAC 246-310-270(9) methodology calculates a net need of 6.4 dedicated outpatient operating rooms by 2005. 12/19/02 RP at 61 and 178; Exhibit 10, page 9.

B. The additional WAC 246-310-270(9) calculations submitted by the Program are admissible. The court, in U.S. v. Trident Seafoods Corp, 60 F.3d 556, 559 (1995), held that when "violation of a regulation subjects private parties to criminal or civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express". The issue in Trident was one of statutory interpretation: neither the statute nor the regulation expressly addressed whether the failure to give advance notice was a one-time or continuous violation. The court further held that no deference is owed when an agency has not formulated an official interpretation of its own regulation, but is merely advancing a litigation position. Trident, at 559. The present case does not involve criminal or civil sanctions – it speaks to the issue whether the Program correctly calculated future need according to the formula in WAC 246-310-270(9). Whether the Program made a calculation error, and provided alternative or corrected versions of those calculations regarding an error, does not equate to the mere advancement of a litigation.

The Petitioner, following Program's response following remand, also cited Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988) (Georgetown University) in further support of its position here. In that case the Supreme Court declined to give deference to an agency counsel's interpretation of a statute where the agency itself had articulated no position on the question. Georgetown University 488 U.S. at 212. "Congress has delegated to the administrative official and not to appellate counsel the responsibility for elaborating and enforcing statutory commands. Georgetown University, at 212 . In the present case Ms. Sigman testified to the Program's position regarding the preferred method, and was available for cross-examination on that issue.

This was not the argument of Program counsel after the fact, but a statement by the Program of its position and its reasons for that position. Where the Program made a calculation error, and provided alternative or corrected versions of those calculations regarding an error, does not equate to the mere advancement of a litigation position.

C. The Program submitted sufficient evidence to support a showing that some need exists for additional outpatient operating rooms in the service area. In addition, the Program determination is supported by the testimony of Ms. Oliver and Mr. Neal, and the uncontested showing that one outpatient surgery facility (Hines/James) will close, with the intention of relocating to the new facility.

2.7 An ambulatory surgical facility must not only meet the need methodology under WAC 246-310-270(9), but must also meet the need criteria contained in WAC 246-310-210. This requires a showing that "the population served or to be served has a need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need." WAC 246-310-210(1). This showing of need includes a determination of the efficiency and appropriateness of the use of existing facilities. WAC 246-310-210(1)(b).

A. The Petitioner indicated it would increase the size of its facility by two outpatient operating rooms. In its analysis the Program did not consider these two operating rooms, as these rooms were not "existing facilities" at the time the Respondent filed its application, nor were they available to the public at the time the Program sent its surveys to the facilities in the service area. In Providence Hospital v. DSHS, 112 Wn.2d 353 (1998), the Supreme Court held, in interpreting WAC 248-19-370 [subsequently recodified as WAC 246-310-210(1)], that while

proposed facilities that do not physically exist or are not currently in use may be considered regarding the availability of services, it is unacceptable to rely on speculative, nebulous announcements that another facility planned to do something in the future. Providence Hospital, at 358. The Petitioner's offer appears speculative in nature, and is therefore unavailable. The Program was not required to consider the Petitioner's proposed two additional outpatient operating rooms in its analysis.

B. Northwest Ambulatory Surgery Services indicated in its survey response to the Respondent's application that it had not been approached regarding utilization of its recently approved outpatient surgery facility. Exhibit 7, page 443. Unlike the Petitioner's proposed expansion, the Northwest Ambulatory Surgery Services outpatient operation rooms did exist at the time of the analysis of the Respondent's application. The Program determined the outpatient operating rooms were unavailable to the public, given the facility specialized in providing interventional chronic pain management. Exhibit 7, pages 442 , 480. *See* Providence Hospital, at 358.

However, these concerns were addressed at hearing by Ms. Sigman. She testified that the Program's preferred application of the calculation methodology was found in Exhibit 10, page 9. This calculation included the Northwest Ambulatory Surgery Center outpatient capacity.

C. There was testimony at hearing regarding the changes in the local economy. Mr. Neal noted that at least one reason Symbion did not expand its facility was the decrease in outpatient operations, which he attributed to the changing demographics of the area. 12/19/02 RP at 81. He based his opinion on information provided to him regarding local employers shutting down facilities. 12/19/02 RP at 81-

82. This information was offset by a showing of the increased populations in Whatcom County (based on census figures). Exhibit 7, page 63. Additionally, both the Intervenor hospital and the Petitioner were operating at or near capacity at the time of the application. The declining economic information, when compared with the population and operating room capacity information, does not prevent a showing of increased need in the service area.

2.8 WAC 246-310-220 indicates that the determination of financial feasibility of a project is based on meeting or showing: (1) immediate and long-range capital and operating costs; (2) costs of the project, including ay construction costs, will probably not result in an unreasonable impact on the costs and charges for health services; and (3) the project is appropriately financed.

A. The debt service criteria guidelines are not part of the regulation, and therefore are not "mandatory" in that regard. Using the guidelines, the Program concluded the financial success of the project is reasonable. Of the four financial ratios, the Program found three of the four criteria were favorable for the project. While the debt service ratio was not favorable, it did improve over the three-year period being examined. It is reasonable to presume that the Respondent's project is likely to succeed, given the financial information available.

B. The operating net profits considered by the Program did met the criteria of WAC 246-310-220(2), in that the analysis shows the Respondent's charges will be lower than the hospital's costs for the same outpatient surgeries. This is a positive impact on costs and charges.

C. The Respondent's application shows sufficient financing is available to complete the project.

2.9 The Respondent indicates it will recruit on a national basis. While the Petitioner raised concerns that insuffient staff will be available, it cannot show with any certainty that sufficient staff will be unavailable to fill the necessary positions.

2.10 The Program did review the Respondent's application on the issue of the withdrawal of the Physician's Surgery Center from the project. The Program's analysis showed the other outpatient facilities are operating at or near capacity. Exhibit 7, page 712. The Respondent provided the Program with updated information that addressed the pivotal unresolved issue concerns. Exhibit 7, pages 388 – 402. This information included revised staffing information, pro forma financial statements and proof of its revised letters of credit. Whether the withdrawal of Physicians Surgery Center from the Respondent's application was a major warning sign, the Program identified a pivotal unresolved issue, reviewed the material provided in response by the Respondent and found it an acceptable explanation in this case. Absent any showing the Respondent's application did not meet the necessary certificate of need criteria, it was reasonable for the Program to approve this criteria here.

A. A superior alternative did not exist. The Petitioner did not add two additional operating rooms. Nor does it appear that the Petitioner intends to add any additional rooms in the near future, based on Mr. Neal's testimony.

B. The Petitioner argued the Program did not consider the existing operating facility at Northwest Ambulatory Surgery Services, and argues that facility will only be operating at 85% capacity by 2004. Petitioner's Post-Hearing Memorandum at 30, lines

1 – 10; see Exhibit 7, page 712. The Northwest Ambulatory Surgery facility contended in its survey response that it had available capacity. Exhibit 7, page 443. Upon remand and at hearing, the Program stated its preferred method would include Northwest Ambulatory Surgery's outpatient operating rooms. That analysis supported the Program's decision.

V. ORDER

Based on the foregoing Procedural History, Findings of Fact and Conclusions of Law, the Program's Analysis of the Certificate of Need Application issued August 7, 2002, and Certificate of Need No. 1246, dated August 23, 2002, as corrected following the interim order on remand, are AFFIRMED.

Dated this 17th day of October, 2003.

_____/s/_____
JOHN F. KUNTZ, Health Law Judge
Presiding Officer

NOTICE TO PARTIES

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

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

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 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 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. RCW 34.05.470(3).

The order remains in effect even if a petition for reconsideration or petition for 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).