#### EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF NORTH CASCADE EYE ASSOCIATES, PS PROPOSING TO ESTABLISH AN AMBULATORY SURGERY CENTER IN EAST SKAGIT COUNTY

### **APPLICANT DESCRIPTION**

In 1985, Nanette Crowell, MD established North Cascade Eye Associates, PS (NCEA) at 2131 Hospital Drive in Sedro Woolley, within Skagit County. NCEA was established as a professional services corporation in 2002, with a governing board and shareholders. The twoperson governing board is Nanette Crowell, MD [president] and C. Dan Siapco, MD [vicepresident]. In addition to the two shareholders, Drs. Crowell and Siapco (ophthalmologists), NCEA employs sub-specialists in eye care, including ophthalmic plastics, cornea, and ophthalmic pediatrics.<sup>1</sup> NCEA also employs a number of optometrists and opticians.

As of the writing of this evaluation, NCEA has expanded to the following three separate locations.

Location/Address	County
2131 Hospital Drive, Sedro Woolley	Skagit
2100 Little Mount Lane, Mount Vernon	Skagit
26910 – 92 <sup>nd</sup> Avenue Northwest, #C6, Stanwood	Snohomish

The practice located in Mount Vernon also has an exempt ambulatory surgery center (ASC) at the same site. On June 19, 2007, the department issued an exemption from Certificate of Need review to NCEA for the establishment of the ASC with two operating rooms. The ASC became operational in mid-year 2008 and has remained in continuous operation since its inception. [source: Application, pp1-2; North Cascade Eye Associates DOR #07-23; and North Cascade Eye Associates website]

#### **PROJECT DESCRIPTION**

NCEA's exempt ASC is currently used by only the owners—Drs Crowell and Siapco—for cataract, eyelid, and laser surgeries. This project proposes to allow physicians not employed by NCEA the opportunity to perform surgeries and procedures at the currently exempt ASC in Mount Vernon. This action requires prior Certificate of Need review and approval.

If the project is approved, the location of the ASC would remain at the existing Mount Vernon site and the number of operating rooms would remain at two. Services offered at the ASC would be expanded to include retina surgeries, ophthalmic plastic surgery (not to include pediatric), and minor cosmetic plastic surgery commonly associated with eye surgery. [source: Application, pp4-5]

The estimated capital expenditure associated with the project is \$331,298 and is solely related to the additional equipment needed to accommodate the expansion in type of surgeries. [source: Application, p12-13]

<sup>&</sup>lt;sup>1</sup> These sub-specialists are not 100% employed by NCEA.

If this project is approved, NCEA anticipates the additional equipment would be purchased and set up as soon as possible. The additional physicians would begin using the ASC within three to six months from approval or by the end of year 2010. Under this timeline, year 2011 would be the ASC's first full calendar year of operation as a CN approved ASC, and 2013 would be year three. [source: Application, p8]

# APPLICABILITY OF CERTIFICATE OF NEED LAW

Even though the exempt ASC is operational, this project requires review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

# **CRITERIA EVALUATION**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction in how the department is to make its determinations. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

- (a) In the use of criteria for making the required determinations, the department shall consider:
  - *(i) The consistency of the proposed project with service or facility standards contained in this chapter;*
  - (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and
  - *(iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."*

In the event the WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

"The department may consider any of the following in its use of criteria for making the required determinations:

- (*i*) Nationally recognized standards from professional organizations;
- (ii) Standards developed by professional organizations in Washington state;
- (iii) Federal Medicare and Medicaid certification requirements;
- *(iv) State licensing requirements;*
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application."

To obtain Certificate of Need approval, North Cascade Eye Associates must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).<sup>2</sup> Additionally, WAC 246-310-270 contains service or facility specific criteria for ASC projects and must be used to make the required determinations.

### APPLICATION CHRONOLOGY

September 21, 2009	Letter of Intent Submitted
December 1, 2009	Application Submitted
December 2, 2009 through	Department's Pre-Review Activities
January 25, 2010	<ul> <li>screening activities and responses</li> </ul>
January 26, 2010	Department Begins Review of the Application
	• public comments accepted throughout the review
	<ul> <li>no public hearing requested or conducted</li> </ul>
March 2, 2010	End of Public Comment
March 17, 2010	Rebuttal Documents Received at Department
May 3, 2010	Department's Anticipated Decision Date
June 14, 2010	Department's Actual Decision Date

#### AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person as: "...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."

Throughout the review of this project, no entities sought and received affected person status under WAC 246-310-010(2).

# SOURCE INFORMATION REVIEWED

- North Cascade Eye Associates Certificate of Need Application received December 1, 2009
- North Cascade Eye Associates supplemental information received January 19, 2010
- Public comment received throughout the review of the application
- North Cascade Eye Associates' rebuttal comments received March 8, 2010
- East Skagit County ASC operating room utilization survey responses
- Office of Financial Management population data for east King planning area
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2005, 2006, and 2007 summaries)
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office

 $<sup>^{2}</sup>$  Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6) and WAC 246-310-240(2).

# SOURCE INFORMATION REVIEWED (continued)

- Office of Financial Management population data released November 2007
- Data obtained from North Cascade Eye Associates' two web pages (ncascade.com and ncascade.net)
- Medical Quality Assurance compliance data webpage (wa.gov/doh/providercrenditalsearch)
- AAAHC, the Accreditation Association for Ambulatory Health Care webpage (aaahc.org)

# CONCLUSION

For the reasons stated in this evaluation and agreement to the following three conditions, North Cascade Eye Associates, PS is approved to establish an ambulatory surgery center in Mount Vernon, with Skagit County.

- 1. The ambulatory surgery center associated with North Cascade Eye Associates, PS will provide charity care in compliance with the charity care policies provided in its Certificate of Need application and the requirements of the applicable law. North Cascade Eye Associates, PS will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by the two hospitals located in the east Skagit County Planning Area during the three most recent years. For historical years 2006-2008, these amounts are 1.54% of gross revenue and 3.30% of adjusted revenue. North Cascade Eye Associates, PS will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies and applicable law.
- 2. North Cascade Eye Associates is limited to providing only those services described within the application and relied upon by the department in this evaluation.
- 3. North Cascade Eye Associates is limited to two operating rooms at the surgery center.

The approved capital expenditure associated with this project is \$331,298 and is solely limited to equipment.

# A. Need (WAC 246-310-210) and Ambulatory Surgery (WAC 246-310-270)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department determines that North Cascade Eye Associates, PS has met the need criteria in WAC 246-310-210 and WAC 246-310-270.

(1) <u>The population served or to be served has need for the project and other services and</u> <u>facilities of the type proposed are not or will not be sufficiently available or accessible to</u> <u>meet that need</u>

# WAC 246-310-270(9) – Ambulatory Surgery Numeric Methodology

The Department of Health's Certificate of Need Program uses the numeric methodology outlined in WAC 246-310-270 for determining the need for additional ASCs in Washington State. The numeric methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient OR's in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 secondary health services planning areas. The proposed ASC would be located in the east Skagit County planning area.

The methodology estimates OR need in a planning area using multi-steps as defined in WAC 246-310-270(9). This methodology relies on a variety of assumptions and initially determines existing capacity of dedicated outpatient and mixed-use operating rooms in the planning area, subtracts this capacity from the forecast number of surgeries to be expected in the planning area in the target year, and examines the difference to determine:

- a) whether a surplus or shortage of OR's is predicted to exist in the target year, and
- b) if a shortage of OR's is predicted, the shortage of dedicated outpatient and mixed-use rooms are calculated.
- c) Data used to make these projections specifically exclude specialty purpose rooms, such as open heart surgery rooms, delivery rooms, cystoscopic rooms, and endoscopic rooms.<sup>3</sup>

# Applicant's Methodology

The numeric portion of the methodology requires a calculation of annual capacity of existing ORs, both outpatient and inpatient. To apply the methodology, NCEA obtained information from the existing providers through a telephone survey. NCEA identified the assumptions it used to apply the numeric methodology. [source: Application, pp9-10; Exhibits K and M] The assumptions used are identified on the following page.

<sup>&</sup>lt;sup>3</sup> WAC 246-310-270(9)(a)(iv).

Assumption	Data Used
Planning Area	East Skagit County – the Swinomish Channel was used
	as the dividing line between east and west Skagit
	County. As a result, the population of Anacortes and
	surrounding Skagit County areas west of the channel
	were subtracted from the total county population.
Population Estimates and Forecasts	Office of Financial Management Population Forecasts
	Updated November 2007
Use Rate	Divide 2009 estimated current surgical cases by
	estimated 2009 populations results in the service area
	use rate of 119.39/1,000 population
Percent of surgery ambulatory vs. inpatient	82.6% ambulatory (outpatient) and 17.4% inpatient
Average minutes per case	Based on telephone survey responses:
	Inpatient 99.98 minutes
	Outpatient 45.42 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or
	mixed-use surgery minutes (per methodology in rule)
Existing providers	OR Capacity: 3 dedicated outpatient and 6 mixed use

Using the assumptions outlined above, NCEA calculated a <u>surplus</u> of .36—rounded to 1— dedicated outpatient ORs by the end of target year 2013.

#### Department's Methodology

Given that the ASC would be located in east Skagit County, the department will apply the methodology to that health service planning area. Using the same geographical boundaries as described by the applicant, the department also deducted patients, population, and facilities located west of the Swinomish Channel from the rest of Skagit County. Based on this geographical distinction, there are six providers in the east Skagit County planning area, including the applicant. The six providers are listed below. [source: CN historical files-ILRS database]

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Two Hospitals / City	Four ASCs / City	
Skagit Valley Hospital/Mount Vernon	Cascade Medical Group/Mount Vernon	
United General Hospital/Sedro Woolley	North Cascade Eye Associates/Mount Vernon (applicant)	
	Northwest Orthopaedic Surgeons/Mount Vernon	
	Skagit Island Orthopedic Surgery Center/Mount Vernon	

# East Skagit Planning Area Providers

As shown above, the six facilities include two hospitals and four ASCs. Since both hospitals are located in the planning area, all appropriate OR capacity at those two facilities will be used in the numeric methodology calculations under WAC 246-310-270.

Of the four ASCs shown above, three—including the applicant—are located within a solo or group practice (considered an exempt ASC) and therefore, the use of these ASCs is restricted to physicians that are employees or members of the clinical practices that operate the facilities. Therefore, these three facilities do not meet the ASC definition found in WAC

246-310-010 and the surgeries and ORs are not included in the methodology for the planning area.

The one remaining ASC—Skagit Island Orthopedic Surgery Center in Mount Vernon—is a CN approved ASC, and the OR utilization and capacity of this ASC is included in the capacity calculations of available ORs for the east Skagit planning area.<sup>4</sup>

To assist in its application of the numeric methodology for this project, on December 21, 2009, the department requested utilization information from each of the facilities identified above. No responses were received from any of the ASCs and only one of the two hospitals provided a response.<sup>5</sup>

To apply the numeric methodology, the department relied on its own survey results and portions of the applicant's survey results. Below are the assumptions used by the department to apply the methodology.

Assumption	Data Used
Planning Area	East Skagit County – the Swinomish Channel was used as the dividing line between east and west Skagit County. As a result, the population of Anacortes and surrounding Skagit County areas west of the channel were subtracted from the total county population.
Population Estimates and Forecasts	Office of Financial Management's Skagit County- medium series, published November 2007, minus the population as described above. Target year is 2013.
Use Rate	Divide estimated current surgical cases by estimated 2009 populations results in the service area use rate of 80.99/1,000
Percent of surgery ambulatory vs. inpatient	Based on survey results & applicant's survey results, 74.4% ambulatory setting; 25.6% inpatient setting
Average minutes per case	Based on DOH survey results and applicant's survey results: Outpatient cases = 50.0 minutes; inpatient cases 99.98 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes
Existing providers	Based on 2009 listing of East Skagit County providers and the applicant's survey results. 3 dedicated outpatient ORs and 4 mixed use ORs.

The department's application of the numeric methodology based on the assumptions described above indicates a surplus of 0.07 mixed-use ORs in year 2013. The surplus is so small—significantly less than one OR—that the department would consider the result to be a demonstration of no need and no surplus of ORs in the planning area. The department's methodology is Appendix A attached to this evaluation

<sup>&</sup>lt;sup>4</sup> Skagit Island Orthopedic Surgery Center was issued CN #1335 on August 8, 2006.

<sup>&</sup>lt;sup>5</sup> Only United General Hospital located in Sedro Woolley provided a response.

In summary, based solely on the numeric methodology contained in WAC 246-310-270, neither need nor surplus of outpatient OR capacity in the East Skagit planning area is demonstrated. [source: department's methodology and utilization surveys]

# WAC 246-310-270(4)

### 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."

This section of the rule implies that the department may approve additional OR capacity in a planning area even if the numeric methodology calculations result in no need for additional OR capacity.

For this project, the numeric methodology results in no need or surplus of outpatient ORs for the east Skagit planning area in year 2013. NCEA provided its rationale for submitting its application to convert its existing CN exempt facility to a CN approved facility. A summary of NCEA's rationale is below. [source: Application p10-11; Exhibit O]

- Of the other surgical providers in the serve area, only United General Hospital is equipped to provide <u>related</u> services. Specifically, United General Hospital provides cataract and YAG laser procedures. They do not have the facility or equipment to provide retinal and ophthalmic plastic surgeries.
- Skagit Valley Hospital—the only other hospital located in the planning area—does not offer ophthalmic procedures and provided a letter of support for this project. [letter of support signed by Gregg Davidson, CEO of Skagit Valley Hospital]
- Retina surgery is not available in the planning area. The closest facility providing retina surgery is Northwest Hospital located in Seattle (King County), which is approximately 57 miles from NCEA.
- Ophthalmic plastic surgery is also not available in the planning area. The closest facility providing ophthalmic plastic surgery is Seattle Surgery Center in Seattle (King County), which is approximately 64 miles from NCEA.
- NCEA concludes that this project is not a duplication of services because many of the services proposed to be offered at the ASC are not provided in the planning area.

Within its utilization survey responses, United General Hospital provided concerns related to approval of this project. The hospital states that NCEA physicians performed their surgeries at the hospital in years 2006, 2007, and part of year 2008. In years 2006 and 2007, the number of surgeries performed by NCEA physicians averaged at 545. NCEA obtained an exemption from Certificate of Need review and then provided the services at their own ASC in year 2008. In year 2008, the number of cases dropped significantly to 210, and in 2009 the number dropped to 9. United General Hospital states it still has the equipment and instruments to do ophthalmology cases. [source: United General Hospital utilization survey responses, p3]

In response to the comments provided by United General Hospital above, NCEA concurred that the significant drop in cases at the hospital occurred in 2008 and was a direct result of NCEA's establishment of the exempt ASC. NCEA asserts that its physicians would not return to United General Hospital to provide surgeries even if this project is denied. The physicians' rationale for leaving the hospital has not changed. A summary of the physicians' rationale is below. [source: NCEA March 8, 2010, rebuttal documents, p1]

- The hospital has limited OR availability. Only one OR is equipped and available for use. The other two are used for storage.
- The hospital has a slow turnover for its only OR, which limits operating surgeon efficiency when performing back-to-back surgeries.
- The hospital does not have the equipment to allow NCEA physicians to provide retinal and ophthalmic plastic surgeries. The costs associated with this project are solely related to the purchase of the equipment needed for these procedures. These services are not available in the planning area.
- Since the hospital has limited anesthesia coverage, it prioritizes the OR use by physicians with larger block times. As a result, many NCEA surgeries would be bumped to later the same day or another day.
- Because of their rural designation<sup>6</sup> and corresponding higher charges, out-ofpocket expenses for patients (co-pays) are considerably higher. Some of the ophthalmic surgeries are only covered by private pay insurers. Patients requiring these higher cost surgeries are choosing more affordable options (such as physicians with access to an ASC).

Based on the information provided above, the following conclusions can be reached to support the need for this project.

- 1. The majority of the services to be provided at the ASC—retina surgery and ophthalmic plastic surgery—are not available in the planning area. The physicians currently providing these services use ORs in Seattle.
- 2. Any utilization impact this ASC would have on United General Hospital occurred when the exempt facility became operational in late 2008.
- 3. Based on the information provided in the application, NCEA intends to provide only eye procedures at the ASC.

The department concludes that existing providers are not sufficiently available and accessible to meet the projected need for this project. Therefore, the department concludes need has been demonstrated. To ensure that NCEA will operate the ASC in accordance with information provided in the application, approval of this project would be contingent upon NCEA agreeing to provide only eye surgeries as described within the application and relied upon by the department in this evaluation. Provided that NCEA would agree to limit the procedures, the department concludes that this sub-criterion is met.

<sup>&</sup>lt;sup>6</sup> United General Hospital obtained Critical Access Hospital designation by the Department of Health's Rural Health Program. The Critical Access Hospital Program was created by the 1997 federal Balanced Budget Act as a safety net device to assure Medicare beneficiaries access to health care services in rural areas. It was designed to allow more flexible staffing options relative to community need, simplify billing methods and create incentives to develop local integrated health delivery systems, including acute, primary, emergency and long-term care. [source: Rural Health Program website]

# WAC 246-310-270(6)

WAC 246-310-270(6) requires a minimum of two ORs in an ASC. The exempt ASC currently operates with two ORs. [source: Application, Exhibit I] This project does not propose to increase or decrease the number of ORs at NCEA.

(2) <u>All residents of the service area, including low-income persons, racial and ethnic minorities,</u> women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

NCEA is currently a provider of ophthalmic services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. As a Certificate of Need approved ASC, NCEA must participate in the Medicare and Medicaid programs. To determine whether all residents of the service area would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion, NCEA provided a copy of its Admission Policy/Non Discrimination Policy currently in use at NCEA. The policy outlines the process/criteria that NCEA uses to admit patients for treatment. The applicant states that all services provided by the facility are available without distinction to all patients and visitors regardless of race, creed, color, ethnic origin, nationality, sex, handicap, age, or affiliation with fraternal or religious organization. [source: Application, Exhibit P]

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination.

NCEA currently provides services to Medicaid eligible patients. Information provided in the application demonstrates that NCEA intends to maintain this status for its existing facilities. A review of the policies and data provided for NCEA reveals the facility's financial pro forma includes both Medicare and Medicaid revenues. [source: Application, Exhibits D, L, & U]

To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

NCEA currently provides services to Medicare patients. Information provided in the application demonstrates that NCEA intends to maintain this status if this project is approved. A review of the policies and data provided for NCEA reveals the facility's financial pro forma includes both Medicare and Medicaid revenues. [source: Application, Exhibits D, L, & U]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or

would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

NCEA demonstrated its intent to provide charity care to residents by submitting it Charity Care/ Policy currently in use at NCEA. The policy outlines the process one would use to access charity care. Further, NCEA included a 'charity care' line item as a deduction from revenue within the pro forma financial documents. NCEA also provided a worksheet, with step-by-step instructions, to be used to determine if a patient would qualify for any full or partial financial assistance. [source: Application, Exhibit P]

WAC 246-310-270(7) states that ASCs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC. For charity care reporting purposes, the Department of Health's Hospital and Patient Data Systems (HPDS), divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. NCEA is located in Skagit County within the Puget Sound region. For charity care reporting purposes, the affected hospitals are the two hospitals operating in the east Skagit planning area—Skagit Valley Hospital in Mount Vernon and United General Hospital in Sedro Woolley. For this project, the department reviewed charity care data for both east Skagit hospitals and the 18 existing hospitals currently operating within the Puget Sound Region.

According to 2006-2008<sup>7</sup> charity care data obtained from HPDS, the three-year average for the Puget Sound Region is 1.95% for gross revenue and 4.23% for adjusted revenue. The combined three-year charity care data reported by Skagit Valley Hospital and United General Hospital is 1.54% of gross revenue and 3.30% of adjusted revenue. [source: OHPDS 2006-2008 charity care summaries]

The applicant's pro formas indicate that the ASC will provide charity care at approximately 1.44% of gross revenue and 3.42% of adjusted revenue. [source: Application, Exhibit D]

Table 1 below is NCEA's projected charity care percentages compared with Puget Sound Regional average and the average of the two hospitals in the planning area.

Charity Care Percentage Comparisons			
	% of Total Revenue	% of Adjusted Revenue	
NCEA (Applicant)	1.44%	3.42%	
Puget Sound Region	1.95%	4.23%	
SVH/UGH Combined	1.54%	3.30%	

 Table 1

 Charity Care Percentage Comparisons

As shown in Table 1 above, NCEA pro formas indicate charity care percentages would be below the regional and two-hospital averages for total revenue. NCEA's pro formas also indicate that the ASC will provide charity care below the regional average, but above the two-hospital combined average for adjusted revenue. If this project is approved, the

<sup>&</sup>lt;sup>7</sup> Year 2009 charity care data is not available as of the writing of this evaluation.

department would attach a condition related to the percentage of charity care to be provided at the ASC.

Based on the documents provided in the application and NCEA's agreement to the condition related to charity care identified in the conclusions section of this evaluation, the department concludes that all residents, including low income, racial and ethnic minorities, handicapped, and other under-served groups would have access to the services provided by the applicant. This sub-criterion is met.

#### B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department concludes North Cascade Eye Associates, PS has met the financial feasibility criteria in WAC 246-310-220.

#### (1) <u>The immediate and long-range capital and operating costs of the project can be met.</u>

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

NCEA is currently operating the ASC under an exemption from Certificate of Need review. If this project is approved, NCEA anticipates the additional physicians would begin using the ASC within three to six months of approval. Under this timeline, year 2011 would be the first year of operation as a Certificate of Need approved facility. [source: Application, p8] To demonstrate compliance with this sub-criterion, NCEA provided its Statement of Operations for the ASC showing years 2010 through 2012.

To determine whether the ASC would meet its immediate and long range operating costs, the department reviewed NCEA's assumptions, projected revenue/expense statements, and projected balance sheets for years 2010 through 2012.

NCEA provided the following statements related to the assumptions used as a basis for the projected number of procedures at the ASC. [source: Application, Exhibits, D & S]

- Cataract, YAGs, and blepharoplasty projections are based on those procedure counts currently performed in the exempt facility. A 10% growth rate is projected because that is the historical growth rate at the exempt facility.
- Lensectomy procedure projections are based on historical surgery counts from Pacific Retina providers for patients from the east Skagit County service area. A conservative growth rate of 10% is projected based on retina service management's determinations due to the influx of baby boomer population needing these services.
- The rest of the procedures are based on patients seen by NCEA.
- Bad debt has historically been about 1% of gross revenues.

- Charity care is based on the percentages provided by all three hospitals in Skagit County.<sup>8</sup>
- Current staffing has been 12% of adjusted charges and is expected to continue at that percentage.
- A 3% increase is projected for supply costs.
- Fixed supplies are based on actual costs from the existing exempt ASC, with a 3% increase per year.
- The existing lease term began in May 2008 and continues until April 2013 without an increase until that time.
- Utility costs are shared with the medical clinic. The ASC occupies 24% of the total square footage of the facility; with the projected increase in ASC activity, these costs were calculated at 40% of total costs.
- Interest expense assumes current debt and additional debt to acquire equipment for this project. An existing equipment loan is \$9,710/month with a 4.5% interest rate. If approved, this project would increase the debt to about \$240,000 which is assumed to begin in 2010. A 7% interest rate is used for projections.
- Accounts receivable are projected to be 15% of production based on historical trends.
- For the projected balance sheet, year-end cash predictions were based on the pro forma income statements.
- All accounts payable are paid out prior to year-end as a matter of policy.

The assumptions relied on by NCEA to project the financial viability of the ASC appear to be reasonable. Table 2 below is a summary of NCEA's projected revenues and expenses for years 2010 through 2012. [source: Application, Exhibits D, L, & U]

North Cascade Eye Associates ASC Revenue and Expense Summary			ГУ
	Year 2010	Year 2011	Year 2012
Number of Procedures	1,268	1,387	1,457
Net Revenue	\$ 888,019	\$ 972,728	\$ 952,784
Total Expenses	\$ 730,266	\$ 791,630	\$ 829,648
Net Profit or (Loss)	\$ 157,753	\$ 181,098	\$ 123,136
Average Revenue per Procedure	\$ 700.33	\$ 701.32	\$ 653.94
Average Expenses per Procedure	\$ 575.92	\$ 570.75	\$ 569.42
Net Profit or (Loss) per Average Procedure	\$ 124.41	\$ 130.57	\$ 84.51

 Table 2

 North Cascade Eye Associates ASC Revenue and Expense Summary

The 'net revenue' line item in Table 2 is the result of gross revenue minus any deductions for contractual allowances, bad debt, and charity care. The 'total expenses' line item includes staff salaries/wages and the ASC's portion of overhead costs based on the assumptions stated above. As shown in Table 2, NCEA anticipates it would operate at a profit from the

<sup>&</sup>lt;sup>8</sup> NCEA used the percentages of all three hospitals located in Skagit County. Two of the three are located in the east Skagit planning area—Skagit Valley Hospital in Mount Vernon and United General Hospital in Sedro Woolley. The third hospital—Island Hospital in Anacortes—is located in Skagit County, but is part of the Whidbey-Fidalgo planning area described in WAC 246-310-270. The Whidbey-Fidalgo planning area includes all of Island County and Fidalgo Island in Skagit County.

beginning in year 2010 which would continue through 2012. It is noted that the profit is expected to decrease in year 2012. This reduction in net profit is the result of a projected growth in expenses without a commensurate growth in revenues.

In addition to the projected Statement of Operations, NCEA also provided its current and projected balance sheets for NCEA, which includes the clinic and the ASC. Table 3 below shows the current balance sheet for year 2010 and the projected balance sheet for year 2012. [source: Application, Exhibits S & U]

North Cascade Eye Associates Current Balance Sneet Year 2010			
Assets		Liabilities	
Current Assets	\$ 424,324	Current Liabilities	\$ 0
Fixed Assets	\$ 574,038	Long Term Debt	\$ 831,119
Board Designated Assets	\$ 0	Other Liabilities	\$ 0
Other Assets	\$ 0	Equity	\$ 167,243
Total Assets	\$ 998,362	Total Liabilities and Equity	\$ 998,362

Table 3
North Cascade Eye Associates Current Balance Sheet Year 2010

North Cascade F	ye Associates Balanc	e Sheet for Proje	cted Vear 2012
Nor in Cascaue E	ye Associates Dalanc	e sheet for i roje	

Assets	Assets Liabilities		
Current Assets	\$ 758,909	Current Liabilities	\$ 0
Fixed Assets	\$ 399,362	Long Term Debt	\$ 546,452
Board Designated Assets	\$ 0	Other Liabilities	\$ 0
Other Assets	\$ 0	Equity	\$ 611,819
Total Assets	\$ 1,158,271	Total Liabilities and Equity	\$ 1,158,271

As shown in the 2010 balance sheet above, NCEA operates the clinic and exempt ASC very lean, which is typical of a specialty procedure practice. However it is clear that NCEA would be financially stable through year 2012.

There were no comments submitted related to this sub-criterion. Based on the financial information above, the department concludes that the immediate and long range capital and operating costs of the project can be met. This sub-criterion is met.

(2) <u>The costs of the project, including any construction costs, will probably not result in an</u> <u>unreasonable impact on the costs and charges for health services.</u>

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

The capital costs associated with this project are \$331,298 and are solely related to the moveable equipment needed to provide the retina, ophthalmic plastic, and minor cosmetic surgeries not currently provided at the ASC. NCEA relied on its own experience to develop the construction costs identified. [source: Application, pp11-12]

To further demonstrate compliance with this sub-criterion, NCEA provided the average sources of patient revenue shown in Table 4 below for its ASC and clinic. [source: Application, Exhibit H]

North Cascade Lye Associates			
Current and Projected Sources and Percentages of Revenue			
Source of Revenue	Current	Projected	
Medicare/Medicare Advantage	77%	61%	
State (Medicaid)	2%	3%	
Commercial	8%	14%	
Other	13%	22%	
Total	100%	100%	

Table 4
North Cascade Eye Associates
Current and Projected Sources and Percentages of Revenue

As shown in Table 4, the majority of revenues are Medicare/Medicare Advantages plans, which is expected to decrease by 16%. This decrease is based on the types of new procedures to be offered that are not typically covered by this revenue source. The commercial and other revenue sources are expected to increase 6% and 9%, respectively. This increase is based on the insurance coverage of the new procedures.

Based on the information provided above, the department concludes that the cost of the project will not result in an unreasonable impact on the costs and charges for health services within the service area. This sub-criterion is met.

# (3) <u>The project can be appropriately financed.</u>

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

NCEA identifies the capital expenditure to be \$331,298, which is solely related to the moveable equipment needed to provide the retina, ophthalmic plastic, and minor cosmetic surgeries not currently provided at the ASC. The funding for the project will be debt financed through a local lending institution.

To demonstrate compliance with this sub-criterion, NCEA provided a letter from its lending institution for the equipment to be purchased. The letter provides NCEA with the projected interest rate (7%) and a five-year repayment schedule. [source: Application, Exhibits Q & R]

Based on the information provided above, the department concludes that the project can be appropriately financed, and this sub-criterion is met.

#### C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department concludes North Cascade Eye Associates, PS has met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) <u>A sufficient supply of qualified staff for the project, including both health personnel and</u> management personnel, are available or can be recruited.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes the planning would allow for the required coverage.

NCEA is currently operating the ASC under an exemption from Certificate of Need review. As an operational ASC, all staff is already in place. Table 5 below summarizes the current/projected staffing at the ASC through 2012. [source: Application, p14]

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Table 5				
North Cascade Eye Associates ASC for Years 2010 and 2012				
	2009 FTEs	2010 Increase	2012 FTEs	
Type of Staff	Current	Projected	Totals	
RN Director	0.75	0.25	1.00	
Circulate RN	0.25	0.50	0.75	
Scrub Tech	0.51	0.74	1.25	
Patient Educator	0.00	0.00	0.00	
Medical Records Clerk	0.00	0.00	0.00	
Admission/Reception	0.25	0.25	0.50	
Administration	0.10	0.00	0.10	
Billing Clerk	0.25	0.25	0.50	
Total FTEs	2.11	1.99	4.10	

As shown in Table 5 above, NCEA anticipates adding two more FTEs in year 2010 once the facility begins offering the additional procedures, then no increase through year 2012. To demonstrate that staff would be available and accessible for this project, NCEA provided the following statements:

"Because our existing surgery is currently under utilized (only one to two surgery days per week), to add the services represented in this project would mean adding about one surgery day per week. The surgery center already has trained staff in place and this project would only involve adding more hours to their work week.

The retina surgeons advise that our existing staff would only require cursory training, which they are willing to give to be able to assist them with their retinal cases. The existing staff is already familiar with the ophthalmic plastic cases. We foresee no problems with staff availability." [source: Application, p15]

Based on the information provided above, the department concludes that staff is available or can be recruited and retained. This sub-criterion is met.

(2) <u>The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.</u> WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

As an operational exempt ASC, NCEA already has established ancillary and support relationships with community healthcare providers for the following services: janitorial services, equipment maintenance, waste management and hazardous waste removal, and pharmacy consulting. For emergent patient transfers, NCEA has established a transfer agreement with Skagit Valley Hospital located less than one mile from the ASC. NCEA provided copies of all agreements, including the transfer agreement with the hospital. [source: Application, p15 and Exhibit V]

Management of the ASC is provided by one of the employees. For medical director services, the two owning physicians share medical director responsibilities for both the clinic and the ASC. Management and medical director services are provided under a job description rather than a contract. [source: Application, p15, and January 19, 2010, supplemental information, p1]

Based on the information provided in the application, the department concludes that the ASC would have appropriate ancillary and support relationships as required. This sub-criterion is met.

(3) <u>There is reasonable assurance that the project will be in conformance with applicable state</u> <u>licensing requirements and, if the applicant is or plans to be certified under the Medicaid or</u> <u>Medicare program, with the applicable conditions of participation related to those</u> <u>programs.</u>

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

NCEA has been operating since mid-year 2008 and holds AAACH accreditation.<sup>9</sup> NCEA does not own or operate any other health care facilities in Washington or any other state. The

<sup>&</sup>lt;sup>9</sup> AAAHC is the Accreditation Association for Ambulatory Health Care. AAAHC is a private non-profit organization formed in 1979 and is a leader in developing standards to advance and promote patient safety, quality,

Department of Health's Investigations and Inspections Office (IIO), which surveys ASCs within Washington State, has completed at least one compliance survey for NCEA.<sup>10</sup> The survey revealed no substantial non-compliance issues for NCEA. [source: IIO compliance data]

The Department of Health's Medical Quality Assurance Commission credentials medical staff in Washington State and is used to review the compliance history for all medical staff, which includes physicians, RNs, and LPNs, associated with NCEA. A compliance history review of all medical staff associated with NCEA, including the owning physicians—Nanette Crowell and C. Dan Siapco—reveals no recorded sanctions for all. [source: MQAC compliance history]

After reviewing the compliance history of NCEA as an exempt ASC and the compliance history of all medical staff associated with the exempt ASC and the medical clinic, the department concludes there is reasonable assurance that NCEA would operate in conformance with applicable state and federal licensing and certification requirements. This sub-criterion is met.

(4) <u>The proposed project will promote continuity in the provision of health care, not result in an</u> <u>unwarranted fragmentation of services, and have an appropriate relationship to the service</u> <u>area's existing health care system.</u>

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

In response to this sub-criterion, NCEA provided the following statements. [source: Application, p15]

"....Currently surgeons either employed part time by NCEA or located within one mile of the center, see patients who are referred to them by other local providers because of their sub-specialty. These patients, who are found to need surgery, are then asked to travel to another facility an hour or more outside their service area for the required surgical care due to the unavailability of this service locally. [Approval of this] project would allow the patients to be seen and receive their surgery in either the same physical location, or in the case of retinal care, within one mile of the same physical location, where they saw their surgeon in consult."

To further demonstrate compliance with this sub-criterion, NCEA acknowledged that it currently operates as an exempt ASC and the addition of services not currently provided in the planning area would complement the services already offered. Further, established ancillary and support agreements are already in place for the exempt facility and would continue if this project is approved. [source: Application, p15]

and values for ambulatory hearth care. AAAHC currently accredits over 4,600 organizations in a wide variety of ambulatory health care setting, which include ASCs and managed care organizations. [source: AAAHC website]<sup>10</sup> Initial compliance survey completed in June 2008.

Based on this information provided above, the department concludes that approval of this project would not cause unwarranted fragmentation of the existing healthcare system. Therefore, this sub-criterion is met.

(5) <u>There is reasonable assurance that the services to be provided through the proposed project</u> will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations. This sub-criterion is evaluated in sub-section (3) above, and based on that evaluation, the department concludes that this sub-criterion is met.

#### D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department concludes North Cascade Eye Associates, PS has met the cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>.

To determine if a proposed project is the best alternative, the department takes a multi-step approach. <u>Step one</u> determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met WAC 246-310-210 through 230 criteria, the department would move to <u>step two</u> in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

<u>Step three</u> of this assessment is to apply any service or facility specific criteria (tie-breaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

#### Step One

For this project, NCEA's project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

#### Step Two

Within the application, NCEA identified only the option of status quo before submitting this application. NCEA rejected this option primarily for the following two reasons:

- The current ASC is underutilized.
- The services are not offered in the planning area or throughout Skagit County.

[source: Application, pp16-18]

Given the only other option to this project is do nothing, taking into account the support of one of the local hospitals, the department concludes that the project described is the best available alternative for the community. This sub-criterion is met.

### Step Three

For this project, only NCEA submitted an application to establish an ASC in the east Skagit County planning area. As a result, step three is not evaluated under this sub-criterion.