

August 22, 2013

CERTIFIED MAIL # 7011 1570 0002 7802 6319

Sandra VanderYacht, RN Northwest Endoscopy Center, LLC 2930 Squalicum Parkway, #202 Bellingham, Washington 98225

Re: CN13-38

Dear Ms. Vander Yacht:

We have completed review of the Certificate of Need application submitted by Northwest Endoscopy Center, LLC proposing to establish an ambulatory surgery center in Bellingham, within Whatcom County. For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Endoscopy Center, LLC agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a three operating room surgery center in Bellingham, within Whatcom County. Services provided at the ambulatory surgery center are limited to endoscopy and gastroenterology related procedures.

Conditions:

- 1. Approval of the project description as stated above. Northwest Endoscopy Center, LLC further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Prior to commencement of the project, Northwest Endoscopy Center, LLC must provide to the department for review and approval a final Admission Policy consistent with the draft policy provided in the application.
- 3. Northwest Endoscopy Center, LLC will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Northwest Endoscopy Center, LLC will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by the hospital currently operating in the Whatcom County planning area. Currently, this amount is 2.30% gross revenue and 5.99% of adjusted revenue. Northwest Endoscopy Center, LLC will maintain records

Sandra VanderYacht, RN Northwest Endoscopy Center, LLC Certificate of Need Application #13-38 August 22, 2013 Page 2 of 2

documenting the amount of charity care it provides and demonstrating compliance with its charity care policies.

Approved Costs:

There is no capital expenditure associated with this project.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail:
Department of Health
Certificate of Need Program
111 Israel Road SE

Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerely,

Steven M. Saxe, FACHE

Director, Health Professions and Facilities

Enclosure

EVALUATION DATED AUGUST 22, 2013, OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST ENDDOSCOPY ASC PROPOSING TO ESTABLISH A NEW HEALTHCARE FACILITY IN WHATCOM COUNTY

APPLICANT DESCRIPTION

There are three main entities associated with this project—Northwest Gastroenterology, PLLC; Physicians Endoscopy, LLC; and Northwest Endoscopy Center, LLC. Below is a brief description of each entity and their respective role in this project.

Northwest Gastroenterology, PLLC

Northwest Gastroenterology, PLLC is an active for-profit Washington State corporation established in June 1998 that is owned by the following six physicians.

Alan Chang	Kelly McCullough	James Schoenecker, Jr.
Barry Levenson	Christoph Reitz	Todd Witte

The endoscopy physician practice is operated under this corporation. The practice has been located at 2979 Squalicum Parkway in Bellingham [98225] since 1998. [source: June 27, 2013, supplemental information, p2 and Washington State Secretary of State website] Prior to its establishment in 1998, the practice was known as Northwest Gastroenterology Clinic and was located at 3149 Ellis Street, #301 in Bellingham [98225]. Hereinafter, Northwest Gastroenterology, PLLC will be referred to as "NW Gastro PLLC."

Physicians Endoscopy, LLC

Physicians Endoscopy, LLC is an 'inactive' Washington State corporation owned by several different entities each with a different percentage of ownership.

Name	% of Ownership
Silver Oak PE ¹	47.33%
DuPont Pension ²	17.11%
Barry Tanner	10.00%
Others, each with less than 5% ownership	25.56%

Physicians Endoscopy, LLC has joint ownership of the ASC associated with the Northwest Endoscopy Center, LLC that is described below.

Northwest Endoscopy Center, LLC

Northwest Endoscopy Center, LLC is an active for-profit corporation established in July 1998. This corporation is jointly owned by NW Gastro, PLLC [70%] and Physician Endoscopy [30%]. The ASC associated with this project would be operated under this jointly-owned corporation. For this project Northwest Endoscopy Center, LLC is considered the applicant.

¹ Silver Oak PE is a private equity firm focused exclusively on service businesses. [source: Silver Oak website]

² DuPont Pension is the pension fund for DuPont retirees.

PROJECT DESCRIPTION

On April 11, 1994, Northwest Gastroenterology Clinic was granted an exemption from Certificate of Need for the establishment of an ambulatory surgery center (ASC) at the Ellis Street site in Bellingham. [source: CN historical files] Construction of the exempt ASC commenced and the facility became operational in the latter part of 1994. In 1998, Northwest Endoscopy Center, LLC was created and a separate tax ID number was established for the ASC. Additionally, 30% of the ownership of the ASC was sold to Physician Endoscopy.³ [source: Application, p6 and DOR 13-08 and supporting documentation]

The ASC has three operating rooms (ORs), two pre- and post-operative and recovery rooms, administration/reception space, and physician offices. [source: Application, Exhibit 5] As of the writing of the evaluation, the ASC continues to function under the umbrella of NW Gastro, PLLC and Physicians Endoscopy, LLC. Further, only physicians with ownership interest in the ASC are allowed to use it. [source: Application p6]

With this application, Northwest Endoscopy Center, LLC (NEC, LLC) proposes to obtain a Certificate of Need for the ASC to ensure conformance with state and federal requirements. While approval of this project could allow physicians that are not part of the group practice to use the ASC, NEC, LLC does not anticipate outside physician use. If approved, the ASC will continue to operate at the same site with three ORs and support space. [source: Application p6]

Services currently provided at the ASC are endoscopy and gastroenterology related procedures, such as colonoscopies, flexible sigmoidoscopies, enteroscopies, and upper endoscopies. Since the initial ASC was established, the services provided at the ASC have always been limited to endoscopy and related gastroenterology. If approved, NEC, LLC proposes to continue providing the same services and does not anticipate expanding to other types of procedures. [source: Application, p6]

Since NEC, LLC does not propose to expand services or the physical facility, there is no capital expenditure associated with this project. [source: Application, p20]

Since the facility is already operational and no new services or construction is required, if this project is approved, NEC, LLC would then be operating in compliance with state and federal guidelines. Completion of the project, as defined in CN Program rules would occur immediately.⁴ Under this timeline, year 2014 would be the ASC's first full calendar year of operation as a CN approved ASC. [source: Application, p9]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need 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).

³ Exemption requests are specific to the facts in place at the time of the request. Once the legal structure of the ASC changed, a new exemption request should have been submitted to the Certificate of Need Program. On October 11, 2012, Northwest Endoscopy Center, LLC submitted a new exemption request that reflected the current ownership and operation of the ASC. On October 26, 2012, the department denied the exemption request. [source: DOR #13-08]

⁴ Washington Administrative Code 246-310-010(13).

EVALUATION CRITERIA

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, the applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment)⁵. Additionally, WAC 246-310-270 (ambulatory surgery) contains service or facility specific criteria for ASC projects and must be used to make the required determinations.

TYPE OF REVIEW

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This application was reviewed under the regular review timeline outlined in WAC 246-310-160, which is summarized on the following page.

⁵ Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-220(2) and (3); and WAC 246-310-240(2).

APPLICATION CHRONOLOGY

Action	Northwest Endoscopy Center, LLC
Letter of Intent Submitted	December 18, 2012
Application Submitted	April 3, 2013
Department's pre-review activities	April 4, 2013
including screening and responses	through June 16, 2013
Beginning of Review	June 17, 2013
 End of Public Comment public comments accepted through the end of public comment No public hearing requested or conducted 	July 22, 2013
Rebuttal Comments ⁶	August 6, 2013
Department's Anticipated Decision Date	September 20, 2013
Department's Actual Decision Date	August 22, 2013

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."

During the review of this project, no entities sought or received affected person status.

SOURCE INFORMATION REVIEWED

- Northwest Endoscopy Center, LLC's Certificate of Need application submitted April 3, 2013
- Northwest Endoscopy Center, LLC's supplemental information received June 10, 2013 and June 27, 2013
- Completed utilization surveys for operating room use and capacity
- Data obtained from the DOH Integrated Licensing & Regulatory System [ILRS] database for operating room use and capacity
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Quality of Care history obtained for out-of-state facilities owned or operated by Physician Endoscopy, LLC
- Department of Health / Health Systems Quality Assurance Provider Credential Information
- Washington State Secretary of State website [www.sos.wa.gov]
- Silver Oak website [www.silveroaksp.com]
- Certificate of Need historical files

⁶ No public comments were submitted during the review of this project. As a result, NEC, LLC did not provide rebuttal comments.

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Northwest Endoscopy Center, LLC proposing to establish a Certificate of Need approved ambulatory surgery center by converting its Certificate of Need exempt ambulatory surgery center is consistent with the applicable review criteria provided Northwest Endoscopy Center, LLC agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a three operating room surgery center in Bellingham, within Whatcom County. Services provided at the ambulatory surgery center are limited to endoscopy and gastroenterology related procedures.

Conditions:

- 1. Approval of the project description as stated above. Northwest Endoscopy Center, LLC further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Prior to commencement of the project, Northwest Endoscopy Center, LLC must provide to the department for review and approval a final Admission Policy consistent with the draft policy provided in the application.
- 3. Northwest Endoscopy Center, LLC will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Northwest Endoscopy Center, LLC will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by the hospital currently operating in the Whatcom County planning area. Currently, this amount is 2.30% gross revenue and 5.99% of adjusted revenue. Northwest Endoscopy Center, LLC will maintain records documenting the amount of charity care it provides and demonstrating compliance with its charity care policies.

Approved Cost

There is no capital expenditure associated with this project.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

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 Northwest Endoscopy Center, LLC's project has met the need criteria in WAC 246-310-210(1) and (2) and the ambulatory surgery center methodology and standards outlined in the WAC 246-310-270.

(1) <u>The population served or to be served has 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.</u>
WAC 246-31-270(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 separate secondary health services planning areas. This project is located in the Whatcom 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 endoscopy rooms and procedures.⁷

NEC, LLC provided a numeric methodology in the application and concluded that there is need for an additional OR capacity in the Whatcom County planning area in year 2015. Below is a summary of NEC, LLC's numeric methodology.

NEC, LLC Numeric Methodology

[source: Application, pp12-15 and Exhibit 7]

NEC, LLC determined existing OR capacity in the Whatcom County planning area to be 9 dedicated outpatient ORs and 7 mixed use ORs. Based on 2011 data, NEC, LLC's methodology identified a use rate of 102.25/1,000 population. Focusing on year 2015, the applicant projected Whatcom County's population to be 210,050. Applying the use rate to the projected population and subtracting the existing number of ORs in the planning area, NEC, LLC projected a need for 3.25 ORs in the Whatcom County for year 2015.

Department's Methodology and Review

The numeric portion of the methodology requires a calculation of the annual capacity of the existing providers inpatient and outpatient OR's in a planning area—Whatcom County. According to the department's historical records, there are 12 planning area providers—including the applicant—with OR capacity. All 12 providers are located in Bellingham, which is the largest city in the county. The 12 providers are listed below . [source: CN historic files and DOH ILRS database]

⁷ WAC 246-310-270(9)(a)(iv).

Table 1
Whatcom County Planning Area Providers

Hospital	ASC
PeaceHealth St. Joseph Medical Center	Bellingham Surgery Center
	Bellingham Urology Specialists
	Mt. Baker Pain Clinic and Interventional Radiology
	Northwest Ambulatory Surgery Center
	Northwest Endoscopy Center ASC (applicant)
	Northwest Surgical Center
	Pacific Cataract and Laser Institute
	Pacific Rim Outpatient Surgery Center
	Parkway Surgical Center
	PeaceHealth Medical Group Endoscopy Center
	Whatcom Surgery Center

As shown above, the 12 facilities include 1 hospital and 11 ASCs, including the applicant's ASC. For the hospital, all known OR capacity and inpatient / mixed-use procedures are included in the methodology calculations for the planning area.

Of the 11 ASCs shown above, two—the applicant and PeaceHealth Medical Group Endoscopy Center—are endoscopy facilities. The numeric methodology deliberately excludes the OR capacity and procedures from the numeric methodology.⁸

For the remaining 9 ASCs, 6 are located within a solo or group practice (considered an exempt ASC) and the use of these ASCs is restricted to physicians that are employees or members of the clinical practices that operate the facilities. Therefore, these 6 facilities do not meet the ASC definition in WAC 246-310-010. For exempt ASCs, the utilization, but not ORs, is included in the methodology for the planning area.⁹

The remaining 3 ASCs are CN approved facilities.¹⁰ For these, the OR capacity and utilization is counted in the numeric methodology.

On December 13, 2012, the department issued an exemption from CN review allowing the consolidation of two CN approved ASCs in Whatcom County. The two ASCs are Bellingham Surgery Center and Northwest Ambulatory Surgery Center. Before consolidation, the two ASCs have a combined total of 6 ORs. After the consolidation, the new owner [Symbion Healthcare] will have 3 ORs and expanded recovery space. For this numeric methodology, department will count 3 ORs for the combined facility.

¹¹ DOR#13-13.

⁸ WAC 246-310-270(9)(iv).

⁹ Bellingham Urology Specialists, Mount Baker Pain Clinic, Northwest Surgical Center, Pacific Cataract and Laser Institute, Parkway Surgical Center, and Whatcom Surgery Center.

¹⁰ Bellingham Surgery Center [CN #1002]; Northwest Ambulatory Surgery Center [CN #1213]; and Pacific Rim Outpatient Surgery Center [CN #1246].

To assist in its application of the numeric methodology, the department reviewed utilization information from each of the operational facilities identified above. Utilization information was obtained from the annual ASC utilization survey. If this data was not available, the department obtained data from its internal database.¹² The assumptions used by the department in the methodology are shown below.

Table 2
Department's Methodology Assumptions and Data

Assumption	Data Used	
Planning Area	Whatcom County	
Population Estimates and Forecasts	Office Of Financial Management Population Data	
	released May 2012:	
	Year 2011 – 202,922	
	Year 2014 – 208,268	
Use Rate	Divide calculated surgical cases by 2011 population	
	results in the service area use rate of 123.466/1,000	
	population	
Percent of surgery ambulatory vs.	Based on DOH survey and ILRS data, 82.53%	
inpatient	ambulatory (outpatient) and 17.47% inpatient	
Average minutes per case	Based on DOH survey and ILRS data	
	Outpatient cases = 55.83 minutes;	
	inpatient cases 155.37 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/ORs	Based on listing of Whatcom County providers.	
	9 dedicated outpatient ORs and 8 mixed use ORs	

It is noted that the applicant's methodology projected to year 2015. Since the ASC is currently operational under an exemption, and proposes no construction or changes for this application, the department does not anticipate any delays in implementing a CN if the project is approved. As a result, year 2014 would be the ASC's first year of operation as an exempt facility. For those reasons, the department used year 2014 as the projection year, rather than 2015.

As shown in Table 2, using 2014 as the projection year, the department's application of the numeric methodology based on the assumptions described above indicates a need for 8.21 outpatient ORs. Since endoscopy ORs are deliberately excluded from the numeric methodology, if this project is approved, the 3 dedicated endoscopy ORs would not affect the projected numeric need calculated in the methodology. The department's methodology is Appendix A attached to this evaluation.

In summary, based on the department's numeric methodology, need for additional OR capacity in Whatcom County is justified.

NEC, LCC also provided the following statements related to the numeric methodology and continued need for the endoscopy services currently provided.

¹² The Department of Health's internal data base is Integrated Licensing & Regulatory System, known as ILRS.

"Even though the numeric methodology shows a need for additional dedicated outpatient capacity in the planning area, the department has previously determined the numeric methodology is not suitable for projecting need for the ORs specific to this type of project. Therefore, the department has considered additional information within the application."

The 'additional information' referenced by the applicant is the five-year historical number of procedures and most recent year patient origin data. This information is summarized in the tables below. [source: Application, p5 and p15]

Table 3
Northwest Endoscopy ASC
Five-Year Historical Utilization

Year	# of Procedures	% Increase / (Decrease) from Previous Year
2007	7,763	
2008	7,833	0.9%
2009	7,957	1.6%
2010	7,890	(0.8%)
2011	7,999	1.4%
2012	8,017	0.2%

Table 4
Northwest Endoscopy ASC
Year 2012 Patient Origin By County

County	% of Patients
Whatcom	90.0%
Skagit	6.0%
San Juan	3.0%
Island	1.0%
Total	100.0%

As shown in Table 3, with the exception of year 2010, the number of procedures at the ASC has increased each year. The five-year growth from 2007 to 2012 is 3.3%. Table 4 shows that the majority of patients are from the applicant's planning area, Whatcom County, with a small percentage coming from adjacent counties.

Based on the applicant's numeric methodology, historical number of procedures, and patient origin data, NEC, LLC concluded that there is need for additional ORs in the planning area and the existing CN exempt ORs at the ASC are needed to continue to provide a much needed service in Whatcom County.

WAC 246-310-270(6)

WAC 246-310-270(6) requires a minimum of two ORs in an ASC. The exempt ASC was constructed to accommodate three ORs and all three have been operation for some time. NEC, LLC does not intend to increase or decrease the number of ORs at the CN approved facility. [source: Application, p6 and Exhibit 5] This standard is met.

In summary, based on the department's application of the numeric methodology, supporting data for historical services, and the applicant's ability to meet the standard above, **this sub-criterion is met.**

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

Even though NEC, LLC has been providing endoscopy services for many years in Whatcom County, for CN purposes, the applicant is considered a new provider to health care services in Washington State. As an exempt ASC, NEC, LLC is not required to meet the access to care standard stated above. As a CN approved ASC, NEC, LLC must demonstrate that it would be available to all residents of the planning area, including low-income, racial and ethnic minorities, handicapped and other underserved groups. NEC, LLC must also participate in the Medicare and Medicaid programs and commit to providing a percentage of charity care in the planning area.

Admission Policy

To determine whether all residents of the service area would have access to the proposed outpatient services, the department requires an applicant 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. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission polity that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, NEC, LLC provided a <u>draft</u> admission policy that would be used at the ASC. The draft policy outlines the process and criteria that would be used to admit patients for treatment. The draft policy also includes the appropriate non-discrimination language required by the department. [source: Application, Exhibit 8]

Medicare and Medicaid Programs

The department uses Medicare certification to determine whether the elderly would have access, or continue to have access, to the proposed services. To demonstrate compliance with this subcriterion, the applicant provided its current and projected source of revenues by payer. Medicare revenues are, and would continue to be, 26% of the total revenues at the ASC. Additionally, the financial data provided in the application shows Medicare revenues. [source: Application, p8, p21 and June 27, 2013, supplemental information, Attachment 2]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. To demonstrate compliance with this sub-criterion, NEC, LLC also provided its current and projected percentage of Medicaid revenues at 5%. NEC, LLC states that approval of this project would not change this payer percentage. Additionally, the financial data provided in the application shows Medicaid revenues. [source: Application, p8, p21 and June 27, 2013, supplemental information, Attachment 2]

Charity Care Policy

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.

To demonstrate compliance with this sub-criterion, NEC, LLC provided a copy of its current charity care policy. The policy includes the appropriate non-discrimination language as required and outlines the process one must use to obtain charity care at the ASC. The pro forma financial documents provided in the application also include a charity care 'line item.' [source: Application, Exhibit 8 and June 27, 2013, supplemental information, Attachment 2]

WAC 246-310-270(7)

WAC 246-310-270(7) requires 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, Southwest, Central, and Eastern. NEC, LLC's ASC is located in Whatcom County, within the Puget Sound Region. Currently, there are 19 hospitals operating, or approved to operate, in the region. Of those, one--PeaceHealth St. Joseph Medical Center--is in Whatcom County and could be affected by approval of this project

For this project, the department reviewed the most recent three years of charity care data for the 19 existing hospitals currently operating within the Puget Sound Region and focused on the hospital located in the applicant's planning area of Whatcom County. The three years reviewed are 2008, 2009, and 2010.¹³ The table below is a comparison of the average charity care for the Puget Sound Region, PeaceHealth St. Joseph Medical Center, and NEC, LLC projected. [source: 2008-2010 HPDS charity care summaries]

Table 5
Charity Care Percentage Comparisons

	% of Total Revenue	% of Adjusted Revenue
Puget Sound Region	2.18%	4.71%
PeaceHealth St. Joseph Medical Center	2.30%	5.99%
NEC, LLC Projected	2.30%	3.33%

As shown in the table above, the regional average is slightly lower than the average provided by the sole hospital in the planning area. NEC, LLC proposes to provide a gross revenue percentage of charity care equal to the PeaceHealth St. Joseph Medical Center.

Since NEC, LLC is an exempt ASC, it did not undergo any review of its charity care policies, procedures, or percentages. To ensure that appropriate charity care percentages would be provided by NEC, LLC, if this project is approved, the department would attach a condition requiring NEC, LLC to provide charity care at certain percentages.

NEC, LLC provided a draft Admission Policy. If this project is approved, department would also attach a condition requiring the applicant to provide a final policy. With the two conditions

¹³ As of the writing of this evaluation, years 2011 and 2012 charity care data is not available.

identified above, the department concludes that all residents of the service area would have access to the proposed ASC. **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 determines that Northwest Endoscopy Center, LLC's project has met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

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.

To evaluate this sub-criterion, the department first reviewed the assumptions used by NEC, LLC to determine the projected number of procedures for the ASC. The assumptions are summarized below. [source: Application, p16]

- As a CN exempt ASC, the types of procedures are limited to endoscopy and gastroenterology surgeries performed by the physicians associated with the practice. The projected number of procedures was based on six years of operating history at the ASC.
- NEC, LLC anticipates hiring an additional physician by the end of year 2013.
- The projected number of procedures assumes an average growth rate of 2% over four years [2014-2017]. This growth rate was assumed to be reasonable since the facility has been in operation for six years and a new physician would increase the number of procedures performed at the ASC.

Using the assumptions stated above, NEC, LLC's projected number of procedures by year is shown below. [source: Application, p16]

Table 6
NEC, LLC Projected Number of Procedures

1120, 220 110 jected 1 tumber of 110 cedares				
2013	2014	2015	2016	2017
8,177	8,341	8,508	8,678	8,851

Based on the assumptions above and taking into consideration that NEC, LLC does not intend to expand its services beyond endoscopy and gastroenterology procedures, the projections shown are considered reasonable.

If approved, NEC, LLC anticipates commencement and completion immediately upon approval. Under this timeline, year 2014 would be the ASC's first full calendar year of operation and 2016 is full year three. NEC, LLC's projected revenue, expenses, and net income using calendar years is shown in the table on the following page. [source: June 27, 2013, Supplemental Information, Attachment 2]

Table 7
Projected Revenue and Expense Statements for Calendar Years 2014 through 2016

		- 0	
	CY 2014	CY 2015	CY 2016
	Full Year 1	Full Year 2	Full Year 3
Net Revenue	\$ 5,101,877	\$ 5,241,964	\$ 5,385,233
Total Expenses	\$ 2,964,298	\$ 3,038,576	\$ 3,115,525
Net Profit /(Loss)	\$ 2,137,579	\$ 2,203,388	\$ 2,269,708

The 'Net Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowance. The 'Total Expenses' line item includes salaries and wages, rent, supplies, and depreciation. As shown above, NEC, LLC projected net profits in all three projected years.

Since the ASC has been operational for six years and does not anticipate any expansion of the types of procedures to be provided if this project is approved, NEC, LLC provided its projected payer mix based on its historic payer mix. The table below shows the expected payer mix for the ASC. [source: Application, p8 and p21]

Table 8
Projected Payer Mix

Payer Source	Percentage	
Medicare	26.0%	
Medicaid	5.0%	
Commercial/Other Insurance ¹⁴	69.0%	
Total	100.0%	

As shown above, the majority of the ASC's payer source has been, and would continue to be, Medicare insurance. Considering the types of procedures historically provided at the ASC, this payer mix is reasonable.

The ASC would remain at its current location at 2979 Squalicum Parkway in Bellingham [98225]. NEC, LLC provided a copy of the lease agreement between RadCo, LLC [landlord] and NEC, LLC [tenant] The lease agreement was executed on August 10 2007, and remains in effect through year 2022. The pro forma Revenue and Expense Statements summarized above also include a 'rent' line item with annual cost increases for the ASC. [source: Application, Exhibit 6]

Physicians Barry Levenson and Christoph Reitz are the current medical director and assistant medical director, respectively. Since both physicians are owners of NEC, LLC, no medical director agreement has been, or would be established, for the services. NEC, LLC provided a medical director job description with roles and responsibilities for review. Information in the document is consistent with medical director responsibilities reviewed in past CN applications. [source: Application, p4 and Exhibit 3]

¹⁴ 'Other' payers include Blue Cross, Premera, and other private insurers.

On July 1, 2009, NEC, LLC entered into a 'Limited Services Agreement' with Physicians Endoscopy, LLC. The agreement allows for a limited amount of financial oversight by performing periodic review of the financial reports. The agreement specifically states that it is not an agreement for management, operational, or clinical oversight of NEC, LLC. The agreement remains in effect for six years from the date of execution, or through June 31, 2015. All costs associated with the agreement are included in the pro forma financial statements provided in the application. [source: June 27, 2013, Supplemental Information, Attachment 2, and June 27, 2013, Supplemental Information, Attachment 1]

In addition to the projected Revenue and Expense Statements shown above, NEC, LLC provided the projected Balance Sheets using the same calendar years. Full year one, (2014) and three (2016) are shown in the tables below. [source: June 27, 2013, Supplemental Information, Attachment 2]

Tables 9
Projected Balance Sheets
Full Calendar Year One - 2014

Assets		Liabilities	
Current Assets	\$ 766,545	Current Liabilities	\$ 222,118
Fixed Assets	\$ 376,047	Long Term Debt	\$ 152,746
Board Designated Assets	\$ 12,000	Equity	\$ 779,728
Total Assets	\$ 1,154,592	Total Liabilities and Equity	\$ 1,154,592

Full Calendar Year Three – 2016

Assets		Liabilities	
Current Assets	\$ 800,700	Current Liabilities	\$ 202,034
Fixed Assets	\$ 162,764	Long Term Debt	\$ 7,013
Board Designated Assets	\$ 12,000	Equity	\$ 766,417
Total Assets	\$ 975,464	Total Liabilities and Equity	\$ 975,464

The balance sheets above show that the ASC would be operating with little liabilities. This is typical of ASC operations that have been reviewed by the department. The balance sheets above show that the ASC would be financially stable through full calendar year 2016.

Based on the source 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**.

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 determines that Northwest Endoscopy Center, LLC's project has met the structure and process 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 compared the proposed project's source of financing to those previously considered by the department.

Since the exempt ASC is already operational, all key staff is in place. Since NEC, LLC expects to hire an additional physician by the end of year 2013, the applicant projected a slight increase in staff for year 2014, and no further increases through 2016. The table below summarizes the current FTEs and proposed FTEs for current year 2013 through full year 2016. [source: June 10, 2013, Supplemental Information, p4]

Table 10 Current and Proposed FTEs Years 2013-2016

Staff	Current Year 2013	Year 1 2014 Increases	Year 2-2015 Increases	Year 3-2016 Increases	Total
Clinical Director	1.00	0.00	0.00	0.00	1.00
RNs	10.00	1.00	0.00	0.00	11.00
LPN/Techs	5.50	0.50	0.00	0.00	6.00
Scope Washers	6.00	0.00	0.00	0.00	6.00
Reception/Registration	1.00	0.00	0.00	0.00	1.00
Medical Assistants	2.00	3.00	0.00	0.00	5.00
Procedure Schedulers	2.00	0.00	0.00	0.00	2.00
Total FTE's	27.50	4.50	0.00	0.00	32.00

In anticipation of hiring a new physician by the end of year 2013, NEC, LLC has already hired the additional support staff for the ASC. Since the ASC already has all the majority of the key staff in place, NEC, LLC was able to provide names and professional license numbers for key staff. [source: Application, Exhibit 1 and June 10, 2013, supplemental information, 4]

Based on the information, the department concludes that sufficient staffing is available or can be recruited. **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(2) 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 relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

NEC, LLC has been an existing provider of healthcare services in Whatcom County for many years. Since the ASC is operational as an exempt facility, long-standing support and ancillary services with existing healthcare providers are in place. To demonstrate compliance with this subcriterion, NEC, LLC provided a copy of its existing transfer agreement with PeaceHealth St. Joseph Medical Center in Bellingham. The agreement defines roles and responsibilities for both

NEC, LLC and the hospital in the event a patient is transferred. [source: Application, p23 and Exhibit 11]

Based on the information above, the department concludes that **this sub-criterion is met**.

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

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria 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. As part of its review, the department must conclude that the proposed service would be operated in a manner that ensures safe and adequate care to the public. 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.

NEC, LLC has been is a provider health care services in Washington State for many years. NEC, LLC or its owning physicians do not have any other healthcare facilities in Washington or any out-of-state facilities.

NEC, LLC has entered into a 'Limited Services Agreement' with Physicians Endoscopy, LLC. The agreement allows for a limited amount of financial oversight by performing periodic review of the financial reports. The agreement specifically states that it is not an agreement for management, operational, or clinical oversight of NEC, LLC.

Since Physicians Endoscopy, LLC has joint ownership of the ASC associated with the NEC, LLC, the department also reviewed the quality of care history of Physicians Endoscopy, LLC. As of the writing of this evaluation, Physicians Endoscopy, LLC has an ownership or management relationship with 28 facilities located in 13 states, including Washington State. Below is a summary of the 13 states and the number of ASCs associated with Physicians Endoscopy within the state.

State	# of Facilities	State	# of Facilitie	es
Arizona	2	Michig	gan 2	
Florida	2	New Jo	Tersey 2	
Georgia	1	New Y	York 6	
Illinois	2	Ohio	2	
Massachusetts	1	Pennsy	ylvania 2	
Maryland	1	Texas	2	
		Washii	ington 3	

The department requested quality of care history for all ASCs identified above. Of the 13 states listed above, information from four of the states was not available either through a compliance survey, e-mail, internet access, or phone call. For Washington State, information was available through its own internal database.

¹⁵ Also WAC 246-310-230(5).

¹⁶ The three states are Arizona, Illinois, Massachusetts, and Texas, which represents 7 of 28 ASCs.

For the remaining 9 states and 20 ASCs, the ASC(s) associated with Physician Endoscopy, LLC was determined to be in compliance with applicable state and federal requirements, with the exception of one ASC located in Ohio. For Ohio, the state surveyors reported that one of the two ASCs was not currently in compliance with state construction standards, however, Physicians Endoscopy, LLC was fully cooperating with the surveyors to come into compliance. [source: Quality of Care data]

As stated in the project description section of this evaluation, Northwest Gastroenterology Clinic obtained an exemption from Certificate of Need in 1994. In 1998, when NEC, LLC was created and Physicians Endoscopy, LLC became an owning entity, NEC, LLC should have notified the Certificate of Need Program because NEC, LLC would no longer qualify for the exemption. NEC, LLC was unaware of this requirement until November 2012, when the department denied NEC, LLC's exemption request based on its current operations. At that time, NEC, LLC began preparation of this application for submission to become compliance with Washington State rules and regulations. As a result, for Washington State, two of the three ASCs are in compliance with state and federal requirements. However, the department recognizes that if this project is approved, all three ASCs would be in compliance. [source: Department of Health Internal Database-ILRS]

NEC, LLC also identified the names and professional license number for all key staff of the ASC. A compliance history review of all staff did not show any current or past enforcement actions. [source: Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of NEC, LLC, Physicians Endoscopy, LLC, and key staff associated with the ASC, the department concludes there is reasonable assurance that the ASC would be operated in conformance with state and federal regulations. **This sub-criterion is met.**

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

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 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.

To demonstrate compliance with this sub-criterion, NEC, LLC provided the following statements. [source: Application, p23]

"This project simply proposes to convert an existing high volume, high quality exempt ASC to a CN approved ASC. No change in the location, service delivery, or working relationships is anticipated as a result of this project. NEWC has been providing services since 1994. NWEC will continue to provide endoscopy and GI related services to the community and will continue the established working relationships with other existing providers."

Since the ASC is operational as an exempt facility, working relationships with existing healthcare facilities have already been established. Since the ASC will not relocate, the department expects these relationships to continue. Further, nothing in the documents provided by NEC, LLC and reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

Based on the source information provided above, the department concludes that approval of this project would not cause unwarranted fragmentation of the existing healthcare system. **This subcriterion is met**.

(5) There is reasonable assurance that the services to be provided through the proposed project 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 no public comments were submitted for this sub-criterion for this application. **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 determines that Northwest Endoscopy Center, LLC's project has met the cost containment criteria in WAC 246-310-240.

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable. WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable. However, the department, through its experience knows that construction projects are usually built to exceed these minimum standards. The department considered information in the applications that addressed the reasonableness of their construction projects that exceeded the minimum standards. Therefore, using its experience and expertise the department assessed the materials contained in the application.

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 the applicable 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, NEC, LLC has met the review criteria under WAC 246-310-210, 220, 230, and the ASC methodology and standards under WAC 246-310-270. Therefore, the department moves to step two below.

Step Two

NEC, LLC states that before submitting this application, it only considered the option of status quo or 'do nothing' and continue to operate the ASC under the exemption. NEC, LLC states that it has operated the ASC within compliance of the exemption obtained in 1998. [source: Application, p25]

Department's Review

Once NEC, LLC allowed Physicians Endoscopy, LLC ownership of the ASC, the ASC would no longer quality for an exemption. As a result, the only option available to NEC, LLC would be to change the ownership structure of the ASC. Since NEC, LLC was unwilling to change the ownership structure, the only option it had is to submit a Certificate of Need application. The department did not identify any other options that should have been considered by NEC, LLC.

Taking into account that the intent of this application is to bring NEC, LLC into compliance with state regulations, and there are no anticipated changes in the physical structure of the ASC or procedures provided at the ASC, the department concludes that NEC, LLC chose the best option available.

Step Three

This step is used to determine between two or more approvable projects which is the best alternative. Since NEC, LLC is the only applicant requesting to establish an ASC in Whatcom County, this step does not apply.

As stated in the need section of this evaluation, the department concluded that NEC, LLC demonstrated that approval of its ASC would not affect current OR supply or projected need in the Whatcom County planning area. The facility is already operational and solely provides endoscopy and GI related services. As a result, approval of this project is reasonable and a good resource for the community. **This sub-criterion is met**.

APPENDIX A

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ATTACHMENT A ASC Need Methodology Whatcom County



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Radiology	Bellingham Surgery Center*	0	0	3	0	0	0	0	20	2,997	149,850	Fer ILRS, outpatient minutes calculated using $50 \times \#$ of cases. Data for FY 2011.
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Surgical Center 0	Pacific Rim Outpatient Surgery Center	0	0	9	0	0	0	0	50	7,873	393,650	Per JLRS, outpatient minutes calculated using 50 x # of cases. Data for FY 2011.
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