

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF NORTHWEST WEIGHT LOSS SURGERY, PLLC PROPOSING TO CONVERT THE EXISTING CERTIFICATE OF NEED EXEMPT AMBULATORY SURGERY CENTER TO CERTIFICATE OF NEED APPROVED FACILITY IN CENTRAL SNOHOMISH COUNTY PLANNING AREA**

**APPLICANT DESCRIPTION**

In April 22, 2004, Northwest Bariatric Surgery Associates (NBSA) operating under the dba of Northwest Weight Loss Surgery was granted an exemption from Certificate of Need review for the establishment of an ambulatory surgery center (ASC)<sup>1</sup>. At that time, NBSA relocated to the city of Everett within Central Snohomish County and continued to operate as part of NBSA clinical practice. The exempt ASC solely provided bariatric surgeries. When the ASC was established, only two physicians, Kevin Montgomery and Brad Watkins, performed surgeries.

**PROJECT DESCRIPTION**

The exempt ASC operates under the Northwest Weight Loss Surgery, PLLC (NWWLS) practice and is currently used by three bariatric surgeons Kevin F. Montgomery, Robert Michaelson and Alana Choch. The practice and ASC remain located at 125 130<sup>th</sup> Street Southeast, in Everett. The applicant proposes to allow physicians not employed by, or partners of, NWWLS the opportunity to perform bariatric weight loss and laparoscopic procedure surgeries at the ASC. The action described requires prior Certificate of Need review and approval. [Source: Application, Page 1]

The estimated capital expenditure associated with the conversion of the CN exempt ASC to CN approved is \$299,789. Of that amount, 61.5% is related to fixed and moveable equipment and the remaining 38.5% is related to fees and taxes. [Source: Application, Page 26 and Supplemental Information April 6, 2010, Exhibit 2]

If this project is approved, NWWLS anticipates it would begin to offer services as a CN approved ASC by January 2011. Under this timeline, year 2011 would be the ASC first year of operation and year 2012 and 2013 would be the second and third years of operation. [Source: Application, Page 1]

**APPLICABILITY OF CERTIFICATE OF NEED LAW**

Even though the exempt ASC is operational, this project is subject to Certificate of Need review as the establishment of a new health care 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).

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<sup>1</sup> CN historic files—Northwest Bariatric Associates

## **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 on 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 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)<sup>2</sup>. 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.

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

## **APPLICATION CHRONOLOGY**

January 4, 2010	Letter of Intent Submitted
March 8, 2010	Application Submitted
March 9, 2010 through March 13, 2010	Department's Pre-Review Activities 1 <sup>st</sup> screening activities and responses
April 14, 2010	Department Begins Review of Application <ul style="list-style-type: none"><li>• Public comments accepted throughout the review</li><li>• No public hearing requested or conducted</li></ul>
May 18, 2010	End of Public Comment
June 2, 2010	Rebuttal Documents Received at Department
July 19, 2010	Department's Anticipated Decision Date
December 10, 2010	Department's Actual Decision Date

## **AFFECTED AND INTERESTED 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, Providence Regional Medical Center Everett, an acute care hospital with two campuses in Snohomish County, sought and received affected person status under WAC 246-310-010(2).

## **SOURCE INFORMATION REVIEWED**

- Northwest Weight Loss Surgery Certificate of Need Application received on March 8, 2010
- Northwest Weight Loss Surgery supplemental information received on April 7, 2010
- Utilization survey response received from Providence Regional Medical Center Everett
- Public comments received from Providence Regional Medical Center Everett on May 18, 2010
- Rebuttal comments received from Northwest Weight Loss Surgery on June 1, 2010
- Number of operating rooms information available at Providence Regional Medical Center Everett webpage
- Claritas and Office of Financial Management population data for Central Snohomish planning area
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Licensing and compliance history data provided by the Department of Health's Medical Quality Assurance Commission

## **CONCLUSION**

For the reasons stated in this evaluation, Northwest Weight Loss Surgery Center, PLLC's Certificate of Need application proposing to establish a two room bariatric weight loss ambulatory surgery center within the city of Everett in Central Snohomish County planning area is approved. Provided that Northwest Weight Loss Surgery Center, PLLC agrees to the term and conditions outlined below, a Certificate of Need would be issued with the following term and conditions.

### **Term**

1. Prior to commencement of the project, Northwest Weight Loss Surgery Center, PLLC must provide for the department's review and approval an adopted charity care policy. The adopted policy must be consistent with the draft policy provided in the application.

### **Conditions**

1. Northwest Weight Loss Surgery Center, PLLC will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Northwest Weight Loss Surgery Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the regional average amount of charity care provided by hospitals in the Puget Sound Region. Currently, this amount is 1.95% of gross revenue and 4.23% of adjusted revenue. Northwest Weight Loss Surgery Center will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.
2. To ensure Medicaid patients have access to procedures at the ASC, a portion of Northwest Weight Loss Surgery Center, PLLC charity care must include Medicaid patient receiving care at the ASC.
3. To ensure Medicare patients have access to procedures at the ASC, a portion of Northwest Weight Loss Surgery Center, PLLC charity care must include Medicare patient receiving care at the ASC.
4. Northwest Weight Loss Surgery Center, PLLC is limited to providing only bariatric weight loss surgeries and the associated plastic surgeries as described within the application and relied upon by the department in this evaluation.

The approved capital expenditure associated with this project is \$229,789.

**A. Need (WAC 246-310-210)**

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

- (1) 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

**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 separate secondary health services planning areas. The proposed ASC would be located in the central Snohomish 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.<sup>3</sup>

**Applicant's Methodology**

The numeric portion of the methodology requires a calculation of annual capacity of existing outpatient and inpatient ORs. To demonstrate need for a new ASC in the planning area, NWWLS identified three scenarios within its application. [Source: Application, Pages 16 - 19] NWWLS stated that each one the scenarios it proposes shows that there is need for additional dedicated outpatient surgery operating rooms in the planning area. Summarized below are the three scenarios identified by NWWLS.

- Scenario #1—NWWLS asserted that the 2006 Edmonds Proliance application shows that there is need for 17.39 dedicated outpatient room in year 2013.
- Scenario #2—was based on the Providence Everett Medical Center Everett Clinic and Western Washington Medical Group projects which NWWLS asserted demonstrates need for 23.70 dedicated outpatient surgery rooms in year 2013.

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

- Scenario #3 assumptions are based utilization data from CON approved ASC facilities in the planning which NWWLS asserted shows need for 5.66 dedicated outpatients surgery rooms in year 2013.

The scenarios outlined above by NWWLS are summarized in the Table 1 below.

**Table 1  
NWWLS Assumptions**

<b>Assumption</b>	<b>Data Used</b>
Planning Area	Central Snohomish
Population Estimates and Forecasts	OFM's Population Forecasts 2009—300,102. Project target year 2013 projected population 762,558
Use Rate <ul style="list-style-type: none"> <li>• Scenario #1</li> <li>• Scenario #2</li> <li>• Scenario #3</li> </ul>	30,601/300,102 = 102.0 27,258/300,102 = 90.83 12,592/300,102 = 41.96
Percent of surgery ambulatory vs. inpatient <ul style="list-style-type: none"> <li>• Scenario #1</li> <li>• Scenario #2</li> <li>• Scenario #3</li> </ul>	72.25% ambulatory (outpatient) and 27.75% inpatient 70.0% ambulatory (outpatient) and 30.0% inpatient 63.8% ambulatory (outpatient) and 36.2% inpatient
Average minutes per case <ul style="list-style-type: none"> <li>• Scenario #1</li> <li>• Scenario #2</li> <li>• Scenario #3</li> </ul>	100 minutes per inpatient and 50 minutes outpatient 120 minutes per inpatient and 79 minutes outpatient 120 minutes per inpatient and 79 minutes outpatient
OR Annual capacity surgery in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes (per methodology in rule).
Existing ORs	12 mixed use ORs

Using the assumptions outlined above, NWWLS asserted its calculations show need for new dedicated outpatient ORs by the end of target year 2013 in the planning area.

- Scenario #1 projects a need of additional 17.39 ORs
- Scenario #2 projects a need for additional 23.70 ORs
- Scenarios #3 projects a need for additional 5.66 ORs

Department's Evaluation

The department disagrees with NWWLS scenarios #1 and #2 because both scenarios did not account for current utilization within the planning area. Both scenarios relied on facilities not located within the planning area. The applicant's scenario #3 follows the methodology as stated in WAC 246-310-270, but the department notes that the scenario did not account for all the available ORs in the planning area. According to responses to the department's utilization survey of facilities located within the planning area, Providence Regional Medical Center has 17 mix-used ORs. Based on the correct number of ORs in the planning area, NWWLS's scenario #3 above significantly undercounted the number of available OR's in the planning area. On page 17, is the department's application of the methodology for central Snohomish County planning area.

Department's Methodology

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. Given that NWWLS is located in central Snohomish County, the department applied the methodology to determine need in the planning area. According to the department's historical records, there are eight providers with OR capacity located in the planning area. The eight facilities are listed in Table 2 below. [Source: CN Historic Files]

**Table 2**  
**Central Snohomish County Planning Area Providers**

<b>Hospital/ City</b>	<b>ASC's</b>
Providence Regional Medical Center, Everett	Everett Clinic
	Everett Orthopedic Surgery Center
	Western Washington Medical Group
	Northwest Surgery Center
	Physician Eye Surgery Center
	Endoscopy Center
	Northwest Weight Loss Surgery, PLLC

As shown in Table 2 above, the eight facilities include Providence Regional Medical Center-Everett, an acute care hospital with two campuses in the planning area. As defined in WAC 246-310-010, Providence Regional Medical Center (Providence Everett) is included in the capacity calculations of available ORs for central Snohomish County planning area. The seven ASCs, including the applicant, are solo or group practices (considered exempt ASCs) and therefore, the use of these ASCs are restricted to physicians that are employees or members of the respective clinical practices that operate each of the facilities. These seven facilities do not meet the ASC definition within WAC 246-310-010 and are not included in the capacity calculations of available ORs for central Snohomish planning area.

To assist in its application of the numeric methodology for this project, on March 16, 2010, the department requested utilization information from each of the facilities identified in the table above. Of the facilities listed in the table, only Providence Everett and Western Washington Medical Group provided completed surveys to the department. To apply the numeric methodology, the department relied on its own survey results. Summarized in Table 3, are the assumptions used by the department.

**Table 3  
Department's Methodology**

<b>Assumption</b>	<b>Data Used</b>
Planning Area	Central Snohomish
Population Estimates and Forecasts	OFM's 2009 population data for Central Snohomish County 284,519. Project target year is 2013 and the projected population is 301,308
Use Rate	Divide 2009 surgical cases by 2009 populations results in the service area use rate of 43.77/1000 population
Percent of surgery ambulatory vs. inpatient	Based on DOH survey results, 36.7% ambulatory (outpatient) and 63.3% inpatient
Average minutes per case	Based on DOH survey results, Outpatient cases = 73.56 minutes; inpatient cases 135.55 minutes
OR Annual capacity in minutes	356,015 outpatient surgery minutes; 1,131,561 inpatient or mixed-use surgery minutes
Existing providers	Per WAC only Providence Everett 17 mixed use ORs

The department's application of the numeric methodology using survey responses results forecast a surplus of 1.22 mixed used OR's in year 2013. The department's methodology is shown in Appendix A attached to this evaluation. In summary, based solely on the numeric methodology contained in WAC 246-310-270, no numeric need or outpatient OR capacity 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 department's application of the numeric methodology did not show need for new outpatient ORs in central Snohomish planning area in year 2013. Summarized below is the applicant's rationale for submitting its application to convert the existing CN exempt ASC to CN approved facility. [Source: Application Page 9-11]

- NWWLS is the only ASC located in the planning area that provides weight loss services.
- As part of NWWLS ongoing commitment to providing a comprehensive weight loss program, it has included the addition of plastic surgery services in its long range plans. Some patients need plastic surgery to remove residual loose skin tissue after weight loss; presently the ASC has limited services for plastic/cosmetic procedures. Upon CN approval, the applicant would allow a plastic surgeon who is not an employee of NWWLS to perform plastic surgery at the facility.



- There are no dedicated outpatient bariatric laparoscopic weight loss surgical providers located within the planning area.

During the review of this application, Providence Everett provided comments related to this sub-criterion. Summarized below are the comments provided by Providence Everett.

#### Providence Everett Comments

Providence Everett does not agree with the applicants methodologies provided in scenarios #1 and #2 because both are flawed and relied on antiquated use rates. Scenario #1 use-rate is derived from an application submitted for a different planning area and scenario 2 relied on old data. Scenario 3 is similar to Providence Everett survey data reported to the department on April 23, 2010. Providence Everett further states that NWWLS scenarios #3 have two significant errors related to the county's population and the number of available ORs in the planning area. Currently, Providence Everett has 17 multi-use ORs that are available, rather than the 12 counted by the applicant. Additionally, the hospital has three ORs not being used, that can be available for use within a short notice. These three rooms are not being used because of lack volume in the planning area to support the use of those rooms.

Using Claritas corrected population figures for the planning area, the percentage of residents is 41.01% or (284,502/693,781). Applying this corrected population percentage to the county's projected 2013 population, shows the central Snohomish population is projected to be 312,706 and not 324,926. OFM's 2009 population figure for Snohomish County is 704,300 and the projected 2013 population figure is 762,558. When the OR supply is corrected to 17 rooms and when the population error is corrected to 312,706, the net need is eliminated and there is a surplus of 0.62 operating rooms in the central Snohomish planning area. [Source: Public comments received May 18, 2010]

In response to the comments provided by Providence Everett, the department received rebuttal comments from NWWLS, which are summarized below.

#### NWWLS Rebuttal Comments

The survey response provided by Providence Everett indicated it has 17 active inpatient/outpatient ORs and 3 closed ORs for a total of 20 ORs. Twice in November 2009, NWWLS contacted Providence Everett to verify the number of ORs at the hospital and was told the hospital had a total of 14 ORs which includes 2 dedicated open heart ORs. It seems highly unlikely that Providence Everett total number of ORs would increase from 14 ORs in November 2009 to 17 ORs in May 2010. NWWLS stands by its rebuttal statements that Providence Everett has 14 ORs.

NWWLS disagrees with comments that its population figures for the planning area are incorrect. Further, NWWLS states that based on the Clarita's population data it used, central Snohomish planning area is 42.6% of Snohomish County or (284,502/667,610). Additionally, NWWLS asserts that its Snohomish County population projections are based on a variety of dynamic factors other than population data alone. [Source: Rebuttal Comments received June 1, 2010, Page 6]

### Department's Evaluation

In order to verify the correct number of active ORs available at Providence Everett, two department staff visited the hospital on June 4, 2010, and physically verified that the hospital has a total of 17 mix-used ORs. As a result, 17 mix-use ORs will be counted in the numeric methodology. Regarding the correct population figure for Central Snohomish in 2009, the department reviewed OFM's population figure for central Snohomish for year 2009 which showed the correct figure was 284,519 and 301,308 for year 2013. The department disagrees with Providence Everett's population figures and notes that Providence Everett attempted to provide an improper rebuttal comments. The department will not consider the improper comments submitted by Providence Everett during the rebuttal comment phase.

Within the application, NWWLS asserted that as an existing CN exempt ASC, it currently provides weight loss bariatric laparoscopic procedures and is seeking CN approval so that non-member physicians can provide cosmetic plastic surgery. While Providence Everett has available ORs, it does not provide bariatric procedures. [Source: Survey Responses received on May 4, 2010] The ability for NWWLS to provide both bariatric and related cosmetic surgeries at its ASC is reasonable. To ensure NWWLS will provide only bariatric laparoscopic procedures and the associated plastic surgeries, the department would condition the approval of this project limiting the types of surgeries at the ASC.

### 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 and does not propose to increase the number of ORs.

[Source: Application, Page 7] This standard is met.

Based on the source information reviewed and the applicant's agreement to providing only bariatric weight loss procedures and the associated plastic surgery, as described and relied upon within the application, the department concludes that this sub-criterion is met.

- (2) 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.

NWWLS is currently a provider of weight loss surgical services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. The department record shows that NWWLS is currently licensed as an Ambulatory Surgical Facility (ASF). This same record shows the ASF is Medicare certified.

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, NWWLS provided a copy of its admission policy. The policy provided the ASC's pre-operative guidelines and demonstrated that patients needing care would be admitted for services without regard to race, creed, color, national nationality, sexual orientation, age, religion or financial status. [Source: Application, Appendix 8]

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. Payment by Medicaid for services is linked to Medicare. If Medicare covers a procedure for its clients, Medicaid will also pay for the procedure for its clients.

NWWLS does not currently provide services to Medicaid eligible patients at its ASC. Currently these patients receive their procedures at an approved hospital. Information provided by the applicant states it intends to request the Centers for Medicare and Medicaid Services add CPT Codes for gastric banding cases. The addition of the CPT Codes would allow ASCs to receive reimbursement for these procedures. [Source: Rebuttal comments received June 1, 2010, Pages 8-10] To ensure Medicaid patients have access to these procedures at the ASC, a condition would be necessary that a portion of the charity care of the ASC include Medicaid patients receiving care at the ASC.

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. Currently NWWLS is Medicare certified however, NWWLS does not currently provide services to Medicare patients at its ASC. Currently these patients receive their procedures at an approved hospital. Information provided by the applicant states it intends to request the Centers for Medicare and Medicaid Services add CPT Codes for gastric banding cases. The addition of the CPT Codes would allow ASCs to receive reimbursement for these procedures. [Source: Rebuttal comments received June 1, 2010, Pages 8-10] To ensure Medicare patients have access to these procedures at the ASC, a condition would be necessary that a portion of the charity care of the ASC include Medicare patients receiving care at the ASC.

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.

NWWLS demonstrated its intent to provide charity care to residents by submitting its draft Charity Care Policy. The policy outlines the process one would use to access charity care. Further, NWWLS included a 'charity care' line item as a deduction from revenue within the pro forma financial documents. If this project is approved, the department would attach a term requiring the submission of an executed charity care policy. [Source: Supplemental Information received April 7, 2010, Exhibit 3] Providence Everett provided comments related to this sub-criterion which is restated below.

#### Providence Everett Comment

Providence Everett public comments states, *“According to the applicant’s Appendix 9, Draft Charity Care Policy for ASC, the patient only can receive a charity care discount if the “physician elects to see [the] patient. This condition effectively makes the draft charity care policy useless. If the physician elects to not see the patient, then no charity will be provided and the patient will not have access to this service”*. [Source: Public comments received May 18, 2010, Page 9]

In response to the comments by Providence Everett above, NWWLS provided the following rebuttal comments.

#### NWWLS Rebuttal Comment

The applicant states it would accept Medicare and Medicaid. Providence Everett misinterprets the statement in the Charity Care Policy. All patient care is dependent upon a physician electing to see the patient. This statement was not intended to provide an excuse for not providing charity care. NWWLS is fully aware that approval requires the acceptance of a condition stating it will provide charity care comparable to the hospital in its planning area. In fact, the pro forma income statement provided in the NWWLS CN application included projections of charity care commitments. NWWLS has already started a charity care program for this year, 2010. [Source: Rebuttal comments received June 1, 2010, Page 10]

#### Department’s Evaluation

Historically NWWLS has not provided charity care at the ASC and states that the Center for Medicare and Medicaid (CMS) does not allow bariatric procedures to be performed in an outpatient setting except in a level one hospital with accreditation. NWWLS asserted that it would be requesting that CMS add gastric banding CPT Codes so that it can accept patients. It is clear from the draft charity care policy NWWLS’s pro-forma statements that it intends to provide charity care.

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, Southwest, Central, and Eastern. NWWLS is located in Snohomish County within the Puget Sound Region. For charity care reporting purposes, the affected hospital is Providence Regional Medical Center Everett. For this project, the department reviewed charity care data for the 18 existing hospitals currently operating within the Puget Sound region.

For the Puget Sound Region, the three year average 2006-2008 charity care average is 1.95% for gross revenue and 4.23% for adjusted revenue. [Source: HPDS 2006-2008 charity care summaries] The department’s review of NWWLS pro forma income expense statement shows the applicant projects to provide charity care at approximately 3.25% of total revenue and 3.36% of adjusted revenue. [Source: Application, Appendix 2 and Supplemental Information received April 7, 2010, Exhibit 3] If this project is approved, the 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 NWWLS's agreement to the conditions identified in the 'conclusion' 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 term and conditions identified in the "conclusion" section of this evaluation, the department determines that the applicant 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 comply with this sub-criterion, NWWLS provided a projected income and expense pro-forma statement. NWWLS anticipates that if this project is approved, it would begin to offer services as CN approved facility in January 2011. Under this timeline, calendar year 2011 would be the first year of operation and years 2012 through 2013 would be the second and third years of operation. [Source: Application, Page 1]

To determine if the facility would meet its immediate and long range operating costs, the department reviewed the assumptions used by NWWLS to prepare its pro-forma income statements, pro-forma cash flow and projected balance sheets for the facility first full three years of operation. [Source: Application, Appendix 2, 10 and 11]

Summarized below, are the assumptions used by NWWLS as the basis for projecting utilization and the number of procedures it expects. [Source: Application, Pages 5 - 7]

- Since opening in year 2005, NWWLS provided a total of 2,600 bariatric procedures
- Increase the types of services available by adding plastic/cosmetic procedures
- Upon CN approval, the second operating room would be equipped for use and NWWLS would allow a non-employee plastic surgeon to use its facility.

As stated above, the assumptions relied on by NWWLS project future case volume that includes adding plastic/cosmetic cases. A review of the applicant's future projections for both plastic and bariatric cases is shown in Table 4 below.

**Table 4**  
**NWWLS Bariatric and Cosmetic/Plastic Surgery Projections Year 2011-13**

<b>Year</b>	<b>Plastic Surgery Case Volume</b>	<b>Bariatric Surgery Case Volume</b>	<b>Total Case Volume</b>
2011	48	429	477
2012	60	459	519
2013	72	494	566

Table 5 below is a summary of NWWLS projected revenues and expenses for current year 2010 and the first three full years of operation. [Source: Application, Appendix 2]

**Table 5**  
**NWWLS Projected Revenue and Expenses for Years 2010 through 2013**

	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>
Case Volume	410	477	516	566
Net Revenue	\$3,730,460	\$4,056,283	\$4,388,566	\$4,764,979
Total Operating Expense	\$2,634,180	\$2,900,611	\$3,202,231	\$3,478,482
Net Profit or (Loss)	\$925,587	\$879,795	\$1,137,291	\$1,252,398
Net Patient Revenue/Procedure	\$9,098.68	\$8,503.74	\$8,455.81	\$8,418.69
Total Operating Exp/Procedure	\$6,841.15	\$6,659.30	\$6,264.50	\$6,205.97
Net Profit or (Loss)/Procedure	\$2,257.53	\$1,844.43	\$2,191.31	\$2,212.72

As shown in the table above, NWWLS projects that the ASC would be profitable from the first year through the third full year of operation. The 'net revenue' line item in Table 5 above, with the exception of year 2010 data, is the result of gross revenue for both bariatric and plastic surgery cases minus any deductions charity care. The 'total expenses' line item includes staff salaries/wages and the ASC's portion of overhead and bad debt. In addition to the projected Statement of Operations, NWWLS also provided its projected balance sheet for years 2010 through 2013 shown in Table 6 below. [Source: Application, Appendix 10]

**Table 6**  
**NWWLS Projected Balance Sheets for- Year 2010**

<b>Assets</b>		<b>Liabilities</b>	
Current Assets	\$1,078,256	Current Liabilities	\$47,150
Net Plant/Property	\$1,041,472	Other Liabilities ( long term debt)	\$460,524
Other Assets	\$1,581	Total Liabilities	\$507,674
		<b>Equity</b>	<b>\$1,613,635</b>
<b>Total Assets</b>	<b>\$2,121,309</b>	<b>Total Liabilities and Equity</b>	<b>\$2,168,459</b>

**NWWLS Projected Balance Sheets for– Year 2011**

<b>Assets</b>		<b>Liabilities</b>	
Current Assets	\$1,512,206	Current Liabilities	\$0.00
Net Plant/Property	\$1,002,786	Other Liabilities ( long term debt)	\$265,126
Other Assets	\$225.00	Total Liabilities	\$265,126
		<b>Equity</b>	<b>\$2,250,091</b>
<b>Total Assets</b>	<b>\$ 2,515,217</b>	<b>Total Liabilities and Equity</b>	<b>\$ 2,515,217</b>

**NWWLS Projected Balance Sheets for– Year 2012**

<b>Assets</b>		<b>Liabilities</b>	
Current Assets	\$2,221,595	Current Liabilities	\$0.00
Net Plant/Property	\$965,889	Other Liabilities ( long term debt)	\$55,603
Other Assets	\$0.00	Total Liabilities	\$55,603
		<b>Equity</b>	<b>\$3,131,882</b>
<b>Total Assets</b>	<b>\$3,187,484</b>	<b>Total Liabilities and Equity</b>	<b>\$3,187,484</b>

**NWWLS Projected Balance Sheets for– Year 2013**

<b>Assets</b>		<b>Liabilities</b>	
Current Assets	\$3,183,551	Current Liabilities	\$0.00
Net Plant/Property	\$932,450	Other Liabilities ( long term debt)	\$0.00
Other Assets	\$0.00	Total Liabilities	\$0.00
		<b>Equity</b>	<b>\$4,116,011</b>
<b>Total Assets</b>	<b>\$4,116,001</b>	<b>Total Liabilities and Equity</b>	<b>\$4,116,001</b>

NWWLS has been operating from its current location since August 2005 and provided a copy of an executed lease agreement between Northwest Bariatric Surgery Associates, PLLC (“Tenant”) and GIO Inc., (“Landlord”). [Source: Supplemental Information received June 6, 2010, Exhibit 2] The agreement outlines the terms and details of the lease. A review of the rent amounts stated in the executed agreement shows that it is comparable to the information used to prepare the revenue and expense summary in the table above.

As stated earlier in this evaluation, the assumption used by NWWLS to project profit includes bariatric surgery and future plastic surgery cases. The department’s application of the methodology shows no new need in the planning area and notes that any one of 17 ORs operational at Providence Everett can be used to provide cosmetic and plastic surgery. However, the department notes that Providence Everett’s responses to the utilization survey of states that it does not provide bariatric surgeries. [Source: Utilization survey response received on May 4, 2010]

Since NWWLS is an existing facility that specializes in performing only bariatric weight loss surgery and given that forecasted cosmetic plastic cases are minimal when compared to the ASCs overall bariatric cases and volumes forecasts, the department concludes an approval is

justifiable. Based on the source information reviewed, 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) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

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.

NWWLS identified the capital expenditure associated with this project to be \$299,789. [Source: Application, Page 26] This project proposes approval of an existing CN exempt ASC. The proposed project is not expected to have any impact on the operating costs and charges for ambulatory surgery services because it's already operating and any impact would have occurred when it first opened.

To further demonstrate compliance with this sub-criterion, NWWLS provided the existing and projected percentage of revenue by source shown in Table 7 below. [Source: Application, Page 28]

**Table 7  
NWWLS Revenue Source**

Source of Revenue	Current 2009	Year 2011	Year 2012	Year 2013
Medicare	-	-	-	-
Medicaid /State	-	-	-	-
PPO	44%	40%	39%	36%
Other Commercial	6%	5%	3%	2%
HMO	-	-	-	-
Workers Comp	-	-	-	-
Private Pay	50%	55%	58%	62%
Total	100%	100%	100%	100%

As shown in the Table 7 above, NWWLS expects the majority of its revenue would be private pay. NWWLS states that the ASC is Medicare certified, but CMS does not reimburse for laparoscopic bariatric surgeries in freestanding ASC and therefore, it does not expect to receive reimbursement from Medicare or Medicaid [Source: Application, Page 2] <sup>4</sup>

As shown above, all of NWWLS's revenue for years 2009 through 2013 would be from private insurance. NWWLS projected that for PPO and commercial insurance, it would have less revenue in year 2011 through year 2013. For private pay, the ASC expects to increase its revenue in year 2011 through year 2013. Based on the information reviewed, the department

<sup>4</sup> The department previously addressed access to these services in the need section of this evaluation.



concludes that the costs of this project would probably not result in an unreasonable impact to the costs and charges for health care services within the services area. This sub-criterion is met.

(3) The project can be appropriately financed.

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.

To demonstrate compliance with this sub-criterion, NWWLS provided the following capital expenditure breakdown for the project which is shown in the table below [Source: Application, Page 26]

**Table 8**  
**NWWLS projected Capital Cost**

<b>Item</b>	<b>Cost</b>	<b>% of Total</b>
Fixed & Moveable Equipment	\$184,283	61.5%
Architectural/Engineering studies & fees	\$75,000	25.0%
Sales Tax, Commission and Fees	\$32,506	10.8%
Delivery Charges and freight	\$8,000	2.7%
<b>Total Project Cost</b>	<b>\$299,789</b>	<b>100.0%</b>

NWWLS states the source of financing for the project is the applicant's cash reserves. The department received a letter of financial commitment from Kevin Montgomery, M.D, NWWLS sole owner. The letters states, "*In the event Northwest Weight Loss Surgery is granted a Certificate of Need, I have allocated reserve funds to be used under the new ASC entity to cover the estimated capital costs of the proposed project*". [Source: Supplemental Information received June 6, 2010, Exhibit 5]

Based on the information, the department concludes the proposed source of funding for this project is appropriate. 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 agreement to the term and conditions identified in the conclusion section of this evaluation, the department determines that the applicant has met the structure and process of care criteria in WAC 246-310-230.

- (1) A sufficient supply of qualified staff for the project, including both health personnel and 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.

NWWLS is currently operating the ASC under an exemption from Certificate of Need review. As an operational ASC, the applicant expects to hire minimal staff because most of the staff needed is already in place. Table 9 summarizes the current and anticipated staffing. [Source: Application, Appendix 15]

**Table 9  
NWWLS Current Year (2010) and Projected FTEs**

<b>FTEs</b>	<b>Current Year 2010</b>	<b>Full Year 3 – Increase 2014</b>	<b>Total</b>
RN Nurse Manager	1.00	-	1.00
RN's -PACU	0.93	1.00	1.93
RN -1 <sup>st</sup> Assist	0.17	0.30	0.47
Circulator	0.80	-	0.80
CMA -2 (Sch & CI)	1.00	-	1.00
Tech OR	0.40	0.50	0.90
Cs Tech	0.85	-	0.85
Housekeeping	0.60	-	0.60
Per Diem RN	0.17	0.20	0.37
Reception	0.50	0.50	1.00
Bill/Coder	0.35	0.15	0.50
Business Office Rep	0.30	-	0.30
Administrative	0.50	-	0.50
<b>Total</b>	<b>7.57</b>	<b>2.65</b>	<b>10.22</b>

As shown in Table 9 above, NWWLS anticipates that it would have all the FTE's needed to operate the proposed ASC by the third year of operation or year 2014. Given that the applicant currently operates a CN exempt facility within the same planning area, the department concludes that the proposed staffing plan can reasonably be expected to be accomplished. Based on the source information reviewed, the department concludes that staffing is available for recruitment. This sub-criterion is met.

- (2) 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.

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.

NWWLS is currently an exempt ASC operating in Central Snohomish and has ancillary and support agreements with Evergreen Hospital that were established in year 2005. The applicant provided a copy of the existing transfer agreement between itself and Evergreen Hospital. The agreement identifies the roles and responsibilities of both entities. In addition, the applicant states, "Evergreen Hospital Medical Center provides inpatient backup care for NWWLS patients in the unlikely event that a patient would require hospitalization. Evergreen Hospital Medical Center is an inpatient hospital which provides bariatric surgery services and is certified as Center of Excellence by the American Society of Metabolic and Bariatric Surgery." [Application, Page 30 and Supplemental Information received April 6, 2010, Exhibit 6]

Based on source information reviewed, the department concludes NWWLS currently has and would continue to have appropriate ancillary and support services with a local health care services provider in the planning area. 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)(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.

NWWLS has been operating at its current location since August 2005 and holds AAACH accreditation.<sup>5</sup> NWWLS's accreditation with AAACH is effective from year 2010 through 2013. NWWLS does not own or operate any other health care facilities in Washington or any other state. The Department of Health's Investigations and Inspections Office (IIO), which surveys ASCs within Washington State, has completed at least one compliance survey for NWWLS.<sup>6</sup> The survey revealed no substantial non-compliance issues for NWWLS. [Source: IIO compliance data]

<sup>5</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, and values for ambulatory health 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>6</sup> Initial compliance survey completed in February 2007.

The Department of Health's Medical Quality Assurance Commission credentials medical staff in Washington State and is used to review of the compliance history for all medical staff, which includes physicians, RNs, and LPNs, associated with NWWLS including Kevin Montgomery, MD, the sole owner of NWWLS. [Source: MQAC compliance history] A compliance history review of all the medical staff associated with NWWLS revealed no recorded sanctions for all. [Compliance history provided by Medical Quality Assurance Commission]

After reviewing the compliance history of NWWLS as an exempt ASC and the compliance history of all medical staff associated with the exempt ASC, the department concludes there is reasonable assurance that NWWLS would continue to operate in conformance with applicable state and federal licensing and certification requirements. 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 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.

NWWLS currently operates as an exempt ASC and has been in operation an exempt ASC since 2005. NWWLS asserted it has established ancillary and support agreements with a local hospital and does not anticipate any changes with the relationship. To show it has appropriate relationships already established, the applicant provided a copy of its existing patient transfer agreement with Evergreen Hospital Medical Hospital. [Application, Page 30 and Supplemental Information received June 6, 2010, Exhibit 6] 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. Therefore, this sub-criterion 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 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 term and conditions identified in the "conclusion" section of this evaluation, the department concludes Northwest Weight Loss Surgery, LLC 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.*

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230 and WAC 246-310-270. 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 step two 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.

Step three 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, NWWLS met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

#### Step Two

Before submitting this application, NWWLS considered only the option of maintaining the status quo as an exempt ASC. The applicant rejected this option because the exemption does not allow physicians not employed by NWWLS to use the ASC. Following laparoscopic bariatric surgery, patients generally are successful in losing a significant amount of body/weight. As a result of this significant loss of weight, some patients need plastic surgery for the removal of residual loose skin tissue. NWWLS does not provide this surgical service and patients must go to other facilities and develop a new set of patient-provider relationships. NWWLS would like to allow a plastic surgeon (who is not an employee of NWWLS) to perform plastic surgery at the existing ASC and thereby expand the range of comprehensive services it offers to weight loss patients. [Source: Application, Page 33]

Given the only other option to this project is do nothing, and the applicant currently provides bariatric weight loss surgery and considering this type of surgical services is needed in the planning area, 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 NWWLS submitted an application to establish an ASC in central Snohomish County planning area. As a result, this step is not applicable to this project.

# **APPENDIX A**

Dept's Meth

Service Area Population 2013:		301,308							
Surgeries @ 43.77/1,000:		13,189							
a.i.	94,250 minutes/year/mixed-use OR								
a.ii.	68,850 minutes/year/dedicated outpatient OR								
a.iii.	0 dedicated outpatient OR's x 68,850 minutes =					0 minutes dedicated OR capacity		0	Outpatient surgeries
a.iv.	17 mixed-use OR's x 94,250 minutes =					1,602,250 minutes mixed-use OR capacity		11,820	Mixed-use surgeries
b.i.	projected inpatient surgeries =	8,349	=			1,131,726 minutes inpatient surgeries			
	projected outpatient surgeries =	4,840	=			355,991 minutes outpatient surgeries			
b.ii.	Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's								
	4,840 -	0	=			4,840 outpatient surgeries			
b.iii.	average time of inpatient surgeries		=			135.55 minutes (per Survey)			
	average time of outpatient surgeries		=			73.56 minutes (per Survey)			
b.iv.	inpatient surgeries * average time		=			1,131,726 minutes			
	remaining outpatient surgeries (b.ii.) * ave time		=			355,991 minutes			
						1,487,717 minutes			
c.i.	if b.iv. < a.iv., divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's								
	USE THIS VALUE								
	1,602,250								
	- 1,487,717								
	114,533	/				94,250	=	1.22	
c.ii.	if b.iv. > a.iv., divide (inpatient part of b.iv - a.iv.) by 94250 to determine shortage of inpatient OR's								
	Not Applicable - Ignore the following values and use results of c.i.								
	1,131,726								
	- 1,602,250								
	(470,524)	/				94,250	=	-4.99	
	divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's								
	355,991	/				68,850	=	5.17	