

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF ADVANCE ENDOSCOPY CENTER, PLLC PROPOSING TO ESTABLISH AN AMBULATORY SURGERY CENTER IN CLARK COUNTY**

**PROJECT DESCRIPTION**

The main entities for this project are: Advanced Gastroenterology, PLLC and Advanced Endoscopy Center, LLC. Each entity's roles and responsibilities are outlined below.

Advanced Gastroenterology, PLLC

Advanced Gastroenterology, PLLC (AG) is a solo practice owned by Mr. Son Do, MD. AG operates as the primary location for Dr. Do's practice and is located at 2415 NE 134<sup>th</sup> Street, #205 in Vancouver, within Clark County. The procedures performed at the site include those procedures typically associated with gastroenterology, such as colonoscopies, colorectal cancer screening, upper gastrointestinal endoscopies. [CN historical files; Application, p2 & 7]

Advanced Endoscopy Center, PLLC

Advanced Endoscopy Center, PLLC (AdvEnd) was formed in April, 2009 and Dr. Do is a 100% owner of the new company. The company was formed to own and operate the proposed ASC. The location for the new ASC is 2101 NE 139<sup>th</sup> Street, Suite 265 in Vancouver. Prior to CN approval, the new facility will operate according to the obligations granted to Dr. Do as an exempt ASC. In the future, the company may sell units of AdvEnd to qualified partners. [Application, p7 & Attachments II-I & II-J]

For this project, AdvEnd is the applicant. The new ASC would have two operating rooms, pre/post operating space, and support/staff areas. The ASC intends to perform routine diagnostic and therapeutic endoscopic procedures. [Application, p8 & Attachment II-J]

The applicant provided a copy of the lease agreements between AdvEnd (tenant), AG (landlord) and Allergy Associates Building Company (landowner) for the site. The lease agreements identify the site and terms associated with the location. The lease agreement was effective as of January 7, 2009. AdvEnd also provided a floor plan and legal description of the property. [Application, Attachments II-I & II-J]

The estimated capital expenditure associated with the establishment of this ASC is \$1,517,388. Of that amount, 36% is related to building construction, 42% is related to equipment, and the remaining 22% is related to fees, taxes, and financing costs. [Application p22]

The site began construction in June 2008 with an expected completion date of November 2009. AdvEnd anticipates operating the new ASC as described upon CN approval. Under this timeline, 2010 would be the facility's first full year of operation; year 2012 would be the third full year of operation. [Application, p8]

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

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).

### **AFFECTED PERSONS**

Throughout the review of this project no entities sought or received affected party status.

### **APPLICATION CHRONOLOGY**

June 11, 2009	Letter of Intent Submitted
August 5, 2009	Application Submitted
August 6, 2009 through September 14, 2009	Department's Pre-Review Activities • 1 <sup>st</sup> screening activities and responses
September 21, 2009	Department Begins Review of Application
October 26, 2009	End of Public Comment (No Public Hearing)
December 28, 2009	Department's Anticipated Decision Date
March 9, 2010	Department's Actual Decision Date

### **SOURCE INFORMATION REVIEWED**

- Advanced Endoscopy Center's Certificate of Need Application received August 5, 2009
- Advanced Endoscopy Center's supplemental information received September 15, 2009
- Public comment received throughout the review of the application
- Clark County ASC operating room utilization survey responses
- Office of Financial Management population data for Clark planning area
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2005, 2006, and 2007 summaries)
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office

### **CRITERIA EVALUATION**

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) and WAC 246-310-270 (ambulatory surgery).<sup>1</sup>

<sup>1</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(3).

## CONCLUSION

For the reasons stated in this evaluation and agreement to the following terms, Advanced Endoscopy Center, PLLC is approved to establish a gastroenterological and endoscopic ambulatory surgery center in Vancouver, within Clark County.

The approved capital expenditure associated with this project is \$1,517,000.

### Terms:

1. Prior to commencement of the project, Advanced Endoscopy Center, LLC must provide to the department for review and approval an adopted version of the Patient Admission Criteria to be used at the Advanced Endoscopy Center ASC. The adopted Patient Admission Criteria must be consistent with the draft agreement provided in the application and contain a copy of the informed consent required as part of the policy criteria.
2. Prior to commencement of the project, Advanced Endoscopy Center, LLC must provide to the department for review and approval an adopted copy of the Charity Care Policy for the proposed ASC. The adopted policy must be consistent with the draft provided in the application.
3. Prior to commencement of the project, Advanced Endoscopy Center, LLC must provide to the department for review and approval, an executed copy of the operating agreement. The agreement must be consistent with the draft provided in the application and contain all the necessary signatures.

Provided that the applicant agrees to the terms outlined above, a Certificate of Need would be issued with the following conditions.

1. The Advanced Endoscopy Center is limited to providing only those endoscopic services described within the application and relied upon by the department in this evaluation.

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

Based on the source information reviewed, 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*

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 Clark 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>2</sup>

Applicant's Methodology

The numeric portion of the methodology requires a calculation of annual capacity of existing ORs, both outpatient and inpatient, and excludes specialized dedicated rooms. Examples of 'dedicated' rooms are open heart surgery rooms, delivery rooms, cystoscopic rooms, and endoscopic rooms. Given that endoscopic rooms are specifically excluded from the utilization calculations, the Applicant states, "Since it is the intent of this applicant to solely provide endoscopic procedures, we believe the need calculation typically found in a freestanding ASC is not warranted here". [Application, p13]

AdvEnd did provide an analysis and projection of the utilization of the services currently performed at the applicant's AG solo practice. The review considered the area's population, the use trends for the population in the planning area, and the patient increases resulting from the hiring of additional doctors at the proposed facility. OFM population data was used to demonstrate its assertion that the Clark planning area is expected to experience continued growth. The applicant also provided patient origin data for its existing practice. This patient origin data shows that approximately 88% of the applicant's solo practice resides in the Clark planning area. [Application, p14 & Exhibit III-B]

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<sup>2</sup> WAC 246-310-270(9)(a)(iv).

Department's Methodology

The department recognizes that dedicated endoscopy ORs are deliberately excluded from the numeric methodology outlined in WAC 246-310-270(9). To assist in its review of this project, CN staff reviewed the National Directory of Health Planning, Policy and Regulatory Agencies. This directory provides a summary of projects that require CN review for all 50 states and the District of Columbia. CN staff contacted the seven states identified in the directory as the most comprehensive scope of review for health care projects.<sup>3</sup> All seven states require CN review of ASC projects and include dedicated endoscopy facilities within the review. However, none of the seven states apply specific methodologies or standards to dedicated endoscopy facilities. In summary, none of the seven states could provide specific assistance to a review for a dedicated endoscopy facility.

To further assist in its review of this project, CN staff also reviewed the Guidelines for Office Endoscopic Services developed under the auspices of the Society of American Gastrointestinal Endoscopy Surgeons<sup>4</sup> and its various committees. The standards include specific requirements related to physician privileges, patient safety, patient and procedure selection criteria, physical facilities, records maintenance, and quality assurance. Based on research and available information regarding endoscopy facilities, the department concludes that documents provided in the application meet or exceed the available guidelines.

In conclusion, the department concurs with the applicant that numeric methodology outlined in WAC 246-310-270(9) is not a predictor of need for the dedicated endoscopic ORs. However, as required by rule, the department also applied the numeric methodology to this project.

Given that the ASC would be located in Clark County, the department applied the methodology to that planning area. There are 8 providers in the Clark County planning area. The facilities are listed below. [CN historical files]

**Table 1**  
**Clark County Planning Area Providers**

<b>Hospital Facilities</b>	<b>Freestanding ASCs / City</b>
Southwest Washington Regional Surgery	Vancouver Clinic Endoscopy Center, Vancouver
Legacy Salmon Creek Medical Center	Vancouver Ear, Nose, and Throat, Vancouver
	Mt. View Surgery Center, Vancouver
	Pacific Cataract & Laser Institute, Vancouver
	Vancouver Eye Surgery, Vancouver
	Salmon Creek Plastic Surgery, Vancouver

As shown above, the 8 facilities include two hospital and six ASCs. Southwest Washington and Legacy both operate in the planning area. The hospital based OR capacity consistent with WAC 246-310-270(9) will be used in the numeric methodology calculations.

<sup>3</sup> The seven states are: Alaska, Georgia, Maine, North Carolina, South Carolina, Vermont, and West Virginia.

<sup>4</sup> www.sages.org

The six freestanding ASCs are located within a solo or group practice (considered an exempt ASC) and therefore, the use of these ASCs is restricted to physicians that are employees or members of the clinical practices that operate the facilities. Since these six facilities do not meet the ASC definition in WAC 246-310-010, the ORs are not included in the capacity calculations of available ORs for the Clark planning area.

To assist in its application of the numeric methodology for this project, on August 17, 2009 the department requested utilization information from the ASC's in the region and received responses from the two CN approved hospital facilities. The department relied on the following assumptions to apply its methodology.

<b>Assumption</b>	<b>Data Used</b>
Planning Area	Clark County
Population Estimates and Forecasts	Office of Financial Management population data for Clark County. Target year 2013
Use Rate	Divide 2008 estimated current surgical cases by estimated 2008 populations results in the service area use rate of 32.66/1,000 population
Percent of surgery ambulatory vs. inpatient	Based on DOH survey results, 84% ambulatory (outpatient) and 16% inpatient
Average minutes per case	Based on DOH survey results, Outpatient cases = 42.83 minutes; inpatient cases 117.94 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes
Existing providers	Based on 2008 listing of Clark County providers OR capacity: 8 dedicated outpatient and 8 mixed use

The department's application of the numeric methodology using available survey responses results forecast a surplus of 5.24 - rounded to 6 - outpatient ORs in the Clark planning area in year 2012. The department's methodology is Appendix A attached to this evaluation.

In summary, the methodology results in a surplus of OR capacity in the Clark County planning area. However, if this project is approved, the addition of two ORs dedicated to endoscopic procedures would not be counted in the OR supply, and therefore would have no impact on the need calculations or the future need for additional ORs in the planning area.

Based on information provided in the application, AdvEnd intends to provide only endoscopic procedures at the proposed facility. To ensure that AdvEnd will operate the proposed facility in accordance with information provided in the application, approval of this project would be contingent upon AdvEnd agreeing to a condition to provide only endoscopic services as described within the application and relied upon by the department in this evaluation. Provided that AdvEnd agree's to these limited procedures, 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.

The Applicant's gastroenterology ASC became operational as an exempt ASC in 2006, and since that time, has been providing health care services to residents of Clark County and surrounding areas, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To demonstrate compliance with this sub-criterion, AdvEnd provided a copy of draft Admission and Charity Care policies to be applied at the proposed ASC.

The draft Admission Policy outlines the process/criteria that AdvEnd uses to admit patients for treatment or care at the ASC. The policy also states that any patient meeting the admission criteria will be accepted for treatment without regard to income, ethnicity, sex, handicap, or age. If this project is approved, a term would be added requiring the AdvEnd to provide to the department for review and approval an executed version of the Patient Admission Criteria to be used at the Advanced Endoscopy Center ASC. The adopted Patient Admission Criteria must be consistent with the draft agreement provided in the application and contain a copy of the informed consent required as part of the policy criteria.

[September 15, 2009 supplemental information, Attachment SA-IV]

To determine whether low income residents would have access to the services at AdvEnd, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access to the facility, the department uses Medicare certification as the measure to make that determination. Information provided by the applicant, and verified in a pending application for accreditation<sup>5</sup>, verifies that the ASC intends to establish and maintain a Medicare contract. Further, within the application, AdvEnd provided its projected sources of revenues, which identifies 5.87% Medicaid. [Application, p5, 11]

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.

AdvEnd demonstrated its intent to provide charity care at the proposed ASC by submitting a draft charity care policy. The draft policy outlines the process a patient would use to access this service. Further, AdvEnd included charity care projections for 2010 through 2013. [Application, p21, Attachment III-O]

Further, WAC 246-310-270(7) states that ASCs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC. For charity care reporting purposes, the Department of Health's Hospital and Patient Data Systems (HPDS), divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. The proposed ASC would be located in Clark County within the Southwest Washington region. For charity

<sup>5</sup> An application is currently pending with the Department of Health's Office of Health Care Survey to obtain the accreditation to receive a Medicare reimbursement.

care reporting purposes, the affected hospitals include Legacy Salmon Creek and Southwest Washington Medical Center. For this project, the department reviewed charity care data for the 14 existing hospitals currently operating within the Southwest Washington region.

According to 2005-2007 charity care data obtained from HPDS, the three-year average for the Southwest Washington Region is 2.74% for gross revenue and 6.16% for adjusted revenue. The three-year charity care data reported by AdvEnd is 5.02% of gross revenue and 6.90% of adjusted revenue. [HPDS 2005-2007 charity care summaries, September 15, 2009 supplemental information, Attachment SA-IV]

These averages are above the average charity care provided in the Southwest Washington Region for gross and adjusted revenues. If this project is approved, a condition requiring AdvEnd to provide to the department, for review and approval, an adopted version of the Charity Care Policy for the proposed ASC. The adopted policy must be consistent with the draft provided in the application.

Based on the information provided in the application and AdvEnd's agreement to the condition related to the admission and charity care policies, the department concludes that all residents, including low income, racial and ethnic minorities, handicapped, and other underserved groups would have access to the services provided by the hospital. This sub-criterion is met.

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

Based on the source information reviewed, 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.

If this project is approved, AdvEnd anticipates that the proposed facility would become operational by January, 2010. As a result, 2010 would be the facility's first 12 months of operation and year 2012 would be three full years of operation. To determine whether proposed would meet its immediate and long range operating costs, the department reviewed its assumptions, projected revenue/expense statements, and projected balance sheets for the first three full years of operation. [Application, p9 & 12]

AdvEnd provided the following statements related to the assumptions used as a basis for the projected number of procedures at proposed. [Application, p18]

- Utilization assumptions are based upon actual 2008 volumes within Dr. Do's current practice.
- Forecasted growth for 2010 considered the addition of a second doctor who is expected to achieve 65% of the annual volumes in their first year.
- Utilization for 2011 and 2012 considered two doctors at 100% of capacity and a 3% annual increase as the new facility establishes itself in the region.

The assumptions relied on by AdvEnd to project the financial viability of proposed appear to be reasonable. Table 2 below is a summary of the proposed ASC's projected revenues and expenses for the first three full years of operation. [September 15, 2009 supplemental information, Attachment SA-IV]

**Table 2  
Proposed ASC Revenue and Expense Summary**

	<b>2010</b>	<b>2011</b>	<b>2012</b>
Number of Procedures	3,086	3,852	3,968
Net Revenue*	\$ 1,546,061	\$ 1,909,998	\$ 1,946,580
Total Expense	\$ 844,140	\$ 916,353	\$ 939,377
Net Profit or (Loss)	\$ 701,921	\$ 993,645	\$ 1,007,203
Net Revenue per Case	\$ 500.99	\$ 495.85	\$ 490.57
Total Expenses per Case	\$ 273.54	\$ 237.89	\$ 236.74
Net Profit or (Loss) per Cases	\$ 227.45	\$ 257.96	\$ 253.83

\*Includes deductions for charity care

As shown in Table 2 above, the ASC projects a profit in each of the facility's first three full years of operation. Table 3 shows a summary of the balance sheets provided by the applicant. As demonstrated, the proposed ASC appears to forecast financial stability. [September 15, 2009 supplemental information, Attachment SA-XI]

**Table 3  
Projected Balance Sheets for Proposed ASC – Years 2010-2013**

**FY 2010**

<b>Assets</b>		<b>Liabilities</b>	
Current Assets	\$ 309,818	Current Liabilities	\$ 252,990
Other Assets	\$ 1,194,645	Other Liabilities ( long term debt)	\$ 1,026,705
		<b>Total Liabilities</b>	<b>\$ 1,279,695</b>
		Equity	\$ 224,768
<b>Total Assets</b>	<b>\$ 1,504,463</b>	<b>Total Liabilities and Equity</b>	<b>\$ 1,504,463</b>

**FY 2011**

Assets		Liabilities	
Current Assets	\$ 1,128,521	Current Liabilities	\$ 253,410
Other Assets	\$ 980,266	Other Liabilities ( long term debt)	\$ 848,290
		<b>Total Liabilities</b>	<b>\$ 1,101,700</b>
		Equity	\$ 1,007,087
<b>Total Assets</b>	<b>\$ 2,108,787</b>	<b>Total Liabilities and Equity</b>	<b>\$ 2,108,787</b>

**FY 2012**

Assets		Liabilities	
Current Assets	\$ 2,369,947	Current Liabilities	\$ 252,511
Other Assets	\$ 753,969	Other Liabilities ( long term debt)	\$ 656,757
		<b>Total Liabilities</b>	<b>\$ 909,268</b>
		Equity	\$ 2,214,648
<b>Total Assets</b>	<b>\$ 3,123,916</b>	<b>Total Liabilities and Equity</b>	<b>\$ 3,123,916</b>

The draft operating agreement provided in the application outlines the terms and details of the proposed company and the obligations for it's members. Prior to commencement of the project, AdvEnd must provide to the department for review and approval an executed copy of the operating agreement. The agreement must be consistent with the draft provided in the application and contain all the necessary signatures. [Application, p39]

Based on the financial information above, the department concludes that the immediate and long range capital and operating costs of the project can be met. This sub-criterion is met.

- (2) 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.

AdvEnd provided a breakdown of the expected capital costs to establish the ASC. The construction costs for the project are approximately \$1.5 million, which includes building construction, architect and engineering fees, and sales tax associated with construction. [Application, p21]

AdvEnd has relied on its own experience, as well as the experience of the building contractor and application consultant, to develop the capital costs totals. The combined experience in construction and understanding of project development leads the Applicant to state, "Under their direction they have brought countless projects on line, on time and within budget". [Application, p23, Attachment IV-K]

The department also compared the projected costs and charges identified in Table 2 of this evaluation to those of recent ASC applications proposing the construction of a new surgery center. The comparison revealed that the costs and charges identified are comparable to those shown in like-type ASC applications.

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

(3) The project can be appropriately financed.

AdvEnd provided the following capital expenditure breakdown for the project. [Application, p23]

**Table 4  
Estimated Capital Costs of Project**

Description	Cost	% of Total
Equipment costs	\$ 543,000	36%
Tenant Improvements	\$ 637,000	42%
Fees	\$ 221,350	15%
Financing Costs	\$ 18,800	1%
Taxes	\$ 96,850	6%
<b>Total Estimated Capital Costs</b>	<b>\$ 1,517,000</b>	<b>100%</b>

The funding for the project will debt financed the balance of 1,166,016 and the remainder funded through member contributions. AdvEnd and AG will be jointly considered the borrower and will be assigned 100% of the debt. An amortization schedule with full terms of repayment was provided in the application. The schedule shows the debt will be fully paid in 2017. The amortized repayment schedule, while ambitious, is not unrealistic. Further the cost of the debt financing is included in the expense line items in the proposed revenue and expense statements shown in Table 2 of this evaluation. Even with the ambitious repayment schedule, the department concludes that proposed ASC could meet its immediate and long range capital and operating costs of the project. [September 15, 2009 supplemental information, Attachment SA-I & SA-VIII]

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

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

Based on the source information reviewed, 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.

AdvEnd anticipates proposed would begin operating as a CN approved ASC in 2010 and would be the facility's first full year of operation. Table 5 below summarizes the projected staffing at proposed for 2010 through 2013. [Application, p26]

**Table 5  
Proposed ASC 2010-2013 Staffing**

<b>FTEs</b>	<b>Full Year 1 - 2010</b>	<b>Full Year 2 - 2011</b>	<b>Full Year 3 - 2012</b>
RN Nurse Manager	1.0	1.0	1.0
RN's	1.0	1.0	1.0
LPN/Techs	2.0	2.0	2.0
Reception	1.0	1.0	1.0
Business Office	0.5	0.5	0.5
<b>Total</b>	<b>5.5</b>	<b>5.5</b>	<b>5.5</b>

As shown in Table 5 above, AdvEnd anticipates hiring all necessary staff in year one and to maintain these staffing levels throughout the projection period. In the third year of operation, the ASC would continue to operate with the equivalent of 5.5 FTEs.

To demonstrate that staff would be available and accessible for this project, AdvEnd reports, "two key positions, that of Nurse Manager and a second RN, both with extensive G-I background have been hired to staff the facility". In reference to the remaining staff needs, AdvEnd continues, "Given the expanding population in the region, and the benefits of working in an 'all new' outpatient surgery center vs. Inpatient hospital with evenings and weekend staffing requirements, there is no expected problem in providing a capable and well-trained staff for this facility". [Application, p27]

Based on the information provided above, the department concludes that staff for a new ASC in Vancouver can be recruited and retained. 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.

AdvEnd's ownership currently operates an exempt ASCs in Clark county and ancillary and support agreements are already in place for the existing facility. This proposed ASC would be in Vancouver, where the exempt facility already operates. A variety of relationships have been established in past years and the Applicants states, "These relationships will be maintained as the facility transitions to the new business model". [Application, p28]

AdvEnd provided a copy of its existing transfer agreement between AG and Legacy Salmon Creek that will be in affect at the proposed ASC. The agreement identifies roles and responsibilities for both entities. [Application, p28, Attachment V-A]

The documents demonstrate AdvEnd currently has, and intends to continue, appropriate relationships with ancillary and support services for the health care services to be provided. 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.*

Dr. Do has been operating as an exempt, Medicare certified ASC in the state of Washington since 2006. AdvEnd does not own or operate any other healthcare facilities in Washington or any other state and has not been surveyed by the Department of Health's Office of Health Care Survey (OHCS), which surveys ASCs within Washington State. The Applicant does have an application pending to obtain the certification necessary to receive Medicare reimbursement at the proposed facility. [Application data provided by Office of Health Care Survey]

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 AdvEnd. A compliance history review of all the medical staff associated with the proposed ASC reveals no recorded sanctions for all. [Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of the ASC and the compliance history of the medical staff associated with the ASC, there is reasonable assurance that AdvEnd would operate the ASC 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.

To demonstrate compliance with this sub-criterion, AdvEnd acknowledged that it currently operates an ASC in Vancouver. The construction of the proposed endoscopy ASC in Vancouver would relocate the services already offered.

Further, established ancillary and support agreements are already in place for its gastroenterology services. These relationships would continue with the establishment of the

proposed ASC in Vancouver. AdvEnd intends to include the new facility in any existing agreements where appropriate, and establish new agreements as necessary. AdvEnd also provided a copy of its existing transfer agreement with Legacy Salmon Creek. The transfer agreement would apply to the new facility. [Application, p28, Attachment V-A]

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

- (5) 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, the department determines that the applicant has met the applicable 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, AdvEnd has 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, AdvEnd considered two alternatives to the application that was submitted. Below is a summary of AdvEnd's reasoning and rationale for the current application. [Application, p29]

#### Maintain the Status quo

AdvEnd discounted this option for two reasons. As stated by the Applicant, "the current exempt facility has capacity for one provider, however given the space constraints, converting the space would have done little to expand capacity...and maintaining the exempt model eliminates the ability of non-member utilization and ownership". [Application, p29]

#### Exploring a joint venture with existing facilities

The applicant considered a form of joint venture with the current hospital-based or free-standing ASC in the area. This was deemed to be impractical with the belief that the current out-of-pocket costs and limited system efficiencies inherent with these facilities make it an unattractive option to pursue. Further, the co-mingling of non-G-I procedures prevented some system efficiencies that come from a facility dedicated to a particular procedure.

#### Submit an application for a CN approved ASC

This application proposes to convert an existing lab facility into one that allows for a more comprehensive set of G-I procedures. Further, the Applicant contends the new facility can provide a model to attract needed providers to the area. [Application, p30]

Taking into account the Applicants reasoning, and the results of AdvEnd's need forecast, the department concludes that the project described is the best available alternative for the community. This sub-criterion is met.

### Step Three

This step is used to determine between two or more approvable projects which is the best alternative. There was no other projected submitted requesting to establish a Cn approved ASC in Clark County. As a result, this step is not applicable to this project.

Based on the information above, the department concludes this project is the best available alternative for Clark counties. This sub-criterion is met.

#### (2) In the case of a project involving construction:

##### (a) The costs, scope, and methods of construction and energy conservation are reasonable:

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Within that evaluation, the department determined the sub-criterion was met, therefore, this sub-criterion would also be considered met.

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Within that evaluation, the department determined the sub-criterion was met, therefore, this sub-criterion would also be considered met.

Based on the above evaluation, the department concludes that costs, scope, and methods of construction and energy conservation are reasonable, and this sub criterion is met.