



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

July 11, 2019

CERTIFIED MAIL # 7016 3010 0001 0575 1232

Rachel Todd, CEO
Puget Sound Gastroenterology, PS

Elana Zana
Ogden Murphy Wallace

RE: CN Application #19-01

Dear Ms. Todd and Ms. Zana:

We have completed review of the Certificate of Need application submitted by Puget Sound Gastroenterology, PS. The application proposes the approval of a 3-operating room (OR) ambulatory surgical facility (ASF) located in Seattle, within North King County. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the application submitted by Puget Sound Gastroenterology, PS proposing to establish an ambulatory surgery in the Fremont neighborhood of Seattle, within North King County, is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Gastroenterology, PS agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a two operating room ambulatory surgical facility located in Seattle, within North King County. Surgical services provided include endoscopic surgeries that can be appropriately performed in an outpatient setting.

Conditions

1. Puget Sound Gastroenterology, PS agrees with the project description as stated above. Puget Sound Gastroenterology, PS further agrees that any change to the project as described in the project description above is a new project that requires a new Certificate of Need.
2. Puget Sound Gastroenterology, PS will maintain Medicare and Medicaid certification, regardless of facility ownership.
3. Puget Sound Gastroenterology, PS will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health. Puget Sound

Gastroenterology, PS will use reasonable efforts to provide charity care consistent with the planning area average. The current planning area average is 1.03% of gross revenue and 2.11% of adjusted revenue. Puget Sound Gastroenterology, PS will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires that these records be available upon request.

Approved Costs

There is no capital expenditure

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response to the Certificate of Need Program, at one of the following addresses.

Mailing Address:

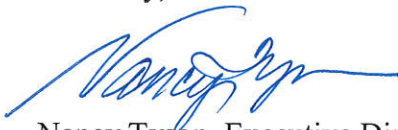
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Physical Address:

Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

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

Sincerely,



Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

July 11, 2019

CERTIFIED MAIL # 7016 3010 0001 0575 1256

Rachel Todd, CEO
Puget Sound Gastroenterology, PS

Elana Zana
Ogden Murphy Wallace

RE: CN Application #19-04

Dear Ms. Todd and Ms. Zana:

We have completed review of the Certificate of Need application submitted by Puget Sound Gastroenterology, PS. The application proposes the approval of a 2-operating room (OR) ambulatory surgical facility (ASF) located in Seattle, within North King County. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the application submitted by Puget Sound Gastroenterology, PS proposing to establish an ambulatory surgery in Seattle, within North King County, is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Gastroenterology, PS agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a two operating room ambulatory surgical facility located in Seattle, within North King County. Surgical services provided include endoscopic surgeries that can be appropriately performed in an outpatient setting.

Conditions

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Gastroenterology, PS will use reasonable efforts to provide charity care consistent with the planning area average. The current planning area average is 1.03% of gross revenue and 2.11% of adjusted revenue. Puget Sound Gastroenterology, PS will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires that these records be available upon request.

Approved Costs

There is no capital expenditure

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

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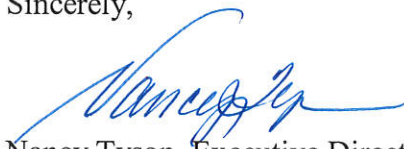
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Sincerely,



Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure

EVALUATION DATED JULY 11, 2019 FOR TWO CERTIFICATE OF NEED APPLICATIONS, EACH PROPOSING AMBULATORY SURGICAL FACILITIES IN SEATTLE, WITHIN NORTH KING COUNTY

- **PUGET SOUND GASTROENTEROLOGY PROPOSES TO ESTABLISH A TWO-OPERATING ROOM CN-APPROVED AMBULATORY SURGICAL FACILITY – FREMONT ENDOSCOPY CENTER**
- **PUGET SOUND GASTROENTEROLOGY PROPOSES TO ESTABLISH A TWO-OPERATING ROOM CN-APPROVED AMBULATORY SURGICAL FACILITY – SEATTLE ENDOSCOPY CENTER**

APPLICANT DESCRIPTION

Puget Sound Gastroenterology, PS

Puget Sound Gastroenterology, P.S. (PSG) is a professional service corporation formed in 2004 by the merger of Digestive Disease Center at Kruger Clinic, P.C., Eastside Gastroenterology, P.S., and Seattle Gastroenterology Associates, Inc., P.S. Puget Sound Gastroenterology, P.S. is a physician-directed organization providing comprehensive gastrointestinal medical services to patients and referring physicians in the Puget Sound area. PSG owns and operates four ambulatory surgery centers (ASCs) and clinics in Fremont, Northgate, Edmonds and Kirkland. [source: PSG website, Washington State Secretary of State office, Application, pdf5]

PSG is owned by the 21 physicians listed below. [source: Application pdf4-5]

Russ Arjal, MD	Crystal Bernstein, MD
Janelle Brown-Chang, MD	Cara Debley, MD
Gary Dines, MD	Sue Eng, MD
Alina Gavrilă, MD	Michelle Gottschlich, MD
Jinfeng Jeff Guo, MD	Peter Justus, MD
David Lee, MD	Arnold Levin, MD
Steven Lewis, MD	Ronald Mason, MD
Gilbert Ong, MD	Alexandra Read, MD
Jason Schneier, MD	Thomas Sloane, MD
Wataru Tamura, MD	Darik Taniguchi, MD
Steven Wegley, MD	

PROJECT DESCRIPTIONS

Fremont Endoscopy Center

PSG proposes to establish a three operating room endoscopy surgical facility at 501 North 34th Street, Suite 101 in the Fremont neighborhood of Seattle [98103] within the North King County planning area by converting a Certificate of Need (CN) exempt facility to CN approved. The facility has been operating since 2004. [source: Application, pdf4, 9]

No new services are proposed with this project. The ASC will continue to provide the same services it has provided in the past, which includes endoscopic gastroenterology procedures. [source: Application, pdf9]

The estimated capital expenditure for the project is \$0. [source: Application, pdf18]

Seattle Endoscopy Center

PSG proposes to establish a two operating room endoscopy surgical facility at 11027 Meridian Avenue North, Suite 100 in Seattle [98133] within the North King County planning area by converting a Certificate of Need (CN) exempt facility to CN approved. The facility has been operating since 1996. [source: Application, pdf4, 9]

No new services are proposed with this project. The ASC will continue to provide the same services it has provided in the past, which includes endoscopic gastroenterology procedures. [source: Application, pdf9]

The estimated capital expenditure for the project is \$0. [source: Application, pdf18]

Because the applicant is the same for both projects, each project will be referred to by the name of the existing facility.

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both applications are subject to Certificate of Need review as the construction, establishment, or other development of a health care facility under RCW 70.38.105(4)(a) and WAC 246-310-020(1)(a).

EVALUATION CRITERIA

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

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

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

In the event that 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:

- (b) “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 experience 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). 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 for applicable criteria in WAC 246-310-210.

TYPE OF REVIEW

Both of these applications proposed ASFs in the North King County secondary service planning area. These applications, though not submitted under a published concurrent review, were reviewed concurrently under the regular timeline outlined in WAC 246-310-160.

The concurrent review process promotes the expressed public goal of RCW 70.38 that the development or expansion of health care facilities be accomplished in a planned, orderly fashion and without unnecessary duplication. For these projects, the concurrent review allows the department flexibility in determining the best interests for North King County residents. The concurrent review timeline used for these two applications is summarized on the following page:

APPLICATION CHRONOLOGY

Action	Fremont	Seattle
Letter of Intent Submitted	April 12, 2018	April 12, 2018
Application Submitted	July 12, 2018	July 9, 2018
Department’s pre-review activities:		
• DOH 1st Screening Letter	August 2, 2018	August 2, 2018
• Applicant’s Responses Received	August 20, 2018	August 20, 2018
• DOH 2nd Screening Letter	September 11, 2018	September 11, 2018
• Applicant’s Responses Received	October 11, 2018	October 11, 2018
Beginning of Review	October 19, 2019	
Public Hearing Conducted	N/A	
Public Comments accepted through the end of public comment	November 26, 2018	
Rebuttal Comments Submitted	December 10, 2018	
Department’s Anticipated Decision Date	January 24, 2019	
Department’s Actual Decision Date	July 11, 2019	

AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines “affected person” as:

“...an “interested person” who:

- (a) *Is located or resides in the applicant's health service area;*
- (b) *Testified at a public hearing or submitted written evidence; and*
- (c) *Requested in writing to be informed of the department's decision.”*

As noted above, WAC 246-310-010(2) requires an affected person to first meet the definition of an ‘interested person.’ WAC 246-310-010(34) defines “interested person” as:

- (a) *The applicant;*
- (b) *Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;*
- (c) *Third-party payers reimbursing health care facilities in the health service area;*
- (d) *Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;*
- (e) *Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;*
- (f) *Any person residing within the geographic area to be served by the applicant; and*
- (g) *Any person regularly using health care facilities within the geographic area to be served by the applicant.*

Under concurrent review, each applicant is an affected person for the other application.

During the course of review, several entities requested to receive copies of the applications, but none qualified for affected person status.

SOURCE INFORMATION REVIEWED

- PSG Certificate of Need applications – Fremont and Seattle
- PSG screening responses – Fremont and Seattle
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission and Nursing Quality Assurance Commission
- Compliance history for facilities and services from the Washington State Department of Health – Office of Health Systems Oversight
- DOH Provider Credential Search website: <http://www.doh.wa.gov/pcs>
- CMS QCOR Compliance website: https://qcor.cms.gov/index_new.jsp
- Historical charity care data for years 2015, 2016, and 2017 obtained from the Department of Hospital/Finance and Charity Care (HFCC) Financial Review
- Department of Health internal database – Integrated Licensing & Regulatory Systems (ILRS)
- Puget Sound Gastroenterology website: <https://www.pugetsoundgastro.com/>
- Washington State Department of Revenue website: <http://www.dor.wa.gov>
- Center for Medicare and Medicaid Services website: <https://www.cms.gov>
- Certificate of Need historical files

CONCLUSIONS

Fremont Endoscopy Center

For the reasons stated in this evaluation, the application submitted by Puget Sound Gastroenterology, PS proposing to establish an ambulatory surgery in the Fremont neighborhood of Seattle, within North King County, is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Gastroenterology, PS agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a three operating room ambulatory surgical facility located in Seattle, within North King County. Surgical services provided include endoscopic surgeries that can be appropriately performed in an outpatient setting.

Conditions

1. Puget Sound Gastroenterology, PS agrees with the project description as stated above. Puget Sound Gastroenterology, PS further agrees that any change to the project as described in the project description above is a new project that requires a new Certificate of Need.
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Approved Costs

There is no capital expenditure

Seattle Endoscopy Center

For the reasons stated in this evaluation, the application submitted by Puget Sound Gastroenterology, PS proposing to establish an ambulatory surgery in Seattle, within North King County, is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Gastroenterology, PS agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a two operating room ambulatory surgical facility located in Seattle, within North King County. Surgical services provided include endoscopic surgeries that can be appropriately performed in an outpatient setting.

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Approved Costs

There is no capital expenditure

CRITERIA DETERMINATIONS

A. NEED (WAC 246-310-210)

Fremont Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS met the applicable need criteria in WAC 246-310-210 and has met the applicable ambulatory surgery facility criteria in WAC 246-310-270.

Seattle Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS met the applicable need criteria in WAC 246-310-210 and has met the applicable ambulatory surgery facility criteria in 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.

To evaluate this sub-criterion, the department uses facility-specific criteria found in WAC 246-310-270.

WAC 246-310-270(6)

WAC 246-310-270(6) requires a minimum of two operating rooms (ORs) in an ASC.

Fremont Endoscopy Center

Puget Sound Gastroenterology identified that the facility would have three ORs. [source: Application pdf35]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The application provided documentation and statements to demonstrate the surgery center would have three ORs. **This sub-criterion is met.**

Seattle Endoscopy Center

Puget Sound Gastroenterology identified that the facility would have two ORs. [source: Application pdf35]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The application provided documentation and statements to demonstrate the surgery center would have two ORs. **This sub-criterion is met.**

WAC 246-310-270(9) – Ambulatory Surgery Numeric Need 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 ASFs in Washington State. The numeric methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient ORs in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 secondary health services planning areas. Both proposed facilities are located in Seattle, within the North King County secondary health service planning area.

The methodology estimates OR need in a planning area using multiple 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 room in the planning area, subtracts this capacity from the forecast number of surgeries expected in the planning area in the target year, and examines the difference to determine:

- (a) Whether a surplus or shortage of ORs is predicted to exist in the target year; and
- (b) If a shortage of ORs is predicted, the shortage of dedicated outpatient and mixed-use rooms are calculated.

Data used to make these projections specifically exclude special purpose and endoscopy rooms and procedures. Dedicated interventional pain management surgical services are also among the excluded rooms and procedures.

Because both projects propose operating rooms that would be exclusively dedicated to endoscopy services, the department will not complete the numeric need methodology and will instead move forward with analysis under WAC 246-310-210, assessing whether existing services are sufficiently available or accessible to serve the projected population.

WAC 246-310-210

In addition to demonstrating need for services within a planning area, the applicant must also demonstrate that existing services are not sufficiently available and accessible to meet that need.

The department's evaluation of each project with respect to this sub-criterion will be discussed at the end of this sub-criterion.

Fremont Endoscopy Center

"To PSG's knowledge, there are no other independent outpatient endoscopy centers in the service area, all are owned and operated by hospitals/health systems."

This project proposes to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC. The ASC is currently operating with the physicians listed above in the area, and projected use of the ASC in the future will likely remain the same as it is now. Therefore, it can be assumed that there will not be unnecessary duplication of services. In fact, if this project is not approved, more than 2000 procedures per year would need to be performed in other facilities and north King County and south Snohomish County residents would experience reduced access to diagnostic and therapeutic endoscopy procedures and potentially increase costs to the community as some of those procedures would likely be done at a hospital outpatient department rather than an independent ASC ..” [source: Application pdf16-17]

“The number of people currently using the services of the ASC will likely see a slight increase due to the addition of Dr. Blais. There is still excess capacity in the ASC. Evidence that supports current and future volume numbers conservatively growing is that there is no indication of significant change in payer mix or referring providers based on the consistent healthcare job market in North King County. Additionally, colonoscopies are recommended every 3-10 years for all adults age 50-75, dependent on family and personal history of polyps. Therefore the number of persons now using the services of the current ASC will likely increase based on the North King County population aging (resulting in more people between the ages of 50-75). In addition, PSG expects the usage of the ASC to grow following the recent article from the American Cancer Society (attached as Exhibit I) recommending screening at the age of 45, rather than 50..” [source: Application pdf16]

“The calculations provided in the utilization forecast do not expect growth from existing physicians, but includes a 1 % growth rate after Dr. Blais is given sufficient time to ramp up. This was based on the past 6 years and the addition of Dr. Blais in August of 2018 . Further, PSG believes that this is a conservative growth rate considering that the King County population is expected to grow by 3.5% by 2021 ..” [source: Application pdf15]

Historical volumes are shown below. [source: Application pdf8]

Applicant’s Table
PSG (Fremont Endoscopy Center)
Annual Procedures, 2013-2017

Year	EGD	Colon	Flex Sig	Total
2012	859	2041	35	2935
2013	810	1974	33	2817
2014	750	1878	14	2642
2015	724	1884	21	2629
2016	670	1773	16	2459
2017	559	1469	14	2042
2018 (projected)	600	1650	25	2275

Public Comments

None

Rebuttal Comments

None

Seattle Endoscopy Center

“To PSG's knowledge, there are no other independent outpatient endoscopy centers in the service area , all are owned and operated by hospitals/health systems.

This project proposes to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC. The ASC is currently operating with the physicians listed above in the area, and PSG has projected use of the ASC in the future to remain the same as it is now. Therefore, it can be assumed that there will not be unnecessary duplication of services. In fact, if this project is not approved , more than 5,600 procedures per year would need to be performed in other facilities and north King County and south Snohomish County residents would experience reduced access to diagnostic and therapeutic endoscopy procedures and potentially increase costs to the community as some of those procedures would likely be done at a hospital outpatient department rather than an independent ASC.” [source: Application pdf16]

“The number of people currently using the services of the ASC will likely continue and will grow with the addition of a new physician in 2019. Evidence that supports current and future volume numbers conservatively growing is that there is no indication of significant change in the payer mix or referring providers based on the consistent healthcare job market in North King County . Additionally, colonoscopies are recommended every 3-10 years for all adults age 50 -75, dependent on family and personal history of polyps. Therefore the number of persons now using the services of the current ASC will likely increase based on the North King County population aging (resulting in more people between the ages of 50-75). In addition , PSG expects the usage of the ASC to grow following the recent article from the American Cancer Society (attached as Exhibit I) recommending screening at the age of 45, rather than 50.” [source: Application pdf15]

“Based on the past six (6) years of the ASC history with continued strong referrals (volume struggles related to provider availability), along with the increasing local adult population, there is an assumption of increased referrals for routine and diagnostic gastrointestinal procedures. With an additional physician, the ASC is conservatively projecting growth based on his/her performance of procedure in 2019 and 2020 and a conservative 1 % growth in years 2021 -2023.” [source: Application pdf15]

Historical volumes are shown on the following page. [source: Application pdf8]

Applicant's Table
PSG (Seattle Endoscopy Center)
Annual Procedures, 2013-2017

Year	EGD	Colon	Flex Sig	Total
2012	1600	4416	23	6039
2013	1602	4460	27	6089
2014	1416	4397	25	5838
2015	1401	4338	45	5784
2016	1464	4377	45	5886
2017	1458	4177	49	5684
2018 (projected)	1458	4177	49	5684

Public Comments

None

Rebuttal Comments

None

Department Evaluation of both projects

Because numeric need is not a factor, the department must instead determine whether other services and facilities for the type proposed are not or will not be sufficiently available and accessible to meet that need.

PSG provided statements related to the availability and accessibility of other providers in the planning area in both applications. PSG's comments focused largely on the continued utilization of highly used endoscopy facilities as well as the lack of other available resources in the planning area, outside of the hospital setting.

The department did not receive any public comment to suggest that other area providers opposed the CN-approval of this existing outpatient surgery capacity in the planning area. To further evaluate this sub-criterion, the department identified the surgical specialties available at the existing planning area surgery centers, below. This list does not include the two facilities under review in this evaluation

Facility Name	Facility License Number	Specialties
Seattle Orthopedic Center - Surgery	ASF.FS.60101053	Orthopedics, Pain Management
Northwest Eye Surgeons	ASF.FS.60101724	Ophthalmology
Eye Associates Northwest Surgery Center	ASF.FS.60102711	Ophthalmology
EVIVA	ASF.FS.60501191	Gastroenterology, General Surgery, Other, Plastic Surgery
Northwest Eye Surgeons	ASF.FS.60977711	Ophthalmology

Only one of the above facilities – EVIVA – appears to provide any type of gastroenterological services. Upon a review of their website, it appears the main gastroenterology services offered

at this facility are related bariatric weight loss surgery – not routine endoscopy like the two facilities under review in this evaluation.

Based on this information and lack of public comment, the department has determined that the existing supply of facilities may not be sufficiently available and accessible to all planning area residents. Further, each project meets the standard under WAC 246-310-270(6). **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.

To evaluate this sub-criterion, the department evaluates an applicant's admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services. 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 assurances regarding access to treatment.

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

Medicare certification is a measure of an applicant's willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals age 65 and over. It is also well recognized that women live longer than men and therefore more likely to be on Medicare longer.

Medicaid certification is a measure of an applicant's willingness to serve low income persons and may include individuals with disabilities.

Charity care shows a willingness of a provider to provide services to individuals who do not have private insurance, do not qualify for Medicare, do not qualify for Medicaid, or are under insured. With the passage of the Affordable Care Act, the amount of charity care is expected to decrease, but not disappear. Specific to ASCs, WAC 246-310-270(7) requires that ASFs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed project.

Because the information provided in each application is similar, the department will evaluate this sub-criterion for both applicants simultaneously.

Fremont Endoscopy Center

PSG provided copies of the following policies, which are currently in use. [source: Application Exhibit C, K, Screening Response 1 Exhibit J]

- Admission Policy
- Standard of Care Policy

- Charity Care Policy

In addition to the policies listed above, PSG provided the following statement:

“PSG services patients regardless of income, race, ethnicity, sex, or disability and fully intends to continue observing the same policy.

A copy of PSG's charity care policy is included within Exhibit J. Consistent with the requirements of WAC 246-310-270(7), PSG projects to provide the average charity care for King County (minus Harborview and Kaiser). According to the CN Evaluation for Minor and James issued on May 3, 2018 , the three year charity average for King County, excluding Harborview and Kaiser is .82% of gross revenue and 1.80% of adjusted revenue.. [source: Application pdf16-17]

**Department’s Table 1
Current and Projected Payer Mix**

Payer	Forecast
Commercial/Other	70.20%
Medicare	28.10%
Medicaid	0.55%
Self Pay	0.55%
Other Government	0.60%
Total	100%

[source Screening 1 response pdf3]

Public Comments

None

Rebuttal Comments

None

Seattle Endoscopy Center

PSG provided copies of the following policies, which are currently in use. [source: Application Exhibit C, K, Screening Response 1 Exhibit J]

- Admission Policy
- Standard of Care Policy
- Charity Care Policy

In addition to the policies listed above, PSG provided the following statement:

“PSG services patients regardless of income, race, ethnicity, sex, or disability and fully intends to continue observing the same policy.

A copy of PSG's charity care policy is included within Exhibit J. Consistent with the requirements of WAC 246-310-270(7), PSG projects to provide the average charity care for

King County (minus Harborview and Kaiser). According to the CN Evaluation for Minor and James issued on May 3, 2018, the three year charity average for King County, excluding Harborview and Kaiser is .82% of gross revenue and 1.80% of adjusted revenue.. [source: Application pdf16-17]

**Department’s Table 2
Current and Projected Payer Mix**

Payer	Forecast
Commercial/Other	70.20%
Medicare	28.10%
Medicaid	0.55%
Self Pay	0.55%
Other Government	0.60%
Total	100%

[source Screening 1 response pdf3]

Public Comments

None

Rebuttal Comments

None

Department Evaluation – Fremont and Seattle

The draft admission policy that was provided includes the required information, including the criteria for admitting patients and a description of the types of patients that would be served. It is currently in use at both facilities

The financial data provided in the application shows Medicare and Medicaid revenues consistent with the tables above. The department concluded that PSG intends for these surgery centers to be accessible and available to Medicare and Medicaid patients based on the information provided. PSG’s facilities are currently Medicare certified.

Based on the historical financials, it appears that the surgery center has provided some charity care in the past. The proposed charity care policy includes the process a patient would need to follow in order to obtain charity care.

Based on the information reviewed and with PSG’s agreement to the conditions identified above, the department concludes **this sub-criterion is met.**

WAC 246-310-270(7) – Charity Care Requirement

WAC 246-310-270(7) requires that ASCs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC.

The department’s evaluation of each applicant with respect to this sub-criterion will be discussed at the end of this sub-criterion.

Fremont Endoscopy Center

“A copy of PSG's Charity Care policy is included within Exhibit J. Consistent with the requirements of WAC 246-310-270 (7), PSG projects to provide the average charity care requirement for King County (minus Harborview and Kaiser). According to the CN Evaluation for Minor and James issued on May 3, 2018, the three year charity average for King County, excluding Harborview and Kaiser is .82% of gross revenue and 1.80% of adjusted revenue..”
[source: Application pdf17]

Public Comments

None

Rebuttal Comments

None

Seattle Endoscopy Center

“A copy of PSG's Charity Care policy is included within Exhibit J. Consistent with the requirements of WAC 246-310-270 (7), PSG projects to provide the average charity care requirement for King County (minus Harborview and Kaiser). According to the CN Evaluation for Minor and James issued on May 3, 2018, the three year charity average for King County, excluding Harborview and Kaiser is .82% of gross revenue and 1.80% of adjusted revenue...”
[source: Application pdf16-17]

Public Comments

None

Rebuttal Comments

None

Department Evaluation – Charity Care Requirement

For charity care reporting purposes, Washington State is divided into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Each of the applications propose ASFs in North King County, within the King County Region.

Currently there are 23 hospitals operating within the region. Of the 23 hospitals, some did not report charity care data for the years reviewed – in 2016, UHS/BHC Fairfax Hospital was late in reporting to DOH. Of these 23, there are three hospitals located in North King County – Seattle Children’s Hospital, University of Washington Medical Center, and UW/Northwest Hospital that would be affected by approval of these projects

Table 3 below compares the three-year historical average of charity care provided by the hospitals operating in the King County Region (with the exception of those that did not report), in North King County, and the applicants’ projected charity care percentages. Adjustments have been made to exclude Harborview Medical Center and Kaiser Permanente Central Hospital. Harborview Medical Center is subsidized by the state legislature to provide charity

care services. Charity care percentages for Harborview make up almost 50% of the total percentages provided in the King County Region. Kaiser Permanente Central Hospital – formerly known as Group Health Central Hospital – is excluded because healthcare charges are prepaid through member subscriptions; therefore, uncompensated healthcare is generally not incurred.

Table 3
Charity Care – Three Year Average

	% of Total Revenue	% of Adjusted Revenue
3-year King County Region	0.87%	1.89%
3-year North King County	1.03%	2.11%
Fremont Endoscopy Center– Projected	0.82%	--
Seattle Endoscopy Center – Projected	0.82%	--

[source: Applications pdf17]

As shown above, the projected percentage of charity care proposed by both facilities is lower than the North King County average, but is generally consistent with the regional average.

The 2014 Report of Charity Care in Washington Hospitals offers the following analysis of decreased charity care across Washington State Hospitals with the introduction of the Affordable Care Act (ACA):

“Implementation of the ACA is changing the landscape of charity care in Washington State. More patients have health coverage, either through Medicaid expansion or through purchase of private coverage. As a result, Washington saw the first decline in the amount of charity care reported by hospitals since the department began gathering these data...”

“As hospitals begin to report all data for calendar year 2014, the ACA becomes fully effective, and the number of insured stabilizes, we will likely see a continued decline in charity care in Washington over the next few years before it levels off again.” [source: 2014 Washington State Charity Care in Washington Hospitals – January 2016]

The Certificate of Need program recognizes that charity care in Washington State is expected to continue to decline as more individuals receive healthcare coverage under the ACA, but charity care is not expected to reach zero.

Both applicants acknowledged the requirement under WAC 246-310-270(7) to provide charity care and committed to the regional average. **With agreement to a charity care condition, this sub-criterion is met for both applicants.** The financial implications of this will be discussed under WAC 246-310-220(1).

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial

portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

Department Evaluation

This sub-criterion is not applicable to this application

- (b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.

Department Evaluation

This sub-criterion is not applicable to this application

- (c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.

Department Evaluation

This sub-criterion is not applicable to this application

- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:

- (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.

Department Evaluation

This sub-criterion is not applicable to this application

- (b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.

Department Evaluation

This sub-criterion is not applicable to this application

- (5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

Department Evaluation

This sub-criterion is not applicable to this application

B. FINANCIAL FEASIBILITY (WAC 246-310-220)

Fremont Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS the applicable financial feasibility criteria in WAC 246-310-220.

Seattle Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS the applicable 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.

Fremont Endoscopy Center

The PSG forecast model uses the following assumptions and methodologies. [source: Application pdf10]

“Applicant anticipates an increase in volume over current numbers in 2018 entirely attributed to the arrival of Dr. Blais in August of 2018. Other growth is limited as the hours of operation will continue to be the same hours of operation. Services offered at the facility will likewise remain the same. Projected growth will be small in 2018 (233 procedures) based on the timing of the arrival of Dr. Blais. PSG then projects that Dr. Blais will perform 600 procedures in 2019 and 700 procedures in 2020 (based on conservative estimates related to past experience with new physicians). The anticipated utilization is as follows:

- 2018 (actuals & projections): 2275
- 2019 (projections): 2642
- 2020 (projections): 2742”

The assumptions PSG used to project revenue, expenses, and net income for the proposed surgery center for the projection years are shown below. [sources: Application pdf20-21]

- *Inflation of revenue is excluded from the proforma.*
- *Average revenue per case was calculated using historical trends/data from 2017 and YTD 2018.*
- *The payer percentages for revenue are provided below (in Table 8)*
- *Since PSG is on a cash basis (from an accounting perspective), no bad debt percentage is assumed since it will just be part of the actual collections.*

- *Charity care is assumed constant at 0.82% of total revenue.*
- *Staffing requirements are based on current FTE counts for the ASC and adjusted in the forecast to reflect conservative volume increases in the facility. The current FTE counts are in Table 9 and the historical FTE counts are in Exhibit N.*
- *Wage and salary figures are specific to each group of FTEs, and are calculated on an hourly basis, based on current PSG estimates. It is assumed a FTE works 2,080 hours per year.*
- *Benefits are calculated as 24.5% of total wages and salaries, based on current PSG estimates.*
- *Supplies, purchased services, and other expenses were calculated on a per case basis, driven off of PSG actuals. Other expenses include recruitment, legal, and travel expenses, among others.*
- *Repairs and maintenance were calculated based on PSG actuals.*
- *Employee development, physician development, and dues/memberships/licenses are calculated by actuals per FTE and projected to adjust for any increases in FTEs.*
- *B&O taxes were calculated at 1.45% of net revenue.*
- *Lease equipment was based on PSG actuals.*
- *Projected rent expense was based on the lease (Exhibit F) with escalator as noted in the lease.*
- *Inflation was excluded from the operating expense forecast”*

PSG’s projected revenue, expenses, and net income for the ASF are shown in Table 4 below.

**Table 4
Fremont Endoscopy Center Projected Revenue and Expenses**

	2020 (year one)	2021 (year two)	2022 (year three)
Procedures	2,742	2,842	2,942
Net Revenue	\$1,836,200	\$1,853,838	\$1,871,663
Total Expenses	\$1,569,983	\$1,611,907	\$1,655,401
Net Profit/(Loss)	\$266,217	\$241,931	\$216,262
Net Profit/(Loss) per Procedure	\$97.09	\$85.13	\$73.51

The “Net Revenue” line item is gross patient revenue, minus deductions from revenue for charity care. The “Total Expenses” line item includes operating expenses, including salaries and wages, benefits, insurance, rentals, and leases. As noted in the application, PSG operates on a cash basis and therefore does not include contractual adjustments or bad debt.

Public Comments

None

Rebuttal Comments

None

Department Evaluation

To evaluate this sub-criterion, the department first reviewed the assumptions used by PSG to determine the projected number of procedures and occupancy of the ASF. The basis for their

volumes is largely driven from existing volumes with growth projected based on past performance, and at less than the planning area population growth. This assumption is reasonable.

PSG based its revenue and expense assumptions for the on the assumptions listed above, including actual historical figures, as an existing facility. This is reasonable.

PSG provided a lease agreement and several amendments to the lease for the site. The lease is between Limpopo Properties, LLC and PSG. The most recent amendment to the lease was effective in 2017 through 2027. The lease identifies the roles and responsibilities for each, party. All costs associated with the lease are substantiated in the revenue and expense statement, as only part of the lease is assigned to the surgery center.

PSG identified the medical director, Dr Steven Wegley, who is an employee of PSG. The role of medical director is compensated through their employment agreement with PSG which is why there is no distinct line item for the medical director. [source Application pdf23].

The pro forma financial statements show revenues exceeding expenses within the first full year of operation and to continue doing so. In year 2022, agreement to the charity care condition would increase the charity care by approximately \$4,000. This does not affect revenue exceeding expenses for this facility.

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

Seattle Endoscopy Center

The PSG forecast model uses the following assumptions and methodologies. [source: Application pdf9-10]

“Applicant does not anticipate an increase in volume over current numbers in 2018, as the hours of operation will continue to be the same hours of operation. Though Dr. Blais will be credentialed to provide services at the Seattle Endoscopy Center, PSG does not anticipate him providing services at this location and therefore does not include any anticipated volume increase. Services offered at the facility will likewise remain the same . PSG is currently recruiting for an additional physician and expect an additional physician to do procedures at the Seattle Endoscopy Center starting in 2019, therefore growth is projected related to a conservative number of procedures (600 additional procedures in 2019 and 700 procedures/year in 2020) for that new physician in 2019 and 2020. The anticipated utilization is as follows:

- *2018 (actuals & projections): 5684*
- *2019 (projections): 6284*
- *2020 (projections): 6384”*

The assumptions PSG used to project revenue, expenses, and net income for the proposed surgery center for the projection years are shown below. [sources: Application pdf19-20]

- Inflation of revenue is excluded from the proforma.
- Average revenue per case was calculated using historical trends/data from 2017 and YTD 2018.
- The payer percentages for revenue are provided below (in Table 8)
- Since PSG is on a cash basis (from an accounting perspective), no bad debt percentage is assumed since it will just be part of the actual collections.
- Charity care is assumed constant at 0.82% of total revenue.
- Staffing requirements are based on current FTE counts for the ASC and adjusted in the forecast to reflect conservative volume increases in the facility. The current FTE counts are in Table 9 and the historical FTE counts are in Exhibit N.
- Wage and salary figures are specific to each group of FTEs, and are calculated on an hourly basis, based on current PSG estimates. It is assumed a FTE works 2,080 hours per year.
- Benefits are calculated as 24.5% of total wages and salaries, based on current PSG estimates.
- Supplies, purchased services, and other expenses were calculated on a per case basis, driven off of PSG actuals. Other expenses include recruitment, legal, and travel expenses, among others.
- Repairs and maintenance were calculated based on PSG actuals.
- Employee development, physician development, and dues/memberships/licenses are calculated by actuals per FTE and projected to adjust for any increases in FTEs.
- B&O taxes were calculated at 1.45% of net revenue.
- Lease equipment was based on PSG actuals.
- Projected rent expense was based on the lease (Exhibit F) with escalator as noted in the lease.
- Inflation was excluded from the operating expense forecast”

PSG’s projected revenue, expenses, and net income for the ASF are shown in Table 5 below.

**Table 5
Seattle Endoscopy Center Projected Revenue and Expenses**

	2020 (year one)	2021 (year two)	2022 (year three)
Procedures	6,384	6,448	6,512
Net Revenue	\$3,970,366	\$4,010,069	\$4,050,172
Total Expenses	\$2,311,922	\$2,381,604	\$2,452,478
Net Profit/(Loss)	\$1,658,444	\$1,628,465	\$1,597,694
Net Profit/(Loss) per Procedure	\$259.78	\$252.55	\$245.35

The “Net Revenue” line item is gross patient revenue, minus deductions from revenue for charity care. The “Total Expenses” line item includes operating expenses, including salaries and wages, benefits, insurance, rentals, and leases. As noted in the application, PSG operates on a cash basis and therefore does not include contractual adjustments or bad debt.

Public Comments

None

Rebuttal Comments

None

Department Evaluation

To evaluate this sub-criterion, the department first reviewed the assumptions used by PSG to determine the projected number of procedures and occupancy of the ASF. The basis for their volumes is largely driven from existing volumes with growth projected based on past performance, and at less than the planning area population growth. This assumption is reasonable.

PSG based its revenue and expense assumptions for the on the assumptions listed above, including actual historical figures, as an existing facility. This is reasonable.

PSG provided a lease agreement and several amendments to the lease for the site. The lease is between Verity Credit Union and PSG. The most recent amendment to the lease was effective in 2016 through 2026. The lease identifies the roles and responsibilities for each, party. All costs associated with the lease are substantiated in the revenue and expense statement, as only part of the lease is assigned to the surgery center.

PSG identified the medical director, Dr Steven Wegley, who is an employee of PSG. The role of medical director is compensated through their employment agreement with PSG which is why there is no distinct line item for the medical director. [source Application pdf22].

The pro forma financial statements show revenues exceeding expenses within the first full year of operation and to continue doing so. In year 2022, agreement to the charity care condition would increase the charity care by approximately \$8,000. This does not affect revenue exceeding expenses for this facility.

Based on the information above, the department concludes that the immediate and long-range 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.

Fremont Endoscopy Center

"This project is not expected to have any impact on capital costs or operating costs and charges for the health services provided, as nothing is anticipated to change if CN approval is granted. The purpose of this application is to convert an existing dedicated outpatient

endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC.” [source: Application pdf18]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

In order to evaluate this sub-criterion, the department performed a calculation of net revenue prior to expenses per procedure after the project to determine whether the applicant’s projections were reasonable.

Table 6
Department Calculation of Net Charges per Case

	2020	2021	2022
Net Revenue	\$1,836,200	\$1,853,838	\$1,871,663
Number of Procedures	2,742	2,842	2,942
Net Revenue (charges) per Procedure	\$669.66	\$652.30	\$636.19

As shown above, the net charges change in favor of patient charges in the projection years.

Furthermore, there is no capital expenditure associated with this project.

Based on the above information, the department concludes that the establishment of Fremont Endoscopy Center as a CN-approved ASF would likely not have an unreasonable impact on the costs and charges for healthcare services in the North King secondary service planning area. **This sub-criterion is met**

Seattle Endoscopy Center

“This project is not expected to have any impact on capital costs or operating costs and charges for the health services provided, as nothing is anticipated to change if CN approval is granted. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC.” [source: Application pdf18]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

In order to evaluate this sub-criterion, the department performed a calculation of net revenue prior to expenses per procedure after the project to determine whether the applicant’s projections were reasonable.

Table 7
Department Calculation of Net Charges per Case

	2020	2021	2022
Net Revenue	\$3,970,366	\$4,010,069	\$4,050,172
Number of Procedures	6,384	6,448	6,512
Net Revenue (charges) per Procedure	\$621.92	\$621.91	\$621.96

As shown above, the net charges change only nominally in the projection years.

Furthermore, there is no capital expenditure associated with this project.

Based on the above information, the department concludes that the establishment of Seattle Endoscopy Center as a CN-approved ASF would likely not have an unreasonable impact on the costs and charges for healthcare services in the North King secondary service planning 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.

Fremont Endoscopy Center

“There are no anticipated capital expenditures associated with this project. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC..” [source: Application pdf19]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As stated above, this project does not have an associated capital expenditure. **This sub-criterion is not applicable.**

Seattle Endoscopy Center

“There are no anticipated capital expenditures associated with this project. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC..” [source: Application pdf18]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As stated above, this project does not have an associated capital expenditure. **This sub-criterion is not applicable.**

C. STRUCTURE AND PROCESS (QUALITY) OF CARE (WAC 246-310-230)

Fremont Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS met the applicable structure and process (quality) of care criteria in WAC 246-310-230.

Seattle Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS met the applicable structure and process (quality) 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 [full time equivalents] that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

Fremont Endoscopy Center

PSG provided the following statement related to this sub-criterion:

“The ASC is an existing facility and the number of staff noted in the answer to number 12 (above) have been sufficient for staffing needs. No change in non –physician staffing is anticipated as a result of CN approval..” [source: Application pdf22]

PSG also provided the table below, showing current staffing and projected staffing, which are one and the same. [source: Screening 1 pdf5]

**Department's Table 8
Fremont Current and Projected FTEs**

	Current and Projected
RN Nurse Manager	0.5
Endo Unit Supervisor	1
RN	3
Endoscopy Tech	2
Front Desk	1
Histology Tech	1
Total FTEs	8.5

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As shown above, the ASF is already fully staffed. No changes are expected in the projection period, as volume growth is minimal.

Information provided in the application demonstrates that PSG is a well-established provider of healthcare services in the North King secondary service planning area. PSG is currently operational with two operating rooms. Information within the application supports that utilization has been fairly consistent at this surgery center since 2012.

Given that the facility is already operational with the majority of necessary staff in place, the department concludes that PSG has the ability to staff the ASF. **This sub-criterion is met.**

Seattle Endoscopy Center

PSG provided the following statement related to this sub-criterion:

“The ASC is an existing facility and the number of staff noted in the answer to number 12 (above) has been sufficient for staffing needs. No change in staffing is anticipated as a result of CN approval..” [source: Application pdf22]

PSG also provided the table below, showing current staffing and projected staffing, which are one and the same. [source: Screening 1 pdf4]

**Department's Table 9
PSG and Projected FTEs**

	Current and Projected
RN Nurse Manager	0.5
Endo Unit Supervisor	1
RN	8.2
Lead Endo Tech	1
Endoscopy Tech	3
Front Desk	1
Histology Tech	1
Total FTEs	15.7

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As shown above, the ASF is already fully staffed. No changes are expected in the projection period, as volume growth is minimal.

Information provided in the application demonstrates that PSG is a well-established provider of healthcare services in the North King secondary service planning area. PSG is currently operational with two operating rooms. Information within the application supports that utilization has been fairly consistent at this surgery center since 2012.

Given that the facility is already operational with the majority of necessary staff in place, the department concludes that PSG has the ability to staff the ASF. **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.

Fremont Endoscopy Center

“This project does not propose the addition of any new services . Existing ancillary and support services are already established and sufficiently meet the service demands of the existing ASC.

The Fremont Endoscopy Center typically sends patients needing imaging services to Northwest Hospital or Via Radiology and patients needing lab services to Northwest Hospital. PSG has its own Histology Lab and Pathologist, so most pathology stays internal to PSG.

The Patient Transfer Agreement between Fremont Endoscopy Center (PSG) and Northwest Hospital is included in Exhibit 0..” [source: Application pdf23]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

PSG has been in existence for many years, and the Fremont facility has existed since 2004. All ancillary and support services are already in place. PSG not expect the existing ancillary and support agreements to change as a result of this project.

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that PSG will continue to maintain the necessary relationships with ancillary and support services if this project is approved. **This sub-criterion is met.**

Seattle Endoscopy Center

“This project does not propose the addition of any new services. Existing ancillary and support services are already established and sufficiently meet the service demands of the existing ASC.

The Seattle Endoscopy Center typically sends patients needing imaging services to Northwest Hospital or Via Radiology and patients needing lab services to Northwest Hospital. PSG has its own Histology Lab and Pathologist, so most pathology stays internal to PSG.

The Patient Transfer Agreement between Seattle Endoscopy Center (PSG) and Northwest Hospital is included in Exhibit 0..” [source: Application pdf22]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

PSG has been in existence for many years, and the Seattle facility has existed since 1996. All ancillary and support services are already in place. PSG not expect the existing ancillary and support agreements to change as a result of this project.

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that PSG will continue to maintain the necessary relationships with ancillary and support services if this project is approved. **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.

Fremont Endoscopy Center and Seattle Endoscopy Center

The information the department uses to evaluate this sub-criterion is very similar between applicants – this sub-criterion will be reviewed for both projects together.

“PSG and the individual owners thereof have no history of a criminal conviction of any kind, nor have they received a denial or revocation of a license to operate a health care facility, to practice a health profession, or a decertification as a provider of services in the Medicare or Medicaid program.” [source: Fremont Application pdf24; Seattle Application pdf23]

“The ASC currently is and will continue to operate in a manner that ensures safe and adequate care, and in accord with applicable federal and state laws, rules, and regulations.” [source: Fremont Application pdf24; Seattle Application pdf23]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As a part of this review, the department must conclude that the proposed services provided by an applicant would be provided in a manner that ensures safe and adequate care to the public.¹ To accomplish this task, the department reviewed the quality of care and compliance history for PSG and the medical professionals that would practice there.

CMS Survey Data

Puget Sound Gastroenterology operates four ASFs – therefore these are the only facilities by which the department can gauge compliance with this sub-criterion.

¹ WAC 246-310-230(5)

Using CMS Quality, Certification & Oversight Reports (QCOR), the department reviewed historical survey data for the four surgery centers.

**Department’s Table 10
Surveys and Enforcement**

Facility	# of CMS Surveys	Enforcement Action?	# of State Surveys	Enforcement Action?
Puget Sound Gastroenterology at Edmonds	0	N/A	1	No
Fremont Endoscopy Center	1	No	0	N/A
Seattle Endoscopy Center	0	N/A	0	N/A
Evergreen Endoscopy Center	0	N/A	0	N/A

Within the last three years, PSG was surveyed once by CMS and this survey did not result in any condition-level deficiencies or necessitate a follow-up visit.² The Office of Health Systems Oversight with the Department of Health has not taken action against any of these facilities’ licenses. [source: ILRS, QCOR Survey Activity Report for PSG]

In addition to the facilities identified above, the department also reviewed the compliance history of the physicians and other staff associated with the surgery centers. The table below shows the key staff identified in the applications. [source: Fremont Application pdf23; Seattle Application pdf22]

**Department’s Table 11
Key Staff**

Facility	Name	Credential Number	License Status
Both	Steven Wegley, MD	MD00021892	Active
Both	Rachel Studhalter, RN	RN60292672	Active

As shown above, all key staff associated with each facility have active credentials. The department did not find any restrictions on the above listed licensees within the last three years. Based on the information above, the department concludes that PSG demonstrated reasonable assurance that the facility would continue to operate in compliance with state and federal requirements if this project is approved. **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 direct how to measure unwarranted fragmentation of services or what types of relationships with a services area’s existing health care system should

² Condition-level deficiencies are deficiencies that violate Medicare’s Conditions of Participation.

be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Fremont Endoscopy Center

“The ASC already exists; thus the continuation as a CN-approved facility will promote continuity in the provision of health care to the North King population and avoid unwarranted fragmentation of services. If this project is not approved that continuity would be interrupted and fragmentation would occur.

The Patient Transfer Agreement between Fremont Endoscopy Center (PSG) and Northwest Hospital is included in Exhibit 0 ..” [source: Application pdf23]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Information in the application demonstrates that as a long-time provider of outpatient surgical services, PSG has the infrastructure in place at their Fremont facility. No letters of opposition were submitted for this project.

PSG provided information within the application to demonstrate it intends to continue existing relationships, and that these relationships are adequate to support the increase in services to be provided. This includes the executed transfer agreement between PSG and an area hospital. Based on the information provided in the application, the department concludes there is reasonable assurance that approval of this this project would continue to promote continuity in the provision of health care services in the community. **This sub-criterion is met.**

Seattle Endoscopy Center

“The ASC already exists; thus the continuation as a CN-approved facility will promote continuity in the provision of health care to the North King population and avoid unwarranted fragmentation of services. If this project is not approved that continuity would be interrupted and fragmentation would occur.

The Patient Transfer Agreement between Fremont Endoscopy Center (PSG) and Northwest Hospital is included in Exhibit 0 ..” [source: Application pdf22-23]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Information in the application demonstrates that as a long-time provider of outpatient surgical services, PSG has the infrastructure in place at their Seattle facility. No letters of opposition were submitted for this project.

PSG provided information within the application to demonstrate it intends to continue existing relationships, and that these relationships are adequate to support the increase in services to be provided. This includes the executed transfer agreement between PSG and an area hospital. Based on the information provided in the application, the department concludes there is reasonable assurance that approval of this this project would continue to promote continuity in the provision of health care services in the community. **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 addressed in sub-section (3) above and is met for both projects.

D. COST CONTAINMENT (WAC 246-310-240)

Fremont Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS met the applicable cost containment criteria in WAC 246-310-240.

Seattle Endoscopy Center

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Puget Sound Gastroenterology, PS 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. 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 has met the applicable criteria in WAC 246-310-210 through 230 criteria, in step two, the department assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in

Step three. The superiority criteria are objective measures used to compare competing projects and Page 187 of 209 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 type superiority criteria as directed by WAC 246-310-200(2) (a)(i), then the department would use 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

Fremont Endoscopy Center met the applicable review criteria under WAC 246-310-210 through 230. Their application will be evaluated further under Steps Two and Three.

Seattle Endoscopy Center met the applicable review criteria under WAC 246-310-210 through 230. Their application will be evaluated further under Steps Two and Three.

Step Two

Fremont Endoscopy Center

PSG currently operates the Fremont Endoscopy Center in the North King County Planning Area; the granting of this certificate of need should have no impact on the current market share, utilization or effect on other providers in the North King County Planning Area. The proposed project is aimed at promoting continuity of care to PSG's patients and the North King County residents in an outpatient setting, which is a lower cost alternative for these patients.

PSG has provided endoscopic procedures for over 10 years and is a premier health care provider in King County. With over 2,000 annual procedures, denying a Certificate of Need will detrimentally impact planning area patients. Further, granting this Certificate of Need will have no impact on current planning area providers, as PSG is not a new entrant to the market and does not expect a noticeable market share shift as a result of Certificate of Need approval.

The PSG facility is fully built-out and operational. It has the specific surgical tools necessary to provide the specialized endoscopic services necessary for the ASC's patients. In addition, over 90% of the ASC's patients state that they would recommend this facility to other patients. A "do nothing" alternative will require patients needing these endoscopic and gastroenterological procedures to find other locations and physicians to provide these services, potentially in a more costly setting. This will create a burden on the patients and physicians and could jeopardize the continuity of care.

PSG weighed the following alternatives:

[The only alternative to the project was “do nothing,” shown below]

“PSG does not believe a "do nothing" approach is realistic, considering its current services to the community, and the fact that along with its sister center, Seattle Endoscopy Center, PSG is the only free-standing endoscopic ASC in the North King Planning Area. Without a CN, patients seeking endoscopic procedures will have to obtain these procedures either outside of the planning area or in a costlier setting. A "do nothing" approach would be detrimental to the community, requiring patients to find alternative facilities and could potentially overburden existing providers, therefore increasing wait times. A "do nothing" approach deprives planning area residents of necessary services and therefore it was rejected..” [source: Application pdf24-25]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Information provided in the application demonstrates that the decision to request CN approval rather was the best available alternative for PSG. PSG provided rationale for foregoing the “no project” option as well as for ruling out a CN application with a narrower scope of services or limitations.

The department did not identify any alternative that was a superior alternative in terms of cost, efficiency, or effectiveness that is available or practicable.

For the Fremont application, the department moves on to step three.

Seattle Endoscopy Center

“PSG currently operates the Seattle Endoscopy Center in the North King County Planning Area; the granting of this certificate of need should have no impact on the current market share, utilization or effect on other providers in the North King County Planning Area. The proposed project is aimed at promoting continuity of care to PSG's patients and the North King County residents in an outpatient setting, which is a lower cost alternative for these patients.

PSG has provided endoscopic procedures for over 20 years and is a premier health care provider in King County. With over 5600 annual procedures, denying a Certificate of Need will detrimentally impact planning area patients. Further, granting this Certificate of Need will have no impact on current planning area providers, as PSG is not a new entrant to the market and does not expect a noticeable market share shift as a result of Certificate of Need approval.

The PSG facility is fully built-out and operational. It has the specific surgical tools necessary to provide the specialized endoscopic services necessary for the ASC's patients. In addition, nearly 90% of the ASC's patients state that they would recommend this facility to other patients.

A "do nothing" alternative will require patients needing these endoscopic and gastroenterological procedures to find other locations and physicians to provide these services, potentially in a more costly setting. This will create a burden on the patients and physicians and could jeopardize the continuity of care.

PSG weighed the following alternatives:

[The only alternative to the project was “do nothing,” shown below]

“PSG does not believe a "do nothing" approach is realistic, considering its current services to the community, and the fact that PSG is the only free-standing solely endoscopic ASC in the Southwest Snohomish Planning Area. Without a CN, patients seeking endoscopic procedures will have to obtain these procedures either outside of the planning area or potentially in a costlier setting. A "do nothing" approach would be detrimental to the community, requiring patients to find alternative facilities and could potentially over burden existing providers, therefore increasing wait times. A "do nothing" approach deprives planning area residents of necessary services and therefore it was rejected.” [source: Application pdf24-25]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Information provided in the application demonstrates that the decision to request CN approval rather was the best available alternative for PSG. PSG provided rationale for foregoing the “no project” option as well as for ruling out a CN application with a narrower scope of services or limitations.

The department did not identify any alternative that was a superior alternative in terms of cost, efficiency, or effectiveness that is available or practicable.

For the PSG application, the department moves on to step three.

Step Three

WAC 246-310 does not contain service or facility-specific criteria for determining superiority between ASF applications in a concurrent review. Each of the applications met the applicable review criteria thus far. Furthermore, numeric need is not a consideration for endoscopy project and both facilities have demonstrated high historical and projected future utilization. Therefore, the department will not identify a superior applicant.

For both applicants, 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;

Fremont Endoscopy Center

This application does not involve construction. This sub-criterion does not apply to the Fremont application.

Seattle Endoscopy Center

This application does not involve construction. This sub-criterion does not apply to the Seattle application.

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

Fremont Endoscopy Center

Department Evaluation

This application does not involve construction. This sub-criterion does not apply to the Fremont application.

Seattle Endoscopy Center

Department Evaluation

This application does not involve construction. This sub-criterion does not apply to the Seattle application.

(3) The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.

Fremont Endoscopy Center

“The existing ASC uses staff and systems efficiently; PSG will continuously reevaluate its methods to ensure the most efficient and productive use of resources. PSG will continue to do so if the ASC is granted a CN” [source: Application pdf25]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

This project has the potential to continue improving the delivery of outpatient services to the residents of North King County and surrounding communities by introducing the first CN-approved multispecialty ASF in the planning area. The department is satisfied the project is appropriate and needed. **This sub-criterion is met.**

Seattle Endoscopy Center

“The existing ASC uses staff and systems efficiently; PSG will continuously re evaluate its methods to ensure the most efficient and productive use of resources . PSG will continue to do so if the ASC is granted a CN..” [source: Application pdf25]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

This project has the potential to continue improving the delivery of outpatient services to the residents of North King County and surrounding communities by introducing the first CN-approved multispecialty ASF in the planning area. The department is satisfied the project is appropriate and needed. **This sub-criterion is met.**