

STATE OF WASHINGTON DEPARTMENT OF HEALTH Olympia, Washington 98504

September 5, 2017

CERTIFIED MAIL # 7016 0910 0000 3454 9351

Rodney W. Joe, M.D. 500 Lilly Road NE, Suite 204, Olympia, Washington 98506

RE: CN Application #17-21

Dear Dr. Joe,

We have completed review of the Certificate of Need application submitted by Gastroenterology Associates, PLLC proposing to establish a three operating room ambulatory surgery center in Olympia, within Thurston County. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Gastroenterology Associates, PLLC agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a three-operating room ambulatory surgery center in Olympia, within Thurston County. The surgery center will serve patients aged 18 and older that can be served appropriately in an outpatient setting. Surgical types are limited to endoscopy and related Gastroenterology (GI) services.

Conditions

- 1. Gastroenterology Associates, PLLC agrees with the project description as stated above. Gastroenterology Associates, PLLC further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Gastroenterology Associates, PLLC will maintain Medicare and Medicaid certification, regardless of facility ownership.
- 3. Gastroenterology Associates, PLLC shall update information on their website to include the approved Financial Assistance Policy. It shall be available in the same location that the surgery center's other patient forms are located.
- 4. Gastroenterology Associates, PLLC will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent

Rodney Joe, Gastroenterology Associates CN Application #17-21 September 5, 2017 Page 2 of 2

policies reviewed and approved by the Department of Health. Gastroenterology Associates, PLLC will use reasonable efforts to provide charity care in the amount identified in the application or the planning area average, whichever is higher. These amounts are 1.88% of gross revenue and 5.48% of adjusted revenue. Gastroenterology Associates, PLLC 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.

- 5. Gastroenterology Associates, PLLC will submit a copy of the final executed medical director agreement prior to offering services as a CN-approved ASF. The agreement must be consistent with the draft provided to the department within the application.
- 6. Gastroenterology Associates, PLLC will submit a copy of the final executed management services agreement prior to offering services as a CN-approved ASF. The agreement must be consistent with the draft provided to the department within the application.

Approved Costs

There is no capital expenditure associated with this project.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above 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.

<u>Mailing Address:</u> Department of Health Certificate of Need Program Mail Stop 47852 Olympia, WA 98504-7852 <u>Physical Address</u>: Department of Health Certificate of Need Program 111 Israel Road SE Tumwater, WA 98501

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

Sincerely,

Nancy Tyson, Executive Director Health Facilities and Certificate of Need

Enclosure

EVALUATION DATED SEPTEMBER 5, 2017 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY GASTROENTEROLOGY ASSOCIATES, PLLC PROPOSING TO ESTABLISH AN AMBULATORY SURGERY CENTER IN THURSTON COUNTY

APPLICANT DESCRIPTION

Gastroenterology Associates, PLLC (GA) is an existing Certificate of Need (CN) exempt ambulatory surgical facility (ASF¹). The facility is located at 500 Lilly Road Northeast, Suite 150. It is jointly owned by seven physicians.² [sources: Application p5; April 5, 2017 screening response p1]

The facility has operated as a CN-exempt facility since 2000, with three operating rooms.³ The facility is exclusively dedicated to endoscopic gastroenterology services. [source: CN Historical Files]

It is currently licensed as an ambulatory surgical facility by the State of Washington, and is Medicare and Medicaid certified. [sources: Application p6]

PROJECT DESCRIPTION

With this application, GA proposes to convert the existing 3-OR surgery center from CN-exempt to CN-approved. This was prompted by the owners' decision to separate the clinical practice from the surgery center, and for the clinical practice to join a larger physician group. The clinical practice will enter into an operating agreement with two other clinical practices to form a new entity to be known as Washington Gastroenterology (WAGI). The ownership of the ASF will remain with GA. [source: May 23, 2017 screening response p1]

The location of the facility, the types of surgeries to be performed, and the types of patients to be served would not change as a result of this project. [source: Application p9]

¹ The facility is licensed by the Washington State Department of Health as an Ambulatory Surgical Facility. It is also certified by Medicare as an Ambulatory Surgery Center (ASC). The department will consistently refer to the facility as an ASF, though the applicant consistently refers to it as an ASF. For the purposes of Certificate of Need review, the difference is not significant.

² The physician owners include: Rodney Joe, Bruce Silverman, Kathryne Wagner, Harpreet Brar, Meimin Xie, Kristine Zhang, and David Owens,

³ For Certificate of Need purposes, any rooms dedicated to surgical services – defined in WAC 246-3330-010(47) – is referred to as an operating room or "OR." The applicant and many other providers commonly refer to operating rooms dedicate to endoscopic services as "procedure rooms." For Certificate of Need purposes, operating rooms and procedure rooms have the same meaning, and will be referred to as operating rooms or ORs throughout this evaluation.

Along with the three operating rooms, the facility includes admission and recovery space, offices, clean and soiled storage and processing, staff areas, and reception. [source: April 5, 2017 screening response Exhibit K]

The ASF would continue to serve patients that can be served appropriately in an outpatient setting. Surgical services to be provided at the ASF would be available to patients ages 18 and older. Surgical types only include endoscopy. [source: Application p9]

There is no associated capital expenditure with this project, as there is no anticipated construction costs or equipment purchases as a result of the project.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This application is subject to review as the construction, development, or other establishment of new health care facility under Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code 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

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

Action	Date
Letter of Intent Submitted	October 19, 2016
Application Submitted	December 23, 2016
Department's pre-review activities	
DOH 1st Screening Letter	January 10, 2017
Applicant's Responses Received	April 5, 2017 ⁴
DOH 2nd Screening Letter	April 26, 2017
Applicant's Responses Received	May 23, 2017
Beginning of Review	May 30, 2017
Public Hearing Conducted	N/A ⁵
Public Comments accepted through end of public comment	July 5, 2017
Rebuttal Comments Due	N/A ⁶
Department's Anticipated Decision Date	September 5, 2017
Department's Actual Decision Date	September 5, 2017

APPLICATION CHRONOLOGY

AFFECTED PERSONS

⁴ GA's first response to screening was originally due to the department on February 24, 2017. GA requested an extension to this date, which was granted.

⁵ No public hearing was requested or conducted

⁶ There were no public comments submitted for this application. As a result, no rebuttal comments could be accepted.

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.

During the course of review, one entity, Providence Health and Services (Providence), requested interested person status. Providence Health and Services owns and operates Providence Saint Peter Hospital in Olympia, Washington. This qualifies Providence as an interested person. Providence did not provide comments related to this project, and cannot qualify as an affected person.

Therefore, there are no affected persons for this project.

SOURCE INFORMATION REVIEWED

- GA's Certificate of Need application submitted December 23, 2016
- GA's screening responses received April 5 23, 2017
- GA's screening responses received May 23, 2017
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission and Nursing Quality Assurance Commission
- Compliance history for GA from the Washington State Department of Health Office of Investigation and Inspection
- DOH Provider Credential Search website: <u>http://www.doh.wa.gov/pcs</u>

- Historical charity care data for years 2013, 2014, and 2015 obtained from the Department of Hospital/Finance and Charity Care (HFCC) Financial Review
- Year 2016 Annual Ambulatory Surgery Provider Survey for Surgical Procedures Performed During Calendar Year 2015 for hospitals, ambulatory surgery centers, or ambulatory surgical facilities located in Benton and Franklin Counties
- Year 2012 OFM population estimates, medium series
- Department of Health internal database Integrated Licensing & Regulatory Systems (ILRS)
- Joint Commission website: <u>http://www.qualitycheck.org</u>
- GA website: https://www.gastroassociates.org/
- Washington State Department of Revenue website: <u>http://www.dor.wa.gov</u>
- Center for Medicare and Medicaid Services website: <u>https://www.cms.gov</u>
- Certificate of Need historical files

CONCLUSIONS

For the reasons stated in this evaluation, the application submitted by Gastroenterology Associates, PLLC proposing to establish a three-operating room ambulatory surgery center in Olympia, within Thurston County, is consistent with the applicable criteria of the Certificate of Need Program, provided Gastroenterology Associates, PLLC agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a three-operating room ambulatory surgery center in Olympia, within Thurston County. The surgery center will serve patients aged 18 and older that can be served appropriately in an outpatient setting. Surgical types are restricted to endoscopy and related Gastroenterology (GI) services.

Conditions:

- 1. Gastroenterology Associates, PLLC agrees with the project description as stated above. Gastroenterology Associates, PLLC further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Gastroenterology Associates, PLLC will maintain Medicare and Medicaid certification, regardless of facility ownership.
- 3. Gastroenterology Associates, PLLC shall update information on their website to include the approved Financial Assistance Policy. It shall be available in the same location that the surgery center's other patient forms are located.
- 4. Gastroenterology Associates, PLLC will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent policies reviewed and approved by the Department of Health. Gastroenterology Associates, PLLC will use reasonable efforts to provide charity care in the amount

identified in the application or the planning area average, whichever is higher. These amounts are 1.88% of gross revenue and 5.48% of adjusted revenue. Gastroenterology Associates, PLLC 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.

- 5. Gastroenterology Associates, PLLC will submit a copy of the final executed medical director agreement prior to offering services as a CN-approved ASF. The agreement must be consistent with the draft provided to the department within the application.
- 6. Gastroenterology Associates, PLLC will submit a copy of the final executed management services agreement prior to offering services as a CN-approved ASF. The agreement must be consistent with the draft provided to the department within the application.

Approved Costs:

There is no capital expenditure associated with this project.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department concludes that Gastroenterology Associates, PLLC has met the need criteria in WAC 246-310-210.

 (1) <u>The population served or to be served has need for the project and other services and facilities</u> 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 in an ASF.

Gastroenterology Associates, PLLC

"GA is not proposing any change to the services offered, operation, ownership makeup or staffing of the ASC. There is currently three (3) operating rooms in the ASC." [source: Application Exhibit D]

Public Comment None

Rebuttal None

Department Evaluation

The application provided documentation and statements to demonstrate the surgery center has three ORs. Information found within the department's internal database confirms that GA has been licensed for 3 ORs since 2009, when the ASF credential was created. **This sub-criterion is met.**

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

WAC 246-310-270(9) provides step-by-step instructions for calculating numeric need in a planning area.

Gastroenterology Associates, PLLC

Within their application, GA elected not to complete the numeric need methodology set out in rule, but instead provided the following information:

"This project does not address unmet health services needs. The existing ASC is currently addressing both community and clinical needs. The ASC is submitting this application in order

to convert an exempt ASC to a CN-approved ASC. No changes to the facility, services or staff are proposed with this application.

Dedicated outpatient endoscopy ASCs are deliberately excluded from the numeric methodology described in WAC 246-310-270(9). See, Mid-Columbia Endoscopy Center, LLC Certificate of Need Determination, 2010 at page 8. In its place, the Department of Health focuses on the specific need for the endoscopy services proposed in the Application. Here, there is a demonstrated need for the current ASC to continue providing services in this geographic location just as it has been for many years. [source: Application pp11-12]

Public Comment None

<u>Rebuttal</u> None

Department's Numeric Methodology and Evaluation

The numeric portion of the methodology requires a calculation of the annual capacity of the existing providers inpatient and outpatient OR's in a planning area – Thurston County.

According to the department's records, there are eight planning area providers with OR capacity. Of these providers, two are hospitals, and six are ambulatory surgical facilities.

Because there is no mandatory reporting requirement for utilization of ASFs or hospital ORs, the department sends an annual utilization survey to all hospitals and known ASFs in the state. When this application was submitted, the most recent utilization survey data available was for year 2015. The data provided in the utilization survey is used, if available.

Below, Table 1 shows a listing of the two hospitals. [source: CN historic files and ILRS]

Thurston County Hospitals			
Facility	License Number		
Capital Medical Center	HAC.FS.00000197		
Providence St Peter Hospital	HAC.FS.00000159		
[source: ILRS]			

Table 1Thurston County Hospitals

For the hospital, all known OR capacity and procedures are included in the methodology calculations for the planning area.

Table 2, below, contains a listing of the six ASFs in the planning area.

Denton-Frankini Franking Area ASFS			
Facility	License Number		
Foley Plastic Surgery Center	ASF.FS.60102721		
Gastroenterology Associates*	ASF.FS.60099811		
Laser and Surgery Center, LLC	ASF.FS.60101649		
Olympia Multi Specialty Clinic Ambulatory	ASF.FS.60100042		
Procedure Center*			
Olympia Surgery Center	ASF.FS.60320652		
Pacific Cataract and Laser Institute	ASF.FS.60101112		

Table 2Benton-Franklin Planning Area ASFs

[source: ILRS, CN historical files]

Of the six ASFs shown above, two are endoscopy facilities (designated with an asterisk). The numeric methodology deliberately excludes the OR capacity and procedures from the numeric need methodology.⁷ As a result, the ORs and procedures for these facilities will not be counted in the numeric need methodology.

Out of the remaining four ASFs within the planning area, two are located within the offices of private physicians, whether in a solo or group practice that have received an exemption (considered a Certificate of Need-exempt ASF). The use of these ASFs is restricted to physicians that are employees or members of the clinical practices that operate the facility. Therefore, these facilities do not meet the ASF definition in WAC 246-310-010. For Certificate of Need-exempt ASFs, the number of surgeries, but not ORs, is included in the methodology for the planning area. In summary, OR capacity will be counted for two Certificate of Need-approved ASFs and two hospitals.

The data points used in the department's numeric methodology are identified in Table 3. The methodology and supporting data used by the department is provided in Appendix A, attached to this evaluation.

Assumption	Data Used		
Planning Area	Thurston County		
Population Estimates and Forecasts	Age Group: 15+		

Table 3Department's Methodology Assumptions and Data

⁷ WAC 246-310-270(9)(iv)

	OFM Population Data released year 2012, medium series: Year 2015 – 217,456 Year 2020 – 236,029		
Use Rate	Divide calculated surgical cases by 2015 population results in the service area use rate of 124.306/1,000 population		
Year 2015 Total Number of Surgical Cases	10,010 – Inpatient or Mixed-Use; 17,021 – Outpatient 27,031 – Total Cases		
Percent of surgery: outpatient vs. inpatient	S. Based on DOH survey and ILRS: 62.97% outpatient; 37.03% inpatient		
Average minutes per case	Based on DOH survey and ILRS: Outpatient cases: 54.61 minutes Inpatient cases: 107.22 minutes		
OR Annual capacity in minutes	68,850 outpatient surgery minutes;94,250 inpatient or mixed-use surgery minutes(per methodology in rule)		
Existing providers/ORs	Based on listing of Thurston County Providers: 13 dedicated outpatient ORs 17 mixed use ORs		
Department's Methodology Results	Surplus of 3.43 Mixed-Use ORs		

Based on the assumptions described in Table 3, the department's application of the numeric methodology indicates a surplus of 3.43 mixed-use ORs in year 2020. The methodology and supporting data used by the department is provided in Appendix A, attached to this evaluation.

As previously stated, special purpose rooms including those dedicated to endoscopy, are specifically excluded from the numeric need methodology. Therefore, even though the numeric methodology shows a surplus of 3.43 mixed use ORs, that surplus would not be a basis to deny this application. As a result of this the department considered additional information within the application to evaluate the need for this project

Gastroenterology Associates, PLLC

GA provided the following statements related to the continued need for the endoscopy services to be provided at the existing facility.

"The ASC provides a valuable and necessary service to the growing local population in the south Puget Sound area. Since 2000, the ASC has provided essential GI procedures such as

symptomatic and screening colonoscopies, EGD and flexible sigmoidoscopy to the community. GA's experience and focus on patient care is well known throughout the region. If this project is not approved, more than nine thousand (9,000) procedures would need to be performed in other facilities." [Source: Application p12]

GA provided historical and projected utilization at the existing facility, along with a discussion of the factors used to project future procedure volumes and why these should be sustainable. [sources: Application p7; April 5, 2017 screening response p8]

mstorical and ribjec				
Year Number of				
	Procedures			
2011	8,532			
2012	8,645			
2013	8,790			
2014	8,797			
2015	9,406			
2016	9,650			
2017	9,650			
2018	9,650			
2019	9,650			
2020	9,650			

Table 4Gastroenterology Associates ASF UtilizationHistorical and Projected

"The endoscopy center is currently operating at its maximum capacity. The number of procedures that are able to be completed each year is based on the number of days the endoscopy center is able to be open (differs each year due to leap year, when holidays fall during the week, and whether there are inclement weather closures). In the last five years, Current GA's endoscopy center has been open from 248-253 days per year based on the above cited variables.

"Now that the applicant has the number of procedures completed in 2016, the applicant revises this answer from its original Certificate of Need Application and now projects that the total number of procedures for the following five (years will be 9,650 each year. This number assumes that the Endoscopy Center will continue to operate at its maximum capacity, with the actual number varying slightly because of the above stated variables.

"Continued growth of patient volume in the next five years to support the endoscopy center continuing to operate at maximum capacity is supported by Thurston County population

growth projecting an 8.3% increase in the population by 2020. Source: Washington State OFM, Postcensal Estimates of April 1 Population by Age and Sex: 2000-Present and May 2012 Projections." [source: April 5, 2017 screening response pp7-8]

Public Comments None

Rebuttal Comments
None

Department Evaluation

Again, the department recognizes the numeric methodology deliberately excludes special purpose rooms, such as endoscopy ORs. As a result, the numeric methodology should not be solely relied upon to determine need for dedicated endoscopy ORs such as those proposed in this application. The applicant provided information to support that utilization at the existing facility is at maximum capacity, and that this should continue. Furthermore, the types of procedures proposed are limited to endoscopic and GI type services. Based on the source information reviewed and GA's agreement to the conditions in the conclusions section of this evaluation, the department concludes that the applicant has demonstrated that there is need for the continued operation of their ASF.

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.

Gastroenterology Associates, PLLC

"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 we have 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 nine thousand (9,000) procedures per year would need to be performed in other facilities, and Thurston, Mason, Grays Harbor, North Pacific and Lewis County residents would experience reduced access to diagnostic and therapeutic endoscopy procedures." [source: Application p16]

"Applicant is aware of four (4) other physicians currently operating as gastroenterologists in the primary service area. They are: Marshall McCabe, M.D., Thomas O'Meara, M.D., Darien Heap, M.D., and John Kuczynski, M.D., all of whom provide services through Olympia MultiSpecialty Clinic LLP and its Ambulatory Procedure Center, Olympia Multi-Specialty Clinic Ambulatory Procedure Center. Source: Public Records." [source: Application p7]

Public Comments None

Rebuttal Comments
None

Department Evaluation

GA correctly points out that there are limited available providers in the planning area. The department agrees, and adds that the only existing outpatient surgery center providing endoscopy is Certificate of Need exempt, and is therefore not required to provide charity care.

The application also identifies that there is no proposed expansion of services; merely a continuation of the existing services. According to the historical volumes provided above in Application Table 3, the facility already provides between 8,000 and 9,000 procedures annually. There is no information to suggest that existing facilities in the planning area have the capacity to absorb these volumes, nor did any area providers provide public comment indicating that their facilities could do so.

Therefore, the department concludes that other resources in the planning area would likely not be available and accessible to absorb these volumes. Furthermore, CN approval would increase the availability and accessibility of this existing facility to planning area residents, as CN-approved ASFs are required to provide charity care and CN-exempt ASFs are not. **This sub-criterion is met.**

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

To evaluate this sub-criterion, the department evaluates an applicant's admission policy, willingness to serve Medicare patients, 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 any 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 agency'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 agency's willingness to serve low income persons and may include individuals with disabilities.

Gastroenterology Associates, PLLC

GA provided copies of the following policies:

- Admission Policy [source: Application Exhibit B]
- Patient Rights and Responsibilities [source: Application Exhibit F]
- Patient Nondiscrimination Policy [source: Application Exhibit F]

Medicare and Medicaid Programs

GA is currently Medicare and Medicaid certified. GA provided its current and projected sources of revenues by payer for the ASF in Table 5. [source: April 5, 2017 screening response p13]

Current and Projected Payer Mix			
Payer Group	Percentage		
Commercial and Contracted Insurances	51.0%		
Medicare	42.4%		
Medicaid	6.5%		
Private Pay	0.1%		
Total	100.0%		

Table 5Current and Projected Payer Mix

GA also provided the surgery center's Medicare and Medicaid numbers – AB20216 and 7107873, respectively. [source: April 5, 2017 screening response p5]

Public Comments
None

<u>Rebuttal</u> None

Department Evaluation

GA provided the existing admission, patient rights and responsibilities, and non-discrimination policies, stating they would continue to be used at the surgery center.

The 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.

The financial data provided in the application shows Medicare and Medicaid revenues consistent with Table 5 above. The department concluded that GA intends for this surgery center to continue to be accessible and available to Medicare and Medicaid patients based on the information provided. If this projected is approved, the department would attach a condition requiring that the facility remain Medicare and Medicaid certified, regardless of facility ownership. Based on the information reviewed, the department concludes **this sub-criterion is met.**

WAC 246-310-270(7)

WAC 246-310-270(7) requires that ASCs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC. For charity care reporting purposes Washington State is divided into five regions: King County, Puget Sound, Southwest, Central, and Eastern. Gastroenterology Associates is located in Thurston County within the Southwest Washington region. Currently, there are 14 hospitals operating in the region. Of those, two hospitals⁸ are within the planning area and could be affected by approval of this project.

GA projected that the ASF will provide charity care at 1.88% of total revenue and 5.48% of adjusted revenue. For this project, the department reviewed the most recent three years of charity care data for the 14 existing hospitals currently operating within the Southwest Washington Region and focused on the two acute care hospital located in the planning area. The three years reviewed are 2013, 2014, and 2015.⁹ Table 6 below is a comparison of the historical average charity care for the Southwest Washington Region as a whole, the historical average charity care in Thurston County, and the projected charity care to be provided at the proposed ASF. [sources: Community Health Systems Charity Care 2013-2015, May 23, 2017 screening response p3]

Table 6			
Charity Care – Three Year Average			

% of Total % of Adjus				
	Revenue	Revenue		

⁸ Capital Medical Center and Providence St Peter Hospital

⁹ As of the writing of this evaluation, year 2016 charity care data is not yet available

3-year Southwest Region ¹⁰	2.16%	5.90%
3-year Thurston County	1.88%	4.74%
Projected Gastroenterology Associates	1.88%	5.48%

As shown above, the three year regional average proposed by GA is consistent with the Thurston County planning area 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. Though the application shows that GA intends to provide charity care within range of the regional average and local average, the department would still attach a condition related to this sub-criterion if this project is approved. The condition would require GA to make reasonable efforts to provide charity care at the levels stated in the application, or the planning area average – whichever is higher. This condition would also require GA to maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department would require that these records be available upon request.

The department would also attach a condition requiring that GA ensure that its financial assistance policy is available and accessible to all patients by posting it on their website, in the same location as patient forms and information.

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

¹⁰ Ocean Beach Hospital did not report timely in 2013 or 2014

- (3) The applicant has substantiated any of the following 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 no residing in the health service areas in which the entities are located or in adjacent health service areas.

Department Evaluation

This 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.

<u>Department Evaluation</u> This criterion is not applicable to this application.

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

<u>Department Evaluation</u> This 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 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.

<u>Department Evaluation</u> This 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 criterion is not applicable to this application.

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

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

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

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

Gastroenterology Associates, PLLC

The assumptions used by GA to determine utilization and the projected number of procedures for its first three full years of operation as a CN-approved ASF are shown below. [source: April 5, 2017 screening response pp2, 7-8, 11-12]

"The endoscopy center is currently operating at its maximum capacity. The number of procedures that are able to be completed each year is based on the number of days the endoscopy center is able to be open (differs each year due to leap year, when holidays fall during the week, and whether there are inclement weather closures). In the last five years, Current GA's endoscopy center has been open from 248-253 days per year based on the above cited variables.

"Now that the applicant has the number of procedures completed in 2016, the applicant revises this answer from its original Certificate of Need Application and now projects that the total number of procedures for the following five (years will be 9,650 each year. This number assumes that the Endoscopy Center will continue to operate at its maximum capacity, with the actual number varying slightly because of the above stated variables. "Continued growth of patient volume in the next five years to support the endoscopy center continuing to operate at maximum capacity is supported by Thurston County population growth projecting an 8.3% increase in the population by 2020. Source: Washington State OFM, Postcensal Estimates of April 1 Population by Age and Sex: 2000-Present and May 2012 Projections."

"The endoscopy center financials are currently (internally) separated in regard to the aspects below. This has been the case since the endoscopy center's inception and will remain separate following approval of the Certificate of Need. There is no expectation that the Endoscopy Center financials will change due to the separation of Endoscopy Center and Clinical Practice.

Assumptions that factor into the Pro Forma Financial Statements (based on past history) regarding volume of services include:

- Maintaining the same capacity in terms of hours of operation:
 - Monday-Friday business week and 30-minute single procedure/45-minute double procedure appointments.
 - There is no plan to change hours, business days of the week or procedure appointment time allowances.
- Maintaining stable patient volumes and utilization of services:
 - Procedure volumes were steadily maintained between from 2009-2014 at 8500-8800 procedures annually, then increased to 9406 in 2015 and 9657 in 2016 (increases were due to an extension of business hours which started in July 2015). No further change in hours is planned.
 - Historically the Center has had a 90-92% utilization rate of procedure slots, unutilized slots being due to no-shows and late cancellations (day prior) which cannot be filled on short notice due to preparations required for procedures.
 - Endoscopy Center has a stable and large primary care and specialty referral base as well as a procedure recall base (for surveillance) which was formed over the past 16 years of business.
 - Endoscopy Center accepts a broad range of insurances including Medicare and Medicaid.
 - The Center is approved by CMS and WA State DOH ASF Survey.
 - The Thurston-Mason county areas continue to expand in population, so presumably the need for GI services will continue to increase.
 - Colonoscopy remains the gold standard for colon cancer screening and polyp removal as well as for surveillance in patients with certain medical conditions."

The assumptions GA used to project revenue, expenses, and net income for the proposed surgery center for projection years 2018-2020 are summarized below. [source: April 5, 2017 screening response pp11-13; May 23, 2017 screening response p3]

"The Pro Forma Financial Statement included as Attachment F shows financial predictions for the Endoscopy Center for four years. The financial predictions are made based on a variety of assumptions provided below. However, it is important to note that these assumptions are based on actual numbers and how the Endoscopy Center is run today, as there are no significant changes anticipated after the separation of Endoscopy Center and Clinical Practice.

- Procedure costs increase annually. This is based on predictable and unpredictable increases in a variety of fixed and variable expenses such as building lease, employee cost-of-living raises, benefits, supply costs, equipment purchases, new regulations that increase requirements, etc.
 - Itemized expenses for the Center have increased annually over the past 3 years as follows (The large increase from 2014 to 2015 correlates with expanding Center hours in July 2015):
 - *2014: \$2,722,359*
 - **2015:** \$3,147,036
 - **2016:** \$3,310,485
 - Cost per procedure has increased annually over the past 3 years as follows:
 - 2014: \$310
 - *2015: \$335*
 - **2016:** \$344
- Procedure charges will remain stable and possibly increase slightly. Charges are variable per negotiated payer contracts. Contracts are negotiated from the starting point of 1.1 x the highest payer allowable for each CPT (current procedural terminology) for the facility fee and of the highest current RYU multiplied by 80. Payer contracts are typically 2-3 years in term and typically auto-renew at the end of a term. Center charges, payments and adjustments history for the past 3 years (shown below) outlines a steady increase in charges, payments and adjustments as allowables increase:

Year	Charges	Payments	Adjustments
2014	\$20,136,779	\$7,961,806	\$12,145,840
2015	\$21,805,625	\$8,464,768	\$13,328,866
2016	\$23,676,785	\$8,667,501	\$14,570,655

• The projected budgeted charity care (percentage of total and adjusted revenue budgeted for charity care), for Year 1, Year 2, Year 3, and Year 4 of the Endoscopy Center is noted in the table below. Note that charitable services have decreased

significantly (for Applicant and for other medical providers such as Providence St. Peter Hospital) due to the dramatic increase of insured patients due to the Affordable Care Act.

	Year 1	Year 2	Year 3	Year 4
Charity Care	\$333,879	\$337,218	\$340,590	\$343,996
Gross Charity Care %	1.88%	1.88%	1.88%	1.88%
Adjusted Charity Care %	5.48%	5.48%	5.48%	5.48%

- No significant change in bad debt write-offs is anticipated.
- Staffing services will be leased from WAGI to Gastroenterology Associates LLC pursuant to the Management Services Agreement."

GA's projected revenue, expenses, and net income for the proposed ASF are shown in Table 7 below. [source: Application Exhibit 15]

	CY2017	CY2018	CY2019	CY2020	
	(current year)	(year one)	(year two)	(year three)	
Net Revenue	\$8,741,367	\$8,828,780	\$8,917,068	\$9,006,239	
Total Expenses	\$3,541,909	\$3,624,287	\$3,709,315	\$3,794,969	
Net Profit/(Loss)	\$5,199,458	\$5,204,493	\$5,207,753	\$5,211,270	
Net Profit/(Loss) per Procedure	\$538.80	\$539.33	\$539.66	\$540.03	

Table 7Projected Revenue and Expenses Years 2017 through 2020

The "Net Revenue" line item is gross patient revenue, minus any deductions from revenue for contractual allowances, bad debt, and charity care. The "Total Expenses" line item includes operating expenses, including salaries and wages, benefits, insurance, rentals and leases, and depreciation.

Public Comment None

<u>Rebuttal</u> None

Department Evaluation

To evaluate this sub-criterion, the department first reviewed the assumptions used by GA to determine the projected number of procedures and occupancy of the ASF. As an existing facility, using existing volumes to project future utilization is an appropriate approach. Furthermore, the applicant made adjustments for inclement weather, holidays, and no-shows. These adjustments were also based on existing patterns at the surgery center. Considering that

GA does not intend to expand the number of ORs or change the type of surgeries to be performed, the department concludes that the volume projections within the application are reasonable.

Consistent with the volume assumptions, GA based its revenue and expense assumptions on the existing operations of the CN-exempt surgery center. This includes all leases and purchased services. Slight adjustments to revenues and expenses were made in the projection years based on past experience. GA also adjusted charity care to be consistent with the planning area average during the forecast period. This is reasonable.

GA provided the executed lease agreement and three amendments between Memorial Medical Plaza and Gastroenterology Associates. The lease identifies the roles and responsibilities for each. The lease commenced in 2009, and has been extended through 2020; the lease also has an option to renew for an additional period of five years. All costs associated with the lease are substantiated in the revenue and expense statement. [source: Application Exhibit E; April 5, 2017 screening response Exhibit L]

GA provided a draft medical director agreement that identifies Kathryne Wagner, MD as the medical director. The agreement outlines the roles, responsibilities, and compensation for the medical director. These costs are consistent with those found in the revenue and expense statement. If this project is approved, the department would attach a condition requiring GA to provide the executed version of this agreement, consistent with the draft.

GA provided a draft management services agreement between WAGI and GA, which is for the purpose of leasing staffing services to GA. The cost associated with this agreement is identified, and can be substantiated within the pro forma financial statements. The term of the agreement is for four years, and has an "evergreen clause," meaning it shall continue to renew annually indefinitely until it is severed by either party. If this project is approved, the department would attach a condition requiring GA to provide the executed version of this agreement, consistent with the draft. [source: May 23, 2017 screening response p5, Exhibit C]

Based on the information above and GA's agreement to the identified conditions, the department concludes that the immediate and long-range operating costs of the project can be met. **This sub-criterion is met.**

(2) <u>The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.</u>
 WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on

costs and charges would be for a project of this type and size. Therefore, using its experience

and expertise the department compared the proposed project's costs with those previously considered by the department.

Gastroenterology Associates

"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 p19]

Public Comment None

<u>Rebuttal</u> None

Department Evaluation

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

Deput intent Sulculuit	Department Culculation of Gross Charges per Case									
	2018	2019	2020							
Gross Revenue	\$17,919,026	\$18,098,216	\$18,279,198							
Number of Procedures	9,650	9,650	9,650							
Gross Revenue (charges) per Procedure	\$1,856.89	\$1,875.46	\$1,894.22							

Table 8Department Calculation of Gross Charges per Case

As shown above, the difference in gross charges year by year is fairly small, and has already been explained to be based on changes in costs under the previous section of this evaluation.

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

Based on the above information, the department concludes that the establishment of GA as a CN-approved ASF would likely not have an unreasonable impact on the costs and charges for healthcare services in Thurston County. **This sub-criterion is met**

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

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-

310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

Gastroenterology Associates

"No financing is required for this project." [source: Application p19]

Public Comments None

<u>Rebuttal</u> None

Department Evaluation

As stated above, there are no capital expenditures associated with this project. The facility is already operational. Therefore, this sub-criterion is not applicable for GA.

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

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

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

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

Gastroenterology Associates

"No change in staffing is anticipated as a result of CN approval except for the fact that staffing services will now be leased from WAGI" [source: Application p21]

The current and projected staffing is shown below.

Table 9							
Current	t and Projecte	d Staffing 2	018-2020				
Staff Type	CURRENT	2018	2019	2020			

RNs	9.0	9.0	9.0	9.0
LPNs	5.3	5.3	5.3	5.3
GI Assistants	6.0	6.0	6.0	6.0
Front Desk	1.2	1.2	1.2	1.2
Histology Tech	1.2	1.2	1.2	1.2
Total	22.7	22.7	22.7	22.7

As stated above under WAC 246-310-210(1), GA provided a draft medical director agreement as well as a management services agreement. GA offers the following rationale for choosing to lease staffing services from the clinical practice:

"Leasing the Endoscopy Center staffing services through WAGI will provide many economies of scale benefits which are beneficial from a financial and a staff and system productivity and efficiency standpoint. These benefits include, but are not limited to: allowing for employee benefits premiums (i .e., medical, dental, life/disability) to be based on a much larger pool of employees, thereby potentially significantly decreasing rates and/or shared benefits costs to the employee; increasing retirement planning options (i.e., 401k) due to a larger member pool; shared administration of timeclock, payroll, W-4, FMLA and other payroll related service administration; and shared human resource policy development, review and revision." [source: April 5, 2017 screening response p18]

Public Comment None

<u>Rebuttal</u> None

Department Evaluation

As shown above, GA does not anticipate any difficulties in recruiting staff, as the staff are already in place. This is reasonable, as the utilization of the facility is not projected to change as a result of the project.

Consistent with the condition under WAC 246-310-210(1), if this project is approved, the department would attach conditions requiring GA to submit executed copies of the Medical Director Agreement and Management Services Agreement, consistent with the drafts provided in the application.

Based on the above information and agreement to the conditions, the department concludes that a sufficient supply of qualified staff is available for this project. This sub-criterion is met.

(2) <u>The proposed service(s) will have an appropriate relationship, including organizational</u> <u>relationship to ancillary and support services, and ancillary and support services will be</u> <u>sufficient to support any health services included in the proposed project.</u>

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

Gastroenterology Associates, PLLC

"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." [source: Application p21]

"Current GA utilizes the following ancillary and support services. It is anticipated that Endoscopy Center will utilize the same ancillary and support services:

- Radiology
 - GA at times send patients with incomplete colonoscopy to radiology for a barium enema. GA uses TRA and South Sound Radiology, both of which accept Medicare and Medicaid.
- Pathology
 - GA has its own Histology Lab to plate specimens taken during the endoscopy procedures. However, the specimens then are sent to a pathology service for the pathology read that accepts Medicare/Medicaid ..
- Lab
 - GA, in extremely rare circumstances, will utilize a lab for blood testing following endoscopy. GA utilized Paclab for this service. Paclab accepts Medicare/Medicaid.

Please note that the above ancillary and support services are currently in use by Current GA (the current entity) and will continue to be used by Endoscopy Center, assuming receipt of the CN." [source: April 5, 2017 screening response p17]

GA provided an executed copy of an emergency patient transfer agreement between GA and Providence St Peter Hospital. [source: April 5, 2017 screening response Exhibit H]

Public Comment None <u>Rebuttal</u> None

Department Evaluation

GA has been providing healthcare services in Thurston County for many years.

All ancillary and support services are already in place, and GA provided examples of the existing services. GA does 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 GA will continue to maintain the necessary relationships with ancillary and support services if this project is approved. **This sub-criterion is met.**

(3) <u>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.</u> WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare and Medicaid certified. 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.

Gastroenterology Associates, PLLC

"GA 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."

"The ASC currently is and will continue to be operated in a manner that ensures safe and adequate care, and in accord with applicable federal and state laws, rules and regulations." [source: Application p22]

Public Comment None

<u>Rebuttal</u> None

Department Evaluation

Gastroenterology Associates has been in operation for many years. As a part of this review, the department must conclude that the proposed services provided at the ASF would be provided in a manner that ensures safe and adequate care to the public.¹¹ To accomplish this task, the department reviewed the quality of care compliance history for the facility, shown below. [source: DOH Office of Investigations and Inspections]

Table 10
Gastroenterology Associates Compliance

Facility Name	License Number	Surveys Since 2014	Substantially Compliant?
Gastroenterology Associates	ASF.FS.60099811	2	Yes

In addition to the facilities identified above, the department also reviewed the compliance history of the physicians associated with GA. The table below shows the 10 physicians and their credential status. [source: Application pp6-7, Medical Quality Assurance Commission]

Gastroenterology Associates Physicians									
Name	Credential Number	License Status							
Harpreet Brar, MD	MD00031629	Active							
Mark Cumings, MD	MD00042468	Active							
Rodney Joe, MD	MD00031073	Active							
Benjamin Merrifield, MD	MD00044510	Active							
William Mitchell, MD	MD00022796	Active							
David Owens, MD	MD00043136	Active							
Bruce Silverman, MD	MD00023325	Active							
Kathryne Wagner, MD	MD00029477	Active							
Meimin Xie, MD	MD00047414	Active							
Kristine Zhang, MD	MD00045083	Active							

Table 11 Gastroenterology Associates Physicians

As shown above, all physicians associated with Gastroenterology Associates have active credentials in good standing. Based on the information above, the department concludes that Gastroenterology Associates 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.**

¹¹ WAC 246-310-230(5)

(4) <u>The proposed project will promote continuity in the provision of health care, not result in an</u> <u>unwarranted fragmentation of services, and have an appropriate relationship to the service</u> 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 be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Gastroenterology Associates

"The ASC already exists; thus, its continuation as a CN-approved facility will promote continuity in the provision of health care to the defined population and avoid unwarranted fragmentation of services. It is only if this project is not approved that continuity would be interrupted and fragmentation would occur." [source: Application p21]

Public Comment None

<u>Rebuttal</u> None

Department Evaluation

Information in the application demonstrates that as a long-time provider of outpatient surgical services, and that GA has the infrastructure in place to continue operations. The application identifies that the only fragmentation of services that could occur would be if the facility were to discontinue operations.

GA provided information within the application to demonstrate it intends to continue existing relationships, and that these relationships are adequate to support services to be provided. This includes the executed transfer agreement between GA and Providence St Peter 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) <u>There is reasonable assurance that the services to be provided through the proposed project</u> will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

Department Evaluation

This sub-criterion is evaluated in sub-section (3) above, is met

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

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

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

To determine if a proposed project is the best alternative, in terms of cost, efficiency, or effectiveness, the department takes a multi-step approach. First the department determines if the application has met the other criteria of WAC 246-310-210 thru 230. If the project has failed to meet one or more of these criteria then the project cannot be considered to be the best alternative in terms of cost, efficiency, or effectiveness as a result the application would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, the department then 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. The adopted superiority 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 type superiority 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.

Department Evaluation

Step One:

The department concluded that Gastroenterology Associates, PLLC met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two.

Step Two:

Gastroenterology Associates

The applicant only considered two options – the requested project, and to do nothing, described below:

"The alternative to applying for a CN to operate the Endoscopy Center is to do nothing. If Current GA does nothing, then upon the division of the Clinical Practice from the Endoscopy Center, the endoscopy center, without a CN obtained, will have to close. Clinical Practice is joining WAGI as a member, and WAGI will not accept any ambulatory surgery centers. If the endoscopy center closes, then more than nine thousand (9,000) people will not be able to receive necessary gastrointestinal procedures every year in Thurston County, Washington." [source: April 5, 2017 screening response pp17-18]

Public Comment None

<u>Rebuttal</u> None

Department Evaluation

Information provided within the application demonstrates that GA holds a significant market share in Thurston County, and that it is also a long-standing resource for patients in other counties. GA also correctly points out that they cannot continue to operate as a CN-exempt facility if the clinical practice and the surgery center separate. Based on this alone, GA appropriately rejected the "do nothing" option.

The statements provided in relation to this sub-criterion can be substantiated, and the department did not identify any alternatives that would be superior in terms of cost, efficiency, or effectiveness. The department concurs that the requested project is reasonable and is the best option presented by GA for the planning area and surrounding communities. **This sub-criterion is met.**

Department Evaluation

Step Three:

This step is applicable only when there are two or more approvable projects. Gastroenterology Associates' application is the only application under review to add outpatient surgical capacity in the Thurston County secondary health service planning area. Therefore, this step does not apply.

Based on the information stated above, this sub-criterion is met.

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

(a) <u>The costs, scope, and methods of construction and energy conservation are reasonable;</u>

Gastroenterology Associates, PLLC

As stated in the project description portion of this evaluation, this project does not involve construction. This sub-criterion is not applicable to this application.

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

Gastroenterology Associates, PLLC

As stated in the project description portion of this evaluation, this project does not involve construction. This sub-criterion is not applicable to this application

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

Gastroenterology Associates, PLLC

"The existing ASC uses staff and systems efficiently; we continuously re-evaluate om methods to ensure the most efficient and productive use of resources. We will continue to do so if the ASC is granted a CN." [source: Application p22]

Public Comment None

<u>Rebuttal</u> None

Department Evaluation

Based on information provided within the application, and evaluated under WAC 246-310-210 and 230, the department is satisfied that his project is appropriate and needed. This project has the potential to improve the delivery of health services. As of the date of this evaluation, there are limited options for outpatient endoscopy in Thurston County, and this would be the first CN-approved dedicated outpatient endoscopy center in the county. This will increase availability and accessibility of outpatient endoscopy services to all patients within the county, especially those reliant on charity care. The department concludes that this project will appropriately improve the delivery of health services. **This sub-criterion is met.**

APPENDIX A



APPENDIX A ASC Need Methodology Thurston County

			Exempt or	Special Procedure	Dedicated Inpatient	Dedicated Outpatient	Mixed Use	Inpatient	Inpatient Cases in Mixed Use		Outrations		0	
Facility	License Number	Zip Code	Approved?	Rooms	ORs	Outpatient ORs	ORs	min/case	ORs	Inpatient Mins. In Mixed Use ORs	Min/Case	Outpatient Cases		Data Source
Providence Saint Peter Hospital	HAC.FS.00000159	98506					10	101.0	7.818	789.920				2016 survey for 2015 info
South Sound Surgery Center	HAC.FS.00000159	98506				5			.,		52	3,975	207.110	2016 survey for 2015 info
Capital Medical Center	HAC.FS.00000197	98502	N/A	1			7	129.3	2,192	283,378	68	2,562		2016 survey for 2015 info
Gastroenterology Associates	ASF.FS.60099811	98506	Exempt						Y ONLY, NOT C					
Olympia Multi Specialty Clinic Ambulatory Proced		98502					El	NDDOSCOP	Y ONLY, NOT C	COUNTED				
Pacific Cataract and Laser Institute	ASF.FS.60101112	98506				2					50.0	2,003		2016 survey for 2015 info
Laser and Surgery Center, LLC	ASF.FS.60101649	98503				2					50.0	3,200	160,000	ILRS
Foley Plastic Surgery Center	ASF.FS.60102721	98506				1					122.0	281	34,271	2016 survey for 2015 info
Olympia Surgery Center	ASF.FS.60320652	98502	Approved			6					51.0	5,000	255,060	2016 survey for 2015 info and ILRS
Totals				1	0	16	17	230.3	10,010	1,073,298		17,021	929,579	
								Avg min/cas	se inpatient	107.22	Avg min/cas	se outpatient	54.61	
ORs counted in numeric methodology						13	17							
ILRS: Integrated Licensing & Regulatory System														
Population data source: Claritas 2016														
Total Surgeries				27,031										
Area population 2015 [0-85+]				217,456										
Use Rate				124.306										
Planning Area projected 0-85+ population Year: 20	20			236,029										
				62.05-1										
% Outpatient of total surgeries				62.97%										
% Inpatient of total surgeries				37.03%										



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Servic	e Area Pop	oulation: 2020	236,029	OFM	15+							
Surge	ries @ 124	.306/1,000:	29,340									
a.i.	94,250	minutes/year/	/mixed-use OR									
a.ii.	68,850	minutes/year/	dedicated outpation	ent OR								
a.iii.	13	dedicated out	tpatient OR's x 68,	850 minute	es =	895.050	minutes de	edicated OF	R capacity	16.389	Outpatient	surgeries
										,	e alpanent	Guigenee
a.iv.	17	mixed-use Of	R's x 94,250 minut	es =		1,602,250	minutes m	nixed-use O	R capacity	14,943	Mixed-use	surgeries
b.i. projected inpatient surgeries =			10,865				patient sure					
	projecte	d outpatient su	irgeries =	18,475	=	1,008,975	minutes o	utpatient su	rgeries			
b.ii.	Forecas		nt surgeries - capa					· ·				
		18,475	-	16,389	=	2,086	outpatient	surgeries				
b.iii.	average	time of inpatie	ent surgeries		=	107.22	minutes					
-	Ŭ	time of outpat			=		minutes					
b.iv.		t surgeries*ave			=	1,164,969						
	remainir	ng outpatient s	urgeries(b.ii.)*ave	time	=		minutes					
						1,278,893	minutes					
c.i.	if b.iv. <	a.iv divide (a	a.ivb.iv.) by 94,25	i0 to determ	nine surolu	s of mixed-u	se OR's					
•												
		1,602,250										
	-	1,278,893										
		323,357	/	94,250	=	3.43						
					04.050.4			(; , op				
c.ii.			patient part of b.iv				ortage of in	ipatient OR	S			
		1,164,969			use resul							
	-	1,602,250										
		(437,281)	/	94,250	=	-4.64						
	divide o		of b.iv. By 68,850 to					OR's				
		113,925	/	68,850	=	1.65						