



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

August 28, 2017

CERTIFIED MAIL # 7016 3010 0001 0575 1492

Mark Johnson, RN Office Manager
Digestive Disease and Endoscopy Center
3261 NW Mount Vintage Way, Suite 221
Silverdale, WA 98383 - 6039

CN: 17-30

Dear Mr. Johnson:

We have completed review of the Certificate of Need application submitted by Digestive Disease and Endoscopy Center proposing to establish a three operating room ambulatory surgery center in Silverdale, within Kitsap 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 Digestive Disease and Endoscopy Center agrees to the following in its entirety.

Project Description

This certificate approves Digestive Disease and Endoscopy Center to convert the three room Certificate of Need exempt ASF located at 3261 NW Mount Vintage Way, Suite 221 within the city of Silverdale [98383-6039] in Kitsap County to Certificate of Need approved. Digestive Disease and Endoscopy Center is approved to provide endoscopy and related Gastroenterology (GI) services to patients who are not expected to require hospitalization and can be served appropriately in an outpatient setting.

Conditions

1. Digestive Disease and Endoscopy Center agree with the project description as stated above. Digestive Disease and Endoscopy Center 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. Digestive Disease and Endoscopy Center will maintain its Medicare and Medicaid certification throughout the life of the facility, regardless of ownership.

3. Digestive Disease and Endoscopy Center will provide charity care in compliance with the charity care policy provided in the application, or any subsequent policies. Digestive Disease and Endoscopy Center will use reasonable efforts to provide charity care in the amount identified in the application, or the planning area average – whichever is higher. Currently, the planning area average is 1.75% of gross revenue and 4.95% of adjusted revenue. Digestive Disease and Endoscopy Center will maintain records of charity care amount provided by Digestive Disease and Endoscopy Center documenting the amount of charity care its provides and demonstrating compliance with its charity care policies.

Approved Costs

The approved capital expenditure for this project is \$73,889.

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:

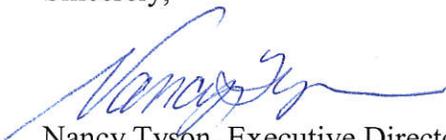
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

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 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 AUGUST 28, 2017, FOR THE CERTIFICATE OF NEED
APPLICATION SUBMITTED BY DIGESTIVE DISEASE AND ENDOSCOPY CENTER
PROPOSING TO ESTABLISH A NEW AMBULATORY SURGICAL FACILITY IN KITSAP
COUNTY SECONDARY HEALTH SERVICES PLANNING AREA**

APPLICANT DESCRIPTION

Digestive Disease and Endoscopy Center is a Certificate of Need exempt ambulatory surgical facility (ASF¹) located at 3261 NW Mount Vintage Way, Suite 221 within the City of Silverdale [98383-6039] in Kitsap County. The facility is certified by the Centers for Medicare and Medicaid Services and accredited by the Accreditation Association for Ambulatory Health Care for Ambulatory Health Care, Inc.² On May 31, 2012, in a Determination of Reviewability decision, the department exempted Digestive Disease and Endoscopy Center from Certificate of Need review. Digestive Disease and Endoscopy Center has three operating rooms³, two of which are currently being used. According to the organizational chart provided within this application, the ownership breakdown shows that Dr. Pankaj Sharma is Digestive Disease and Endoscopy Center Chairman and owns 33%, Dr. Yuen San Yee is the CEO and owns 33%, and Dr. Narendra Siddaiah is the CMO, CAO and owns 33%.

[Source: Application, Pages 2- 6 and Exhibit 1; and DOR decision May 31, 2012]

PROJECT DESCRIPTION

Digestive Disease and Endoscopy Center proposes to convert their three room Certificate of Need exempt ASF to a Certificate of Need approved ASF. Digestive Disease and Endoscopy Center currently provides endoscopy and related Gastroenterology (GI) services and is not proposing any changes to its ownership or existing services or practices. [Source: Application, page 6-9] The capital expenditure associated with the project is \$73,889. Of this amount \$58,600 or 79.3 % is related to moveable equipment, \$9,500 is for the installation of this equipment, and the remaining \$5,789 or 7.8% is for sales tax. [Source: Application Page 19]

If this project is approved, Digestive Disease and Endoscopy Center anticipates the project would become operational by the end of October 2017. Under this timeline, year 2018 would be the facility's first full calendar year of operation and 2020 would be year three. [Source: Application Page 9 and Supplemental information received May 10, 2017, page 1]. For ease of reference within this evaluation, the department would refer to Digestive Disease and Endoscopy Center as 'DDEC'.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the construction, development, or other establishment of a new healthcare facility under Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

¹ The Washington State Department of Health licenses Ambulatory Surgical Facilities – ASFs. The Centers for Medicare and Medicaid Services certify Ambulatory Surgery Centers – ASCs. It is not uncommon for a facility to be both an ASF and an ASC. Though the department will refer to this facility as an ASF, it is also an ASC, and the applicant refers to it as such.

²The Accreditation Association for Ambulatory Health Care (AAAHC) is a private, non-profit organization formed in 1979. AAAHC currently accredits more than 6,000 organizations in a wide variety of ambulatory health care settings including ambulatory surgery centers, community health centers, medical and dental group practices, medical home practices, and managed care organizations, as well as Indian and student health centers, among others. AAAHC accreditation for ASCs holds Medicare deemed status from the Centers for Medicare and Medicaid Services (CMS). [Source: AAAHC website]=

³ For Certificate of Need purposes, operating rooms and procedure rooms are the same thing.

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:

“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 ASF 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.

APPLICATION CHRONOLOGY

Action	Digestive Disease and Endoscopy Center
Letter of Intent Submitted	December 27, 2016
Application Submitted	February 21, 2017
Department’s Pre-review Activities including <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant’s 1st Screening Responses Received • DOH 2nd Screening Letter • Applicant’s 2nd Screening Responses Received 	March 14, 2017 May 10, 2017 ⁴ N/A N/A
Beginning of Review	May 22, 2017
End of Public Comment <ul style="list-style-type: none"> • Public comments accepted through⁵ • Public hearing conducted⁶ • Rebuttal Comments Received 	June 28, 2017 N/A N/A
Department's Anticipated Decision Date	August 28, 2017
Department's Actual Decision Date	August 28, 2017

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(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.*

⁴ DDEC requested extension to the timeline to submit screening responses. Responses were due on April 28, 2017.

⁵ The department did not receive any public comment therefore; DDEC did not provide rebuttal comment.

⁶ The department did not conduct a public hearing.

Providence Health & Services

Providence Health & Services asked to be informed of the department's decision, however Providence Health Services does not meet the definition of an "interested person" under WAC 246-310-010(34). Providence does not provide services in Kitsap County, it has not submitted a letter of intent to do so within the last twelve months, it is not a third-party payer, and there is no information available to suggest that Providence "uses" the services within the geographic area – Kitsap County. Without first qualifying as an interested person, Providence cannot qualify as an affected person.

SOURCE INFORMATION REVIEWED

- Digestive Disease and Endoscopy Center Certificate of Need application received on February 21, 2017.
- Digestive Disease and Endoscopy Center screening responses received on May 10, 2017.
- 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 Kitsap County secondary health services planning area.
- Department of Health's Integrated Licensing and Regulatory System [ILRS] data obtained for ambulatory surgery centers or ambulatory surgical facilities located in Kitsap County secondary health services planning area.
- OFM Medium Series Population Data
- Historical charity care data obtained from Department of Health Office of Community Health Systems, Charity Care and Hospital Financial Data Program.
- Licensing data provided by the Medical Quality Assurance Commission
- The Accreditation Association for Ambulatory Health Care www.aaahc.org

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Digestive Disease and Endoscopy Center proposing to convert the three operating rooms Certificate of Need exempt ASF to Certificate of Need approved in Silverdale with Kitsap County secondary Health services planning area is consistent with applicable criterion of the Certificate of Need is Program provided Digestive Disease and Endoscopy Center agree to the following conditions.

Project Description:

This certificate approves Digestive Disease and Endoscopy Center to convert the three room Certificate of Need exempt ASF located at 3261 NW Mount Vintage Way, Suite 221 within the city of Silverdale [98383-6039] in Kitsap County to Certificate of Need approved. Digestive Disease and Endoscopy Center is approved to provide endoscopy and related Gastroenterology (GI) services to patients who are not expected to require hospitalization and can be served appropriately in an outpatient setting.

Conditions:

1. Digestive Disease and Endoscopy Center agree with the project description as stated above. Digestive Disease and Endoscopy Center 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. Digestive Disease and Endoscopy Center will maintain its Medicare and Medicaid certification throughout the life of the facility, regardless of ownership.

3. Digestive Disease and Endoscopy Center will provide charity care in compliance with the charity care policy provided in the application, or any subsequent policies. Digestive Disease and Endoscopy Center will use reasonable efforts to provide charity care in the amount identified in the application, or the planning area average – whichever is higher. Currently, the planning area average is 1.75% of gross revenue and 4.95% of adjusted revenue. Digestive Disease and Endoscopy Center will maintain records of charity care amount provided by Digestive Disease and Endoscopy Center documenting the amount of charity care its provides and demonstrating compliance with its charity care policies.

Approved Cost:

The approved capital expenditure for this project is \$73,889.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed, and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Digestive Disease and Endoscopy Center project has met the need WAC 246-310-210 and WAC 246- 310- 270

- (1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

WAC 246-310-270(6)

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

Digestive Disease and Endoscopy Center

“DDEC has three procedure rooms.” [Sources: Application, page 6, Exhibit 4]

Public Comment

None

Rebuttal

None

Department Evaluation

DDEC has three procedure rooms but the application states that only two are currently used. DDEC intends to use all three procedure rooms. A review of the facility floor layout submitted in the application confirmed it has three operating rooms. [Sources: Exhibit 4] **This sub-criterion is met.**

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

The methodology in WAC 246-310-270(9) divides Washington States into 54 secondary health services planning areas. The numeric methodology provides a basis of comparison for existing operating room (OR) capacity for both outpatient and inpatient ORs in a planning area using the current utilization of existing providers.

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 rooms in the planning area, it subtracts this capacity from the forecasted number of surgeries expected in the planning area in the target year, and it 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 operating rooms and procedures.

Digestive Disease and Endoscopy Center Application of the Numeric Methodology

- *“This project does not address an “unmet” need for additional new ORs per se, but rather positions DDEC to support non-owner gastroenterologists in performing endoscopies in a lower cost freestanding ASC setting”.* [Source: Application page 11]

- “Consistently, in its recent endoscopy ASC decision, the CN Program has employed a two-step methodology for evaluating need. In the first step, the CN Program employed the numeric methodology outlined in WAC 246-310-270(9) for determining the need for additional general ASC’s in Washington State. The methodology separate Washington State into 54 secondary health services planning, and DDEC is located in the Kitsap County Secondary Health Services Planning Area (Kitsap)”. [Source: Application page 11]
- “In the case of endoscopy or GI ASCs, after performing this Step 1 calculation, the CN Program employs a “Step 2”, because: The department recognizes the numeric methodology deliberately excludes special purpose rooms, such as endoscopy ORs.⁷” [Source: Application page 12]
- “Using survey data collected by the CN Program, DDEC identified six facilities providing surgery services. This includes one hospital and five free standing facilities (including 3 that are CN approved). The existing hospital, Harrison Medical Center, has a total of 12 ORs (on its two campuses). Two ASCs operating as ‘exempt’, including the applicant, do not meet the definition of free standing ASC as defined in WAC 246-310-010 and therefore are not included in the count of current supply”. [Source: Application page 12]
- “Available data from all ORs in Kitsap results in a calculation of a Kitsap County OR use rate of 109.32 per 1,000 population. The projected Kitsap County planning area population in 2020 is 275,546. Applying the use rate to the projected population and subtracting the existing surgery capacity in the planning area, results in no need for additional dedicated outpatient ORs in Kitsap County. A copy of the methodology and all of underlying assumptions is included in Exhibit 6.” [Source: Application page 12]
- “2016 patient origin data for DDEC, detailed in Table 4, demonstrates that nearly 87% of our patients live in Kitsap County. Another 9% came from neighboring Jefferson and Mason Counties.

Table 4 (Reproduced)
Digestive Disease and Endoscopy Centers
Patient Origin⁸

Zip	City	County Name	% of Total
98370	Poulsbo	Kitsap	12.4%
98311	Bremerton	Kitsap	12.1%
98312	Bremerton	Kitsap	11.8%
98310	Bremerton	Kitsap	9.7%
98383	Silverdale	Kitsap	9.0%
98366	Port Orchard	Kitsap	8.5%
98367	Port Orchard	Kitsap	5.7%
98110	Bainbridge	Kitsap	4.2%
98346	Kingston	Kitsap	3.9%
98380	Seabeck	Kitsap	2.6%
98337	Bremerton	Kitsap	2.0%
98340	Hansville	Kitsap	1.0%
98393	Tracyton	Kitsap	0.9%
98362	Suquamish	Kitsap	0.7%

⁷ Department of Health, Certificate of Need Decision, CHI Franciscan Health, proposing to establish an Ambulatory Surgery Center in King County, July 1, 2016, page 6.

⁸Source: Applicant

98342	<i>Indianola</i>	<i>Kitsap</i>	<i>0.5%</i>
98345	<i>Keyport</i>	<i>Kitsap</i>	<i>0.5%</i>
98315	<i>Silverdale</i>	<i>Kitsap</i>	<i>0.4%</i>
98359	<i>Olalla</i>	<i>Kitsap</i>	<i>0.4%</i>
98353	<i>Manchester</i>	<i>Kitsap</i>	<i>0.3%</i>
98322	<i>Burley</i>	<i>Kitsap</i>	<i>0.2%</i>
98364	<i>Port Gamble</i>	<i>Kitsap</i>	<i>0.1%</i>
98364	<i>South Colby</i>	<i>Kitsap</i>	<i>0.1%</i>
98386	<i>Southworth</i>	<i>Kitsap</i>	<i>0.1%</i>
98061	<i>Rollingbay</i>	<i>Kitsap</i>	<i>0.0%</i>
98314	<i>Bremerton</i>	<i>Kitsap</i>	<i>0.0%</i>
98378	<i>Retsil</i>	<i>Kitsap</i>	<i>0.0%</i>
	<i>Subtotal</i>	<i>Kitsap County</i>	<i>86.9%</i>

[Source: Application page 14]

- “As noted in response to earlier sections, DDEC is submitting this CN application so as to be able to extend the use of its facility to physicians who are not member of the group practice. For purpose of this CN, DDEC has assumed only a modest increase in projected utilization. Specifically, DDEC assumed an average annual rate of growth of 2.9% over the next five years; based on historical DDEC utilization (2012-2016).

Table 5 (Reproduced)
Digestive Disease and Endoscopy Center
Projected Utilization, 2017-2021

Year	No. of Procedures
2017	4,532
2018	4,663
2019	4,798
2020	4,937
2021	5,080”

[Source: Application page 15]

Public Comments

None

Rebuttal Comments

None

The Department Application of the Numeric Methodology

The numeric portion of the methodology requires a calculation of annual capacity of the existing providers’ inpatient and outpatient ORs in a planning area – Kitsap County.

According to the department’s historical records, there are six providers located within the Kitsap County secondary health services planning area including the applicant with OR capacity. Of the six providers, Harrison Medical Center is the only hospital, and there are five ASFs⁹. [Source: CN historic files and DOH ILRS database]

⁹ Pacific Surgery Center, Surgery Center of Silverdale; Pacific Cataract and Laser Institute; the Doctors Clinic and Digestive Disease and Endoscopy Center, PLLC.

Harrison Medical Center OR capacity and inpatient/mixed-use procedures are included in the methodology calculations for the planning area. Because there is no mandatory reporting requirement for utilization of ASFs or hospital ORs, the departments sends an annual utilization survey to all hospitals and known ASFs in Washington. When DDEC submitted its application on February 21, 2017, the department most recent annual utilization survey was year 2015. On August 5, 2016, the department conducted its year 2015 annual survey and collected the most recently available provider’s data. Since the data provided in the year 2015 annual utilization survey, is the most recently available data, the department would use this data.

Of the five ASFs located within the services area, Pacific Surgery Center, the Doctors Clinic; and Surgery Center of Silverdale are CN approved therefore the facilities OR capacity and utilization is counted in the numeric methodology. The ASF numeric methodology deliberately excludes endoscopy facilities’ OR capacity and procedures from the numeric methodology.¹⁰ As a result, DDEC ORs and procedures will not be counted in the numeric methodology.

Pacific Cataract and Laser Institute is located within a solo or group practice (considered a Certificate of Need-exempt ASF) and the use of these ASF is restricted to physicians that are employees or members of the clinical practices that operate the facility. Therefore, this facility does not meet the ASF definition in WAC 246-310-270. For Certificate of Need-exempt ASFs, the number of surgeries, but not ORs, is included in the methodology for the planning area.

If a facility does not complete and return a utilization survey, then the other data source that can be used is the department’s internal database known as the Integrated Licensing and Regulatory System (ILRS). WAC 246-330-100(2), licensed ambulatory surgical facilities must submit to the department an annual update form. The data provided on this annual update form includes the number of ORs and the approximate number of procedures performed at the facility during the year. This data is updated in ILRS as it is received. The department uses the listed number of surgical procedures and multiplies the number by 50 minutes which is the default minutes per outpatient surgery as identified under WAC 246-310-270(9)(b)(iii).

The data points used in the department's numeric methodology are identified in Table 1. The methodology and supporting data used by the department is provided in the attached Appendix A with this evaluation.

**Table 1
Department’s Methodology Assumptions and Data**

Assumption	Data Used
Planning Area	Kitsap County
Population Estimates and Forecasts	Age Group: 0-85+ OFM Population Data released year 2017: Year 2020 – 275,546 Year 2016 – 264,698
Use Rate	Divide calculated surgical cases by 2015 population results in the service area use rate of 82.014/1,000 population

¹⁰ WAC 246-310-270(9)(iv).

Year 2016 Total Number of Surgical Cases	8,860 – Inpatient or Mixed-Use; 12,849 – Outpatient 21,709 – Total Cases
Percent of surgery: ambulatory vs. inpatient	Based on DOH survey and ILRS data: 59.19% ambulatory (outpatient); 40.81% inpatient
Average minutes per case	Based on DOH survey and ILRS Data: Outpatient cases: 45.47 minutes Inpatient cases: 93.09 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 Kitsap County Providers: 8 dedicated outpatient ORs 12 mixed use ORs
Department’s Methodology Results	Surplus of 2.89 mixed-use ORs

Based on the assumptions described in Table 1, the department’s application of the numeric methodology indicates a surplus of 2.89 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 2.89 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

Digestive Disease and Endoscopy Center

DDEC provided the following statements related to the continued need for the endoscopy services to be provided at by the CN exempt facility. [Source: Application page 5, 15]

“DDEC volumes for the period of 2012-2016 are detailed in Table 3.

Table 3 Reproduced
Digestive Disease and Endoscopy Center
Number of Procedures, 2012-2016

Year	No. of Procedures	% of Change
2012	3,948	
2013	3,829	-3.0%
2014	4,278	11.7%
2015	4,384	2.5%
2016	4,380	-0.9% ¹¹

Source: Applicant

For the purpose of this CN, DDEC has assumed only a modest increase in projected utilization. Specifically, DDEC assumed an average annual rate of growth of 2.9% over the next five years based on historical DDEC utilization (2012-2016). [Source: Application page 15]

¹¹ Please note that 2016 volumes flattened due to a change in call coverage that resulted in one of the physician providers having less availability for performing procedures.

Table 5 Reproduced
Digestive Disease and Endoscopy Center
Projected Utilization, 2017-2021

Year	No. of Procedures
2017	4,532
2018	4,663
2019	4,798
2020	4,937
2021	5,080

Source: Applicant

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 on to determine need for dedicated endoscopy ORs such as those proposed in this project. The applicant provided information to support that utilization at the existing facility is growing, and that they expect this growth to continue. Furthermore, the types of procedures proposed are limited to endoscopic and GI type services. Based on the source information reviewed and DDEC’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.

Digestive Disease and Endoscopy Center

“DDEC provides endoscopy and GI related services only. Other providers of endoscopy services in Kitsap County include Harrison Medical Center and the Doctor's Clinic. Combined these two providers have two rooms for endoscopy.

This project proposes to convert an existing exempt ASC to a CN approved ASC. No change in service is proposed. If this facility were not available, planning area residents would experience reduced access to diagnostic and therapeutic endoscopy procedures, and payers and patients will be limited in their choice for freestanding lower cost endoscopy services. For these reasons, this project does not constitute an unnecessary duplication of services as there is no change in service delivery with this project.” [source: Application p16]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

DDEC correctly points out that there are only two other providers of digestive endoscopic services in Kitsap County, one of which is the hospital. 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 over 4,000 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) 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 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 do 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.

A facility's charity care policy should show a willingness of a provider to provide services to patients 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 (ACA), the amount of charity care is expected to decrease, but not disappear.

Digestive Disease and Endoscopy Center

- *“DDEC serves patients regardless of race, income, ethnicity, sex or handicap. A copy of DDEC's charity care and admission policies are included as Exhibit 7”.* [Source: Application page 17 and Screening responses received May 10, 2017, Attachment 6]
- *A copy of DDEC's patients' rights policy, which contain its non-discrimination policy is included in Exhibit 7. Exhibit 7 also contains DDEC's admission policy.* [Source: Application page 17 and Screening responses received May 10, 2017, Attachment 6]

- DOH staff reproduction of WCPM historical and projected sources of revenue based on screening responses. [Source: Screening responses received May 10, 2017, page 3]

Table 1 Reproduced
Digestive Disease and Endoscopy
Cases and gross revenue Centers,
Patients and Revenue by Payer, Current and Projected

Payer	% Cases of Patients – Current (2016)	% of Net Revenue Current (2016)	% of Patient - Projected (2020)	% of Net Revenue Projected (2020)
<i>Medicare</i>	39.1%	27.2%	37.7%	28.8%
<i>Medicaid</i>	0.1%	0.0%	4.9%	3.6%
<i>HMO/Kaiser</i>	21.7%	25.6%	21.0%	23.3%
<i>Commercial/Health Care Contractor</i>	33.3%	39.8%	31.1%	37.1%
<i>VA/Tricare</i>	5.5%	7.2%	5.1%	7.7%
<i>Other Government/L&I</i>	0.0%	0.0%	0.0%	0.0%
<i>Other/Self-Pay</i>	0.2%	10.6%	0.2%	0.2%
Total	100.0%	100.0%	100.0%	100.0%

“Please note that DDEC’s capacity issues have constrained the number of Medicaid patients we can serve. These patients have been receiving their outpatients endoscopy services at a hospital because they can be more timely scheduled at the hospital. This is because the State Medicaid Program requires that endoscopy procedures be scheduled within 30 days of performing the health and physical exam. If this cannot be done timely, another health and physical exam must be performed. Therefore, DDEC physicians have scheduled these patients’ procedures at the hospital. While they are still being serve by DDEC physicians, they are largely not receiving services at the outpatient ASC. The opening of a 3rd procedure room and the addition of the 4th physician at DDEC will allow many of the Medicaid patients to be scheduled timely at DDEC, instead of having to use the hospital”. [Sources: Application page 3 and Screening responses received May 10, 2017, page 3]

Public Comment

None

Rebuttal

None

Department Evaluation

The admission and patient right policies provided by DDEC outlines the process and criteria the applicant uses to admit patients for treatment and ensures that patients will receive appropriate care at the ASF. DDEC stated it is certified to provide services to Medicare and Medicaid eligible patients. Information provided in the application shows DDEC expects reimbursements from Medicare and Medicaid. DDEC stated it will continue to maintain its Medicare and Medicaid certification. [Sources: Application page 3 and Exhibit 7]

If this project is approved, the department would attach a condition requiring the applicant to continue to maintain its Medicare and Medicaid certification consistent with the information

provided in the application. If DDEC project is approved, the department would attach a similar condition. The department notes that DDEC demonstrated its intent to provide charity care to patients receiving treatments at the ASF by submitting a charity care policy to be used at the facility. A review of the policy outlines the process patients would use to access services when they do not have the financial resources to pay for required treatments. [Source: Application, Exhibit 7]

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

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

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 ASF.

Digestive Disease and Endoscopy Center

- *A copy of DDEC’s Charity care policy is included in Exhibit 7*. [Source: Application page 18]
- *“...In addition, consistent with the requirement of WAC, we estimate providing the average charity care percentage for the Puget Sound Region. According to 2013-2015 charity care data produced by the Department of Health (the latest data available), the three year average for the Puget Sound region was 1.84% of gross revenue and 4.82% of adjusted revenue. However, since 2014, with Medicaid expansion and the participation in the exchange, charity acre in the Puget Sound Region has decreased by more than 46%. The CN Program had previously recognized that charity care has declined and that the three-year regional average will adjust. For this application, DDEC however, has assumed that charity care would be 1.84% of gross revenue.”* [Source: Application page 17]
- DoH staff summary of DDEC Charity care data based on screening responses. [Source: Screening responses received May 10, 2017, page 4]

***Table 2 Reproduced
Historical Charity Care***

	<i>Charity Care as a % of Total Revenue (2013-2015)</i>	<i>Charity Care as a % of Adjusted Revenue (2013-2015)</i>
Hospitals in Puget Sound	1.84%	4.82%
Planning area Hospital Combined-Harrison Medical Center	1.65%	4.90%
Digestive Disease & Endoscopy Center (2016 only)	0.4%	N/A

Public Comments

None

Rebuttal Comments

None

Department Evaluation

For charity care reporting purposes, HPDS, divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. DDEC is located in Puget Sound Region and there 19 general acute care hospitals in the region. However, Harrison Memorial Hospital is the only hospital that could be affected with the approval this project and located within Kitsap County secondary health services area planning area. For this project, the department reviewed the most recent three years of charity care data for Harrison Memorial Hospital and the three years reviewed are 2013, 2014, and 2015.¹²

For this project, the department reviewed the most recent three years charity care data for the 19 existing hospitals currently operating within the Puget Sound Region, but mainly focused on Harrison Memorial Hospital the only acute care hospital within Puget Sound Region. The three years of charity care data reviewed are 2013, 2014, and 2015. Shown in Table 2 is a comparison of the three years average charity care for the Puget Sound Region as a whole, Harrison Memorial Hospital charity care averages, and DDEC projected charity care for this project. [Sources: Department of Health Office of Community Health Systems, Charity Care and Hospital Financial Data Program Charity Care 2013-2015, DDEC Supplemental information received May 10, 2017, Page 7 and Attachment 7]

**Table 2
Charity Care**

	% of Total Revenue	% of Adjusted Revenue
Puget Sound Region	1.88%	4.65%
Harrison Memorial Hospital	1.75%	4.95%
DDEC Projected	1.84%	-

As shown above, the proposed charity care level represented in DDEC application is slightly below the regional average, but exceeds the average at Harrison Memorial Hospital. In its pro forma financial statement, DDEC also included a ‘charity care’ line item as a deduction from expenses. [Sources: Screening responses received May 10, 2017, Attachment 7] Based on the review of DDEC historical financial statements, it does not appear the applicant currently provide charity care. If this project is approved, the department would attach a condition requiring the applicant to provide a copy of the final charity care policy consistent with the policy documentation.

Based on the above analysis, if this project is approved, the department would attach a condition requiring DDEC 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 DDEC 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.

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

¹² As of the writing of this evaluation, year 2016 charity care data is not available.

(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 the 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 the application.

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

Department Evaluation

This sub-criterion is not applicable to the 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 the 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 the 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 the application.

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

Based on the source information reviewed and the applicant's agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Digestive Disease and Endoscopy Center has met the financial feasibility criteria in WAC 246-310-220.

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

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma operating 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.

Digestive Disease and Endoscopy Center

- *As noted in response to earlier sections, DDEC, is submitting this CN application so as to be able to extend the use of its facility to physicians who are not a member of the group practice. For purposes of this CN, DDEC has assumed only a modest increase in projected utilization. Specifically, DDEC assumed an average annual rate of growth of 2.9% over the next five years; based on historical DDEC utilization (2012-2016).* [Source: Application page 15]
- *"The requested statements are included in Exhibit 8".* [Source: Application page 21]
- *"This project requires no capital expenditures beyond those identified in the proposal* [Source: Application page 21]
- *A revised pro forma financial, including 2017 as a partial year is included in Attachment 7".*
- DOH staff summary of operating and expenses based on Attachment 7 screening responses [Source: Screening responses received May 10, 2017, Attachment 7, page 180]

DDEC Projected Revenue and Expenses Years 2017 through 2020

	2017	2018	2019	2020
Net Revenue	\$2,345,006	\$2,391,915	\$2,440,211	\$2,489,526
Total Expenses	\$1,316,622	\$1,443,339	\$1,454,583	\$1,466,211
Net Income/(Loss)	\$1,028,384	\$948,576	\$985,628	\$1,023,315

- *"Table 3 details the expenses per procedure, 2017-2020*
- *"Exhibit 9 contains historical financial statements for DDEC".* [Source: Application page 21 and Screening responses received May 10, 2017, Attachment 7, page 178-179]

DDEC Projected Balance Sheet Year 2017

Assets	Liabilities		
Total Current Assets	\$164,527	Current Liabilities	\$211,430
Fixed Assets	(\$45,370)	Long Term Debt	(\$67,727)
Other Assets	\$468,490	Equity	\$446,133
Total Assets	\$587,647	Total Liabilities and Equity	\$589,836

DDEC Projected Balance Sheet Year 2018

Assets		Liabilities	
Total Current Assets	\$16,233	Current Liabilities	\$18,422
Fixed Assets	-	Long Term Debt	-
Other Asserts	\$571,414	Equity	\$571,414
Total Assets	\$587,647	Total Liabilities and Equity	\$589,836

Public Comments

None

Rebuttal Comments

None

Department Evaluation

DDEC anticipates this project would become operational by the end of October 2017. Under this timeline, year 2018 would be the facility’s first full calendar year of operation and 2020 would be year three. [Source: Supplemental information received May 10, 2017, page 1] Summarized in Table 3 below is DDEC pro forma financial statement for the project.

**Table 3
DDEC Projected Revenue and Expenses Years 2017 through 2020**

	2017	2018	2019	2020
Net Revenue	\$2,345,006	\$2,391,915	\$2,440,211	\$2,489,526
Total Expenses	\$1,316,622	\$1,443,339	\$1,454,583	\$1,466,211
Net Income/(Loss)	\$1,028,384	\$948,576	\$985,628	\$1,023,315

The “Total Expenses” line item includes salaries and wages and benefits, lease and interest costs. As shown above, DDEC anticipate Certificate of Need approval will contribute to profitability over time, as services are able to expand. Dr. Narendra Siddaiah, MD an employee was identified as medical director of the ASF. This position does not require a contract. [Source: Application page 24 and Exhibit 10]

DDEC is located at 3261 NW Mount Vintage Way, Suite 221 in the City of Silverdale and facility currently leases office space from Tower Medical Center, LLC. DDEC provided an executed lease agreement between Tower Medical Center, LLC (Landlord) and Digestive Disease and Endoscopy Center, PLLC (Tenant). [Source: Application, Exhibit 5] The lease expires in 2020 and the tenant has the right or option to extend the lease. The executed lease agreement outlines the roles and responsibilities of the lessor and lessee.

Based on the information above, the department concludes 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.

Digestive Disease and Endoscopy Center

- *“Even though opening the third room is not CN reviewable event, we have elected to include all costs associated with purchasing and installing the equipment in the capital expenditure for this project”* [Source: Application page 6]
- *“The capital expenditure for this project noted are for the equipping of the third room and will occur regardless of the outcome of this CN application”*. [Source: Application page 19]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Consistent with Certificate of Need Program practices, DDEC submitted a letter of intent identifying the total costs for the project to be \$72,000. The capital costs identified in the application is consistent with the costs in the letter of intent. [Source: Application, page 19 and Exhibit 2]

There is no construction associated with this project, but there are equipment costs associated with this project. The impact of the cost is already included in the current operating revenue and expenses statement of the facility.

It does not appear that converting the currently exempt ASF to an open CN approved ASF would have an impact on the costs and charges of surgeries performed at this ASF. Any increase in operating costs will be associated with the increase in the number of procedures to be performed in the existing operating rooms. Based on the information, the department concludes this project may not have an unreasonable impact on the costs and charges for healthcare services in Kitsap County secondary health services 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.

Digestive Disease and Endoscopy Center

- *“This project will be financed through exiting capital reserves of DDEC. This is the least costly method of financing the acquisition as it does not require any financing costs.* [Source: Application page 20]
- *“Since the application was submitted, DDEC has made a decision to lease the equipment needed for the addition of a 3rd procedure room.*

Included in Attachment 2 is copy of the document from Olympus Financial Services documenting the costs and terms of the financing. Please note that the actual costs of the financing are slightly less than what was estimated in the application. The cost of the equipment, as outlined in Attachment 2, is \$55,852.33, before taxes. DDEC had estimated \$58,660 in the application for equipment. As the balance sheet demonstrates, the funds are available. However, after submitting the application, the DDEC board made a decision to finance the equipment through a lease. Included in Attachment 3 is a letter from Dr. Sharma indicating that DDEC will use reserve for the remaining capital costs which are for the installation of the equipment". [Source: Screening responses received May 10, 2017, page 5]

DDEC provided historical financial statements to document availability of cash reserve to pay for the project costs.

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As stated above, DDEC intends to finance their equipment purchases using existing financial resources. The balance sheet provided by DDEC shows total current cash available from checking and savings at \$174,932.66. Only the cost of equipment installation is upfront, at \$9,600, whereas the equipment purchase (a lease with the option to purchase) has been included in the pro forma financial statements, and substantiated by a document from Olympus. The estimated upfront capital expenditure of \$9,600 represents approximately 5% of this total. The department concludes that this financing method is appropriate. **This sub-criterion is met.**

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

Based on the source information reviewed and provided the applicant agrees to the conditions identified in the conclusion section of this evaluation, the department determines Digestive Disease and Endoscopy Center has met the structure and process of care criteria in WAC 246-310-230.

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

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

Digestive Disease and Endoscopy Center

- *"DDEC will need to increase its staffing due to the opening of the 3rd procedure room. DDEC has been conservative in its projections (annual growth of 2.9% per year) but does want to open a 3rd room to reduce waiting times and improve access for patients*
- *Table 6 identifies the staffing, by FTE, for each of the first three years of CN approved operation". [Source: Application page 22]*

Table 6 (Reproduced)
Digestive Disease and Endoscopy Center
Estimated Staffing 2017-2020

Position	Current	2017	2018	2019	2020
Nurse Manager	1.0	1.0	1.0	1.0	1.0
Asst. Nurse Manager	1.0	1.0	1.0	1.0	1.0
Registered Nurses	4.5	4.7	4.7	4.7	4.7
Medical Assistants/Endo Techs	4.0	4.0	6.0	6.0	6.0
Receptionist	1.0	1.0	1.0	1.0	1.0
Total	11.5	11.7	13.7	13.7	13.7

- *The core staff is already in place. With the addition of a third procedure room, which will open in 2017, DDEC will need to recruit additional clinical staff (estimated to be 2.2 FTEs by 2018). DDEC offers a competitive wage and benefit package. Additionally, a free-standing ASC offers more attractive scheduling as staff are not required to work evenings and weekends and DDEC will offer part-time and/or flexible positions, all of which we believe will be attractive recruitment and retention tools. For these reasons, DDEC does not anticipate any difficulties recruiting staff for this project. [Source: Application page 23]*
- DOH staff summary of DDEC active staff. [Source: Application page 2 and 24]

Active Medical Staff: Physicians

Name
Pankaj Sharma, M.D.
Narendra Siddaiah, M.D.
Yuen San Yee, M.D.

Other staff

Name
Christensen, Nancy, RN
Johnson, Mark, RN
Lovato, Jenn, Endotech
Lutz, Melanie
Mulligan, Brittany, MA
Payne, Joy, RN
Rodriguez, Amanda, MA
Santiago, Kalae, MA
Strobel, Rebecca, RN
VanVuren, Andi, RN
Walton-Whitaker, Sheelagh, RN
Wiest, Karen, RN

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As shown in reproduced Table 6 above, it appears that DDEC currently have the majority of the FTE’s needed for this project. A review of year 2017 to year 2020 shows that DDEC expects to add another 2.2 FTEs to the ASF. Dr. Narendra Siddaiah an employee of the ASF was identified as the medical director. This position does not require a contract. Given that the facility is already operational with staff in place, the department concludes that DDEC has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **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) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that 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 history in meeting these standards at other facilities owned or operated by the applicant.

Digestive Disease and Endoscopy Center

- *“As stated in other sections of this application, this project does not propose the addition of any new services. Existing ancillary and support services are already established and in place. No changes are planned for this project”.* [Source: Application Page 24]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

DDEC has been operational for many years. All ancillary and support services are already in place. DDEC 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 DDEC 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 no 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.

Digestive Disease and Endoscopy Center

- *“Neither DDEC nor any of the individuals physicians owners have history with respect to the actions noted in WAC 246-310-230(5)(a).*
- *DDEC is and will continue to be operated in conformance with applicable federal laws, rules and regulation”.* [Source: Application Page 25]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

DDEC has been a provider in Kitsap County secondary health services planning area since at least 2012. As a part of this review, the department must conclude that the services provided by the ASF would continue to be provided in a manner that ensures safe and adequate care to the public.¹³ To accomplish this task, the department reviewed the quality of care compliance history for the ASF.

DDEC is accredited by the Accreditation Association for Ambulatory Health Care (AAAHC).¹⁴ AAAHC accreditation for ASFs is awarded for three years. DDEC accreditation by the AAAHC is effective through April 2018. DDEC provided a copy of its most recent survey by AAAHC.

The last survey conducted in January 2017 by Washington State office of Investigation and Inspection revealed no substantial non-compliance issues for DDEC. [Sources: AAAHC website, Application page 3 and Supplemental information received May 10, 2017, Attachment 1] The department conducted quality of care check for all DDEC active medical staff and others through the Nursing Quality Assurance Commission (NQAC) and Health Systems Quality Assurance (HSQA OCS). The department quality check shows that DDEC credentialed staff members licenses are in good standing, and this includes the ASF designated nurse manager Mark Johnson. [Source: Application Page 24 and NQAC, HSQA OCS]

In addition to verifying the quality of care for the ASF, the department also performed a quality of care check for the three physician owners of DDEC. The results of the quality of care for all three physicians show that none has unrestricted licenses with the State of Washington. [Sources: DOH Provider Credential Search and application pages 2 and 24]

Given the compliance history of DDEC and staff, there is reasonable assurance the ASF would continue to be operated and managed in conformance with applicable state and federal licensing and certification requirements.

¹³ WAC 246-310-230(5)

¹⁴ The Accreditation Association for Ambulatory Health Care (AAAHC) is a private, non-profit organization formed in 1979. AAAHC currently accredits more than 6,000 organizations in a wide variety of ambulatory health care settings including ambulatory surgery centers, community health centers, medical and dental group practices, medical home practices, and managed care organizations, as well as Indian and student health centers, among others. AAAHC accreditation for ASCs holds Medicare deemed status from the Centers for Medicare and Medicaid Services (CMS). [Source: AAAHC website]

Based on the information reviewed, the department concludes that there is reasonable assurance that DDEC would continue to operate and managed in conformance with applicable state and federal licensing and certification 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 directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Digestive Disease and Endoscopy Center

- *“...This project proposes to convert an existing high volume, high quality exempt CN approved ASC to a CN approved ASC. No change in the location service delivery, or working relationships is anticipated as a result of this project—through CN approval will allow us to provide access for physicians seeking a freestanding, lower cost setting. DDEC has operated under its DNR since 2012. DDEC will continue to provide endoscopy and GI related services to the community and will continue the established working relationships with other existing providers. A copy of the existing transfer agreement with Harrison Medical Center is included as Exhibit 11”.* [Source: Application Page 25]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The ASF is operational as an exempt facility, and has working relationships with existing healthcare providers in the planning area. Since the ASF will remain in the same planning area, the department expects existing relationships to continue. As discussed under WAC 246-310-230(2), DDEC asserted that all ancillary and support agreements will not be affected by Certificate of Need approval.

The department considered DDEC's history of providing care to residents of Kitsap County secondary health services planning area and concludes the applicant has been providing services for at least four years and has appropriately participated in relationships with the community healthcare providers to provide medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change the relationships.

Based on the source documents evaluated, the department concludes approval of this project would promote continuity in provision of healthcare for the planning area, and may not result in an unwarranted fragmentation of services. **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**.

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

Based on the source information reviewed and provided the applicant agrees to the conditions identified in the conclusion section of this evaluation, the department concludes that Digestive Disease and Endoscopy Center project has met the cost containment criteria in WAC 246-310-240

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.
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, 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 in Step three. The 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 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.

Department Evaluation

Step One

The department determined DDEC met the applicable review criteria under WAC 246-310-210, 220, and 230 including WAC 246-310-270. Therefore, the department moves to step two.

Step Two

For this project, DDEC has met the review criteria in the applicable sections of WAC 246-210, WAC 246-310-220, and WAC 246-310-230. Therefore, the department reviews the proposed alternatives by the applicant.

Digestive Disease and Endoscopy Center

- *“DDEC only considered two options: 1) do nothing or 2) undertake the project contained in this application. As noted in earlier sections of this application, DDEC does not propose any new services but has submitted this application to convert an exempt ASC to a CN approved ASC. This approval will allow DDEC to open it cost effective facility option to*

community surgeons, payers and patients. We are confident that this will improve access to services for Kitsap residents”. [Source: Application Page 26]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The department did not identify any other alternatives that would equal to or superior to those considered by the applicant. A key rationale considered by DDEC to support the approval of this project stated that approval of this project would allow non-member physicians to use the facility and this would expand patient’s volumes. As a result, the department considered the applicant project the only available alternative. Based on the source information evaluated the department concludes that **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;

Department Evaluation

There is no construction associated with this project; this sub-criterion is not applicable to the 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.

Department Evaluation

There is no construction associated with this project; this sub-criterion is not applicable to the 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.

Department Evaluation

This project has the potential to improve delivery of ambulatory surgical services within the planning area, as it will open the facility to additional surgeons, and will increase the efficiency of existing planning area ORs. The department concludes **this sub criterion is met.**

APPENDIX A

APPENDIX A
ASC Need Methodology
Kitsap County

	Service Area Population: 2020	275,546	OFM	Age: 0-85+					
	Surgeries @ 82.014/1,000:	21,709							
a.i.	94,250	minutes/year/mixed-use OR							
a.ii.	68,850	minutes/year/dedicated outpatient OR							
a.iii.	8	dedicated outpatient OR's x 68,850 minutes =		550,800	minutes dedicated OR capacity	12,114	Outpatient surgeries		
a.iv.	12	mixed-use OR's x 94,250 minutes =		1,131,000	minutes mixed-use OR capacity	12,149	Mixed-use surgeries		
b.i.		projected inpatient surgeries =	8,860	=	824,817	minutes inpatient surgeries			
		projected outpatient surgeries =	12,849	=	584,207	minutes outpatient surgeries			
b.ii.		Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's							
		12,849	-	12,114	=	735	outpatient surgeries		
b.iii.		average time of inpatient surgeries		=	93.09	minutes			
		average time of outpatient surgeries		=	45.47	minutes			
b.iv.		inpatient surgeries*average time		=	824,817	minutes			
		remaining outpatient surgeries(b.ii.)*ave time		=	33,407	minutes			
					858,224	minutes			
c.i.		if b.iv. < a.iv. , divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's							
		USE THIS VALUE							
		1,131,000							
		- 858,224							
		272,776	/	94,250	=	2.89			
c.ii.		if b.iv. > a.iv., divide (inpatient part of b.iv - a.iv.) by 94,250 to determine shortage of inpatient OR's							
		Not Applicable - Ignore the following values and use results of c.i.							
		824,817							
		- 1,131,000							
		(306,183)	/	94,250	=	-3.25			
		divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's							
		33,407	/	68,850	=	0.49			



**APPENDIX A
ASC Need Methodology
Kitsap County**

Facility	Credential Number	ZIP Code	Special Procedure Rooms	Dedicated Inpatient ORs	Dedicated Outpatient ORs	Mixed Use ORs	Inpatient min/case	2015 Inpatient Cases in Mixed Use ORs	2015 Inpatient Mins. In Mixed Use ORs	Outpatient Min/Case	Outpatient Cases	Outpatient Mins.	Data Source
Harrison Medical Center - Bremerton	HAC.FS.00000142	98310	2	0	0	4	98.3	4,053	398,447				Year 2014 Data obtained from Year 2015 survey.
Harrison Medical Center - Silverdale	HAC.FS.00000142	98383				4	73.3	2,831	207,427				Year 2014 Data obtained from Year 2015 survey.
Harrison Medical Center - (Orthopedic)	HAC.FS.00000142	98383				4	110.8	1,976	218,943				
Pacific Surgery Center	ASF.FS.60100106	98370	0	0	3	0	0.0	0	0	31.5	3,720	117,161	Year 2015 data obtained from year 2016 survey. Minutes/surgery calculated.
Surgery Center of Silverdale	ASF.FS.60100155	98383	1	0	2	0	0.0	0	0	52.4	3,714	194,565	Year 2015 data obtained from year 2016 survey. Minutes/surgery calculated.
Digestive Disease and Endoscopy Center, PLLC	ASF.FS.60287214	98383						ENDOSCOPY ORS & MINUTES NOT COUNTED					
Pacific Cataract and Laser Institute	ASF.FS.60622145	98383	0	0	2	0				50.0	1,626	81,300	Year 2015 data obtained from year 2016 survey. Minutes/surgery calculated.
The Doctors Clinic ASC and Endoscopy	ASF.FS.60100079	98383	2	0	3	0	0.0	0	0	50.5	3,789	191,181	Year 2015 data obtained from year 2016 survey. Minutes/surgery calculated.
Totals			5	0	10	12	282.4	8,860	824,817	184	12,849	584,207	
							Avg min/case inpatient		93.09	Avg min/case outpatient		45.47	
ORs counted in numeric methodology					8	12							
ILRS: Integrated Licensing & Regulatory System													
Population data source: OFM Medium Series													
Total Surgeries			21,709										
Area population 2016 [0-85+]			264,698										
Use Rate			82.014										
Planning Area projected 0-85+ population Year: 2020			275,546										
% Outpatient of total surgeries			59.19%										
% Inpatient of total surgeries			40.81%										