

# STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington 98504

December 31, 2018

CERTIFIED MAIL # 7016 3010 0001 0575 0594

Kevin Michelson, CEO Walla Walla Clinic, Inc. PS 55 West Tietan Street Walla Walla, Washington 99362

RE: Certificate of Need Application #18-14

We have completed review of the Certificate of Need application submitted by Walla Walla Clinic, Inc. PS. The application proposes the establishment of an ambulatory surgery center in Walla Walla, within Walla Walla 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 Walla Walla Clinic, Inc. PS agrees to the following in its entirety.

# **Project Descriptions:**

This certificate approves the establishment of a three-operating room ambulatory surgical facility in Walla Walla, within Walla Walla County. The surgery center will serve patients from one year and older that require surgical services that can be served appropriately in an outpatient setting. Walla Walla Surgery Center currently performs procedures under both general and local anesthesia in the following specialties: gastroenterology, general surgery, obstetrics and gynecology, orthopedics/interventional pain, otolaryngology, plastic surgery, podiatry and urology. The types of surgeries and procedures will remain the same.

### **Conditions:**

- 1. Walla Walla Clinic agrees with the project description as stated above. Walla Walla Clinic 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. Walla Walla Clinic will provide charity care in compliance with its charity care. Walla Walla Clinic will use reasonable efforts to provide charity care consistent with the regional average or the amount identified in the application whichever is higher. The regional charity care average from 2015-2017 was 0.81% of gross revenue and 2.54% of adjusted revenue. Walla Walla Clinic will maintain records of charity care applications received and the dollar amount

Kevin Michelson, CEO Walla Walla Clinic, Inc. PS Certificate of Need Application #18-14 December 31, 2018 Page 2 of 2

of charity care discounts granted at the location of the surgery center. The records must be available upon request.

3. Walla Walla Clinic agrees that the surgery center will maintain Medicare and Medicaid certification, regardless of facility ownership.

# **Approved Costs:**

The approved capital expenditure associated with this project is \$175,000. The costs are solely related to the equipment needed for the expansion of the number of physicians and number of procedures that would be provided at the surgery center.

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

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

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

Mailing Address:

Department of Health

Certificate of Need Program

Mail Stop 47852

Olympia, WA 98504-7852

Physical Address:

Department of Health

Certificate of Need Program

111 Israel Road SE

Tumwater, WA 98501

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

Sincerely,

Nancy Tyson, Executive Director

Health Facilities and Certificate of Need

Enclosure

# EVALUATION DATED DECEMBER 31, 2018 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY WALLA WALLA CLINIC PROPOSING TO ESTABLISH AN AMBULATORY SURGICAL FACILITY IN WALLA WALLA COUNTY

# APPLICANT DESCRIPTION AND HISTORICAL INFORMATION

Walla Walla Clinic Inc. PS is a for-profit Washington State professional service corporation <sup>1</sup> specializing in a variety of health care services. Walla Walla Clinic, Inc. PS is located at 55 West Tietan Street in Walla Walla [99362], within Walla Walla County. Walla Walla Clinic Inc. PS does not operate any facilities outside of Washington State. [source: Application, p2 and Walla Walla Clinic website] For reader ease, the applicant, Walla Walla Clinic Inc. PS, will be referenced throughout this evaluation as "Walla Walla Clinic."

On April 14, 1999, the Certificate of Need (CN) Program approved Walla Walla Clinic to establish an exempt ambulatory surgical facility (ASF) at the practice site. [source: April 14, 1999, Determination of Non-Reviewability] The surgery center became operational at the West Tieton site in suite #B in year 2000. Services currently provided at the CN exempt surgery center include gastroenterology, general surgery, obstetrics and gynecology, orthopedics/interventional pain, otolaryngology, plastic surgery, podiatry and urology. [source: CN historical files and June 7, 2018, screening response, p1]

The surgery center currently has three operating rooms (ORs). One OR is dedicated to gastroenterology procedures and the remaining two are used for the other procedures. Consistent with the exemption approval, only physicians that are associated with Walla Walla Clinic perform surgeries at the exempt surgery center. [source: CN historical files and October 19, 2018, ASF license application]

#### PROJECT DESCRIPTION

This project focuses on the surgery center associated with Walla Walla Clinic known as Walla Walla Clinic Ambulatory Surgery Center. For reader ease, the surgery center will be referenced as "Walla Walla Clinic ASC" in this evaluation.

Walla Walla Clinic submitted this project for CN review to allow access to the surgery center by physicians that are not associated with Walla Walla Clinic. The types of procedures provided at Walla Walla Clinic ASC is not anticipated to change from those currently provided. If this project is approved, the surgery center will remain at 55 West Tietan Street, #B in Walla Walla. The number of operating rooms will remain at three. [source: March 26, 2018, screening response, p1 and June 7, 2018, screening response, p1]

Since this project does not propose any structural changes to the surgery center, there is no construction costs associated with the project. The estimated capital expenditure of \$175,000 is solely related to the equipment needed for the expansion of the number of physicians and number of procedures that would be provided at the surgery center. [source: March 26, 2018, screening response, Exhibit 17]

Walla Walla Clinic ASC is licensed by the Washington State Department of Health as an ambulatory surgical facility, ASF.FS.60103014. It is also certified by the Centers for Medicare and Medicaid Services and accredited by the Accreditation Association for Ambulatory Health Care. [source: Application, p3]

<sup>&</sup>lt;sup>1</sup> Incorporated in December 1970; UBI #600 034 580.

If this project is approved, Walla Walla Clinic will maintain operations and meet any specific conditions related to the Certificate of Need approval within two months following approval. Based on the timing of this decision and the associated steps that an applicant must take in order to execute a Certificate of Need, Walla Walla Clinic proposes that its first full year of operation as a CN-approved ASF is year 2019 and year three is year 2021. [source: March 26, 2018, screening response, p3]

# APPLICABILITY OF CERTIFICATE OF NEED LAW

This application proposes to convert an exempt surgery center to a Certificate of Need approved facility. This action 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 ASF projects and is used to make the required determinations for applicable criteria in WAC 246-310-210.

#### TYPE OF REVIEW

This application was submitted on December 12, 2017. On January 19, 2018, Providence Health & Services dba Providence St. Mary Medical Center (Providence St. Mary) submitted an application proposing to establish an ambulatory surgery center in Walla Walla County. Since both projects proposed to establish an ambulatory surgery center in Walla Walla County, they were reviewed concurrently under the regular timeline outlined in WAC 246-310-160.

On December 14, 2018, the department declared a pivotal unresolved issue on the Providence St. Mary project. As a result, the department bifurcated the two applications and continued with this evaluation for the Walla Walla Clinic project. As a result, the timeline below includes both applications, and then shows the bifurcation and completion dates for the Walla Walla Clinic project.

APPLICATION CHRONOLOGY

Action	Walla Walla Clinic	Providence St. Mary	
Letter of Intent Submitted	July 18, 2017	October 27, 2017	
Application Submitted	December 12, 2017	January 19, 2018	
Department's pre-review activities			
DOH 1st Screening Letter	January 4, 2018	February 9, 2018	
Applicant's Responses Received		26, 2018	
<ul> <li>DOH 2nd Screening Letter</li> </ul>		6, 2018	
Applicant's Responses Received	June 7	', 2018	
Beginning of Review	June 27, 2018		
Public Hearing Conducted and End of Public Comment	August 20, 2018		
Rebuttal Comments Received	Septembe	er 4, 2018	
Department's Anticipated Decision Date	October	19, 2018	
Bifurcation of Applications	December 14, 2018	December 14, 2018	
Pivotal Unresolved Issue	None	December 14, 2018	
Department's Anticipated Decision Date	October 19, 2018		
Department's Anticipated Decision Date	January 18, 2019		
with 90-day Extension	-		
Department's Actual Decision Date	December 31, 2018		

#### **AFFECTED PERSONS**

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

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

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

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

Under concurrent review, each applicant is an affected person for the other application(s). Even though the Providence St. Mary's decision will be released after completion of the PUI, Providences Health & Services continues to qualify as affected person for the Walla Walla Clinic project. In addition, the following entities requested affected person status on either the Walla Walla Clinic or Providence St. Mary project.

- Jim Dawson, Program Director FUSE Washington
- Andrew Edwards, MD Walla Walla Eye Center
- Arthur Giebel, MD Lifestyle Eye

- Ursula Mlynarek
   SEIU Healthcare 1199NW
- Chris Nelson Walla Walla community member
- Abigail Scholar Bangs
   Walla Walla community member and FUSE Washington

Below is a brief description of each entity and the affected person qualification.

#### Jim Dawson, Program Director FUSE Washington

Abigail Scholar Bangs, community member and member of FUSE Washington

An excerpt from the FUSE Washington website [www.fusewashington.org] is below.

"FUSE Washington is the state's largest progressive organization-people creating change online, on the ground, and on issues that matter. Our goals at FUSE are to help progressives win more often and give ordinary people a strong voice in politics. We aim to provide organizing and communication power that helps progressives win today and tomorrow on critical issues and electoral campaigns, while strengthening the foundation for increase success over time..."

Members from FUSE Washington requested to be informed of the department decision on both Walla Walla ASC projects, attended the August 20 public hearing, and provided comments. FUSE Washington met the affected person qualifications identified above.

# Andrew Edwards, MD, Walla Walla Eye Center

Dr. Edwards from Walla Walla Eye Center requested interested person status. Walla Walla Eye Center is an eye clinic specializing in eye health symptoms and services and located in Walla Walla County. [source: Walla Walla Eye Center website at <a href="https://www.wweyecenter.com">www.wweyecenter.com</a>] Dr. Edwards requested to receive all

documents associated with the review of this project, however, Dr. Edwards did not provide any written or oral comments. Neither Andrew Edwards, MD nor Walla Walla Eye Center meet the affected person qualifications identified above.

# Arthur Giebel, MD, Lifestyle Eye

Dr. Giebel from Lifestyle Eye requested interested person status. Lifestyle Eye is an eye clinic specializing in cataract care, dry eye treatment, cornea care, and lifestyle medicine (i.e. treatment for type 2 diabetes). Lifestyle Eye has two locations: one in Walla Walla and one in Hermiston Oregon. [source: Lifestyle Eye website at <a href="www.lifestyle.com">www.lifestyle.com</a>] Dr. Giebel requested to receive all documents associated with the review of this project, however, Dr. Giebel did not provide any written or oral comments. Neither Arthur Giebel, MD nor Lifestyle Eye meet the affected person qualifications identified above.

# Ursula Mlynarek, SEIU Healthcare 1199NW

A representative from SEIU (Services Employees International Union) 1199NW requested interested person status. SEIU 1199NW is a statewide union of nurses and healthcare workers. According to its website, SEIU 1199NW represents more than 30,000 nurses and healthcare workers across Washington State. [source: SEIU 1199NW website] It is not clear whether SEIU 1199NW represents employees of either Walla Walla Clinic or Providence St. Mary. Therefore, the department does not have sufficient information to determine whether SEIU 1199NW could qualify as an interested person. Absent public comments – which SEIU 1199NW did not provide – the department does not consider them to be an interested or affected person for this project.

#### Chris Nelson, Walla Walla community member

Chris Nelson is a resident of Walla Walla and a user of the health care services provided in the community. Chris Nelson requested to be informed of the department's decision on this project. Department records show that Chris Nelson did not attend the August 20 public hearing or submit written or oral comments for either project. Since Chris Nelson did not provide public comments on this project, the definition of an affected person is not met.

# **SOURCE INFORMATION REVIEWED**

- Walla Walla Clinic's Certificate of Need application submitted December 12, 2017
- Walla Walla Clinic's screening responses received March 27, 2018
- Walla Walla Clinic's screening responses received June 7, 2018
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission and Nursing Quality Assurance Commission
- Compliance history for Walla Walla Clinic obtained from the Washington State Department of Health Office of Health Systems and Oversight<sup>2</sup>
- Department of Health Provider Credential Search website: http://www.doh.wa.gov/pcs
- Historical charity care data for years 2015, 2016, and 2017 obtained from the Department of Health's Hospital/Finance and Charity Care (HFCC) office
- Year 2017 Annual Ambulatory Surgery Provider Survey for Surgical Procedures Performed During Calendar Year 2016 for hospitals, ambulatory surgical facilities, or ambulatory surgical facilities located in Walla Walla County

<sup>&</sup>lt;sup>2</sup> Formerly the Office of Investigations and Inspections.

# **SOURCE INFORMATION REVIEWED (continued)**

- Office of Financial Management population estimates released May 2018
- Department of Health internal database Integrated Licensing & Regulatory Systems (ILRS)
- Walla Walla Clinic website: https://www.wallawallaclinic.com
- Washington State Secretary of State website: <a href="https://www.sos.wa.gov">https://www.sos.wa.gov</a>
- Washington State Department of Revenue website: http://www.dor.wa.gov
- Center for Medicare and Medicaid Services website: https://www.cms.gov
- Certificate of Need historical files

# **CONCLUSION**

For the reasons stated in this evaluation, the application submitted by Walla Walla Clinic proposing to establish a three operating room ambulatory surgical facility in Walla Walla, within Walla Walla County secondary service planning area is consistent with the applicable criteria of the Certificate of Need Program, provided Walla Walla Clinic agrees to the following in its entirety.

#### **Project Description:**

This certificate approves the establishment of a three-operating room ambulatory surgical facility in Walla Walla, within Walla Walla County. The surgery center will serve patients from one year and older that require surgical services that can be served appropriately in an outpatient setting. Walla Walla Surgery Center currently performs procedures under both general and local anesthesia in the following specialties: gastroenterology, general surgery, obstetrics and gynecology, orthopedics/interventional pain, otolaryngology, plastic surgery, podiatry and urology. The types of surgeries and procedures will remain the same.

#### **Conditions:**

- 1. Walla Walla Clinic agrees with the project description as stated above. Walla Walla Clinic 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. Walla Walla Clinic will provide charity care in compliance with its charity care. Walla Walla Clinic will use reasonable efforts to provide charity care consistent with the regional average or the amount identified in the application whichever is higher. The regional charity care average from 2015-2017 was 0.81% of gross revenue and 2.54% of adjusted revenue. Walla Walla Clinic will maintain records of charity care applications received and the dollar amount of charity care discounts granted at the location of the surgery center. The records must be available upon request.
- 3. Walla Walla Clinic agrees that the surgery center will maintain Medicare and Medicaid certification, regardless of facility ownership.

# **Approved Costs:**

The approved capital expenditure associated with this project is \$175,000. The costs are solely related to the equipment needed for the expansion of the number of physicians and number of procedures that would be provided at the surgery center.

# **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 Walla Walla Clinic has met the need criteria in WAC 246-310-210.

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

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

The Department of Health's Certificate of Need Program uses the numeric methodology outlined in WAC 246-310-270 for determining the need for additional ASFs in Washington State. The numeric methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient ORs in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 secondary health services planning areas. Walla Walla Clinic is located in the Walla Walla County secondary health service planning area.

The methodology estimates OR need in a planning area using multiple steps as defined in WAC 246-310-270(9). This methodology relies on a variety of assumptions and initially determines existing capacity of dedicated outpatient and mixed-use operating room in the planning area, subtracts this capacity from the forecast number of surgeries expected in the planning area in the target year, and examines the difference to determine:

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

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

#### Walla Walla Clinic

Walla Walla Clinic determined the existing capacity in the Walla Walla County secondary health service planning area to be 0 dedicated outpatient ORs and 5 mixed use ORs. Based on a computed use rate, Walla Walla Clinic projected a need for 2.25 dedicated outpatient ORs in the planning area for year 2022. [source: Application, Exhibit 9]

Walla Walla Clinic provided the following statements related to the numeric need methodology. [source: Application, p10]

"Exhibit 8 contains Walla Walla Clinic Surgery Center's need methodology evaluation. The evaluation shows that there is a need for an additional 2.25 outpatient operating rooms by the year 2022 in the Walla Walla County secondary health services planning area. Currently there is a shortage of 2.19 outpatient operating rooms in the Walla Walla County secondary health services planning area. If granted a CN, Walla Walla Clinic Surgery Center has the capacity to provide 81,208 additional outpatient operating room minutes annually. This equates to approximately 1.18 additional outpatient operating rooms. Walla Walla Clinic Surgery Center has commitments from 12 providers to use the proposed ASC. A CN would allow all patients a choice between a hospital

outpatient surgery department and a free-standing ambulatory surgery center. The cost per procedure for the patient as well as his or her insurance company is significantly less in a free-standing surgery center."

**Public Comment** 

None

Rebuttal Comment

None

#### **Department's Numeric Methodology and Evaluation**

The numeric portion of the methodology requires a calculation of the annual capacity of the existing provider's inpatient and outpatient ORs in the Walla Walla County planning area. This application was submitted on December 12, 2017 and at that time, year 2016 utilization data was the most recent data available for this methodology. According to department records, in 2016, there were three planning area providers with OR capacity. Of the three providers, two are hospitals and one is an ambulatory surgery center.

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. The data provided in the utilization survey is used, if available.

Table 1 shows a listing of the hospitals and the one ASF. [source: CN historic files and ILRS]

Table 1
Walla Walla County Planning Area Hospitals and ASFs

Type of Facility	Facility	Status
Hospital	Providence St. Mary Medical Center	Operational
Hospital	Walla Walla General Hospital	Closed-07/24/17
CN Exempt ASF	Walla Walla Clinic (Applicant)	Operational

For Providence St. Mary Medical Center all known OR capacity and procedures are included in the methodology calculations for the planning area. For Walla Walla General Hospital, since the facility closed in year 2017, all known OR procedures are included in the methodology calculations, but the ORs are not included.

For the applicant's facility—Walla Walla Clinic—the use of this ASF is restricted to physicians that are employees or members of the clinical practice. Therefore, this facility does 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.

The data points used in the department's numeric methodology are identified in Table 2. The methodology and supporting data used by the department is provided in Appendix A attached to this evaluation.

Table 2
Department's Methodology Assumptions and Data

Assumption	Data Used
Planning Area	Walla Walla County
	Age Group: 0 – 85%+
	Office of Financial Management Population Data
Population Estimates and Forecasts	released year 2017
	Year 2016 – 60,930
	Year 2021 – 62,378
	Divide the calculated surgical cases by 2016
Use Rate	population results in the service area use rate of
	133.694/1,000 population
	1,134 – Outpatient
Year 2016 Total Number of Surgical Cases	7,012 – Inpatient or Mixed-Use
	8,146 – Total Cases
	Based on DOH survey and ILRS:
Percent of surgery: outpatient vs. inpatient	13.92% outpatient;
	86.08% inpatient
	Based on DOH survey and ILRS:
Average minutes per case	Outpatient cases: 49.82 minutes
	Inpatient cases: 160.41 minutes
	68,850 outpatient surgery minutes;
OR Annual capacity in minutes	94,250 inpatient or mixed-use surgery minutes
	(per methodology in rule)
F : .: /O.D.	Based on listing of Walla Walla County Providers:
Existing providers/ORs	0 dedicated outpatient ORs
	5 mixed use ORs
Department's Methodology Results	Shortage of 0.84 outpatient ORs

Based on the assumptions described in Table 2 above, the department's application of the numeric methodology indicates a shortage of 0.84 outpatient ORs in year 2021.

When comparing the applicant's and department's methodology, there are differences in three main data points. Noted differences are shown below.

Data Points		
Historical and Forecast Population Estimates		
Surgical Cases		
Use Rate		

These three data points are tightly connected. When the 2016 total number of surgical cases is divided by the year 2016 <u>population</u>, the result is a planning area <u>use rate</u>. The use rate is then applied to the projected population.

Once the methodology projects the number of ORs needed in a planning area, the existing number of ORs is subtracted, resulting in the net need or surplus of ORs for a planning area.

#### Population Estimates/Forecasts

Both the applicant and department used Office of Financial Management data for the historical and projected population source. However, the applicant used 2017 population data and projected to year 2022. Given that the utilization data used in the methodology is for year 2016, the department use 2016 population data and projected to year 2021. Year 2021 is the projected third year of operation for the Walla Walla Clinic project. The department considers its own approach to be more accurate.

#### Surgical Cases

A comparison review of the department's and the applicant's numeric methodology shows that the surgical cases, both inpatient and outpatient is the largest difference in the two methodologies. The applicant calculated 4,852 inpatient cases and 3,010 outpatient cases, for a planning area total of 7,862 cases. However, the department calculated 7,012 four inpatient cases and 1,134 outpatient cases, for a planning area total of 8,146 cases. It appears that the applicant again used 2017 data in its calculations.

#### Use Rate

As stated above, the data points used in this numeric need methodology are tightly connected. The population figures are a factor used in the methodology to determine the use rate in the planning area. A use rate per 1,000 residents is calculated by dividing the total number of surgeries by the base year (2016) population and then dividing by 1,000. The applicant calculated a use rate of 129.544/1,000 residents for the Walla Walla County planning area. The department calculated a use rate of 133.694/1,000 residents in the planning area. For this project, the department's use rate is more accurate because it included the same population information as used in the utilization data. The use rate is applied to the projected population. Walla Walla Clinic used 2022 population and the department used 2021 projected population.

In summary, while the two methodologies are very similar and the use rates used are not significantly different, the department considers its numeric methodology more accurate than that provided by the applicant.

The department's numeric methodology calculates a need for less than one additional OR in Walla Walla County. Walla Walla Clinic is requesting approval of three ORs at its surgery center. Below is the additional information considered to evaluate the need for this project.

#### Walla Walla Clinic

To further support approval of its project, Walla Walla Clinic provided historical utilization of the facility for years 2012 through 2017. [source: Application, p5 and March 26, 2018 screening response, Exhibit 28] The table below shows historical procedures for full years 2015 through 2017.

Historical Procedure	Year 2015	Year 2016	Year 2017
Orthopedic Surgery/Interventional Pain	620	614	628
Otolaryngology	170	234	184
General Surgery	159	197	327
Urology	422	356	435
Podiatry	91	123	116
Gastroenterology	1,289	1,370	1,739
Obstetrics & GYN	77	103	78
Plastic	334	310	225
<b>Total Procedures</b>	3,162	3,307	3,732

Walla Walla Clinic also provided the following supplemental information under this sub-criterion. [source: March 26, 2018, screening response, pp3-5]

"As detailed in Exhibit 8 to CN Application #18-14, Walla Walla Clinic's calculations show that there is currently a shortage of 2.19 outpatient operating rooms ("ORs") in the Walla Walla County secondary health services planning area. Further, the calculations show that there will be shortage of 2.25 outpatient ORs by the year 2022 in the planning area.

In addition to Walla Walla Clinic's calculations showing that there is a need for additional outpatient ORs, logic dictates that there is a demand for additional outpatient ORs as a result of the closure of Walla Walla General Hospital and the loss of the ORs associated with that hospital.

Further, WAC 246-310-270(4) provides discretion for the CN Program to approve ORs that would not ordinarily be approved. For example, the CN Program can issue a CN without a showing of numeric need if the applicant can show that through existing volumes the facility will have no impact on market share, the facility is necessary to provide access to specific surgical types, or the existing healthcare system supports continued operation of the facility.

As indicated above, there is a shortage of ORs in the Walla Walla County secondary health services planning area. However, even if there were no numerical need, the additional ORs Walla Walla Clinic is requesting should be approved for a number of reasons. First, the planning area has experienced recent upheaval, with the closing of one of the local hospitals. The patient population that would have used that hospital for surgeries - and their physicians - now have to find an alternative. Walla Walla Clinic provides an alternative.

There is now only one hospital in the health planning area. That one hospital has a religious affiliation that prohibits it from offering common reproductive surgical services, including ones related to sterilization, contraception and fertility. With the closing of Walla Walla General Hospital, patients seeking these services will be forced to travel outside their community to receive these services, unless the patients are allowed to receive these services from Walla Walla Clinic. Granting Walla Walla Clinic the CN it is requesting will help ensure all reproductive or other services not performed by the one local hospital in the health planning area will remain available to local residents.

In addition, allowing Walla Walla Clinic to make its ORs available to physicians outside its physician practice will save patients and payors significant cost because most surgeries performed at the Walla Walla Clinic are significantly less costly than having that same surgery performed at the one local hospital.

ASCs are able to perform surgeries much more efficiently than hospitals. ASCs do not incur the often substantial administrative and overhead costs associated with a hospital. This enables ASCs to provide these services at substantially less cost to the Medicare Program and other payors - and to patients - than their hospital counterparts.

Today, Medicare reimburses ASCs at an average of 58 percent of the rate it reimburses hospitals for the same procedures. The savings that accrue over time, even for individual procedures, are significant. For example, during the four-year period from 2008 to 2011, the lower ASC reimbursement rate generated a total of \$7.5 billion in savings for the Medicare program and its beneficiaries. Approximately \$6 billion of these savings were realized by the federal Medicare program. The remaining approximately \$1.5 billion was saved by Medicare beneficiaries themselves. In other words, Medicare patients nationwide saved \$1.5 billion as a result of the less expensive care offered at ASCs.

In summary, even if there were no demonstrated need, Walla Walla Clinic should still be awarded a CN in order to make its ORs available to physicians outside its practice in order to increase access of needed outpatient service services general, maintain the availability of certain common reproductive surgical services in particular, and reduce the cost of outpatient surgical services when compared to the cost of the same services being provided a local hospital."

# Public Comment

As previously stated, the department initially reviewed this project under a concurrent review with the application submitted by Providence St. Mary. A combined public hearing was conducted in Walla Walla on August 20, 2018, ad comments were provided for both projects. Since the department bifurcated the review of the two projects, the focus of the public comment in this evaluation is Walla Walla Clinic's project.

Public comments were submitted by residents and healthcare providers in Walla Walla County. Below are excerpts of the some of the public comment received related to this sub-criterion.

# Barbara Clark, resident of Walla Walla County

"I urge you to grant the certificate of need to Walla Walla Clinic, or else to condition any certificate of St. Mary on their providing medical care based on medical rather than religious standards. ... only the proposal by Walla Walla Clinic would at least partially maintain the level of service that was available while Walla Walla General Hospital was open. The Clinic facility would allow patients and physicians of all faiths to receive and provide appropriate medical care based on medical needs and standards."

#### Clinton Streifling, resident of Walla Wall County

"It is advantageous for me as a patient to have this Surgery Center available, because the cost of care, and the out-of-pocket expense to me is dramatically less in the Walla Walla Clinic Surgery Center than it would be if I were an outpatient at Providence St. Mary Medical Center."

# Kate Follett, resident of Walla Walla County

"It is advantageous for me as a patient to have this Surgery Center available, because the cost of care, and the out-of-pocket expense to me is dramatically less in the WW Clinic Surgery Center than it would be if I were an outpatient at Providence St. Mary Medical Center. I am quite sure about this, because it is well known that costs of care in hospital systems nationwide exceed by wide margins cost of care in private facilities like surgery centers and clinics."

# Robert Smith, MD, Chief of Staff, Providence St. Mary Medical Center

"It is my professional opinion that BOTH certificate of need applications for Walla Walla should be accepted. The primary reason, as I stated in the hearing, is that we are unable to have a single emergency surgical operating room available. What this means is that we usually have nowhere to bring a trauma or emergency surgical patient for care because the operating room is being used for elective cases.

You might ask: "So why not just leave an operating room open for emergencies then?" Well, it's because we don't have enough capacity for elective cases from the community. We know we lack the capacity because, when benchmarked against the other 52 Providence hospitals, we operate at 200% of the average for our OR space. Here's some other facts you may find helpful.

- The majority of our general surgery cases are performed after hours due to a lack of OR space for urgent and emergent surgery during the daytime. Many studies have demonstrated worse patient outcomes for after-hours cases.
- Most anesthesia providers in Walla Walla work at 95-99%ile when benchmarked nationally due to inability to recruit new providers to work after hours. Again, this is due to lack of OR space.
- We have one of the highest turnover rates of surgical techs and OR nurses in the system primarily due to burnout from working after hours.
- Cases, and staff, are scheduled in all 5 of the Saint Mary operating rooms from 7:30am-7:30pm five days a week and 8 hours on weekends for elective cases. Three rooms regularly run past 7:30 PM weekdays. With this, we still do not have enough capacity for elective cases.
- Finding staff to run ORs through the night and longer on weekends has proven impossible in Walla Walla. Many staff members are only staying contingent on a successful CON application. If the process fails, we won't have staff to run ORs during regular hours or surgical emergencies.
- 32% of our surgical and procedural patients come from Oregon. Many patients travel 2-2.5 hours to get to Walla Walla. The reasons are that they have Medicare/Medicaid or the services are not available in their areas. Despite the insistence that the CON process in Washington does not take in to account patients from out-of-state, we are not going to build a wall of medical refusal at the border 7 miles to the south of the hospital or clinic. If we do not get significantly more OR space in Walla Walla we will continue to care for these patients and continue to lack open operating room space for urgent and emergent cases.
- 100% of the OR space at the hospital, 7:30am-7:30pm, is blocked out to current providers. Many of the surgeons have no operating room block time because we have none to give. If these providers leave then we will no longer be able to provide 24/7 coverage for General Surgery, Orthopedic Surgery, ENT, Ophthalmology, and Gastroenterology. For clarification, there is no hospital in Tri-Cities, Yakima, or most of Eastern Oregon that provides 24/7 coverage in ALL of these specialties. We regularly accept patients from 2 hours away (Washington and Oregon) for

emergent gastroenterology cases, especially ERCP. There is not a hospital in Tri-Cities that has emergency ophthalmologic coverage.

The long story short is: The surgical and GI space capacity at Saint Mary was stretched before the Walla Walla General Hospital closed. Staff are burned out, overworked, and only willing to stay until an ASC comes online to decompress space problems. Often, we have no space for urgent or emergent surgery. Several hundred patients have been transferred out or diverted for this reason.

As one of the primary architects of the system to ensure safe patient care in Walla Walla it is my opinion that BOTH the certificate of need requests should be granted. Basically, the Clinic will add one additional OR and Providence will add two. We need at least this many. Either the ASC for the Walla Walla Clinic or Providence will be inadequate for the practitioners to provide elective and emergent surgical services. The only reasonable alternative is to approve them both.

This has the added benefit of ensuring local reproductive health services as well as reasonable market competition in the area. If the DOH cannot approve both CON requests, then we (the medical community) will need some help from the Department of Health to build an acceptable system of care for the community that doesn't burn out every provider."

# Bonnie Szuch, resident of Walla Walla County

"I'm not opposed to both Walla Walla Clinic and Providence having an ASC. I'm sure both would be an asset to the community. I'm also a Vietnam-era Air Force veteran and I know veterans can now use private doctors for services. If it has to be only one, I would choose Walla Walla Clinic because they can provide reproductive services and pediatric services not provided by Providence. I have friends and family who are lower income and can't get time off to travel for pregnancy/reproductive choices/vasectomies. Please consider the large population of hard working, low income folks in Walla Walla."

# Margaret Ann Ryan, resident of Walla Walla County

"I resonated with Dr. Robert Smith's statement that BOTH Facilities be issued a Celtificate of Need. WW Clinic will be able to offer reproductive surgeries that Providence St. Mary Medical Center cannot because of the Hospital's association with the Roman Catholic Church.

Barbara Clark was clear in her statement that ALL patients be able to secure medical services based on 'Medical rather than Religious needs'. I agree with Barbara's statement.

I write on behalf of BOTH Medical Organizations and request that each be granted a Certificate of Need."

#### Carlan Bradshaw, resident of Walla Walla County

"Sitting through the whole public comment hearing this morning, it would be my hope that both Providence and WW Clinic are approved. We don't want a Providence monopoly nor do we want to leave this city without full women's reproductive services. I know I would feel better served with both facilities operating with everything they need for the public good. Approve them both. Thank you for your efforts and oversight."

# Joshua Slepin, resident of Walla Walla County

"I somehow neglected to say in my previous email that I strongly support the application from WW Clinic. I am neutral on the application from St. Mary's, as I do not necessarily see the two in opposition. However, should the department see them as such, then I would vote against the latter. We have a greater need for the lower cost proposal of WW Clinic that allows for more options."

# Diane Knight, resident of Walla Walla Clinic

"I wish to submit this letter of support for the Walla Walla Clinic's application, as part of the public opinion/hearing. I also wish to voice concern re: approval of the Providence application if the WWC application is denied, as this would severely limit access for some procedures in this rural community. I speak as both a provider advocating for this community and as a woman concerned about limiting options for the women of this community.

With the closing of [Walla Walla] General, as this community is growing, I feel BOTH requests/Certificates of Need, could be granted. However, if it's only one, then it needs to be at Walla Walla Clinic, for the sake of ensuring access to quality care- ALL care. Thank you for the opportunity to voice these concerns and to support the Walla Walla Clinic application."

#### Elaine Couture, Providence Health & Services Washington/Montana

"Since the closure of Walla Walla General Hospital last year, Providence is now the only provider of surgical services in Walla Walla County that accepts all patients, regardless of payor. That includes Medicaid and Medicare patients, as well as the 2,500 incarcerated individuals at the Washington State Penitentialy in Walla Walla and uninsured patients. In 2017, Providence St. Mary invested more than \$3 million in free and reduced cost of care for the poor, and more than \$10 million in Medicaid reimbursement shortfalls."

#### Rebuttal Comment

The majority of Walla Walla Clinic's rebuttal comments focus on information provided by Providence Health and Services for the Providence St. Mary project. Since this evaluation focuses on the Walla Clinic project, the excerpts below focus on comments provided for the Walla Walla Clinic project. Below is Walla Walla Clinic's rebuttal comments.

# Walla Walla Clinic Surgery Center Provides Services to All Patients, Regardless of Payor

[source: Walla Walla Clinic, September 4, 2018, rebuttal comments, p4]

"Throughout the August 20, 2018 public hearing and the written comments offered by its employed physicians and staff, Providence has stated, "Providence is now the only provider of surgical services in Walla Walla County that accepts all patients, regardless of payor." This statement is misleading. In fact, Walla Walla Clinic accepts Medicare patients and Medicaid patients, and it provides charity care to patients who are unable to pay. Moreover, Walla Walla Clinic has indicated a willingness to comply with any conditions on a certificate of need issued to it related to providing care to those in need."

Walla Walla Clinic Surgery Center Provides Important Reproductive Services Not Available Elsewhere in the Community

[source: Walla Walla Clinic, September 4, 2018, rebuttal comments, pp5-6]

"The Walla Walla Clinic project would allow patients and physicians of all faiths to receive appropriate health care based on medical needs and standards of care. Walla Walla Clinic will not refuse treatment to patients based on religious directives or moral imperatives.

Currently, Walla Walla Clinic Surgery Center is the only facility in the community that provides certain important reproductive surgical services. If Providence's certificate of need application is approved, it will threaten the long-term viability of Walla Walla Clinic Surgery Center. If Walla Walla Clinic Surgery Center were to close, important reproductive services will be unavailable in the community.

Only one in six hospital patients is not treated in a Catholic facility, according to the Catholic Health Association, a membership organization that includes 90 percent of the Catholic hospitals in the United States. Moreover, in a growing number of rural areas – such as Walla Walla – a Catholic hospital is the sole provider of acute care. Approving Providence's certificate of need application would ensure Providence becomes the sole certificate of need approved provider of outpatient surgical care in the Walla Walla community."

# **Department Evaluation**

Walla Walla Clinic provided information to support that utilization at the existing facility should continue within the planning area. With CN approval, physicians not associated with Walla Walla Clinic Surgeons could use the surgery center.

During the August 20, 2018 public hearing conducted for both ASC projects, many members of the community requested approval of both Walla Walla Clinic and Providence St. Mary's ASC. The rationale for this approach is addressed in the public comment above, specifically, there are some services that are provided by Walla Walla Clinic that are not, and will not be provided, at the Providence St. Mary ASC. Community members recognize an overlap of services provided at each facility, but suggest the duplication should not be a reason to deny this project. The department also recognizes that some of the services overlap, but do not consider either project to be an unnecessary duplication of services.

Since Walla Walla Clinic does not intend to increase the number of ORs (3) or the types of procedures provided at the surgery center, limited growth at the surgery center is expected.

Based on the source information reviewed, which includes the numeric need methodology, and Walla Walla Clinic'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. **This sub-criterion is met.** 

#### WAC 246-310-270(6)

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

#### Walla Walla Clinic

Walla Walla Clinic ASC currently operates with three ORs. This project does not intend to decrease or increase the number of ORs. [source: Application p5 and Exhibit 7]

### **Public Comment**

None

#### Rebuttal Comment

None

# **Department Evaluation**

WAC 246-310-270(6) requires a minimum of two ORs in an ASF. Walla Walla Clinic ASC is currently operating with three ORs. This project does not propose to increase or decrease the number of ORs at the facility. **This standard is met.** 

(2) <u>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.</u>

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 for 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.

Charity care shows a willingness of a provider to provide services to individuals who do not have private insurance, do not qualify for Medicare, do not qualify for Medicaid, or are under insured. With the passage of the Affordable Care Act in 2010, the amount of charity care decreased over time. However, with recent federal legislative changes affecting the ACA, it is uncertain whether this trend will continue. Specific to ASFs, WAC 246-310-270(7) requires that ASFs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed project.

#### Walla Walla Clinic

Walla Walla Clinic provided copies of the following policies used at both the clinic and the surgery center.

- Financial Assistance and Charity Care Policy [source: Application Exhibit 11]
- Patient Notice of Financial Assistance Explaining Walla Walla Clinic Charity Care Policy [source: March 26, 2018, screening response, Exhibit 24]
- Admission Policy [source: March 26, 2018, screening response, Exhibit 25]

#### Medicare and Medicaid Programs

Walla Walla Clinic ASC is currently Medicare and Medicaid certified. Walla Walla Clinic provided its current and projected source of revenues by payer shown in Table 3. [source: Application p15]

Table 3
Historical and Projected Payer Mix

Payer Group	Historical	Projected
Medicare	30.0%	30.0%
Medicaid	6.0%	6.0%
Commercial/Health Care Contractor	58.0%	58.0%
Other Government/L & I	5.0%	5.0%
Other (self pay)	1.0%	1.0%
Total	100.0%	100.0%

# **Charity Care**

Walla Walla Clinic also provided the following statements related to the charity care percentage to be provided at the ASC. [source: Application, p13]

"Consistent with the requirements of WAC 246-310-270(7), Walla Walla Clinic Surgery Center projects to provide the average charity care for Walla Walla County, or 1.52% for gross revenue and 4.67% for adjusted revenue."

Walla Walla Clinic also provided three tables showing its historical amounts of charity care provided for each of the full years 2015, 2016, and 2017. One table shows the clinic, another table shows the surgery center, and the third table shows the combined historical charity care for the clinic and the surgery center. The applicant's combined charity care table is replicated below. [source: March 26, 2018, Exhibit 26]

Applicant's Charity Care Table Walla Walla Clinic and ASC

	Dollar Amounts				
Years	Gross Revenue	Adjusted Revenue	Charity Care		
2015 Full Year	\$66,916,286	\$35,509,690	\$154,362		
2016 Full Year	\$68,970,274	\$35,991,225	\$180,017		
2017 Full Year	\$74,746,080	\$37,845,109	\$173,528		

The applicant's charity care table for the surgery center alone is replicated below. [source: March 26, 2018, Exhibit 26]

# Applicant's Charity Care Table Walla Walla Clinic ASC

	Dollar Amounts				
Years	Gross Revenue	Adjusted Revenue	Charity Care		
2015 Full Year	\$10,531,045	\$6,739,869	\$78,983		
2016 Full Year	\$10,701,692	\$6,849,083	\$80,263		
2017 Full Year	\$10,874,408	\$6,959,621	\$81,558		

Public Comment

None

Rebuttal Comment

None

#### **Department Evaluation**

Walla Walla Clinic provided the Admission Policy, Notice of Financial Assistance Policy, and Charity Care Policy currently in use and would continue to be used at Walla Walla Clinic ASC.

The Admission policy that was provided includes the required non-discrimination language to ensure patients would be admitted for treatment regardless of age, race, color, religion, sex, national origin, handicap or sexual preference. The policy also includes the criteria for admitting patients and a description of the types of patients that would be served. The Admission Policy also notes that all patients are provided with a copy of the "Patient Rights" at pre-op visit in doctor's office. The Admission Policy is consistent with those approved by the department in past evaluations.

The Charity Care Policy is used in conjunction with the "Patient Notice of Financial Assistance" Policy. Combined, these policies provide the process one must use to access charity care, explain the eligibility for charity care, and allow for consultations with Clinic staff regarding charity care. Within the application, Walla Walla Clinic provided a table showing the historical dollar amounts for charity care provided by the ASC and the Clinic separately. This information demonstrates that Walla Walla Clinic currently provides charity care to the community and supports the applicant's assurance it would continue to provide charity care if this project is approved.

The financial data provided in the application shows both Medicare and Medicaid revenues consistent with Table 3 above. The department concludes that Walla Walla Clinic intends for this proposed surgery center to continue to be accessible and available to Medicare and Medicaid patients based on the information provided.

#### WAC 246-310-270(7)

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. For charity care reporting purposes Washington State is divided into five regions: King County, Puget Sound, Southwest, Central, and Eastern. Walla Walla Clinic ASC is located with Walla Walla County within the Eastern Washington Region. In year 2017, Walla Walla General Hospital closed, as a result, there are 20 hospitals currently operating in the region. Of the 20

hospitals, one is located in Walla Walla County—Providence St. Mary. This hospital could be affected by approval of this project.

Walla Walla Clinic stated that the surgery center will provide charity care at 1.52% for gross revenue and 4.67% for adjusted revenue. For this project, the department reviewed the most recent three years of charity care data for the 20 existing hospitals currently operating within the Eastern Washington Region and focused on Providence St. Mary because it could be affected by approval of this project. The three years reviewed are 2015, 2016, and 2017.<sup>3</sup>

Table 4 below is a comparison of the historical average charity care for the Eastern Washington Region as a whole, the historical average charity care by Providence St. Mary, and the projected charity care to be provided at Walla Walla Clinic with the surgery center. [source: Community Health Systems Charity Care 2015-2017 and June 7, 2018, screening response, Exhibit D]

Table 4
Charity Care – Three Year Average

	% of Total Revenue	% of Adjusted Revenue
3-year Eastern Washington Region	0.81%	2.54%
3-year Providence St. Mary	1.65%	4.74%
Projected Walla Walla Clinic ASC	1.57%	2.45%

As shown above, the three year average proposed by Walla Walla Clinic for the surgery center is higher than the regional average and lower than the historical average for Providence St. Mary Medical Center, the sole hospital operating in Walla Walla County planning area.

Though the application shows that Walla Walla Clinic would provide charity care above the planning area average, the department would still attach a condition related to this sub-criterion if this project is approved. The condition would require Walla Walla Clinic to make reasonable efforts to provide charity care at the levels stated in the application. This condition would also require Walla Walla Clinic 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 kept on site at the ASF and available upon request.

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

- (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.

<sup>&</sup>lt;sup>3</sup> Walla Walla General Hospital closed in July 2017. Historical year 2015 includes charity care data for the hospital as reported to the Department of Health. Walla Walla General Hospital did not report charity care data for years 2016 and 2017.

#### **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.

### **Department Evaluation**

This criterion is not applicable to this application.

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

# **Department Evaluation**

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.

#### Department Evaluation

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 Walla Walla Clinic has met the financial feasibility criteria in WAC 246-310-220.

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

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

# Walla Walla Clinic

Before the department performs its review of the financial documents provided in this application, a review of the projected number of procedures is necessary. Within the application, Walla Walla Clinic provided the following clarification regarding the types of procedures to be provided. [source: June 7, 2018, screening response, p1]

"The ASC is not anticipating performing any types of surgeries or other procedures that it is not currently performing. Walla Walla Surgery Center currently performs procedures under both general and local anesthesia in the following specialties: gastroenterology, general surgery, obstetrics and gynecology, orthopedics/interventional pain, otolaryngology, plastic surgery, podiatry and urology. If certificate of need approval is granted, Walla Walla Surgery Center anticipates increasing the number of procedures performed in these specialties by allowing community surgeons access to its facility. Increasing Walla Walla Surgery Center's volume will provide Providence St. Mary Medical Center with additional capacity to handle more complex procedures that cannot be performed in the ambulatory surgical setting.

Importantly, Walla Walla Surgery Center performs and would continue to perform essential reproductive health surgical services that are not offered by any other certificate of need approved facility in the health planning area and that would not be offered by Providence St. Mary Medical Center if its certificate of need application is approved. Providing access to these surgical services in the health planning area is critical to the area's residents."

In addition, Walla Walla Surgery Center has the capacity and willingness to add ophthalmology and oral surgery procedures; but the cost of related equipment was not contemplated in our certificate of need capital expenditure amount. As such, volumes for these specialties have been excluded from projections.

Walla Walla Clinic understands the necessity for complete projections of the types of services to be provided. The ASC is not anticipating performing any types of surgeries or other procedures that it is not currently performing. The types of surgeries and procedures will remain the same. Please see answer to Question #1."

Walla Walla Clinic provided the following assumptions used to determine the projected number of procedures by type at the surgery center. [source: Application, Exhibit 12]

#### Current Services

- Orthopedic Surgery: Current volume plus 74 additional cases per year initially; Capacity for six additional cases per week; WWGH's annual outpatient volume was 240.
- Otolaryngology: Current volume plus 120 additional cases per year initially; Capacity for 4 additional cases per week; WWGH's annual outpatient volume was 138.
- General Surgery: Current volume plus 52 additional cases per year initially; Capacity for six additional cases per week; WWGH's annual outpatient volume was 248.
- Urology: Current volume. No additional growth assumed for conservative reasons but potential for two additional cases per week if CON granted.
- Podiatry: Current volume. No additional growth assumed for conservative reasons; potential growth exists with Podiatrists outside of Walla Walla County.
- Gastroenterology: Current volume. No additional growth assumed for conservative reasons; potential growth exists based on experience since WWGH closure in July 2017.
- Obstetrics and Gynecology: Current volume. No additional growth assumed given our group is only OB/GYN provider group in community.

#### New Services

• Interventional pain, plastic surgery, ophthalmology, and oral surgery
For purposes of creating the pro forma and to be conservative with respect to its financial
predictions, Walla Walla Clinic made all of its projections based on current numbers without
any increases. Thus, since these services were not previously offered, there are no projected
cases. Although no new specialties were assumed in the pro forma, if the CN is granted, Walla
Walla Clinic would evaluate the need to add these specialties if there is need in the health
planning area.

Consistent with its assumptions identified above, Walla Walla Clinic provided the historical and projected number of cases and procedures at the surgery center. Historical years are 2015 through 2017 and projection years are 2018 through 2021. The information is summarized in Table 5. While Walla Clinic provided a breakdown of the historical and projected number of cases by type, the table below does not show that detail.

Table 5 Walla Walla Clinic ASC Historical Cases and Procedures

	Historical		Projected				
	2015	2016	2017	2018	2019	2020	2021
Total Number of Cases	2,091	2,158	2,423	2,614	2,620	2,626	2,632
Total Number of Procedures	3,162	3,307	3,732	4,052	4,061	4,070	4,080

Walla Walla Clinic provided the following explanation regarding the difference between cases and procedures. [source: June 7, 2018, screening response, p5]

"The total number of projected surgical cases is not projected to decrease. The total number of projected surgical cases is projected to increase. Each surgical case may include multiple procedures. The historical data provided in Exhibit 28 represents surgical procedures, not surgical cases. The projected volumes in 2018 and beyond represent surgical cases. Walla Walla Clinic has prepared the following table to clarify historical and projected volumes by both surgical case and procedure."

Walla Walla Clinic provided the following clarification regarding the market share assumptions used for the projections above. [Application, Exhibit 12]

"Note: Rounding allows for some discrepancy.

- 2018 market share based on percentage of anticipated procedures to be acquired as a result of the closure of Walla Walla General Hospital (Assumption of a market share of 12.8% of 1876 cases).
- 2018 2023 growth rate based on an assumption of 12.8% market rate in the Walla Walla Planning Area and the predicted population growth by OFM. Data using the 2017.
- DOH surveys for Walla Walla Clinic and Walla Walla General Hospital as well as the 2016 DOH survey for Providence Hospital were utilized in the assumption.
- This was calculated on projected population growth by the OFM and surgical occurrences at 129.544/1000.
- The population is expected to grow 2.23 percent from 2018-2022. This would equate to an additional 220 cases over 5 years. Walla Walla clinics anticipated portion of this at 12.8% is an additional of approximately 30 cases.

Please note that this is an extremely conservative projection. Based on Walla Walla Clinic's ability to provide a total of 206,550 OR minutes in 3 ORs and the assumption that outpatient cases require 50 minutes per case, the ability equates to 4131 cases per year. Considering the ability of the clinic to provide the same procedures as the hospital at a much lower cost, the actual utilization may be much higher that the market share portion shows."

The assumptions Walla Clinic used to project revenue, expenses, and net income for the proposed surgery center for projection years 2018-2021 are summarized below. [source: Application, pp29-30; March 26, 2018, screening response, pp15-16; and June 7, 2018, screening response, p3]

- Revenue is calculated based on historical reimbursement per case and projected case volumes by specialty.
- Deductions from revenue are calculated based on historical payer mix an increase in charity care based on expanded patient population.
- Salaries and wages are calculated based on projected staffing levels and annual cost of living adjustments.
- Employee taxes and benefits are calculated based on historical experience with annual CPI increase for benefits.
- Medical supplies projected are based on assumed case mix and historical cost per case by specialty.
- Office supplies are projected based on historical with anticipated increase due to higher volumes and number of physicians using facility.
- Pharmacy is projected based on historical volumes per case and assumed increase in utilization.

  An annual cost increase is also assumed.

- Equipment lease and maintenance is projected based on historical experience plus annual increase due to inflation and normal aging of facility.
- Depreciation is projected based on current capital assets plus depreciation of \$175,000 capital expenditure for CN project and future capital expenditures based on 1.5% of net revenue.
- Utilities are projected based on historical experience with assumed annual rate increases and additional usage related to CN.
- Other expenses include interest, instruments, housekeeping, purchased services, food/beverage, facility licensure and accreditation, and books and subscriptions.
- No medical director fees are included because physicians are employed and not additionally compensated.
- No allocated costs because the clinic and the surgery center are both assets and departments of a single corporate entity, Walla Walla Clinic, Inc., P.S. The entity does not allocate or charge costs from one department to another.
- No laboratory costs because Walla Walla Clinic owns its own onsite laboratory. Certain samples are sent to outside reference laboratories. The cost of processing and transporting these samples are borne by the reference laboratories.
- No building costs because Walla Walla Clinic owns the ASC building.

As previously stated in the evaluation, the payer mix percentages are not expected to change. The percentages are shown below.

Payer Group	Projected
Medicare	30.0%
Medicaid	6.0%
Commercial/Health Care Contractor	58.0%
Other Government/L & I	5.0%
Other (self pay)	1.0%
Total	100.0%

Based on the assumptions above, Walla Walla Clinic provided its projected revenue, expenses, and net income for Walla Walla Clinic ASC. The projections are summarized below. [source: June 7, 2018, screening response, Exhibit D]

Table 6
Projected Revenue and Expenses for Calendar Years 2018 through 2021

	CY2018	CY2019	CY2020	CY2021
	(partial year)	(year one)	(year two)	(year three)
Net Revenue	\$3,915,443	\$3,978,889	\$4,043,105	\$4,108,100
Total Expenses	\$2,352,379	\$2,423,872	\$2,478,605	\$2,534,503
Net Profit/(Loss)	\$1,563,064	\$1,555,017	\$1,564,500	\$1,573,597

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/leases, and depreciation.

# Public Comment

None

#### Rebuttal Comment

None

#### **Department Evaluation**

To evaluate this sub-criterion, the department first reviewed the assumptions used by Walla Walla Eye Clinic to determine the projected number of procedures and occupancy of the ASF. For existing procedures, Walla Walla Eye Clinic based its projections on existing volumes, with conservative increases in volumes. This approach is reasonable.

Walla Walla Clinic based its market share assumption on a variety of factors, including the 2017 closure of Walla Walla General Hospital, county population growth as projected by the Office of Financial Management, and its own ability to accommodate additional patients and procedures in its current surgery center. This approach to market share assumption is also reasonable.

For procedures not previously provided at the surgery center, Walla Walla Clinic did not project any cases. Its revenues and expenses do not include any of the new services of interventional pain, plastic surgery, ophthalmology, or oral surgery. Walla Walla Clinic considers this approach to be conservative.

During the review of this project, the department requested Walla Walla Clinic to clarify whether this project was requesting to expand its surgical procedures beyond those already provided. In response to this request, Walla Walla Clinic provided the following clarification. [source: June 7, 2018, screening response, pp2-3]

"The ASC is not anticipating performing any types of surgeries or other procedures that it is not currently performing. Walla Walla Surgery Center currently performs procedures under both general and local anesthesia in the following specialties: gastroenterology, general surgery, obstetrics and gynecology, orthopedics/interventional pain, otolaryngology, plastic surgery, podiatry and urology. If certificate of need approval is granted, Walla Walla Surgery Center anticipates increasing the number of procedures performed in these specialties by allowing community surgeons access to its facility. Increasing Walla Walla Surgery Center's volume will provide Providence St. Mary Medical Center with additional capacity to handle more complex procedures that cannot be performed in the ambulatory surgical setting. ... In addition, Walla Walla Surgery Center has the capacity and willingness to add ophthalmology and oral surgery procedures; but the cost of related equipment was not contemplated in our certificate of need capital expenditure amount. As such, volumes for these specialties have been excluded from projections."

Based on the information above, the department will not consider this application a request to expand the types of procedures at the surgery center. If Walla Walla Clinic intends to expand its types of procedures in the future, a new Certificate of Need application must be submitted and reviewed.

As state above, Walla Walla Clinic based its revenue and expense assumptions for the ASF on the assumptions listed above. As this is an existing facility, and the surgery center has documented experience in operating the ASF since year 2000, these assumptions are reasonable.

Walla Walla Clinic provided documentation to demonstrate ownership of the site and the building. [source: Application, Exhibit 7]

Walla Walla Clinic identified the medical director, Ryan T. Cornia, DPM, who is a Walla Walla Clinic partner. The role of medical director is uncompensated, and there is no associated contract. Walla Walla Clinic provided a job description for the medical director, which includes roles and responsibilities for both Walla Walla Clinic and the medical director. [source: Application, p17 and Exhibit 4]

The pro forma financial statements show revenues exceeding expenses within the first full year of operation and to continue doing so. To demonstrate long term financial viability of both the clinic and the surgery center, Walla Walla Clinic provided its historical balance sheets for years 2014 through 2017, current balance sheet for year 2018, and projected balance sheets for years 2019 through 2021. Below is the 2017 historical balance sheet and the 2021 projected balance sheet. [source: June 7, 2018, screening response, Exhibit E and Exhibit F]

Tables 7
Walla Walla Clinic and Surgery Center
Historical Balance Sheet 2017

Assets		Liabilities			
Current Assets	\$9,813,301	Current Liabilities	\$6,380,186		
Board Designated Assets	\$ 0	Other Liabilities	\$0		
Property/Plant/Equipment	\$9,837,576	Long Term Debt	\$5,740,123		
Other Assets	\$ 0	Equity	\$7,530,568		
<b>Total Assets</b>	\$19,650,877	<b>Total Liabilities and Equity</b>	\$19,650,877		

# Walla Walla Clinic and Surgery Center Projected Balance Sheet 2021

Assets	•	Liabilities			
Current Assets	\$11,578,439	Current Liabilities	\$6,056,913		
Board Designated Assets	\$ 0	Other Liabilities	\$0		
Property/Plant/Equipment	\$9,892,156	Long Term Debt	\$5,514,493		
Other Assets	\$ 0	Equity	\$9,899,189		
<b>Total Assets</b>	\$21,470,595	<b>Total Liabilities and Equity</b>	\$21,470,595		

Based on the information above, the department concludes that the immediate and long-range operating costs of the project can be met. Based on the financial data provided above, the department concludes that approval of this project would not have a negative financial impact on Walla Walla Walla Clinic as a whole. **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.

#### Walla Walla Clinic

In response to this sub-criterion, Walla Walla Clinic provided the following information. [source: March 26, 2018, screening response, p7]

"The proposed project is expected to increase capital costs in Year 1 by \$175,000 (see detail provided in response to question #15). No additional capital costs related to this project are assumed in Years 2-5."

# **Public Comment**

None

#### Rebuttal Comment

None

#### **Department Evaluation**

Walla Walla Clinic's response to the capital expenditure question above may be the result of a misunderstanding of the question. The question focuses on the capital expenditure necessary to implement the proposed project. It appears that Walla Walla Clinic misunderstood the question to refer to start-up costs for the project. After reviewing the financial information provided in the application, Walla Walla Clinic is identifying an estimated capital expenditure of \$175,000 in year one, but no other costs in subsequent years.

Walla Walla Clinic provided a current and projected payer mix for the surgery center. As previously stated in the evaluation, the payer mix percentages are not expected to change. The percentages are shown below.

Payer Group	Projected
Medicare	30.0%
Medicaid	6.0%
Commercial/Health Care Contractor	58.0%
Other Government/L & I	5.0%
Other (self pay)	1.0%
Total	100.0%

The payer mix identified by Walla Walla Clinic is based on its existing payer mix for the surgery center. This approach for determining a payer mix is reasonable.

Based on the information above, the department concludes that approval of this project would not have an unreasonable impact on costs and charges for healthcare services in Walla Walla County. **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.

# Walla Walla Clinic

Walla Walla Clinic states that the capital cost of \$175,000 associated with the ASC will be financed through operating reserves and an existing line of credit of Walla Walla Clinic. To demonstrate compliance with this sub-criterion, Walla Walla Clinic provided the following documents.

- US Bank National Association Revolving Credit Note for \$500,000 as of July 26, 2017.
- Walla Walla ASC Historical Revenue and Expense Statements
- Walla Walla ASC Historical Cash Flow Statement
- Breakdown of the Equipment for the Capital Expenditure
- Years 2015-2017 Historical Audited Financial Statements for Walla Walla Clinic, Inc. PS
- Years 2015-2017 Historical Revenue and Expense Statements for Walla Walla Clinic, Inc. PS [source: Application, p6, Exhibit 6, Exhibit 13, and Exhibit 14; March 26, 2018, screening response, Exhibit 17, Exhibit 19, and Exhibit 29; and June 7, 2018, screening response, Exhibit B]

# **Public Comment**

None

#### Rebuttal Comment

None

# **Department Evaluation**

Walla Walla Clinic provided documentation to demonstrate it has, or has access to, the funds necessary for this project. Further, Walla Walla Clinic provided its historical financial statements for full calendar years 2014 through 2016. Since the owners of Walla Walla Clinic submitted this application, by that action, members of the clinic have demonstrated a financial commitment to the project.

Based on the documents provided under this review criterion, if this project is approved, a condition is necessary to ensure that the project would be financed as described in the application. With written agreement to the financing condition, Walla Walla Clinic's project **meets this sub-criterion**.

# 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 Walla Walla Clinic 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 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.

#### Walla Walla Clinic

In response to this sub-criterion, Walla Walla Clinic provided the following statements. [source: Application, p16 and March 26, 2018, screening response, p9]

"Walla Walla Clinic Surgery Center intends to continue employment of all its staff in good standing. Accordingly, a sufficient number of qualified health manpower and management personnel are already in place.

When Walla Walla General Hospital closed, Walla Walla Clinic hired new staff by offering parttime jobs to the former employees of Walla Walla General Hospital. If the CN is granted, the parttime employees from Walla Walla General Hospital will transition into full-time positions."

Walla Walla Clinic provided a listing of all existing staff, which includes the staff hired after closure of Walla Walla General Hospital. Table 8 summarizes the information. [source: March 26, 2018, screening response, p8 and June 7, 2018, screening response, pp8-9]

Table 8
Years 2018 through 2021
Walla Walla Clinic ASC Current and Projected Staffing

2018 2019 2020 2021 Total FTE by Type **Current Year** Staff **Increase** Increase Increase Director of Nursing/Charge Nurse 1.00 0.00 0.00 0.00 1.00 RNs 0.00 0.00 10.50 10.50 0.00 LPNs/Techs 5.35 0.00 0.00 0.00 5.35 Housekeeping 0.00 1.00 0.00 0.00 1.00 Registration/Receptionist 2.50 0.00 0.00 0.00 2.50 **Total FTEs** 20.35 0.00 0.00 0.00 20.35

Walla Walla Clinic also clarified that none of the physicians, whether associated with the clinic or the ASC, are included in the table above because they are not employees. [source: Application, Exhibit 1]

# **Public Comment**

None

#### Rebuttal Comment

None

#### **Department Evaluation**

As shown above, the ASF staff are already in place, and Walla Walla Clinic does not anticipate any increases in staff during the projection years.

Information provided in the application demonstrates that Walla Walla Clinic is a well-established provider of healthcare services in Walla Walla County. The associated surgery center has been operational with three ORs as a CN-exempt facility since year 2000.

Given that Walla Walla Clinic already offers a variety of surgical services as a CN-exempt ASF, the department concludes that Walla Walla Clinic has the ability to staff the ASF if this project is approved.

Based on the above information, 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 relationship to ancillary and support services, and ancillary and support services will be 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.

# Walla Walla Clinic

Walla Walla Clinic provided the following statements and referenced specific exhibits provided in the application relating to ancillary and support services required for the surgery center. [source: Application, p17; and March 26, 2018, screening response, pp9-10]

"Walla Walla Clinic Surgery Center will offer all of the necessary ancillary and support services on site. Walla Walla Clinic has a Professional Services Agreement with Providence St. Mary Medical Center Hospital for the provision of Anesthesiologists and Anesthesia Services. A copy of the agreement with Providence St. Mary Medical Center Hospital is attached as Exhibit 20.

Walla Walla Clinic has a Pharmacy Consultant Agreement with Colette Richman, R.Ph. A copy of the agreement is attached as Exhibit 21.

Walla Walla Clinic has a transfer agreement with Providence St. Mary Medical Center Hospital. A copy of the executed Patient Transfer Agreement between Walla Walla Clinic and Providence St. Mary Medical Center Hospital dated January 11, 2000 was submitted as Exhibit 15 to CN Application # 18-

14. Walla Walla Clinic hopes that physicians who use the Providence St. Mary's Medical Center Hospital ORs would also use Walla Walla Clinic's ASC ORs.

None of the existing ancillary or support agreements are expected to change as a result of this project."

#### **Public Comment**

None

#### Rebuttal Comment

None

# **Department Evaluation**

Walla Walla Clinic has been providing healthcare services in Walla Walla County for many years and operating an associated surgery center since year 2000. The ancillary and support required for the operation of the ASF are already in place and available.

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that Walla Clinic will maintain the necessary relationships with ancillary and support services to provide outpatient surgical services the surgery center. The department concludes that there is no indication that the operation of this existing CN-exempt ASF as a CN-approved ASF would adversely affect the existing relationships. **This sub-criterion is met.** 

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

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

# Walla Walla Clinic

Walla Walla Clinic provided the following statements related to this sub-criterion. [source: Application p17]

"Walla Walla Clinic Surgery Center has no history with respect to the actions described in CN criteria WAC 246-310-230(5)(a). Walla Walla Clinic Surgery Center operates all existing programs in conformance with applicable state and federal laws, rules and regulations."

#### Public Comment

None

#### Rebuttal Comment

None

# **Department Evaluation**

As a part of this review, the department must conclude that the proposed services provided by an applicant would be provided in a manner that ensures safe and adequate care to the public.<sup>4</sup> To accomplish this task, the department reviewed the quality of care and compliance history for the healthcare facilities owned, operated, or managed by Walla Walla Clinic.

# Washington State Survey Data

As stated in the "Applicant Description" section of this evaluation, Walla Walla Clinic currently owns and operates one clinic and surgery center. The surgery center is certified by Centers for Medicare and Medicaid Services (CMS) and accredited by the American Association for Accreditation of Ambulatory Surgery Facilities<sup>5</sup>.

Using its own internal database, the department reviewed historical survey data for Walla Walla Clinic and its associated surgery center from year 2014 through present. The survey data is summarized by facility in the table below. [source: DOH Office of Health System Oversight]

Table 9
Walla Walla Clinic Survey History

License #	Type of License	Year of State Survey
MTSC.FS.00000378	Medical Test Site Categorized <sup>6</sup>	2014, 2016, & 2018
ASF.FS.60103014	Ambulatory Surgical Facility	2015 & 2016

As shown above, Walla Walla Clinic has had recent surveys for both the surgical and the medical test site licenses. Information provided by the Department of Health internal database shows that the facility is substantially compliant.

<sup>&</sup>lt;sup>4</sup> WAC 246-310-230(5)

<sup>&</sup>lt;sup>5</sup> "AAAASF accreditation programs help facilities demonstrate a strong commitment to patient safety, standardize quality, maintain fiscal responsibility, promote services to patients and collaborate with other health care leaders. AAAASF provides official recognition to facilities that have met 100% of its high standards. Accreditation assures the public that patient safety is top priority in a facility. An accredited facility must comply with the most stringent set of applicable standards available in the nation and meet our strict requirements for facility directors, medical specialist certification and staff credentials. It also must pass a thorough survey by qualified AAAASF surveyors. An accredited facility is re-evaluated through a self-survey every year, and an onsite survey every three years. Facilities must continuously comply with all AAAASF accreditation standards between surveys. Upon approval, an accredited facility must prominently display its accreditation certificate in public view. An accredited facility must be fully equipped to perform procedures in the medical specialties listed on its accreditation application." [source AAAASF website]

<sup>&</sup>lt;sup>6</sup> "Medical test site" or "test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A medical test site does not mean:

<sup>(</sup>a) A facility or site, including a residence, where a test approved for home use by the Federal Food and Drug Administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction; or

<sup>(</sup>b) A facility or site performing tests solely for forensic purposes. [source: Washington Administrative Code 246-338-010(25)]

In addition to the surveys above, the department also reviewed the compliance history of the physicians and other staff associated with Walla Walla Clinic. The summary of the review is below.

The table below provides a listing of the physicians associated with either the clinic or the surgery center. [source: March 26, 2018, screening response, p6]

Table 10
Walla Walla Clinic Staff Credential Information

LNAME	FNAME	MNAME	CREDENTIAL #	STATUS
Anderson	Kevin	Robert	MD60197541	Active
Ball	Eric	M	MD00024609	Active
Becker	Jonathan	Wingate	MD00027574	Active
Bergstrom	Theodore	John	MD00022923	Active
Carmody	Robert	William	MD00020000	Active
Chapin	John	Edward	MD60067848	Active
Cornia	Ryan	T	PO00000699	Active
Fry	Scott	T	MD00043909	Active
Gryler	Eric	С	MD00038529	Active
Haugen	Mark	David	MD60024498	Active
Hardy	Malcolm	W.G.	MD60747884	Active
Haveman	Gregory	Alan	MD60388989	Active
Jauhiainen	Eric	J	MD00035426	Active
Kaminsky	Daniel	F	MD00038343	Active
McCollaugh	Bryony	Jo	OP60191983	Active
Montagnino	Denise	JJ	OP60564329	Active
Morgan	Phillip	Reeves	MD00017276	Active
Newbold	Scott	G	MD00028915	Active
O'Conner	Timothy	Isamu	MD60658842	Active
Olswanger	Justin	NMI	OP60093051	Active
Panther	David	James	MD60726633	Active
Pryor	Jeffrey	M	OP60557607	Active
Robinson	Kristin	R	PO60487677	Active
Rogers	Trent	Davis	MD60150941	Active
Schmitz	Joanne	Mary	MD00036385	Active
Schribner	Jane	NMI	MD60646305	Active
Sislow	John	Gerard	MD00021765	Active
Vandersloot	James	Alan	OP00001762	Active
Wagner	William	D	OP00001866	Active
Wilcox	Michael	J	MD00034335	Active
Wilwant	Michael	J	OP00002294	Active
Wong	Siew	Min	MD60223678	Active
Wuest	Julie	A	MD00036120	Active

Ryan Cornia, MD listed in the table above is the current medical director for the surgery center.

Walla Walla Clinic also states that has commitments from other providers that have expressed interest in using the surgery center if this project is approved. A listing of those physicians is shown in the table below. [source: March 26, 2018, screening response, p6]

Table 11
Walla Walla Clinic Potential Staff Credential Information

wana wana Chine Fotentiai Staff Credentiai Information								
LNAME	FNAME	MNAME*	CREDENTIAL #	STATUS				
Crabtree	Gary	McClendon	MD00021822	Active				
Marsh	Glyn		MD00022960	Active				
Harri	James	Ely	MD00020665	Active				
Laing	Patrick	John	MD60683058	Active				
Hames	Charles	Stanley	MD60308244	Active				
Casey	Kelly	Joseph	MD60555315	Active				
Lawson	Sarah	Margaret	MD60759246	Active				
Steinle	Ernest	William	MD60538610	Active				
Field	Fred	Ian	MD00027722	Active				
Giebel	Arthur	W.	MD00046257	Active				
Edwards	Andrew	Seth	MD60142403	Active				
Lewis	David	Alan	MD60663338	Active				
Gunshefski	Linda	Anne	MD00034061	Active				
Caso	Antonio	Diego	DE00008739	Active				
Henderson	Richard	L	MD00046369	Active				
Willard	Kirk	Е	MD00037859	Active				
Zierenberg	Adam	T	MD60082337	Active				
Lenhart	Dennis	Eugene	MD60219945	Active				
Marsh	Glyn	E.A.	MD00046815	Active				
Conley	Gene	Raymond	MD60394336	Active				
Hutton	David	A	MD00035397	Active				
Spendlove	Joshua	Dahl	MD60762111	Active				

Walla Walla Clinic also provided a listing of its non-physician credentialed staff. Carri Balk, RN listed in the table below is the director of nursing. A summary of the non-physician credentialed staff is below. [source: March 26, 2018, screening response, Exhibit 18]

Table 12 Walla Walla Clinic Non-Physician Staff Credential Information

LNAME	FNAME	MNAME	CREDENTIAL #	STATUS
Balk	Carri	G	RN00145601	Active
Base	Tricia	I	RN00131653	Active
Wright	Sunnie	A	RN00126548	Active
Knight	Yolande	A	RN00121250	Active
Frewing	Deborah	R	RN00169524	Active
Studer	Danette	Lynn Baker	RN60609072	Active
Dwonch	Elizabeth	Harris	RN00066139	Active
Ferraro	Melanie	L	RN00156221	Active
McClanahan	Leslie	Brown	RN00061575	Active
Boettcher	Brenda	Carol	RN00120168	Active
Hargreaves	Jill	S	RN00095881	Active
Balk	Carri	G	RN00145601	Active
Maiuri	Angie	Marie	RN60471895	Active
Newton	Linda	Е	RN00088030	Active
Kuhlman	Janet	Lynn	RN60243791	Active
Andrews	Debra	Frankie	RN60214232	Active
Bennett	Audrey	K	ST00000558	Active
Coleman	Susan	Marie	ST00000972	Active

As shown above, all physicians and other credentialed professionals associated with Walla Walla Clinic have active credentials in good standing. Based on the information above, the department concludes that Walla Walla Clinic demonstrated reasonable assurance that the facility would continue to operate in compliance with state and federal requirements if this project is approved.

#### This sub-criterion is met.

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that direct how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

#### Walla Walla Clinic

Walla Walla Clinic provided the following statements related to this sub-criterion. [source: Application, p18]

"Walla Walla Clinic Surgery Center has a presence in the Walla Walla County secondary health services planning area, and the proposed project will build upon this presence and offer Walla Walla Clinic Surgery Center and other patients of group practices convenient access to surgical services. Walla Walla Clinic Surgery Center is committed to providing high quality, affordable care in the Walla Walla County secondary health services planning area, and the proposed project will help accomplish this goal. The proposed project promotes continuity of care with Walla Walla Clinic Surgery Center's other services as well as cost containment. Making the ASC available to other qualified, credentialed and privileged physicians in good standing is significantly less costly than building a new ASC to address waiting times for surgical services resulting from the closure of Walla Walla General Hospital."

#### **Public Comment**

None

#### Rebuttal Comment

None

# **Department Evaluation**

With the increased access CN approval brings, the department concludes that the establishment of this free-standing ASF does not represent unwarranted fragmentation of services. Furthermore, the applicant provided statements identifying how the ASF operates, and would continue to operate, in relation to the existing facilities and services in the planning area. Based on this information, the department concludes that the ASF would have an appropriate relationship to the service area's existing health care system. **This sub-criterion is met.** 

(5) <u>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.</u>

#### 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 Walla Walla Clinic 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.

#### Step One:

#### Walla Walla Clinic

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

# Step Two:

# Walla Walla Clinic

Walla Walla Clinic provided the following statements related to their consideration of alternatives prior to submitting this project. [source: Application, pp18-19 and March 26, 2018, screening response, pp10-11]

"As discussed above, there is significant net need for outpatient surgery operating rooms in the Walla Walla County secondary health services planning area. The proposed project will improve access, a key criterion of CN. The proposed project will also provide a low cost, freestanding ASC in the health planning area to meet the needs of patients and help residents of the planning area avoid wait times for procedures.

Walla Walla Clinic Surgery Center has a presence in the Walla Walla County secondary health services planning area, and the proposed project will build upon this presence and offer Walla Walla Clinic Surgery Center and other patients of group practices convenient access to surgical services. Walla Walla Clinic Surgery Center is committed to providing high quality, affordable care in the Walla Walla County secondary health services plmming area, and the proposed project will help accomplish this goal. The proposed project promotes continuity of care with Walla Walla Clinic Surgery Center's other services as well as cost containment. Making the ASC available to other qualified, credentialed and privileged physicians in good standing is significantly less costly than building a new ASC to address waiting times for surgical services resulting from the closure of Walla Walla General Hospital.

Walla Walla Clinic Surgery Center is requesting a CN for the proposed ASC so that all other qualified, credentialed and privileged physicians in good standing can utilize this facility, which will be operational upon issuance of a CN. As part of its due diligence, Walla Walla Clinic Surgery Center examined alternatives to the proposed project and evaluated those alternatives.

The primary objective of the proposed project is to provide needed access to a high quality, low cost ASC in the planning area where there is clear demonstrated need. Patients who need outpatient surgery will have the option to have their procedure in an ASC where they can obtain the same quality surgical experience, but at a lower cost. This ASC will offer care that is both affordable and local. The ASC will be open to all qualified, credentialed and privileged physicians in good standing in the planning area, offering more choices for patients and further contributing to overall cost containment."

Options considered and rejected by Walla Walla Clinic include:

- Do nothing or status quo;
- Establish a new (different) surgery center in Walla Walla County;
- Partner with another provider (hospital or physicians) to create a new surgery center in the planning area;

Below is a discussion of each option and why it was rejected.

# Do nothing or status quo

"Walla Walla Clinic Surgery Center rejected a "do nothing" alternative. The Walla Walla County secondary health services planning area currently has too few outpatient operating rooms. Planning area residents are underserved relative to the forecasted demand for surgical services and must travel or wait to obtain care. Walla Walla Clinic Surgery Center has a presence in the Walla Walla County secondary health services planning area and can add value to community health services by extending its continuum of care to additional residents of the community and other patients. A "do nothing" alternative strategy is detrimental to the community, in that such a strategy would do nothing to reduce the wait times for surgical services, would further restrict needed health care services within the health planning area, and would not improve the cost effectiveness of care delivery. There is no advantage to the "do nothing" alternative, so it was not considered feasible."

# Establish a new (different) surgery center in Walla Walla County

"Walla Walla Clinic considered establishing a new surgery center. However, it believes that much of the demand for services caused by the closure of Walla Walla General Hospital can be accommodated by expanding the number of physicians who can perform surgeries its ASC. Simply stated, Walla Walla Clinic believes it is more economically feasible to allow use of the capacity of its existing ORs by opening those ORs up to other physicians rather than wait for a new facility to be built and needlessly incur the costs associated with new construction. Making Walla Walla Clinic's ASC available to other qualified, credentialed and privileged physicians in good standing is significantly more efficient and less costly than building a new surgery center. This choice addresses the increase in waiting times for surgeries caused by the closure of Walla Walla General Hospital, provides an immediate solution, and results in the lowest expenditure of funds.

Walla Walla Clinic considered purchasing Walla Walla General Hospital. However, purchasing the entire hospital just to open its ORs is not financially feasible."

<u>Partner with another provider (hospital or physicians) to create a new surgery center in the planning</u> area

"Walla Walla Clinic approached Providence St. Mary's Medical Center Hospital about joint venturing on Walla Walla Clinic's ASC. Providence St. Mary's Medical Center Hospital rejected the idea of any joint venture with Walla Walla Clinic."

After considering the alternatives discussed above, Walla Walla Clinic provided the following rationale for submitting this application. [source: Application, p18]

"In contrast to the "do nothing" approach, the advantages of a CN-approved ASC are clear. A CN-approved ASC would afford increased access and local choice for the health planning area residents and local, independent physicians. The ASC will be open to all qualified, credentialed and privileged physicians in good standing, increasing their ease of access and improving their ability to deliver high quality care to their patients. This alternative model reduces the overall cost of care and passes these relative cost and efficiency advantages of a freestanding ASC to patients and payers.

There are no disadvantages to granting Walla Walla Clinic Surgery Center's request for CN approval. The data demonstrates there would not be a duplication of services, given a projected net demand of over 2.25 outpatient operating rooms in the health planning area.

A CN-approved ASC would better serve the interests of the planning area residents and achieve Walla Walla County secondary health services planning area's desire to reduce wait times for outpatient surgical services."

**Public Comment** 

None

Rebuttal Comment

None

#### **Department Evaluation**

Information provided within the application demonstrates that it is unlikely Walla Walla Clinic had a better alternative than submission of this application. Specifically, since its main purpose of converting the exempt ASF to a CN approved ASF is to allow other physicians, not part of the Walla Walla Clinic practice, access to the ASF. This action alone requires prior CN review and approval. Based on this alone, Walla Walla Clinic appropriately rejected the "do nothing" option.

The other alternatives to the requested project explored by Walla Walla Clinic would require either a partner or a Certificate of Need application with a larger capital expenditure. These alternatives were appropriately rejected.

The statements provided in relation to this sub-criterion can be substantiated, and the department did not identify any other 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 of those considered by Walla Walla Clinic 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. As previously stated, both Providence St. Mary Medical Center and Walla Walla Clinic submitted applications to add outpatient surgical capacity in Walla Walla County. Since this evaluation focus solely on the Walla Walla Clinic project, 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) The costs, scope, and methods of construction and energy conservation are reasonable;
  - (b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.
    - As stated in the project description portion of this evaluation, this project does not involve construction. This sub-criterion is not applicable to this project.
- (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.

# Walla Walla Clinic

"There is no construction, renovation, or expansion associated with this project. Walla Walla Clinic's surgery center's operating rooms are fully build-out and operational." [source: Application p20]

#### **Public Comment**

None

# Rebuttal Comment

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. The department concludes the addition of a CN-approved ASF will appropriately improve the delivery of health services in Walla Walla County. **This sub-criterion is met.** 

# **APPENDIX A**



# APPENDIX A ASC Need Methodology Walla Walla County

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#### APPENDIX A ASC Need Methodology Walla Walla County

CN APP #18-14 CN APP #18-22

Facility	Special Procedure Rooms		Dedicated Outpatient ORs		Mixed Use min/case	Inpatient Cases in Mixed Use ORs	Inpatient Mins. In Mixed Use ORs			-	Data Source
Providence St. Mary Medical Center	2	0	0	5	100.5	4.813	483,763	0.0	0	0	Year 2016 data from 2017 survey provided during screening of application #18-22.
Walla Walla General Hospital (CLOSED 2017]	1	0	0	4	59.9	2,199	131,717	0.0	0	0	Year 2016 data from 2017 survey. Facility closed on July 24, 2017.
Walla Walla Clinic ASC	1	0	2	0	0.0	0	0	49.8	1,134	56,492	Year 2016 data from 2017 survey. Applicant
Totals	4	0	0	9	160.4	7,012	615,480	49.8	1,134	56,492	
					Avg min/ca	se inpatient	160.41	Avg min/case	outpatient	49.82	
ORs counted in numeric methodology			0	5							
ILRS: Integrated Licensing & Regulatory System											
Population data source: OFM released 2017											
Total Surgeries	8,146										
Area population 2016 [0 - 85+]	60,930		using 2016	populatio	on b/c using	2016 survey data					
Use Rate	133.694										
Planning Area projected population Year: 2021	62,378		Note: Walla	a Walla C	Clinic ASF a	ge range is 0-85+					
			St. Mary M	ledical C	enter ASF a	ge range is 5-85+					
% Outpatient of total surgeries	13.92%										
% Inpatient of total surgeries	86.08%										