

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

November 26, 2019

CERTIFIED MAIL # 7016 0910 0000 3454 9368

Tammy Tanula, RN Eye Associates Northwest, P.C. 1455 NW Leary Way, Suite 300 Seattle, WA 98107

Emily R. Studebaker, Esq. Studebaker Nault, PLLC 11900 NE 1st Street, Suite 300 Bellevue, WA 98005

RE: Certificate of Need Application #19-68

Dear Ms. Tanula and Ms. Studebaker

We have completed review of the Certificate of Need application submitted by Eye Associates Northwest, P.C. The application proposes to establish a two operating room ambulatory surgery center in Seattle within north King secondary health services planning area. 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 Eye Associates Northwest, P.C. agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a two-operating room ambulatory surgical facility in Seattle, within north King County secondary health services planning area. The surgery center will serve patients age 18 years and older that require surgical services that can be served appropriately in an outpatient setting. Surgical services provided within the two ORs (operating rooms) are limited to those associated with ophthalmic surgical procedures, Lasik and refractive surgery, facial and aesthetic surgery; optometry; cataract surgery; DSAEK; retina, glaucoma, and cornea procedures; and blepharoplasty.

Tammy Tanula, RN Eye Associates Northwest, P.C.

Emily R. Studebaker, Esq. Studebaker Nault, PLLC Certificate of Need App #19-68 November 26, 2019 Page 2 of 3

Conditions:

- 1. Eye Associates Northwest, P.C. agrees with the project description as stated above. Eye Associates Northwest, P.C. 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. Eye Associates Northwest, P.C. will provide charity care in compliance with its charity care policy provided in the application, or any subsequent policies. Eye Associates Northwest, P.C. will use reasonable efforts to provide charity care in the amount identified in the application, or the planning—whichever is higher. Currently, the planning area is 1.02% of gross revenue and 2.25% of adjusted revenue. Eye Associates Northwest, P.C. will maintain records of charity care amount provided by Eye Associates Northwest, P.C. documenting the amount of charity care its provides and demonstrating compliance with its charity care policies.
- 3. Eye Associates Northwest, P.C. 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.
- 4. Eye Associates Northwest, P.C. agrees that the facility will maintain Medicare and Medicaid certification, regardless of the facility ownership.

Approved Costs:

There is no capital expenditure associated with this project.

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

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

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

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

Tammy Tanula, RN Eye Associates Northwest, P.C.

Emily R. Studebaker, Esq. Studebaker Nault, PLLC Certificate of Need App #19-68 November 26, 2019 Page 3 of 3

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 NOVEMBER 26, 2019, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY EYE ASSOCIATES NORTHWEST, P.C. PROPOSING TO ESTABLISH AN AMBULATORY SURGICAL FACILITY IN SEATTLE WITHIN NORTH KING COUNTY SECONDARY HEALTH SERVICES PLANNING AREA.

APPLICANT DESCRIPTION

Eye Associates Northwest, P.C. is a for-profit Washington State Professional Limited Liability Company wholly owned by the following four physicians each with equal ownership: Brant F. Carroll M.D., Jeanna M. Hoyt, M.D., and Daniel P. Kelly, M.D.; and Brain R. McKillop, M.D. Eye Associates Northwest, P.C. was incorporated on December 3, 1993. Eye Associates Northwest, P.C. operates ophthalmology clinics and optical sites in King County. Eye Associates Northwest, P.C. does not operate any facilities outside of Washington State Listed in the table below are the clinics and optical sites operated by the applicant. [Source: Application, page 3, Washington Secretary of State; and Washington Department of Revenue]

Practice Site Address	Туре	Licensed Number
1101 Madison Street, Suite 600, Seattle 98104	Clinic	N/A
1455 NW Leary Way, Suite 300, Seattle 98107	Clinic/Surgery	ASF.FS.60102711
1555 NE 100 th Street, Seattle 98125	Clinic	N/A
11919 NE 128 th Street, Suite A, Kirkland 98034	Clinic	N/A
1101 Madison Street, Suite 600, Seattle 98104	Optical Services	N/A
155 NE 100 th Street, Suite 110, Seattle 98125	Optical Services	N/A
11919 NE 128 th Street, Suite A, Kirkland 98034	Optical Services	N/A

HISTORICAL INFORMATION

This project focuses on the clinic/surgery center located in Seattle and shown in bold in the table above. For reader's ease, the applicant is Eye Associates Northwest, PC and throughout this evaluation, it will be referred to as "Eye Associates Northwest."

On June 7, 2012, the Certificate of Need (CN) Program approved Eye Associates Northwest to establish an exempt ambulatory surgical facility (ASF²) located at 1455 Northwest Leary Way #300 in Seattle [98107]. The CN exempt ASC is licensed by the Washington State Department of Health³ and certified by the Centers for Medicare and Medicaid Services as an ambulatory surgical center.⁴

Approved services to be provided at the CN exempt surgery center include those associated with ophthalmic surgical procedures, such as cataract extraction and laser eye surgery.⁵ The ASF currently has one operating room (OR). Consistent with the limitations of the exemption approval, only physicians

¹ UBI #601 509 781

² The Washington State Department of Health licenses Ambulatory Surgical Facilities – ASFs. The Centers for Medicare and Medicaid Services certify Ambulatory Surgery Centers – ASCs. It is not uncommon for a facility to be both an ASF and an ASC. Throughout the evaluation the department will refer to this facility as an ASF, it is also an ASC, and the applicant refers to it as such.

³ ASF.FS.60102711

^{4 50-}C0001014

⁵ Determination of Reviewability #12-32 dated June 7, 2012.

that are owners or employees of Eye Associates Northwest can perform surgeries at the exempt surgery center. [Source: CN historical files]

PROJECT DESCRIPTION

Eye Associates Northwest is seeking CN approval to expand the exempt surgery center from one to two operating rooms. Eye Associate Northwest would allow physicians that are not associated with the surgery center to have access to the facility. This action requires that Eye Associates Northwest seek Certificate of Need review and approval. [Source: Application page 7 and 11]

If this project is approved, the surgery center will continue to be located at 1455 NW Leary Way, Suite 300 in Seattle, [98107]. Eye Associates Northwest will provide care to patients 18 years of age and older who require ambulatory surgery and are not expected to require hospitalization, and can be treated an outpatient surgery setting.

Ophthalmic surgical procedures to be provided by Eye Associates Northwest are Lasik and refractive surgery, Facial and Aesthetic surgery; optometry; cataract surgery; DSAEK⁶; rețina, glaucoma, and cornea procedures; and blepharoplasty. [Source: June 3, 2019, Supplemental information page 4] There is no capital expenditure associated with the proposed project because the one operating room to be added to capacity is currently is built out and ready to operate. [Source: Application page 8]

Eye Associates Northwest is licensed by the Department of Health and is Medicare and Medicaid certified. If this project is approved, Eye Associates Northwest will maintain its operations and ensure the surgery center meet any specific conditions related to the Certificate of Need approval. Based on the timing of this decision and the steps this applicant must take to execute a Certificate of Need, Eye Associates Northwest's first full year of operation as a CN-approved surgery center is calendar year 2020 and calendar year three is 2022. [Source: Application page 8, and June 3, 2019, Supplemental information, Exhibit E]

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.

⁶ Descemet Stripping Automated Endothelial Keratoplasty (DSAEK). A DSAEK procedure is a partial-thickness corneal transplant that replaces only the inner portion of the cornea containing the endothelial layer. A thin piece of donor tissue is inserted onto the back (inner) surface of the patient's cornea. This involves a smaller surgical incision, requires far fewer stitches, heals faster and more reliably, and allows for a faster visual recovery. [Source: https://www.eanw.net/dsaek]

- (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 must be used to make the required determinations for applicable criteria in WAC 246-310-210.

TYPE OF REVIEW

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

APPLICATION CHRONOLOGY

Action	Eye Associates Northwest
Letter of Intent Submitted	January 10, 2019
Application Submitted	March 26, 2019
Department's pre-review activities	
DOH 1st Screening Letter	April 16, 2019
Applicant's Responses Received	June 3, 2019
DOH 2nd Screening Letter	June 24, 2019
Applicant's Responses Received	July 15, 2019
Beginning of Review	July 22, 2019

Action	Eye Associates Northwest
End of Public Comment/No Public Hearing Conducted	
Public comments accepted through end of public comment	August 26, 2019
Rebuttal Comments Received ⁷	September 10, 2019
Department's Anticipated Decision Date	October 24, 2019
Department's Anticipated Decision Date with 30-day Extension ⁸	November 25, 2019
Department's Actual Decision Date	November 26, 2019

AFFECTED PERSONS

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

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

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

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

During the course of review of this application, no entities requested interested or affected person status for this project.

SOURCE INFORMATION REVIEWED

- Eye Associates Northwest, P.C. Certificate of Need application submitted March 26, 2019
- Eye Associates Northwest, P.C. 1st screening responses received June 3, 2019
- Eye Associates Northwest, P.C. 2nd screening responses received July 15, 2019
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission and Nursing Quality Assurance Commission
- Compliance history for Eye Associates Northwest, P.C. obtained from the Washington State Department of Health Office of Health Systems and Oversight
- DOH Provider Credential Search website: http://www.doh.wa.gov/pcs

⁷ The department did not receive any public comments; as a result, no rebuttal comments were submitted.

⁸ Thirty day extension letter sent to the applicant on October 25, 2019

- Historical charity care data for years 2016, 2017, and 2018 obtained from the Department of Health's Hospital/Finance and Charity Care office (HFCC)
- Year 2017 Annual Ambulatory Surgery Provider Survey for Surgical Procedures Performed During Calendar Year 2017 for hospitals, ambulatory surgical facilities, or ambulatory surgical facilities located in north King County
- Year 2018 Claritas population estimates
- Department of Health internal database Integrated Licensing & Regulatory Systems (ILRS)
- Washington State Secretary of State website: https://www.sos.wa.gov
- Washington State Department of Revenue website: http://www.dor.wa.gov
- Center for Medicare and Medicaid Services website: https://www.cms.gov
- CMS QCOR Compliance website: https://qcor.cms.gov/index new.jsp
- Eye Associates Northwest—Patient Education website: https://www.eanw.net/dsaek
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Eye Associates Northwest, P.C. proposing to establish a two-operating room ambulatory surgical facility in Seattle, within the north King County secondary service planning area is consistent with the applicable criteria of the Certificate of Need Program, provided Eye Associates Northwest, P.C. agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a two-operating room ambulatory surgical facility in Seattle, within north King County secondary health services planning area. The surgery center will serve patients age 18 years and older that require surgical services that can be served appropriately in an outpatient setting. Surgical services provided within the two ORs (operating rooms) are limited to those associated with ophthalmic surgical procedures, Lasik and refractive surgery, facial and aesthetic surgery; optometry; cataract surgery; DSAEK; retina, glaucoma, and cornea procedures; and blepharoplasty.

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4. Eye Associates Northwest, P.C. agrees that the facility will maintain Medicare and Medicaid certification, regardless of the facility ownership.

Approved Costs:

There is no capital expenditure associated with this project.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department concludes that Eye Associates Northwest, P.C. 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. Eye Associates Northwest is located in Seattle, within the north King 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 QRs 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.

Eye Associates Northwest

Eye Associates Northwest determined the existing capacity in the north King County secondary health service planning area to be (5.75) dedicated outpatient ORs and (6.10) mixed use ORs. Based on a computed use rate of 168.7, Eye Associates Northwest calculated need for an additional 16.21 outpatient ORs in the north King County secondary health service planning area. [Source: Application Exhibit 7, page 137]

Eye Associates Northwest provided the following statements related to the numeric need methodology.

"According to the Department's records, there is a total of 18 planning area providers with OR capacity. Of these 18 providers, seven are hospitals, and 11 are ASFs. Because there is no mandatory reporting requirement for utilization of hospital or ASF ORs, the Department sends an annual utilization survey to all hospitals and known ASFs in the state. When this application was submitted, the most recent utilization survey data available was for year 2018.

Table 3 above shows a listing of the seven hospitals with OR capacity. For the seven hospitals, all known OR capacity and procedures are included in the methodology calculations for the planning area.

Table 4 above contains a listing of the 11 ASFs in the planning area.3 Shown in Table 4 above, out of these 11 ASFs, two are CN-approved ASFs, and the number of surgeries and the number of ORs is counted in the numeric methodology. Of the 9 remaining ASFs, two provide endoscopy or endoscopy and pain management services only. The numeric methodology excludes these special purpose rooms and cases from the calculation. This exclusion leaves seven ASFs remaining. Seven are located within the offices of private physicians, whether in a solo or group practices, which have received an exemption and are considered a CN-exempt ASF. The use of these ASFs is restricted to physicians who are employees or members of the clinical practices that operate the facility. Therefore, these seven facilities do not meet the ASF definition in WAC 246-310-010. For CN-exempt ASFs, the number of surgeries, but not ORs, is included in the methodology for the planning area.

In summary, surgical cases and ORs for the seven hospitals and two CN-approved surgery centers will be counted in the numeric methodology. Surgical cases, but not ORs, for the seven CN exempt surgery centers will be counted in the numeric methodology. The data points used in the numeric need methodology are identified in Exhibit 7. The application of the numeric need methodology shows a surplus of mixed use ORs in North King County Secondary Health Services Planning Area, resulting in numeric need for an additional 16.21 outpatient ORs in projection year 2023. In conclusion, based solely on the results of numeric need methodology, there is need for an additional 16.21 outpatient ORs in North King County Secondary Health Services Planning Area. Please see Exhibit 7". [Source: Application, page 13]

"See Exhibit B. Based on the Department's quantitative need methodology, the North King Secondary Health Services Planning Area is projected to need more than 16.12 additional outpatient ORs by 2023". [Source: June 3, 2019, screening responses received page 8]

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 a planning area. North King County secondary health services planning area ZIP codes are identified in the 1980 State Health Plan. A review of the ZIP codes shows that no new ZIP codes have been created for north King County.

Department's Table 1
North King County Secondary Health Services ZIP Codes

1980 State Health Plan		
ZIP Code	City	County
98103	Seattle	King
98105	Seattle	King
98107	Seattle	King
98115	Seattle	King
98117	Seattle	King
98125	Seattle	King
98133	Seattle or Shoreline	King
98155	Seattle or Shoreline, Lake Forest Park	King
98160	Seattle	King
98177	Seattle or Shoreline	King
98185	Seattle	King
98195	Seattle	King

According to the department's records, there are 13 planning area providers; of those, 11 have OR capacity. Of the remaining 11 providers, five are hospitals and six are ambulatory surgical facilities.

Because there is no mandatory reporting requirement for utilization of ASFs or hospital ORs, the department sends an annual utilization survey to the hospitals and known ASFs in the state. When this application was submitted in December 2018, the most recent utilization survey data available was for year 2017. The data provided in the utilization survey is used, if available.

Below, Table 2 shows a listing of the five hospitals. [Source: CN historic files and ILRS]

Department's Table 2
North King County Planning Area Hospitals

Trouble Country 2 mining 121 on 2200 parties		
Facility	ZIP Code	
Seattle Children's Hospital, includes outpatient facility	98105	
Swedish First Hill-Ballard Campus	98107	
University of Washington Medical Center	98195	
University of Washington Medical Center Roosevelt site	98105	
UW Medicine/Northwest Hospital	98133	

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

Table 3 below, contains a listing of the six ASFs in the planning area. [Source: Department of Health internal database-ILRS]

⁹ Kindred Hospital-Northgate and Seattle Cancer Care Alliance are located in the planning area but do not have OR capacity.

Department's Table 3
North King County Planning Area ASFs

Facility	ZIP Code	CN Approved or Exempt?	
Eye Associates Northwest Surgery Center (Applicant)	98107	Exempt	
PSG-Fremont Endoscopy*	98103	Exempt	
Northwest Eye Surgeons	98133	Approved	
Puget Sound Surgical Center-Shoreline	98155	Exempt	
PSG-Seattle Endoscopy Center*	98133	Exempt	
Seattle Orthopedic Center-Surgery	98103	Approved	

Of the six ASFs shown above, two are endoscopy facilities (designated with an asterisk).¹⁰ The numeric methodology deliberately excludes the OR capacity and procedures from the numeric need methodology.¹¹

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

The data points used in the department's numeric methodology are identified in Table 4. The methodology and supporting data used by the department is provided in Appendix A attached to this evaluation.

Department's Table 4 Methodology Assumptions and Data

Assumption	Data Used	
Planning Area	North King County	
	Age Group: 0-85	
Population Estimates and Forecasts	Claritas Population Data released year 2018	
ropulation Estimates and Porecasts	Year 2018 – 366,764	
	Year 2022 – 385,682	
	Divide the calculated surgical cases by 2022	
Use Rate	population results in the service area use rate of	
	149.317/1,000 population	
Voor 2019 Total Number of Surgical	44,055 – Inpatient or Mixed-Use;	
Year 2018 Total Number of Surgical	10,709 – Outpatient	
Cases	54,764 – Total Cases	
Percent of surgery: outpatient vs.	Based on DOH survey and ILRS:	
inpatient	19.55% outpatient;	

¹⁰ Puget Sound Gastroenterology Associates operates Fremont Endoscopy and Seattle Endoscopy Center.

11 WAC 246-310-270(9)(iv)

Assumption	Data Used
	80.45% inpatient
(Based on DOH survey and ILRS:
Average minutes per case	Outpatient cases: 52.69 minutes
***	Inpatient cases: 130.93 minutes
	68,850 outpatient surgery minutes;
OR Annual capacity in minutes	94,250 inpatient or mixed-use surgery minutes
	(per methodology in rule)
	Based on listing of north King County Providers:
Existing providers/OR's	10 dedicated outpatient OR's
	57 mixed use OR's
Department's Methodology Results	Need for 1.8 ORs in the planning area

Based on the assumptions described in Table 4 above, the department's application of the numeric methodology calculated a need for 1.8 outpatient ORs in year 2022.

The department noted some differences between its methodology and Eye Associates Northwest methodology for the planning area. When comparing the applicant's and department's methodology, there are differences in five main data points. The noted differences are shown below. These data points are tightly connected.

.Data Points		
Projection Year		
Number of ORs to be counted		
Population data		
Surgical cases		
Use Rate		

Projection Year and Population Data

Eye Associates Northwest application was received on March 26, 2019, within the application; Eye Associates Northwest anticipates that its first full year of operation is 2019 and based its projection year on year 2021.

However, year 2019 is a partial year of operation for the surgery center, so the department identified year 2020 as the first full calendar year of operation for the ASC and 2022 as year three. For this reason, the department's methodology projects to year 2022. The projection year also affects the population data factor in the table above.

The applicant also used population data for residents 18 year of age and older in the North King planning area. The department's methodology uses population for residents 0-85+. This difference in the population data would also affect the methodology.

Number of ORs to be counted

In the application, Eye Associates Northwest counted all dedicated outpatient ORs, including those associated with Certificate of Need exempt surgery centers, in their methodology. This approach is inconsistent with the department's practice of counting cases, but not ORs for Certificate of Need exempt surgery centers. As a result, the department's count of ORs is more reliable.

Surgical Cases and Use Rate

When the total number of surgical cases—both inpatient and outpatient—is divided by the current year population, the result is a planning area <u>use rate</u>. The use rate is then applied to the projected population. If the number of cases used is significantly different, the resulting use rate would be different for each of the methodologies.

The applicant used both 2015 and 2016 survey data and applied 2015 and 2016 population data to obtain a use rate. The resulting use rates were applied to projection year 2021. This approach, while correct, does not use the most recent survey data available, which is 2017. It also projects to full calendar year 2 of the project.

The department used 2017 survey data and population, and projected to year 2022, which is the third full year of operation for the project. This approach includes the most recent data available and is considered most reliable.

In summary, the data used in both methodologies is significantly different. Eye Associates Northwest calculated a need for 16.21 outpatient ORs; the department calculated a need for 1.80 outpatient ORs. The department considers its numeric methodology more reliable and will rely on the results for this evaluation. Based on the numeric methodology alone, numeric need for two outpatient ORs in north King County planning area is not demonstrated.

WAC 246-310-270(4) allows approval of additional ORs in a planning area absent numeric need. Below is a review of the information provided by the applicant under this sub-criterion.

WAC 246-310-270(4)

Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need.

Eye Associates Northwest

To support approval of this project Eye Associates Northwest provided information to support that utilization at the ASF Should continue within the planning area.

The population data for the North King County Secondary Health Services Planning Area included in Exhibit 6 demonstrates that the current total population of approximately 359,936 continues to grow and is expected to increase to 382,758 in 2023, an increase of 22,822.

Eye Associates Northwest has developed the proposed project to ensure that there is sufficient capacity in the planning area to meet current and projected need. There is no construction,

renovation, or expansion associated with this project. The proposed ASF's OR's are fully buildout and ready to operate.

<u>Table 11</u> below shows an increase in the total number of cases from 2,515 in 2019 to 2,830 in 2023. Conservatively, Eye Associates Northwest projects there will be at least an increase of 315 procedures performed annually from 2019 to 2023. In addition to making the proposed ASF available to Eye Associates Northwest' patients, which will account for the number of procedures performed at the proposed ASF, population growth will also cause an increase in the number of procedures to be performed. Accordingly, Eye Associates Northwest could also make the proposed ASF available to other qualified, credentialed and privileged physicians in good standing.

Eye Associates Northwest has taken a conservative approach in estimating growth, and the projections are far below the likely increase in utilization.

As noted in other sections of this application, the establishment of the proposed ASF is being undertaken to provide additional capacity for the planning area. The proposed ASF will not duplicate services. Instead, it is necessary in order to expand the services offered at EANSC. [Source: Application pages 15-16]

The applicant provided an updated projections table below. [Source: June 3, 2019, screening responses received pdf 5]

Table 11
Proposed ASF Projected Utilization

Year	Number of Procedures
2019	2,515
2020	2,590
2021	2,668
2022	2,748
2023	2,830
2024	2,914

Public Comment None

Rebuttal Comment None

Department Evaluation

With CN approval, the built out OR that is not currently used concurrently with the one CN approved OR would be made available for use. If the built out OR is approved, there is no capital expenditure associated with this project. Eye Associates Northwest projected a modest increase in the types of procedures provided by the ASF the department anticipates that limited growth at the surgery center will occur.

Information in the application supports that the exempt surgery center is a highly utilized facility in the planning area that provides ophthalmology and laser eye services to a wide age range. Historical volumes provided by the applicant support that utilization of the facility has grown over time. As the methodology demonstrates, there is a shortage of outpatient operating rooms

Based on the historical utilization of this facility and lack of opposition from planning area providers, the department concludes this project is needed, assuming the applicant agree 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 Eye Associates Northwest. **This subcriterion is met.**

WAC 246-310-270(6)

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

Eye Associates Northwest

Eye Associates Northwest is seeking CN approval to expand the exempt surgery center from one to two operating rooms. This action means that the number of ORs counted in the north King County planning area would increase. Documentation provided in the application demonstrates that this project should be approved. Since the surgery center will have two ORs, **this standard is met**.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

WAC 246-310-270(6) requires a minimum of two ORs in an ASF. Eye Associates Northwest is currently operating with one OR. This project proposes to increase 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 as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the planning area would have access to the proposed services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

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

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

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.

Eye Associates Northwest

To demonstrate compliance with this sub-criterion, the applicant provided the following two policies currently in use at the surgery center. [Source: Application page 16, Exhibit 8 and 9]

Charity Care Policy
 Language in this policy clarifies that the applicant does not refuse services based on the patient's ability to pay. The policy provides the process the patient and the surgery center would use to determine eligibility for charity care.

Further, Eye Associates Northwest provided the following information regarding charity care. "It is the Policy of Eye Associates Northwest Surgery Center (the "Center") to not refuse services to any patient because such patient is unable to pay for services. The Center shall not discriminate against Medicare, Medicaid or indigent patients, and the Center intends to provide services without charge or at a reduced charge to eligible patients who cannot afford to pay for care". [Source: June 3, 2019, screening responses received Exhibit D]

Within the application, Eye Associates Northwest pro forma financial statement identified the amounts of charity care for full years 2019–2024. [Source: June 3, 2019, screening response, Exhibit E]

Admission Policy

The Admission Policy provides the following language regarding admission.

"It is the policy of Eye Associates Northwest Surgery Center to admit and treat all persons without regard to race, color, national origin, handicap, religious, or fraternal organization, or age. The same requirements are applied to all, and patients are assigned without regard to race, color, national origin, handicap, religious or fraternal organization, or age. All services are available without distinction to all patients and visitors regardless of race, color, national origin, handicap, religious or fraternal organization or age. All persons and organizations having occasion to refer persons for services or to recommend the center are advised to do so without regard to the person's race, color, national origin, handicap, religious or fraternal organization, or age".

Eye Associates also provided it Patient Bill of Rights Policy. [Source: June 3, 2019, screening response, Exhibit D]

• Patient Bill of Rights states:

This center has established this Patient's Bill of Rights as a policy with the expectation that observance of these rights will contribute to more effective patient care and greater satisfaction for the patient, his physician, and the group organization. It is recognized that a personal relationship between the physician and the patient is essential for the provision of proper medical care. The traditional physician-patient relationship takes on a new dimension when care is rendered within an organizational structure. Legal precedent has established that the facility itself also has a responsibility to the patient. It is in recognition of these factors that these rights are affirmed. If a patient is adjudged incompetent under applicable state health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under state law to act on the patient's behalf. If a state court has not adjudged a patient incompetent, any legal representative designated by the patient, in accordance with the state law, may exercise the patients' rights to the extent allowed by state law.

The Patient has the Right to:

- 1. Impartial treatment without regard to race, color, sex, national origin, religion, handicap or disability.
- 2. To be treated and cared for with dignity, free from acts of discrimination or reprisal, and to confidentiality, security, spiritual care, and communication.
- 3. To receive considerate, respectful, and safe care at all times and to be protected from abuse, harassment, neglect and the right to have access to protective services.
- 4. Knowledge of the name and professional status of those caring for you.
- 5. To receive information from the surgeons about your diagnosis, treatment plan, prognosis, and expected outcome before the procedure is performed. If communication restrictions are necessary for your care and safety, we will document and explain the restrictions to you or your family.
- 6. To be informed about unanticipated outcomes of care and treatment.
- 7. To participate actively in decisions regarding your medical care, to be informed, and agree to your care. To the extent permitted by law, this includes the right to refuse treatment. If the patient is adjudged incompetent or the patient has designated a legal representative or nonlegal representative, the person appointed/designated shall fully participate in decisions regarding the patient's care.
- 8. Full consideration of privacy concerning your medical care program. Case discussion, examination, and treatment are confidential and should be conducted as discretely as possible.
- 9. To be asked if you have an Advance Directive and if so, for it to be prominently placed it in your chart.
- 10. To be advised that should an unexpected life-threatening event occur, you will receive resuscitative or other stabilizing measures and be transferred to an acute facility that will...

Medicare and Medicaid Programs

Eye Associates Northwest is currently Medicare and Medicaid certified. Eye Associates Northwest provided the current and projected source of revenues by payer for the surgery center. Eye Associates Northwest current and projected source of revenues by payer is restated in Table 5 below. [Source: June 3, 2019, screening response, page 6]

Department's Table 5

Eye Associates Northwest Historical and Projected Payer Mix

Payer Group	Historical	Projected
Medicare	69%	69%
Medicaid	1%	1%
Commercial/Health Care Contractor	27%	27%
HMO	0%	0%
Other Government/L & I	<1%	<1%
Self-Pay	<2%	<2%
Other	<1%	<1%
Total	100.0%	100.0%

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Eye Associates Northwest provided its Admission /Treatment Policy, Patient Bill of Rights Policy, and updated Charity Care Policy that are currently used at the surgery center.

The Admission /Treatment Policy, Patient Bill of Rights Policy, and updated Charity Care Policy include the required information, and the criteria for admitting patients and a description of the types of patients that would be served. These policies are consistent with those approved by the department in past evaluations. The Charity Care Policy includes the process one must use to access charity care.

The department concludes that Eye Associates Northwest anticipate the surgery center would 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. Eye Associates Northwest is located within the King County Region. Currently, there are 23 hospitals operating in the region.

Of those, seven hospitals are located within the north King County planning area. ¹² Of these seven, six hospitals could be affected by approval of this project. ¹³¹⁴

Eye Associates Northwest projected that the ASF will provide charity care at 2.30% of total revenue and 2.36% of adjusted revenue. For this project, the department reviewed the most recent three years of charity care data for the 23 hospitals operating within the King County Region and focused on the seven hospitals that could be potentially affected by this project. The three years reviewed are 2016, 2017, and 2018.

Table 6 below is a comparison of the historical average charity care for the King County Region as a whole, the historical average charity care within the planning area, and the projected charity care to be provided by Eye Associates Northwest. [Source: Community Health Systems Charity Care 2016-2018 and July 15, 2019, screening response, page 1, and Exhibit 1]

Department's Table 6
Three Year Average—Charity Care

	% of Total Revenue	% of Adjusted Revenue
3-year King County Region	1.02%	2.25%
3-year North King County Hospital ¹⁵	0.94%	1.92%
Eye Associates Northwest ¹⁶	2.30%	2.36%

As shown above, the three-year total revenue average proposed by Eye Associates Northwest is higher than the regional average, and also higher compared to the combined adjusted revenue average of the six hospitals operating in north King County secondary health services planning area.

Eye Associates Northwest historical financial statement of profit and loss did not show that the applicant provided charity care at the surgery center. Given the surgery center is operating as an exempt ambulatory surgery center, exempt facilities are not required to offer charity care. Therefore, attaching a condition to the approval of this project requiring Eye Associates Northwest to provide charity care is reasonable.

For Certificate of Need purposes, Eye Associates Northwest is a new health care facility. To ensure that Eye Associates Northwest would provide appropriate charity care percentages, if this project is approved, the department would attach condition requiring Eye Associates Northwest 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 2016-2018 was 1.02 % of gross revenue and 2.25 % of adjusted revenue.

¹² Kindred Hospital-Seattle, Seattle Cancer Care Alliance, Seattle Children's Hospital, University of Washington Medical Center, Swedish First Hill-Ballard; UW/Medicine Northwest Hospital.

¹³ Harborview Medical Center is located in the King County Region. Harborview Medical Center is subsidized by the state legislature to provide charity care services. Charity care percentages for Harborview make up almost 50% of the total percentages provided in the King County Region. Therefore, for comparison purposes, the department excludes Harborview Medical Center's percentages from the regional average.

¹⁴ Kindred Hospital in Seattle did not report any charity care for year 2018.

¹⁵ Kindred Hospital –Seattle did not provide year's 2016-2018 charity care data to the department.

¹⁶ Eye Associates Northwest projected charity care three-year average for years 2020-2023.

This condition would also require Eye Associates Northwest to maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department also would require that charity care records be kept on site at the ASF and available upon request. With the conditions identified above and Eye Associates Northwest agreement to the conditions, 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.
 - (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.
 - (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.
 - (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 Eye Associates Northwest, P.C. 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.

Eye Associates Northwest

The assumptions used by Eye Associates Northwest to determine utilization and the projected number of procedures for the surgery center for the first three full calendar years of operation are summarized below.

"The data points used in the numeric need methodology are identified in Exhibit 7". [Source: Application page 12]

"The ASF forecast provided below uses a comprehensive, statistically valid survey of ambulatory surgery cases by the National Center for Health Statistics, which is based on 2006 survey statistics and published in a revised report in September 2009. This survey includes surgery use rates by major age cohort groups. It demonstrates use rates for persons 65-74 years old are 2.6 times the average use rate, and 2.4 times higher for persons 75 years of age and older. These use rates are presented in Table 9 below. Considering the much higher growth in the 65+ age cohort, these use rate differences signify demand for health services will be much higher in the future as populations age.

Applicant's Table 9 Reproduced National Center for Health Statistics Ambulatory Surgery Use Rates Per 10,000 Residents, by Major Age Cohort

	Overall Average	Persons < 15 years old	Persons 15- 44 years old	Persons 45- 64 years old	Persons 65- 74 years old	Persons > 75 years old
Use Rate	1,788.3	537.5	1,019.2	2,695.9	4,584.0	4,325.3
Use Rate/Overall Use Rate	1.	0.3	0.6	1.5	2.6	2.4

There is an increasing need for additional outpatient surgery capacity in the North King County Secondary Health Services Planning Area and surrounding areas. There continues to be significant shifting of surgeries to outpatient settings, where costs are lower and patient satisfaction is higher due to patients' preference for outpatient-based care. Having a local ASF for ophthalmic surgery not only reduces travel time and costs, it reduces inconvenience and anxiety when patients are able to obtain both clinical and surgical care in the same location". [Source: Application page 12]

Based on the assumptions described above, Eye Associates Northwest provided its calculated projections for years 2019 through 2024. Table 7 below shows the historic and the total projected number of procedures for the north King secondary health services planning area.

, Department's Table 7
Eve Associates Northwest Projected Utilization

	2019	2020	2021	2022	2023	2024
Number of Procedures	2,515	2,590	2,668	2,748	2,830	2,914

Recognizing that the projections show the ASF would perform more than 50% of the total overall surgeries projected in the planning area, Eye Associates Northwest provided the following information related to market share and historical utilization of the ASF. [Source: June 3, 2019, screening response, page 10]

"...Conservatively, Eye Associates Northwest projects there will be at least an increase of 315 procedures performed annually from 2019 to 2023. In addition to making the proposed ASF available to Eye Associates Northwest' patients, which will account for the number of procedures performed at the proposed ASF, population growth will also cause an increase in the number of procedures to be performed". [Source: Application page 15]

In this application, Eye Associates Northwest projected that its historic commercial insurance payer mix would not change. The percentages are shown below. [Source: June 3, 2019, screening response, page 6]

Eye Associates Northwest Historical and Projected Payer Mix

Payer Group	Historical	Projected
Medicare	69%	69%
Medicaid	1%	1%
Commercial/Health Care Contractor	27%	27%
HMO	0%	0%
Other Government/L & I	<1%	<1%
Self-Pay	<2%	<2%
Other	<1%	<1%
Total	100.0%	100.0%

[&]quot;Exhibit 11 to the Eye Associates Northwest Application is an historical income statement. It was prepared using a cash basis. The income statements include financials for Eye Associates Northwest, including EANWSC".

The assumptions Eye Associates Northwest used for its present year 2019, and projection years 2019 -2024 revenue, expenses, and net income for the ASF are summarized below.

Assumptions

- Revenue is projected to increase 5% per year.
- Wages and salaries are projected to increase 3% per year.
- Equipment and instruments is projected to increase 2% per year.
- General office expense is projected to increase 2% per year.

- Professional services are projected to increase 2% per year.
- IT Expenses is projected to increase 2% per year.
- License and taxes is projected to increase 2% per year.
- Depreciation is projected to increase 2% per year.
- Medical supplies are projected to increase 2% per year.
- Rent and maintenance are projected to increase 3% per year.
- Total direct expense will increase 3% per year. [Source: July 15, 2019, screening response, Exhibit 1]

Based on the assumptions above, Eye Associates Northwest provided its current year and projected revenue, expenses and net income statement for the ASF. That information is summarized below. [Source: July 15, 2019, screening response, Exhibit 1]

Department's Table 8 Current Year and Projected Revenue and Expenses for Calendar Years 2019 through 2022

	CY2019	CY2020	CY2021	CY2022	CY2023
	Current Year	Year 1	Year 2	Year 3	Year 4
Net Revenue	\$1,604,676	\$1,684,910	\$1,769,155	\$1,857,613	\$1,950,494
Total Expenses	\$1,603,321	\$1,644,239	\$1,729,342	\$1,729,342	\$1,773,590
Net Profit/(Loss)	\$1,355	\$40,671	\$128,271	\$128,271	\$176,904

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

Public Comment None

Rebuttal Comment

None

Department Evaluation

To evaluate this sub-criterion, the department first reviewed the assumptions used by Eye Associates Northwest to determine the projected number of procedures and occupancy of the ASF. Eye Associates Northwest used a combination of existing volumes and published utilization statistics. The NCHS report used by Eye Associates Northwest to assume surgical use in the planning area is the most recently available utilization survey for outpatient surgery trends in the United States. After reviewing Eye Associates Northwest utilization assumptions, the department concludes they are reasonable. Eye Associates Northwest based its revenue and expense assumptions for the ASF on the assumptions listed above. Eye Associates Northwest is an existing provider in the planning area and has documented experience operating the ASF, the department concludes that the assumptions are reasonable.

Eye Associates Northwest provided a copy of the current lease agreement for the site. The agreement is between Hanover Investment, LLC (landlord) and Eye Associates Northwest, P.C. (tenant). The lease agreement was executed on March 22, 2012, and is effective for 10 years. The lease agreement

expires on March 31, 2023. The agreement identifies the roles and responsibilities for each entity and all costs associated with the lease agreement can be substantiated in the revenue and expense statement.

Eye Associates Northwest identified Dr. Brant Carroll, M.D. as the medical director for the ASF. The role of medical director is uncompensated because Dr. Meyer is an owner of C Eye Associates Northwest. A Medical Director agreement was provided however, the position is not compensated. Eye Associates Northwest provided a job description for the medical director that identified the roles and responsibilities for both Eye Associates Northwest and the medical director.

The pro forma financial statements provided for Eye Associates Northwest shows the ASF's revenues exceeding expenses beginning current year (2019), and from the first full calendar year of operation 2020 through the four year of by year 2024. Eye Associates Northwest provided an historical balance sheet for the practice and the surgery center that is summarized below.

Department's Table 9
Eye Associates Northwest, P.C. Historical Balance Sheets

Historical Year 2017									
Assets Liabilities									
Total Current Assets	(\$738,230)	Total Current Liabilities	\$437,080						
Property/Plant/Equipment \$1,821,863		Long Term Liabilities	\$1,140,282						
Other Assets -		Total Equity	(\$493,728)						
Total Assets	\$1,083,634	Total Liabilities and Equity	\$1,083,634						

Historical Year 2018								
Assets Liabilities								
Total Current Assets	\$1,194,985	Total Current Liabilities	\$2,696,527					
Property/Plant/Equipment \$1,615,291		Long Term Liabilities	\$589,998					
Other Assets -		Total Equity	(\$476,248)					
Total Assets	\$2,810,277	Total Liabilities and Equity	\$2,810,277					

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 balance sheet data provided for Eye Associates Northwest the department concludes that approval of this project would not have a negative financial impact on Eye Associates Northwest 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.

Department Evaluation

There are no costs associated with this project. This sub-criterion is not applicable to this project.

(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.

Department Evaluation

There are no costs associated with this project. This sub-criterion is not applicable to this project.

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 Eye Associates Northwest, P. C. 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.

Eve Associates Northwest

In response to this sub-criterion, Eye Associates Northwest provided the following statements.

"<u>Table 13</u> identifies the projected staffing, by FTE, for each of the first three years of operation. Information regarding the salaries, wages, and employee benefits is included in the pro forma financials contained in Exhibit 9". [Source: Application, page 19]

Applicant's Table 13 Reproduced
Proposed ASF Estimated Total Staffing 2019-2023

Position	2018	2019	2020	2021	2022	2023
Clinical Director/Charge Nurse	1	, 1	1	1	1	1
RNs	4	4.5	4.5	4.5	4.5	4.5
Surgical Technologists	4.25	4.25	4.75	4.75	4.75	4.75
Registration	1	1	1	1	1	1
Receptionists	1	1	1	1	1	1
Total	11.25	11.75	12.25	12.25	12.25	12.25

In addition to the statements above, Eye Associates Northwest also provide the following statement.

"The proposed ASF intends to continue employment of all its staff in good standing. A sufficient number of qualified health manpower and management personnel are already in place and will be added, as needed, in accordance with <u>Table 13</u>". [Source: Application, page 20]

Eye Associates Northwest also provided the following statement and information related to its key staff for the ASF. [Source: Application, Page 5]

"Medical staffs currently employed by Eye Associates Northwest are listed in Table 2 below.

Applicant's Table 2 Reproduced
Eye Associates Northwest Medical Staff

Physicians	Specialties
Deepa G. Abraham, M.D.	Glaucoma
David H. Barr, M.D.	Comprehensive Ophthalmology
Thomas E. Gillette, M.D.	Cornea and External Disease and Refractive Surgery
Roya N. Habibi, O.D.	Optometry
J. Timothy Heffernan, M.D.	Plastic and Orbital Surgery
Jeanna M. Hoyt, M.D.	Comprehensive Ophthalmology
D. Patrick Kelly, M.D.	Comprehensive Ophthalmology
Anita S. Lam, O.D.	Optometry
Thao Phuong Lee, M.D.	Pediatric Ophthalmology
Hoi Leung, O.D.	Optometry
Hubert H. Pham, M.D.	Comprehensive Ophthalmology
Dennis D. Waltman, M.D.	Comprehensive Ophthalmology
Theodore M. Zollman, M.D.	Comprehensive Ophthalmology"

Public Comment

None

Rebuttal Comment

None

Department Evaluation

As shown in the table above, all FTEs and physician staff intending to use the surgery center at Eye Associates Northwest are already in place. Eye Associates Northwest anticipates that less than one surgical technologist FTE would be needed. Given that just one staff is needed, the applicant provided specific information about how it would retain current staff.

However, in the event that additional staff is required in the future, the statements provided by Eye Associates Northwest about recruitment and retention of staff are reasonable.

Information provided in the application demonstrates that Eye Associates Northwest is a well-established and current provider of healthcare services in north King County, the department concludes that Eye Associates Northwest has the ability to recruit additional staff if necessary.

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</u> to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

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

Eye Associates Northwest

Eye Associates Northwest provided the following statements relating to ancillary and support services required for the proposed project. [Source: Application page 21]

"Eye Associates Northwest will offer all of the necessary ancillary and support services on site.

Exhibit 13 contains a copy of the executed Transfer Agreement between Swedish Medical Center/Ballard and Eye Associates Northwest."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Eye Associates Northwest has been providing healthcare services at in north King County for many years. The ancillary and support required for continued operation of the ASF are already in place and available. Information provided in the application demonstrates that the additional services will not require added ancillary and support services.

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that the ASF will continue to maintain the necessary relationships with ancillary and support services to provide outpatient surgical services in north King County.

The department concludes that nothing in the information reviewed indicate that the continued operation of the one operating room CN-exempt ASF and the addition of one operating to capacity and converting the ASF to CN-approved ASF, would adversely affect the relationships already established. 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.

Eye Associates Northwest

Eye Associates Northwest provided the following statements related to this sub-criterion.

"Eye Associates Northwest has no history with respect to the actions described in CN criteria WAC 246-310-230(5)(a)". [Source: Application page 21]

"EANSC is licensed by the Department as an ambulatory surgical facility (#ASF.FS.60102711). It is also certified by the Centers for Medicare and Medicaid Services as an ambulatory surgical center (#50C0001014), and it participates in the Medicaid program (#1184689408)". [Source: Application page 4]

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.¹⁷ To accomplish this task, the department reviewed the quality of care and compliance history for the Eye Associates Northwest.

CMS Survey Data

Using the Center for Medicare and Medicaid Services Quality, Certification & Oversight Reports (QCOR), website the department reviewed the historical survey for Eye Associates Northwest. Eye Associates Northwest QCOR review show the facility had one standard survey¹⁸ within the last five years with no follow up visits. During the survey, condition level deficiencies were identified and Eye Associates submitted plan of corrections that were accepted by CMS¹⁹. [Source: QCOR Survey Activity Report for Eye Associates Northwest]

¹⁷ WAC 246-310-230(5)

¹⁸ Eye Associates Northwest was surveyed by QCOR on 11/10/2014

¹⁹ Condition-level deficiencies are deficiencies that violate Medicare's Conditions of Participation.

Washington State Survey Data

As stated in the "Applicant Description" section of this evaluation, Eye Associates Northwest is seeking certificate of need approval for its existing ambulatory surgical facility. The applicant operates one surgery center in Seattle, within Washington State and does not own or operate any out-of-state facilities.

Using its own internal database, the department reviewed the historical survey data for healthcare facilities associated with Eye Associates Northwest. The survey data is summarized by facility in the table below. [Source: Application page 3-4 and DOH Office of Health System Oversight]

Department's Table 10
Eye Associates Northwest Facilities

Practice Site Address	License #	Year of State Survey
1101 Madison Street, Suite 600, Seattle 98104	N/A	N/A
1455 NW Leary Way, Suite 300, Seattle 98107	ASF.FS.60102711	07/06/2015
	AST.FS.00102/11	05/05/2017
1555 NE 100 th Street, Seattle 98125	N/A	N/A
11919 NE 128th Street, Suite A, Kirkland 98034	N/A	N/A
1101 Madison Street, Suite 600, Seattle 98104	N/A	N/A
155 NE 100 th Street, Suite 110, Seattle 98125	N/A	N/A
11919 NE 128th Street, Suite A, Kirkland 98034	N/A	N/A

As shown above, Eye Associates Northwest most recent survey is May 2017. Information provided by the Department of Health internal database show that the facility was substantially compliant.

In addition to the facility identified in Table 10, the department also reviewed the compliance history of key staff associated with the surgery center. A listing of the staff is shown in the table below. [Source: Application page 20, Exhibit 3, and Medical Quality Assurance Commission]

Eye Associates Northwest Active Staff

Name	Credentialed	License Status
	Number	
Brant Carroll	MD00036720	Active
Tammy Tanula	RN00132119	Active
Jeanna M. Hoyt	MD00033999	Active
Daniel P. Kelly	MD00038815	Active
Brian R. McKillop	MD00015938	Active
Deepa G. Abraham	MD60286874	Active
David H. Barr	MD00015394	Active
Thomas E. Gillette	MD00018179	Active
Roya N. Habibi.	OD60594891	Active
J. Timothy Heffernan	MD00016843	Active
Jeanna M. Hoyt	MD00033999	Active
D. Patrick Kelly	MD00038815	Active
Anita S. Lam	OD000003728	Active
Thao Phuong Lee	MD60836561	Active

Name	Credentialed Number	License Status
Hoi Leung.	OD60169544	Active
Hubert H. Pham	MD60446483	Active
Dennis D. Waltman	MD00015138	Active
Theodore M. Zollman	MD00037264	Active

The department review of the compliance history of the key staffs associated with the surgery center, shows the staffs credentials remain active and in good standing.

Based on the information above, the department concludes that Eye Associates Northwest demonstrated reasonable assurance that the ASF 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.

Eye Associates Northwest

Eye Associates Northwest provided the following statements related to this sub-criterion.

"For nearly 20 years, Eye Associates Northwest has been working to improve the health and wellbeing of residents of the North King County Secondary Health Services Planning Area. The proposed project will expand the services Eye Associates Northwest can provide, consistent with its long-term strategy. Specifically, Eye Associates Northwest is seeking CN-approval for its existing ASF, EANSC, which currently operates pursuant to Determination of Reviewability #12-32. Eye Associates Northwest understands the Department requires it to obtain CN approval to operate a second OR at EANSC. Eye Associates Northwest has a second OR built out and ready to operate. Therefore, Eye Associates Northwest is seeking approval to operate that second OR so that it has a total of two operational ORs". [Source: Application, page 10]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

With the increased access this approval brings, the department concludes that the establishment of this freestanding 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 continue to have appropriate relationships with the providers in the service area. **This sub-criterion is met.**

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

Department Evaluation

This sub-criterion is evaluated in sub-section (3) above, this sub-criterion 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 Eye Associates Northwest, P.C. has met the cost containment criteria in WAC 246-310-240.

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

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

Step Two:

Eye Associates Northwest provided the following information related to this sub-criterion. [Source: Application, page 21-22]

"As discussed above, there is significant net need for outpatient surgery ORs in the North King County Secondary Health Services Planning Area. The proposed ASF will improve access, a key criterion for a CN. The proposed ASF will also provide a low cost, freestanding ASF in the health planning area to meet the needs of patients and help residents of the planning area avoid wait times for procedures and lower health care costs.

Eye Associates Northwest has a presence in the North King County Secondary Health Services Planning Area, and the proposed ASF will build upon this presence and offer the proposed ASF and patients' convenient access to surgical services. Eye Associates Northwest is committed to providing high quality, affordable care in the North King County Secondary Health Services Planning Area, and the proposed ASF will help accomplish this goal. The proposed project promotes continuity of care with Eye Associates Northwest' other services as well as cost containment. Making the proposed ASF available to qualified, credentialed, and privileged physicians in good standing is significantly less costly than building a new ASF to address waiting times for surgical services.

Eye Associates Northwest is requesting a CN for the proposed ASF so that its employed providers can use the second OR at its facility, which is fully built-out and ready to operate. In addition, other qualified, credentialed, and privileged physicians in good standing could utilize the facility. As part of its due diligence, Eye Associates Northwest examined alternatives to the proposed project and evaluated those alternatives. The alternatives are addressed below.

Alternative 1: "Do Nothing"

Eye Associates Northwest rejected a "do nothing" alternative. The North King County Secondary Health Services Planning Area currently has too few outpatient ORs. Planning area residents are underserved relative to the forecasted demand for surgical services and must travel or wait to obtain care. Eye Associates Northwest has a presence in the North King 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.

Alternative 2: Request Approval for a Freestanding ASC, i.e., The Proposed Project

In contrast to the "do nothing" approach, the advantages of a CN-approved ASF are clear. A CN-approved ASF would afford increased access and local choice for the health planning area residents and local, independent physicians. It would increase physicians' and patients' ease of access and improve their ability to deliver and receive high quality care. This alternative model reduces the overall cost of care and passes these relative cost and efficiency advantages of a freestanding ASF to patients and payers.

There are no disadvantages to granting Eye Associates Northwest' request for CN approval. It is second OR is built out and ready to operate. The data demonstrates there would not be a duplication of services, given a projected net demand of over 16.21 outpatient ORs in the health planning area.

A CN-approved ASF would better serve the interests of the planning area residents and achieve North King County Secondary Health Services Planning Area's desire to reduce wait times for outpatient surgical services".

Step Three:

This step is applicable only when there are two or more approvable projects. Eye Associates Northwest is the only project submitted to add outpatient surgical capacity in north King County. Therefore, this step does not apply.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided within the application shows that Eye Associates Northwest did not consider any other alternative other than to submit this application. Eye Associates Northwest's main purpose of submitting this application is to add one OR to the surgery center, for a total of two OR's and convert the exempt surgery center to CN approved. Given the statements by the applicant and the surgery center utilization, the department did not identify any other alternatives that would be superior in terms of cost, efficiency, or effectiveness.

For this project, Eye Associates Northwest's rejection of the do nothing option and to seek approval so it can operate as a two operating room Certificate of Need approved facility is reasonable. Further, approval of this project would provide needed access to ambulatory surgical facility in the planning area.

The department concurs that the requested project is reasonable and is the best option to those considered by Eye Associates Northwest for the planning area and surrounding communities. **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.

Department Evaluation

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.

Department Evaluation

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.

Service Area Population: 2022 366,764 Claritas Age: 18+
Surgeries @ 149.317/1,000: 54,764

a.i. 94,250 minutes/year/mixed-use OR

a.ii. 68,850 minutes/year/dedicated outpatient OR

a.iii. 10 dedicated outpatient OR's x 68,850 minutes = 688,500 minutes dedicated OR capacity 13,066 Outpatient surgeries
a.iv. 57 mixed-use OR's x 94,250 minutes = 5,372,250 minutes mixed-use OR capacity 41,032 Mixed-use surgeries

b.i. projected inpatient surgeries = 44,055 = 5,768,024 minutes inpatient surgeries projected outpatient surgeries = 10,709 = 564,295 minutes outpatient surgeries

b.ii. Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's

10,709 - 13,066 = -2,357 outpatient surgeries

b.iii. average time of inpatient surgeries = 130.93 minutes average time of outpatient surgeries = 52.69 minutes

c.i. if b.iv. < a.iv., divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's **Not Applicable - Go to c.11. and ignore any value here.**

 $-\frac{0}{0} \\ 0 / 0 =$ **0.00**

c.ii. if b.iv. > a.iv., divide (inpatient part of b.iv - a.iv.) by 94,250 to determine shortage of inpatient OR's USE THESE VALUES

5,768,024 - 5,372,250 395,774

94,250 = **4.20**

divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's
-124,205 / 68,850 = -1.80

Washington State Department Health

APPENDIX A ASC Need Methodology North King County

	-		Dedicated		Mixed	Inpatient Cases					
		-	Outpatient	Use	Use		Inpatient Mins. In			_	
Facility	Rooms	ORs	ORs	ORs	min/case	ORs	Mixed Use ORs	Min/Case	Cases	Mins.	Data Source
Kindred Hospital-Northgate	0	0	0	0	0.0	0	0	0.0	0	0	No operating rooms; does not provide surgical services
Seattle Cancer Care Alliance	0	0	0	0	0.0	0	0	0.0	0	0	No operating rooms; does not provide surgical services
Seattle Children's Hospital, includes outpatient facility	1	0	0	15	134.4	11,447	1,538,311	0.0	0	0	Year 2017 data from 2018 survey.
Swedish First Hill-Ballard Campus	2	0	0	4	35.3	9,487	335,361	0.0	0	0	Year 2017 data from 2018 survey.
University of Washington Medical Center	7	0	0	26	199	14,834	2,951,444	0.0	0	0	Year 2017 data from 2018 survey.
University of Washington Medical Center Roosevelt	0	0	2	0	0.0	0	0	96.8	1,527	147,778	Year 2017 data unavailble; year 2017 data used.
UW Medicine Northwest Hospital	4	0	4	12	113.8	8,287	942,908	85.2	1,686	143,669	Year 2017 data from 2018 survey.
Eye Associates Northwest Surgery Center (Applicant)	0	0	2	0	0.0	0	0	50.0	1,278	63,905	Year 2017 data survey from Year 2018 survey. # of cases calculated.
Fremont Endoscopy		ENDOSCO	PY ORS, CA	SES, & N	MINUTES N	OT COUNTED					ENDOSCOPY ORS, CASES, & MINUTES NOT COUNTED
Northwest Eye Surgeons (CN Issued)	0	0	2	0	0.0	0	0	13.0	4,100	53,300	Year 2016 data from 2017 survey.
Puget Sound Surgical Center	0	0	1	0	0.0	0	0	118.9	140	16,641	Year 2016 data from 2017 survey. Facility now known as EVIVA.
Seattle Endoscopy Center		ENDOSCO	PY ORS, CA	SES, & N	MINUTES N	OT COUNTED					ENDOSCOPY ORS, CASES, & MINUTES NOT COUNTED
Seattle Orthopedic Center-Surgery (CN Issued)	1	0	2	0	0.0	0	0	70.3	1,978	139,002	Year 2017 data from 2018 survey.
Totals	14	0	13	57	482.5	44,055	5,768,024	434.1	10,709	564,295	
					Avg min/ca	se inpatient	130.93	Avg min/case	e outpatient	52.69	
ORs counted in numeric methodology			10	57							
ILRS: Integrated Licensing & Regulatory System											
Total Surgeries	54,764										
Area population 2022 [0-85]	366,764										
Use Rate	149.317										
Planning Area projected 0-85 population Year: 2022	385,682										
Or Outration of total annualis	19.55%										
% Outpatient of total surgeries											
% Inpatient of total surgeries	80.45%		-								