



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

August 2, 2019

CERTIFIED MAIL # 7016 3010 0001 0575 0020

Louise Coomes, Controller
Clearview Eye and Laser, PLLC
7520 – 35th Avenue Southwest
Seattle, Washington 98126

RE: Certificate of Need Application #19-28

Dear Ms. Coomes:

We have completed review of the Certificate of Need application submitted by Clearview Eye and Laser, PLLC. The application proposes to establish an ambulatory surgery center in Seattle, within southwest King 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 Clearview Eye and Laser, PLLC 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 southwest King County secondary health services planning area. The surgery center will serve patients age 15 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 ophthalmological services, otolaryngological, oral maxillofacial, and plastic surgery.

Conditions:

1. Clearview Eye and Laser, PLLC agrees with the project description as stated above. Clearview Eye and Laser, PLLC further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Clearview Eye and Laser, PLLC will provide charity care in compliance with its charity care policy. Clearview Eye and Laser, PLLC will use reasonable efforts to provide charity care consistent with the regional average. The regional charity care average from 2015-2017 was 0.86% of gross revenue and 1.88% of adjusted revenue.

3. Clearview Eye and Laser, PLLC 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. Clearview Eye and Laser, PLLC 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:

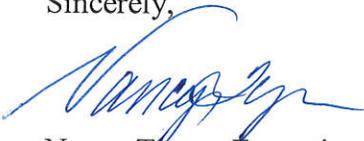
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Physical Address:

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

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 AUGUST 2, 2019, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY CLEARVIEW EYE AND LASER, PLLC., PROPOSING TO ESTABLISH AN AMBULATORY SURGICAL FACILITY IN SEATTLE WITHIN SOUTHWEST KING COUNTY SECONDARY HEALTH SERVICES PLANNING AREA.

APPLICANT DESCRIPTION

Clearview Eye and Laser, PLLC is a for-profit Washington State Professional Limited Liability Company wholly owned by Thomas G. Mulligan, M.D., Marcus A. Meyer, M.D., and Aaron P. Weingeist, M.D. each with equal ownership. Clearview Eye and Laser was incorporated on July 24, 2014.¹ [source: Application, page 1]

On September 19, 2014, the department issued Determination of Reviewability #14-33 to Clearview Eye and Laser, PLLC approving the establishment of a Certificate of Need exempt surgery center located at 7520 –35th Avenue Southwest in Seattle [98126]. The surgery center is known as Westwood Eye Surgery and Laser and provides ophthalmic surgical services in King County. Westwood Eye Surgery and Laser is licensed by the Washington State Department of Health² and certified by the Centers for Medicare and Medicaid Services as an ambulatory surgical center.³ [source: CN Historical file and Application page 1-2]

Clearview Eye and Laser operates two ophthalmology clinics and one ophthalmic surgery center in King County. Clearview Eye and Laser does not operate any facilities outside of Washington State. Listed in the table below are the two sites.

Practice Site Address	Type	Licensed Number
7520 – 35 th Avenue Southwest, Seattle, 98126	Clinic/Surgery Center	ASF.FS.60532154
16259 Sylvester Road Southwest, #304, Burien, 98166	Clinic Only	N/A

This project focuses on the surgery center located in Seattle shown in the table above.

For reader’s ease, the applicant is Clearview Eye and Laser, PLLC and throughout this evaluation will be reference to as “Clearview Eye and Laser.”

PROJECT DESCRIPTION

Clearview Eye and Laser submitted this application for review primarily so that it can allow physicians that are not associated with surgery center to have access to the facility. The applicant also proposes to add surgical services to the surgery center.

If this project is approved, the surgery center will continue to be located at 7520 – 35th Avenue SW in Seattle, [981026]. Clearview Eye and Laser will continue to provide care to patients 15 years of age and older who require ambulatory surgery and are not expected to require hospitalization, and can be treated an outpatient surgery setting.

¹ UBI #603 260 547

² ASF.FS.60532154

³ 50-C0001256

Surgical services currently provided at the surgery center include ophthalmological services, laser eye services, and ophthalmology plastic surgery. This application proposes to expand services to include otolaryngological (ear and throat), retinal ophthalmology, and plastic surgery. The number of operating rooms will remain at two. [Source: Application, page 1]

With Certificate of Need approval, Clearview Eye and Laser will also allow other physicians who are not associated with the practice an opportunity to perform surgeries and procedures at the surgery center. This action requires that Clearview Eye and Laser seek Certificate of Need review and approval. [Source: Application page 2]

Since this project does not propose any structural changes to the facility or an expansion of ORs, there is no capital expenditure associated with this project. [Source: Application page 4]

Clearview Eye and Laser is licensed by the Department of Health and is Medicare and Medicaid certified. If this project is approved, Clearview Eye and Laser will maintain its operations and ensure that the surgery center meet any specific conditions related to the Certificate of Need 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, Clearview Eye and Laser proposes that its first full year of operation as a CN-approved surgery center is calendar year 2020 and calendar year three is 2022. [Source: Application page 4, and January 17, 2019, screening response, Exhibit C]

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 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	Clearview Eye and Laser
Letter of Intent Submitted	May 8, 2018
Application Submitted	November 7, 2018
Department’s pre-review activities <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant’s Responses Received • DOH 2nd Screening Letter • Applicant’s Responses Received 	December 3, 2018 January 17, 2019 February 11, 2019 March 28, 2019
Beginning of Review	April 5, 2019
End of Public Comment/No Public Hearing Conducted <ul style="list-style-type: none"> • Public comments accepted through end of public comment 	May 5, 2019
Rebuttal Comments Received ⁴	
Department’s Anticipated Decision Date	July 8, 2019
Department’s Anticipated Decision Date with 30-day Extension ⁵	August 7, 2019
Department’s Actual Decision Date	August 2, 2019

⁴ No public comments were submitted; as a result, no rebuttal comments were submitted.

⁵ Thirty-day extension letter was sent to Clearview Eye and Laser, PLLC on July 8, 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 review of this project, one entity requested to receive copies of the application and to be inform of the department decision, but no entity qualified for affected person status.

SOURCE INFORMATION REVIEWED

- Clearview Eye and Laser, PLLC Certificate of Need application submitted November 7, 2018
- Clearview Eye and Laser, PLLC 1st screening responses received January 17, 2019
- Clearview Eye and Laser, PLLC 2nd screening responses received February 1, 2019
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission and Nursing Quality Assurance Commission
- Compliance history for Clearview Eye and Laser, PLLC 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>
- Historical charity care data for years 2015, 2016, and 2017 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 2016 for hospitals, ambulatory surgical facilities, or ambulatory surgical facilities located in southwest King County
- Year 2016 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>
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Clearview Eye and Laser, PLLC proposing to establish a two-operating room ambulatory surgical facility in Seattle, within the southwest King County secondary service planning area is consistent with the applicable criteria of the Certificate of Need Program, provided Clearview Eye and Laser, PLLC 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 southwest King County secondary health services planning area. The surgery center will serve patients age 15 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 ophthalmological services, otolaryngological, oral maxillofacial, and plastic surgery.

Conditions:

1. Clearview Eye and Laser, PLLC. agrees with the project description as stated above. Clearview Eye and Laser, PLLC further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Clearview Eye and Laser, PLLC will provide charity care in compliance with its charity care policy. Clearview Eye and Laser, PLLC will use reasonable efforts to provide charity care consistent with the regional average. The regional charity care average from 2015-2017 was 0.86% of gross revenue and 1.88% of adjusted revenue.
3. Clearview Eye and Laser, PLLC 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. Clearview Eye and Laser, PLLC 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 Clearview Eye and Laser, PLLC 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. Clearview Eye and Laser is located in Seattle, within the southwest 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 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.

Clearview Eye and Laser

Clearview Eye and Laser determined the existing capacity in the southwest King County secondary health service planning area to be 0 dedicated outpatient ORs and 9-mixed use ORs. Based on a computed use rate of 69.0, Clearview Eye and Laser calculated need for an additional 13.05 outpatient ORs in the southwest King County secondary health service planning area. [Source: March 28, 2019, screening response, Exhibit A]

Clearview Eye and Laser provided the following statements related to the numeric need methodology.

*“Clearview Eye and Laser is requesting CN approval to establish an ASF to improve access to accessible, affordable, and local ambulatory surgical services to the Southwest King Secondary Health Services Planning Area residents. Based on the Department’s quantitative need methodology, the Southwest King Secondary Health Services Planning Area is projected to need more than **13.05** additional outpatient ORs by 2022.*

Clearview Eye and Laser’s proposed project will respond to projected planning area demand for outpatient ORs and is validated by the need methodology, as shown below.

Current Supply of CN-approved ORs - Southwest King Secondary Health Services Planning Area
There are nine CN-approved ORs in the Southwest King Secondary Health Services Planning Area. These are all inpatient/mixed use ORs. There are zero CN-approved outpatient ORs in the Southwest King Secondary Health Services Planning Area. Furthermore, while licensed, CN exempt outpatient ORs have been identified and their outpatient surgery volumes included in the methodology to determine planning area surgery use rates, their ORs have not been included in the count of ORs within the forecast need model. The methodology also excludes gastroenterology/endoscopy ORs. Thus, the number of such ORs and the procedure volumes from these facilities are also excluded from the methodology. [Source: Application, page 9-10]

“Exhibit 9 contains the applicant’s need methodology evaluation. The evaluation shows that there is a need for an additional 13.05 outpatient ORs by the year 2022 in the Southwest King County secondary health services planning area. Currently there is a shortage of 13.05 outpatient ORs in the Southwest King County secondary health services planning area. A CN would allow all patients a choice between a hospital outpatient surgery department and a freestanding ambulatory surgery center. The cost per procedure for the patient as well as his or her insurance company is significantly less in a freestanding ASF. For the above reasons, we believe that the proposed project meets applicable need criteria”. [Source: Application, page 11]

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. Southwest 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 Southwest King County.

**Department’s Table 1
Southwest King County Secondary Health Services ZIP Codes**

1980 State Health Plan		
ZIP Code	City	County
98013	Burton	King
98062	Seahurst	King
98070	Vashon	King
98106	Seattle	King
98109	Seattle	King
98116	Seattle	King
98126	Seattle	King
98136	Seattle	King
98146	Seattle	King
98148	Seattle	King
98158	Seattle	King
98166	Seattle	King
98168	Seattle	King
98188	Seattle	King

According to the department’s records, there are seven providers in southwest King County secondary health services planning area with OR capacity. In the planning area, there is one hospital and six⁶ ambulatory surgical facilities.

⁶ This figure includes Clearview Eye and Laser/Westwood Eye Surgery

Because there is no mandatory reporting requirement for utilization of ASFs or hospital ORs, the department sends an annual utilization survey to the hospital 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.

Table 2 shows a listing of the only hospital located in the planning area. [Source: CN historic files and ILRS]

**Department’s Table 2
Southwest King County
Secondary Health Services Planning Area Hospital**

Facility	ZIP Code
Highline Medical Center	98166

For Highline Medical Center, all known OR capacity and inpatient/mixed-use 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]

**Department’s Table 3
Southwest King County Secondary Health Services Planning Area ASFs**

Facility	ZIP Code	CN Approved or Exempt?
Northwest Center for Plastic Reconstructive Surgery	98166	Exempt
Aesthetic and General Dermatology of Seattle	98166	Exempt
Southwest Seattle Surgical Center	98166	Exempt
La Belle Vie Cosmetic Surgery Centers	98188	Exempt
Clearview Eye and Laser dba Westwood Eye Surgery [Applicant]	98126	Exempt
Northwest Center for Plastic Surgery	98166	Exempt

All of the six ASFs shown above are located within the offices of private physicians, whether in a solo or group practice that have received an exemption (considered a Certificate of Need-exempt ASF). The use of these ASFs is restricted to physicians that are employees or members of the clinical practices that operate the facility. Therefore, these facilities do not meet the ASF definition in WAC 246-310-010. For Certificate of Need-exempt ASFs, the number of surgeries, but not OR’s, is included in the methodology for the planning area.

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	Southwest King County
Population Estimates and Forecasts	Age Group: 15+ Claritas Population Data released year 2016 Year 2017 – 229,430 Year 2021 – 239,588
Use Rate	Divide the calculated surgical cases by 2017 population results in the service area use rate of 35.536/1,000 population
Year 2017 Total Number of Surgical Cases	3,710 – Inpatient or Mixed-Use; 4,443– Outpatient 0 – Inpatient 8,153 – Total Cases
Percent of surgery: outpatient vs. inpatient	Based on DOH survey and ILRS: 54.50% outpatient; 45.50% inpatient
Average minutes per case	Based on DOH survey and ILRS: Outpatient cases: 51.53 minutes Inpatient cases: 103.09 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes (per methodology in rule)
Existing providers/OR's	Based on listing of southwest King County Providers: 0 dedicated outpatient OR's 9 mixed use OR's
Department's Methodology Results	Surplus of mixed use ORs – 2.23

Based on the assumptions described in Table 4 above, the department's application of the numeric methodology calculates a surplus of 2.23 mixed use ORs in year 2021.

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

Data Points
Outpatient cases
Use Rate

These two data points are tightly connected. When the 2017 total number of surgical cases is divided by the year 2017 population, the result is a planning area use rate. The use rate is then applied to the projected population. If the number of cases is significantly different, the calculated use rate is different. The applicant identified 15,736 cases in the planning area for year 2017; the department calculated 8,153 cases. The difference is in the number of outpatient cases. The applicant identified 15,736 and the department identified 4,443 cases. The source data for applicant's methodology is unknown. The department will rely on its own number of calculated cases.

Population Estimates/Forecasts

The source of the applicant's population is the similar to that used by the department (Claritas). Both the applicant and the department used 2017 data and projected to year 2021. The population data is not exact, but the differences are not significant.

Use Rate

As stated above, the data points used in this numeric need methodology are inter 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 (2017) population and then dividing by 1,000. The applicant calculated a use rate of 69.0/1,000 for southwest King County planning area. The department calculated a use rate of 34.536/1,000 residents in the planning area. These two use rates are significantly different and the use rate is the main driver for this methodology. The department will rely on its own use rate.

Number of Existing OR's

A comparison review of the department's and the applicant's numeric methodology shows that both the department and the applicant counted the same of OR's in the numeric methodology. Clearview Eye and Laser counted nine inpatient and/or mixed use OR's and zero dedicated outpatient OR's. The department also counted nine inpatient and/or mixed use OR's and zero dedicated outpatient OR's.

In summary, the data used in both methodologies is significantly different. Clearview Eye and Laser calculated a need for 13.05 outpatient ORs; the department calculated a surplus of 2.23 outpatient ORs. The department considers its numeric methodology accurate and will rely on the results for this evaluation.

Based on the numeric methodology alone, need for outpatient ORs in Southwest King County is not demonstrated.

WAC 246-310-270(4) provides the following guidance when numeric need for additional outpatient ORs is not demonstrated for a planning area.

“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.”

Clearview Eye and Laser provided the following information to demonstrate need and support approval of its project. [Source: Application, pages 3, 10, and 11]

“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 ASF.”

For the above reasons, we believe that the proposed project meets applicable need criteria.

In addition to the above reasons that demonstrate the proposed ASF meets applicable need criteria, Clearview Eye and Laser requests that, if needed, the Department exercise its discretion under WAC 246-310-270(4) to grant a CN for the proposed ASF. Without a CN, Clearview Eye and Laser cannot

make available the proposed ASF and the additional surgical services it seeks to provide, despite the fact that the ASF is built out and operational. Issuing a CN to the proposed ASF will allow these to receive the care they need and to receive that care locally.”

Clearview also provided a table showing historical use of the current exempt surgery center.

**Table 1- Reproduced
Westwood Eye Surgery and Laser Historical Utilization**

<i>Year</i>	<i>Utilization</i>
2018	1,610 <i>(through September 30, 2018)</i>
2017	2,070
2016	2,112
2015	2,097
2014	1,800
2013	1,853

Clearview Eye and provided the following supplemental information under this sub-criterion.

“Clearview Eye and Laser has developed this 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 ORs are fully built-out and operational. Without a CN, however, Clearview Eye and Laser cannot make available the proposed ASF to physicians who are not owners or employees of Clearview Eye and Laser or their patients. These patients currently are experiencing delays in receiving needed care or are being forced to travel significant distances to receive the care.

Table 7 below shows an increase in the total number of cases from 2,146 in 2018 to 2,950 in 2023. Conservatively, Clearview Eye and Laser projects there will be at least an increase of 75 procedures performed annually from 2019 to 2023. In addition to making the proposed ASF available to Clearview Eye and Laser’s patients for ophthalmic and other surgical procedures, 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, Clearview Eye and Laser could also make the proposed ASF available to other qualified, credentialed and privileged physicians in good standing.

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

***Clearview Eye and Laser Table –7 Reproduced
Proposed ASF Projected Utilization***

<i>Year</i>	<i>Number of Procedures</i>
<i>2018</i>	<i>2,146</i>
<i>2019</i>	<i>2,600</i>
<i>2020</i>	<i>2,700</i>
<i>2021</i>	<i>2,850</i>
<i>2022</i>	<i>2,925</i>
<i>2023</i>	<i>2,950</i>

[Source: December 24, 2018, screening response, page 12-13]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Clearview Eye and Laser provided information to support that utilization at the ASF should continue within the planning area. With CN approval, physicians not associated with Clearview Eye and Laser could use the surgery center. However, since Clearview Eye and Laser does not intend to increase the number of ORs (2), but 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.

WAC 246-310-270 allows flexibility to approve operating rooms absent numeric need. One particular item to be noted is that the “surplus” of mixed use ORs is two which is not a significant surplus for a planning area. Additionally, as the methodology demonstrates, there are currently no CN approved ORs in the planning area, therefore, the surplus of mixed-use ORs does not negate the fact that 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 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 Clearview Eye and Laser. **This sub-criterion is met.**

WAC 246-310-270(6)

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

Clearview Eye and Laser

Clearview Eye and Laser currently operates with two Certificate of Need exempt ORs. This project proposes to convert the exempt surgery center to CN approved. This action means that the number of ORs counted in the southwest 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. Clearview Eye and Laser is currently operating with two ORs. This project does not propose to increase or decrease the number of ORs at the facility. **This standard is met.**

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

To evaluate this sub-criterion, the department evaluates an applicant’s admission 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.

Clearview Eye and Laser

Clearview Eye and Laser provided copies of the following policies.

- Admission policy [Source: Application page 14, Exhibit 10]
- Charity care Policy [Source: March 28, 2019, screening responses received Exhibit B]
- Non-Discrimination Policy [Source: March 28, 2019, screening responses received Exhibit B]
- Patients Right Policy [Source: March 28, 2019, screening responses received Exhibit B]

Clearview Eye and Laser stated that the Non-Discrimination Policy is used in conjunction with the Admission Policy and the Patient Rights Policy.

Medicare and Medicaid Programs

Clearview Eye and Laser is currently Medicare and Medicaid certified. Clearview Eye and Laser provided the current and projected source of revenues by payer for the ASF. That information is restated in Table 5 below. [Source: March 28, 2019, screening response, page 3-4]

**Department’s Table 5
Clearview Eye and Laser Historical and Projected Payer Mix**

Payer Group	Historical	Projected
Medicare	71%	71%
Medicaid	5%	5%
Commercial/Health Care Contractor	22%	21%
HMO	0%	0%
Other Government/L & I	0%	0%
Self-Pay	2%	3%
Total	100.0%	100.0%

Charity Care

Clearview Eye and Laser’s Charity Care provided the following statements related charity care at the surgery center.

Charity care health care services at Clearview Eye and Laser, PLLC, to persons whose family income is at or below 200 percent of the federal poverty level. Charity care is considered secondary to all other financial resources available to the patient including: medical plans, workers' compensation, Medicare, Medicaid, federal and military programs, third party liability situations and any other situation in which a person or entity may have a legal responsibility to pay for the cost of medical services.

All patient accounts that are preparing to receive services at Clearview Eye and Laser, PLLC, are eligible for charity care consideration. Patient eligibility will be identified prior to eligible provided services. Patient eligibility approval will be for a one-time adjustment for medical service charges rendered at Clearview Eye and Laser, PLLC. Services eligible for charity care are defined as fees related to appropriate ASC-based medical services. [Source: March 28, 2019, screening response, page 7-15, Exhibit B]

Within the application, Clearview Eye and Laser pro forma financial statement identified the amounts of charity care for full years 2019–2023. [Source: March 28, 2019, screening response, Exhibit 1]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Clearview Eye and Laser provided its Admission, Non-Discrimination Policy, Patient Rights Policy, and Charity Care Policy that are currently used Westwood Eye and Laser.

The Admission Policy, Non-Discrimination Policy, Patient Rights 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 Clearview Eye and Laser 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. Clearview Eye and Laser is located with King County within the King County Region. Currently, there are 23 hospitals operating in the region. Of those, Highline Medical Center is the only hospital located within the southwest King County secondary health services planning area that could be affected by the approval of this project.⁷

Clearview Eye and Laser projected that the ASF will provide charity care at 0.60% of total revenue and 1.00% 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 one hospital that could be potentially affected by this project. The three years reviewed are 2015, 2016, and 2017.

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 Clearview Eye and Laser. [Source: Community Health Systems Charity Care 2015-2017 and March 28, 2019, screening response, page 1, and Exhibit C]

⁷ 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.

**Department's Table 6
Three Year Average—Charity Care**

	% of Total Revenue	% of Adjusted Revenue
3-year King County Region	0.86%	1.88%
3-year Southwest King County Hospital	0.80%	2.61%
Clearview Eye and Laser Surgery Center ⁸	0.60%	1.00%

As shown above, the three-year regional average proposed by Clearview Eye and Laser is lower than the regional average, and the combined average of the only hospital operating in southwest King County secondary health services planning area.

For this particular application review, the department is focusing its charity care evaluation on the regional average because there is just one hospital within the planning area that could be affected by this decision. Therefore, for that reason, the department will use the regional average charity care.

For Certificate of Need purposes, Clearview Eye and Laser is a new health care facility. To ensure that Clearview Eye and Laser would provide appropriate charity care percentages, if this project is approved, the department would attach condition requiring Clearview Eye and Laser to provide charity care consistent with the regional average. The regional charity care average from 2015-2017 was 0.86% of gross revenue and 1.88% of adjusted revenue.

This condition would also require Clearview Eye and Laser 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 Clearview Eye and Laser's 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:*

⁸ Clearview Eye and Laser's projected charity care three year average for years 2020-2023

- (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 Clearview Eye and Laser, PLLC 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.

Clearview Eye and Laser

The assumptions used by Clearview Eye and Laser to determine utilization and the projected number of procedures for its first three full years of operation are summarized below.

"As shown in Exhibit 8, the Southwest King Secondary Health Services Planning Area has shown steady population growth and is forecasted to continue growing steadily through 2025. Please see Exhibit 8 for additional historical and projected resident population statistics for the Southwest King Secondary Health Services Planning Area.

In addition, 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 5. 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

	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

[Source: Application page 8-9]

Based on the assumptions described above, Clearview Eye and Laser provided its calculated projections for years 2018 through 2023. Table 7 below shows the historic and the total projected number of procedures for the southwest King secondary health services planning area.

**Department’s Table 7
Clearview Eye and Laser Projected Utilization**

	2018	2019	2020	2021	2022	2023
Number of Procedures	2,146	2,600	2,700	2,850	2,925	2,950

Recognizing that the projections show the ASF would perform more than 50% of the total surgeries projected in the planning area, Clearview Eye and Laser provided the following information related to market share and historical utilization of the ASF.

“Clearview Eye and Laser estimates a 5 percent increase in cases 2019. As providers are added to its ASC medical staff, Clearview Eye and Laser estimates a 9 percent increase in cases in 2020. Clearview Eye and Laser estimates a two percent increase for the following three years”. [Source: March 28, 2019, screening response, page 3]

The assumptions Clearview Eye and Laser used for its historic year 2018, present year 2019, and projection years 2020-2022 revenue, expenses, and net income for the ASF are summarized below.

“Revenue provided was net of adjustments. Clearview Eye and Laser estimates 40 percent contractual adjustments for Medicare and Medicaid for the last three years.

Overhead allocation to ASC identified in the pro forma financial statement includes the following: administrative wages, billing services, computer and communication costs, office expenses, rent, and utilities.

The pro forma shows depreciation on existing equipment. The equipment will be fully depreciated in 2019. Clearview Eye and Laser does not anticipate purchasing additional equipment for the proposed project”. [Source: March 28, 2019, screening response, page 1-4]

In this application, Clearview Eye and Laser projected that its historic commercial insurance payer mix would change slightly. The percentages are shown below. [Source: January 17, 2019, screening response, page 1]

Payer	Percentage of Patients	Percentage of Payer Source
Medicare	71%	73%
Medicaid	5%	2%
Commercial/Health Care Contractor	21%	22%
HMO	0%	0%
Other Government/L&I	0%	1%
Self-Pay	3%	2%
Total	100.0%	100%

Based on the assumptions above, Clearview Eye and Laser provided its current year and projected revenue, expenses and net income for the ASF summarized below. [Source: March 28, 2019, screening response, page 3]

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

	CY2019 Current Year	CY2020 Year 1	CY2021 Year 2	CY2022 Year 3
Net Revenue	\$2,122,800	\$2,312,700	\$2,377,825	\$2,453,832
Total Expenses	\$1,571,233	\$1,542,960	\$1,591,439	\$1,641,628
Net Profit/(Loss)	\$551,567	\$769,740	\$786,386	\$812,204

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 Clearview Eye and Laser to determine the projected number of procedures and occupancy of the ASF. Clearview Eye and Laser used a combination of existing volumes and published utilization statistics. The NCHS report used by Clearview Eye and Laser 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 Clearview Eye and Laser’s utilization assumptions, the department concludes they are reasonable.

Clearview Eye and Laser based its revenue and expense assumptions for the ASF on the assumptions listed above. Given that the applicant is an existing provider in the planning area and has documented experience operating the ASF, the department concludes that the assumptions are reasonable.

Clearview Eye and Laser provided a copy of the current lease agreement for the site. The agreement is between Over the Moon Investments, LLC (landlord) and Clearview Eye and Laser, PLLC (tenant). The lease agreement was executed on October 2, 2018, and it commenced on April 1, 2017, and is effective for 15 years. The lease agreement expires on April 2032. 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.

Clearview Eye and Laser identified Dr. Marcus A. Meyer as the medical director for the ASF. The role of medical director is uncompensated because Dr. Meyer is an owner of Clearview Eye and Laser. As a result, there is no Medical Director contract or agreement. Clearview Eye and Laser provided a job description for the medical director that identified the roles and responsibilities for both Clearview Eye and Laser and the medical director.

The pro forma financial statements provided for Clearview Eye and Laser shows the ASF’s revenues exceeding expenses beginning from the first full calendar year of operation (2020) through year three (2023). Clearview Eye and Laser provided an historical balance sheet for the practice and the surgery center which is summarized below.

**Department’s Table 9
Clearview and Laser, PLLC Historical Balance Sheets**

Historical Year 2016			
Assets		Liabilities	
Total Current Assets	\$2,050,105	Total Current Liabilities	\$129,500
Property/Plant/Equipment	\$671,825	Long Term Liabilities	-
Other Assets	\$20,993	Total Capital	\$2,613,423
Total Assets	\$2,742,923	Total Liabilities and Equity	\$2,742,923

Historical Year 2017			
Assets		Liabilities	
Total Current Assets	\$2,349,453	Total Current Liabilities	\$652,523
Property/Plant/Equipment	\$147,281	Long Term Liabilities	-
Other Assets	-	Total Capital	\$1,844,211
Total Assets	\$2,496,734	Total Liabilities and Equity	\$2,496,734

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 Clearview Eye and Laser the department concludes that approval of this project would not have a negative financial impact on Clearview Eye and Laser as a whole. **This sub-criterion is met.**

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the

department compared the proposed project’s costs with those previously considered by the department.

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 Clearview Eye and Laser, PLLC has met the structure and process (quality) of care criteria in WAC 246-310-230.

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

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs 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.

Clearview Eye and Laser

In response to this sub-criterion, Clearview Eye and Laser provided the following statements.

“Table 9 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 13”. [Source: Application, page 17]

***Applicant’s Table 9
Clearview Eye and Laser Proposed ASF Estimated Total Staffing 2018-2023***

<i>Position</i>	<i>2018</i>	<i>2019</i>	<i>2020</i>	<i>2021</i>	<i>2022</i>	<i>2023</i>
<i>Clinical Director/Charge Nurse</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>
<i>Registered Nurse</i>	<i>0.7</i>	<i>0.7</i>	<i>0.7</i>	<i>0.7</i>	<i>0.7</i>	<i>0.7</i>
<i>LPN/Techs/MA</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>
<i>Registration/Receptionist</i>	<i>2</i>	<i>2</i>	<i>2</i>	<i>2</i>	<i>2</i>	<i>2</i>
<i>Total</i>	<i>4.7</i>	<i>4.7</i>	<i>4.7</i>	<i>4.7</i>	<i>4.7</i>	<i>4.7</i>

In addition to the statements above, Clearview Eye and Laser 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 Table 9”. [Source: Application, page 17]

Clearview Eye and Laser also identified the following key staff for the ASF. [Source: Application, Page 30, Exhibit 3]

***Applicant’s Table
Clearview Eye and Laser, PLLC –Medical Staff***

<i>Name</i>	<i>Specialty</i>
<i>Keshia Casimir, O.D.</i>	<i>Ophthalmology</i>
<i>Marcus A. Meyer, M.D., FACS</i>	<i>Ophthalmic Surgery</i>
<i>Thomas G. Mulligan, M.D.</i>	<i>Ophthalmic Surgery</i>
<i>Aaron P. Weingeist, M.D.</i>	<i>Ophthalmic Surgery</i>

Public Comment

None

Rebuttal Comment

None

Department Evaluation

As shown above, the ASF staff is already in place and additional staff is not anticipated. However, in the event additional staff is required, Clearview Eye and Laser provided the specific information above.

Information provided in the application demonstrates that Clearview Eye and Laser is a well-established and current provider of healthcare services in Southwest King County, the department concludes that Clearview Eye and Laser 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) *The proposed service(s) will have an appropriate relationship, including organizational relationship to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.*

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

Clearview Eye and Laser

Clearview Eye and Laser provided the following statements relating to ancillary and support services required for the proposed project. [Source: Application page 18]

“Clearview Eye and Laser will offer all of the necessary ancillary and support services on site. Exhibit 16 contains a copy of the executed Patient Transfer Agreement between Clearview Eye and Laser, PLLC and Highline Medical Center, CHI Franciscan Health.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Clearview Eye and Laser has been providing healthcare services at in southwest 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 southwest King County. The department concludes that nothing in the information reviewed indicate that the continued operation of this existing CN-exempt ASF as a 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.

Clearview Eye and Laser

Clearview Eye and Laser provided the following statements related to this sub-criterion.

“Clearview Eye and Laser has no history with respect to the actions described in CN criteria WAC 246-310-230(5)(a)”. [Source: Application page 19]

“Westwood Eye Surgery and Laser is licensed by the Washington State Department of Health as an ASF, License #ASF.FS.60532154. It is also certified by the Centers for Medicare and Medicaid Services as an ambulatory surgical center, 50-C0001256”. [Source: Application page 2]

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.⁹ To accomplish this task, the department reviewed the quality of care and compliance history for the healthcare facilities owned, operated, or managed by Clearview Eye and Laser.

Washington State Survey Data

As stated in the “Applicant Description” section of this evaluation, Clearview Eye and Laser is seeking certificate of need approval for its existing ambulatory surgical facility known as Westwood Eye Surgery and Laser.

Using its own internal database, the department reviewed the historical survey data for healthcare facilities associated with Clearview Eye and Laser. The survey data is summarized by facility in the table below. [Source: Application page 18 and DOH Office of Health System Oversight]

**Department’s Table 10
Clearview Eye and Laser Facilities**

Practice Site Address/County	License #	Year of State Survey
Westwood Eye Surgery and Laser 7520 35 th Avenue SW Seattle, 98126 King County	ASF.FS.60532154	06/12/2017

As shown above, Westwood Eye Surgery and Laser most recent survey is June 2017. Information provided by the Department of Health internal database show that the facility was substantially compliant.

In addition to the facility identified above, 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 18, Exhibit 3, and Medical Quality Assurance Commission]

⁹ WAC 246-310-230(5)

**Department's Table 11
Westwood Eye Surgery and Laser Active Staff**

Name	Credentialed Number	License Status
Marcus A. Meyer ¹⁰	MD00038833	Active
Keshia Casimir	OD60307982	Active
Thomas G. Mulligan ¹¹	MD00030216	Active
Aaron P. Weingeist	MD00033005	Active
Shelby Milne	RN00140446	Active

The department's review shows two physicians, Dr. Meyer and Dr. Mulligan, have closed cases; however both credentials are active and in good standing.

Based on the information above, the department concludes that Clearview Eye and Laser demonstrated reasonable assurance 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.

Clearview Eye and Laser

Clearview Eye and Laser provided the following statements related to this sub-criterion.

“For nearly 13 years, Clearview Eye and Laser has been working to improve the eye health and well-being of residents of the Southwest King Secondary Health Services Planning Area. Its proposed ASF will expand the scope of services it can provide, consistent with its long-term strategy. Additionally, approval of this project will allow Clearview Eye and Laser to offer a more convenient, lower-cost alternative to hospital-based outpatient surgery for an array of procedures. This is increasingly an important consideration for our physicians and their patients”. [Source: Application, page 6]

“Clearview Eye and Laser will offer all of the necessary ancillary and support services on site. Exhibit 16 contains a copy of the executed Patient Transfer Agreement between Clearview Eye and Laser, PLLC and Highline Medical Center, CHI Franciscan Health”. [Source: Application, page 18]

¹⁰ Closed enforcement action; credential is active and in good standing.

¹¹ Closed enforcement action; credential is active and in good standing.

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 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 Clearview Eye and Laser, PLLC has met the cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.
To determine if a proposed project is the best alternative, 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:

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

Step Two:

The applicant provided the following information related to this sub-criterion. [Source: Application, page 18-21]

“... There is significant net need for outpatient surgery ORs in the Southwest King Secondary Health Services Planning Area. The proposed ASF will improve access, a key criterion for a certificate of need. 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.

Clearview Eye and Laser has a presence in the Southwest King Secondary Health Services Planning Area, and the proposed ASF will build upon this presence and offer the proposed ASF and other patients convenient access to surgical services. Clearview Eye and Laser is committed to providing high quality, affordable care in the Southwest King Secondary Health Services Planning Area, and the proposed ASF will help accomplish this goal. The proposed project promotes continuity of care with Clearview Eye and Laser’s 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.

Clearview Eye and Laser is requesting a CN for the proposed ASF so that other qualified, credentialed and privileged physicians in good standing can utilize this facility. As part of its due diligence, Clearview Eye and Laser examined alternatives to the proposed project and evaluated those alternatives. The alternatives are addressed below.

Alternative 1: “Do Nothing”

Clearview Eye and Laser rejected a “do nothing” alternative. The Southwest King 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. Clearview Eye and Laser has a presence in the Southwest King 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 ambulatory surgical facility are clear. A CN-approved ambulatory surgical facility 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 ambulatory surgical facility to patients and payers.

*There are no disadvantages to granting Clearview Eye and Laser's request for CN approval. The facility 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 **13.05** outpatient ORs in the health planning area.*

A CN-approved ambulatory surgical facility would better serve the interests of the planning area residents and achieve Southwest King 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. Clearview Eye and Laser is the only project submitted to add outpatient surgical capacity in southwest King County. Therefore, this step does not apply.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided within the application shows that Clearview Eye and Laser did not consider any other alternative other than to submit this application. Given that Clearview Eye and Laser main purpose of converting the exempt the ASF to a CN approved is to allow physicians not associated with the practice to use the surgery center, there were no other options available. The department did not identify any other alternatives that would be superior in terms of cost, efficiency, or effectiveness.

For this project, Clearview Eye and Laser's rejection of the do nothing option and to seek approval so it can operate as a 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 Clearview Eye and Laser 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.**

APPENDIX A



**APPENDIX A
ASC Need Methodology
Southwest King County**

	Service Area Population: 2021	239,588	Claritas	Age:15+									
	Surgeries @ 35.536/1,000:	8,514											
a.i.	94,250	minutes/year/mixed-use OR											
a.ii.	68,850	minutes/year/dedicated outpatient OR											
a.iii.	0	dedicated outpatient OR's x 68,850 minutes =			0	minutes dedicated OR capacity			0	Outpatient surgeries			
a.iv.	9	mixed-use OR's x 94,250 minutes =			848,250	minutes mixed-use OR capacity			8,229	Mixed-use surgeries			
b.i.		projected inpatient surgeries =	3,874	=	399,384	minutes inpatient surgeries							
		projected outpatient surgeries =	4,640	=	239,101	minutes outpatient surgeries							
b.ii.		Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's											
		4,640	-	0	=	4,640	outpatient surgeries						
b.iii.		average time of inpatient surgeries		=	103.09	minutes							
		average time of outpatient surgeries		=	51.53	minutes							
b.iv.		inpatient surgeries*average time		=	399,384	minutes							
		remaining outpatient surgeries(b.ii.)*ave time		=	239,101	minutes							
					638,485	minutes							
c.i.		if b.iv. < a.iv. , divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's											
		USE THIS VALUE											
		848,250											
		- 638,485											
		209,765	/	94,250	=	2.23							
c.ii.		if b.iv. > a.iv., divide (inpatient part of b.iv - a.iv.) by 94,250 to determine shortage of inpatient OR's											
		Not Applicable - Ignore the following values and use results of c.i.											
		399,384											
		- 848,250											
		(448,866)	/	94,250	=	-4.76							
		divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's											
		239,101	/	68,850	=	3.47							



**APPENDIX A
ASC Need Methodology
Southwest King County**

Certificate of Need Applications:
CN19-08

Facility	Credential Number	ZIP Code	Special Procedure Rooms	Dedicated Inpatient ORs	Dedicated Outpatient ORs	Mixed Use ORs	Inpatient min/case	2018 Inpatient Cases in Mixed Use ORs	2018 Inpatient Mins. In Mixed Use ORs	Outpatient Min/Case	Outpatient Cases	Outpatient Mins.	Data Source
Highline Medical Center	HAC.FS.00000126	98166	3	0	0	9	103.1	3,710	382,451				Data obtained from Year 2018 survey.
Northwest Center for Plastic Reconstructive Surgery	ASF.FS.60099243	98166	0	0	1	0	0.0	0	0	50.0	120	6,000	Year 2018 data obtained from year 2016 survey. Minutes/surgery calculated.
Aesthetic and General Dermatology of Seattle	ASF.FS.60099259	98166	0	0	4	0	0.0	0	0	50.0	1,100	55,000	ILRS database; surgeries provided; minutes calculated using 50/case
Southwest Seattle Surgical Center	ASF.FS.60101076	98166	0	0	2	0	0.0	0	0	50.0	890	44,500	ILRS database; surgeries provided; minutes calculated using 50/case
La Belle Vie Cosmetic Surgery Centers	ASF.FS.60208682	98188	0	0	2	0	0.0	0	0	50.0	499	24,950	Year 2018 data obtained from year 2017 survey. Minutes/surgery calculated.
Clearview Eye & laser dbx Westwood Eye Surgery and Laser Center	ASF.FS.60532154	98126	0		2	0	0.0	0	0	50.0	1,700	85,000	Year 2018 data obtained from year 2017 survey. Did not provide minutes/case. Used 50 x # of cases.
Northwest Center Plastic Surgery	ASF.FS.60099243	98166	0	0	1	0	0.0	0	0	100.9	134	13,514	Year 2018 data obtained from year 2017 survey. Minutes/surgery calculated
Totals			3	0	12	9	103.1	3,710	382,451	350.9	4,443	228,964	
							Avg min/case inpatient		103.09	Avg min/case outpatient		51.53	
ORs counted in numeric methodology					0	9							
ILRS: Integrated Licensing & Regulatory System													
Population data source: Claritas 2016													
Total Surgeries			8,153										
Area population 2017 [15+]			229,430										
Use Rate			35.536										
Planning Area projected 15-85+ population Year: 2021			239,588										
% Outpatient of total surgeries			54.50%										
% Inpatient of total surgeries			45.50%										