



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

March 23, 2016

CERTIFIED MAIL # 7009 0960 0000 5565 0659

Hannah Lahrson, Practice Administrator
Seattle Orthopedic Center
2409 N. 45th St
Seattle, WA 98101

RE: Certificate of Need Application #16-05

Dear Ms. Lahrson:

We have completed review of the Certificate of Need (CN) application submitted by Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center proposing to convert the existing two-OR ambulatory surgery center into a Certificate of Need-approved Ambulatory Surgery Center. 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 Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center agrees to the following in its entirety.

Project Description

This certificate approves the establishment of a two-operating room ambulatory surgery center in Seattle, within North King County. The surgery center would serve patients ages 12 years and older who require orthopedic, ENT, eye, endocrine, digestive, GYN, neurosurgery, plastic, urologic, vascular, and general surgery that can be appropriately performed in an outpatient setting.

Conditions

1. Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center agrees with the project description as stated above. Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Before commencement of the project, Proliance Surgeons, Inc., PS dba Seattle Orthopedic Center must provide to the department, for review and approval, a final copy of the Admission Policy for Seattle Orthopedic Center. The policy must include the required non-discrimination

- policy, and must identify the admitting process and appropriate candidates for outpatient surgery.
3. The approved Admission Policy must be posted on the surgery center webpage in the same location that the surgery center's other patient forms are located.
 4. Before commencement of the project, Proliance Surgeons, Inc., PS dba Seattle Orthopedic Center must provide to the department, for review and approval, a final copy of the Charity Care Policy for Seattle Orthopedic Center. This policy must be facility-specific and shall include the procedure for notifying patients of charity care. It must also include the process one must use to obtain charity care.
 5. The approved Charity Care Policy must be posted on the surgery center webpage in the same location that the surgery center's other patient forms are located.
 6. Proliance Surgeons Inc., P.S. dba Seattle Orthopedic Center must maintain Medicare and Medicaid certification.
 7. Proliance Surgeons Inc., P.S. dba Seattle Orthopedic Center will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Seattle Orthopedic Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the regional average amount of charity care provided by affected hospitals in North King County. Currently, this amount is 2.20% of gross revenue and 4.09% of adjusted revenue. Seattle Orthopedic Center will maintain records documenting the amount of charity care it provides and demonstrating compliance with its charity care policies.
 8. Proliance Surgeons Inc., P.S. will ensure that charity care information related to the ASC is accessible to patients by referencing it on the Patient Financial Responsibility information that is available via the web, in person, or any other means.

Approved Capital 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.

Hannah Lahrson, Seattle Orthopedic Center
CN Application #16-05
March 23, 2016
Page 3 of 3

Mailing Address:

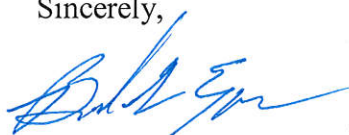
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Physical Address:

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

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

Sincerely,



Bart Eggen
Acting Director, Community Health Systems

Enclosure

**EVALUATION DATED MARCH 23, 2016 OF THE CERTIFICATE OF NEED
APPLICATION SUBMITTED BY PROLIANCE SURGEONS, INC., P.S. DBA SEATTLE
ORTHOPEDIC CENTER PROPOSING TO ESTABLISH AN AMBULATORY
SURGERY CENTER IN NORTH KING COUNTY**

APPLICANT DESCRIPTION

Proliance Surgeons, Inc., P.S.

Proliance Surgeons, Inc., P.S. (Proliance) is a for-profit Washington State professional service corporation, equally owned by over 175 physicians. Proliance operates more than 60 care centers in Washington State, including medical clinics, ambulatory surgery centers (ASCs)¹, physical/occupational therapy clinics, and imaging centers. All Proliance facilities that provide ambulatory care are licensed by the Washington State Department of Health and hold accreditation through the Joint Commission, the Accreditation Association for Ambulatory Health Care (AAAHC), or the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF).

All personnel at Proliance care centers and facilities are employees of Proliance, including physicians and surgeons. Proliance physician employees are classified either as shareholders or non-shareholder employed physicians (typically with the option to become a shareholder after two years of employment).

The corporate structure includes a CEO, COO, CFO, and a governing Board of Directors composed entirely of physician shareholders that are elected by the rest of the shareholders.

The applicant, Seattle Orthopedic Center, is a Proliance-owned facility. [sources: Proliance website, application p. 10, November 23, 2015 supplemental information pp. 1-2]

Seattle Orthopedic Center

Seattle Orthopedic Center (SOC) currently operates as a two operating room Certificate of Need-exempt ambulatory surgery center. SOC was established in February 2005. SOC is licensed by the Washington State Department of Health, is Medicare and Medicaid certified, and is accredited in good standing by the Accreditation Association for Ambulatory Health Care (AAAHC). SOC is authorized to provide orthopedic and general surgery under DOR #05-08 in Seattle, within North King County. [sources: Certificate of Need historical files, application p. 10]

PROJECT DESCRIPTION

With this application, Seattle Orthopedic Center proposes to establish an ambulatory surgery center located in Seattle, within the North King County secondary service planning area. As mentioned above, SOC already operates under a Certificate of Need exemption granted in 2005 (DOR #05-08). After Certificate of Need approval, SOC would continue to operate at its current location at 2409 N. 45th Street, Seattle, WA 98101. Physical therapy and MRI services are also provided on site. [sources: Certificate of Need historical files, SOC website]

¹ For the purposes of Certificate of Need review, the terms “Ambulatory Surgery Centers” (ASCs) and “Ambulatory Surgery Facilities” (ASFs) are interchangeable. The department’s review will consistently refer to these facilities as ASCs; however, the applicant does reference ASFs through the application, and quotations from the applicant will reflect as such.

SOC has two operating rooms. Surgical services include only orthopedics at this time, however the exemption also allows SOC to provide general surgery. SOC serves patients aged 12 years and older that require surgical services that can be served appropriately in an outpatient setting. [sources: Certificate of Need historical files, November 23, 2015 supplemental information p. 3]

With Certificate of Need approval, SOC intends to expand their surgical services to include ENT, eye, endocrine, digestive, GYN, neurosurgery, plastic, urologic, vascular, and general surgery that can be appropriately performed in an outpatient setting. While the range of services would broaden with the project, the general types of patients will not change. This project proposes to allow other physicians the opportunity to perform surgeries and procedures at the ASC. This action requires prior Certificate of Need review and approval. [source: application p. 12]

There is no capital expenditure associated with this project, as there is no project-associated construction or equipment purchase. While SOC intends to expand the services provided at the ASC, the two operating rooms are fully equipped with lighting, anesthesia machines/carts, and other large equipment to accommodate the new procedures. The costs associated with any new instrument sets to be used for the new procedures are treated as operating expenses, rather than capital expenditure. [source: November 23, 2015 supplemental information p. 6]

If this project is approved, SOC will begin operation as a CN approved ambulatory surgery center immediately following approval in early 2016. [source: application p. 12]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This application is subject to review as the establishment of a new healthcare facility under Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction in how the department is to make its determinations. It states:

“Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

(a) In the use of criteria for making the required determinations the department shall consider:

(i) The consistency of the proposed project with service or facility standards contained in this chapter;

(ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and

(iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project”

In the event that WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards

the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

“The department may consider any of the following in its use of criteria for making the required determinations:

- (i) Nationally recognized standards from professional organizations;*
- (ii) Standards developed by professional organizations in Washington State;*
- (iii) Federal Medicare and Medicaid certification requirements;*
- (iv) State licensing requirements;*
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized experience related to a proposed undertaking, with whom the department consults during the review of an application.”*

To obtain Certificate of Need approval, the applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment).² Additionally, WAC 246-310-270 (ambulatory surgery) contains service or facility specific criteria for ASC projects and must be used to make the required determinations for applicable criteria in WAC 246-310-210.

TYPE OF REVIEW

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

APPLICATION CHRONOLOGY

Action	
Letter of Intent Submitted	June 29, 2015
Application Submitted	August 26, 2015
Department’s pre-review activities <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant’s Responses Received 	September 17, 2015 November 23, 2015 ³
Beginning of Review	December 23, 2015
Public Hearing Conducted	N/A ⁴
Public Comments accepted through end of public comment	January 27, 2016
Rebuttal Comments Due	February 11, 2016 ⁵
Department’s Anticipated Decision Date	March 28, 2016
Department’s Actual Decision Date	March 23, 2016

² Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-220(3); and WAC 246-310-240(2) and (3).

³ Under the regular review timeline, the applicant has 45 days to respond to screening. The applicant’s screening responses were due on October 23, 2015, but were granted a 30 day extension.

⁴ No public hearing was requested or conducted

⁵ There were no public comments submitted for this application. As a result, no rebuttal comments could be accepted.

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.*

No entities sought status as either an interested or affected party, and no public comment was received throughout the course of review.

SOURCE INFORMATION REVIEWED

- Seattle Orthopedic Center’s Certificate of Need application submitted August 26, 2015
- Seattle Orthopedic Center’s screening responses received November 23, 2015
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Customer Service Center
- DOH Provider Credential Search website www.doh.wa.gov/pcs
- Historical charity care data for years 2012, 2013, and 2014 obtained from the Department of Health Hospital and Patient Data Systems Office
- Year 2015 Annual Ambulatory Surgery Provider Survey for Surgical Procedures Performed During Calendar Year 2014 for hospitals, ambulatory surgery centers, or ambulatory surgical facilities located in North King County.
- Year 2014 Claritas population data received in year 2015
- Washington State Department of Ecology King County ZIP code map prepared by GIS Technical Services and released August 3, 2006.
- Department of Health internal database – Integrated Licensing & Regulatory Systems (ILRS)
- Proliance Surgeons website: www.proliancesurgeons.com
- Seattle Orthopedic Center website: www.seattleorthopediccenter.com
- Washington State Secretary of State website: www.sos.wa.gov
- Washington State Department of Revenue website: www.dor.wa.gov
- Certificate of Need historical files

CONCLUSIONS

For the reasons stated in this evaluation, the application submitted by Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center proposing to establish a two-operating room multispecialty ambulatory surgery center in Seattle, within North King County is consistent with the applicable criteria of the Certificate of Need Program, provided Seattle Orthopedic Center agrees to the project description, conditions, and approved costs listed below.

Project Descriptions:

This certificate approves the establishment of a two-operating room ambulatory surgery center in Seattle, within North King County. The surgery center would serve patients ages 12 years and older who require orthopedic, ENT, eye, endocrine, digestive, GYN, neurosurgery, plastic, urologic, vascular, and general surgery that can be appropriately performed in an outpatient setting.

Conditions:

1. Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center agrees with the project description as stated above. Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Before commencement of the project, Proliance Surgeons, Inc., PS dba Seattle Orthopedic Center must provide to the department, for review and approval, a final copy of the Admission Policy for Seattle Orthopedic Center. The policy must include the required non-discrimination policy, and must identify the admitting process and appropriate candidates for outpatient surgery.
3. The approved Admission Policy must be posted on the surgery center webpage in the same location that the surgery center's other patient forms are located.
4. Before commencement of the project, Proliance Surgeons, Inc., PS dba Seattle Orthopedic Center must provide to the department, for review and approval, a final copy of the Charity Care Policy for Seattle Orthopedic Center. This policy must be facility-specific and shall include the procedure for notifying patients of charity care. It must also include the process one must use to obtain charity care.
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7. Proliance Surgeons Inc., P.S. dba Seattle Orthopedic Center will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Seattle Orthopedic Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the regional average amount of charity care provided by affected hospitals in North King County. Currently, this amount is 2.20% of gross revenue and 4.09% of adjusted revenue. Seattle Orthopedic Center will maintain records documenting the amount of charity care it provides and demonstrating compliance with its charity care policies.
8. Proliance Surgeons Inc., P.S. will ensure that charity care information related to the ASC is accessible to patients by referencing it on the Patient Financial Responsibility information that is available via the web, in person, or any other means.

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 Seattle Orthopedic Center 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 ASCs 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. Seattle Orthopedic Center is located in Seattle, and will remain in its current location within the North King County 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.

Seattle Orthopedic Center Methodology

Seattle Orthopedic Center determined the existing capacity in the North King County planning area to be 4 dedicated outpatient ORs and 53 mixed use ORs. Based on 2014 utilization and population data, the methodology identified a use rate of 137.78/1,000 population. Focusing on year 2018, the applicant projected North King County's population to be 351,567. Applying the use rate to the projected population and subtracting the existing number of ORs in the planning area, Proliance projected a need for 6.23 dedicated outpatient ORs in North King County for projection year 2018. [source: November 23, 2015 supplemental information Excel file]

Department's Numeric Methodology and Review

The numeric portion of the methodology requires a calculation of the annual capacity of the existing providers' inpatient and outpatient ORs in a planning area – North King County. To determine the zip codes associated with North King County, the department relied on the map and breakdown of zip codes identified in the 1980 State Health Plan for North King County. While the State Health Plan was sunset in 1989, it continues to be a reliable tool for

some projects. The department continues to use the zip codes listed by planning area as a starting point for determining ASC planning area zip codes.

For ASC planning areas, the state health plan identifies 12 North King County zip codes. When the 12 zip codes are charted on the Department of Ecology King County zip code map, inclusion of another zip code appears reasonable based on the geographic location of the zip codes. Table 1 below shows the zip codes and associated cities for the 13 zip codes associated with North King County. [source: 1980 SHP and Washington State Department of Ecology King County zip code map prepared by GIS Technical Services and released August 3, 2006]

**Table 1
North King County Planning Area Zip Codes**

Zip Code	City by Zip Code
98103	Seattle
98105	Seattle
98107	Seattle (Ballard)
98115	Seattle (Wedgwood)
98117	Seattle (Crown Hill)
98125	Seattle (Lake City)
98133	Seattle (Shoreline)
98145	Seattle (UW)
98155	Seattle (Lake Forest Park)
98160	Seattle (Richmond Beach)
98177	Seattle (Shoreline)
98185	Seattle (SafeCo Plaza)
98195	Seattle (UW)

According to the department’s historical records, there are 18 planning area providers – including the applicant – with OR capacity. Of the 18 providers, seven are hospital campuses and ten are ASCs. Below, Table 2 shows a listing of the seven hospitals campuses. [source: CN historic files and DOH ILRS database]

**Table 2
North King County Planning Area Hospitals**

Hospitals	City/Zip	DOH License
Kindred Hospital Seattle – Northgate	Seattle/98125	HAC.FS.00000148
Northwest Hospital Outpatient Medical Center	Seattle/98133	HAC.FS.00000130
Seattle Children’s Hospital	Seattle/98105	HAC.FS.00000014
Swedish First Hill (Ballard)	Seattle/98107	HAC.FS.00000001
University of Washington Medical Center	Seattle/98195	HAC.FS.00000128
University of Washington Medical Center – Roosevelt	Seattle/98105	HAC.FS.00000128
UW Medicine/Northwest Hospital	Seattle/98133	HAC.FS.00000130

[source: ILRS]

For the seven hospitals campuses, all known OR capacity and inpatient/mixed-use procedures are included in the methodology calculations for the planning area, with the exception of Seattle Children’s Hospital. In supplemental information, the applicant stated that they will exclusively serve patients aged 12 and over. As this hospital is exclusively dedicated to serving a pediatric population, the ORs and utilization will not be counted in this methodology.

Because there is no mandatory reporting requirement for utilization of ASCs or hospital ORs, the department sends an annual utilization survey to all hospitals and known ASCs in the state. When this application was submitted in August 2015, the most recent utilization survey was mailed in May 2015 and collected data for year 2014; however, not all providers submitted responses. The data provided in the utilization survey is used, if available. All four of the hospitals completed and submitted the 2015 Annual Ambulatory Surgery Provider Survey.

Table 3, below, contains a listing of the ten ASCs in the planning area.

Table 3
North King County Planning Area Ambulatory Surgery Centers

Ambulatory Surgery Centers	City/Zip
Ageless ⁶	Seattle/98103
Downey Plastic Surgery	Seattle/98133
Eye Associates Northwest Surgery Center	Seattle/98107
Fremont Endoscopy Center*	Seattle/98103
Hand and Wrist Surgery Center of Washington ⁷	Seattle/98155
Northwest Eye Surgeons	Seattle/98133
Pacific Dermatology and Cosmetic Center	Seattle/98133
Puget Sound Surgical Center	Seattle/98155
Seattle Endoscopy Center*	Seattle/98133
Seattle Orthopedic Center	Seattle/98103

[source: ILRS]

Of the ten ASCs shown above, two are endoscopy facilities (designated with an asterisk in the above table). The numeric methodology deliberately excludes the OR capacity and procedures from the numeric methodology.⁸ As a result, the ORs and procedures for these two facilities will not be counted in the numeric methodology.⁹

⁶ Facility is no longer in operation at this location. Per website, has relocated to address with ZIP code 98101. Volumes for 2014 surgeries still counted in the methodology, as the facility license did not expire until partially through year 2014. [sources: ILRS, Ageless website at www.agelessinseattle.com]

⁷ Facility is no longer in operation at this location as of June 2014. Per facility website, it is no longer operating. Site now occupied by Puget Sound Surgical Center. [sources: ILRS, <http://myedmondsnews.com/2015/06/notice-to-patients-of-northwest-hand-specialists-inc-p-s/>]

⁸ WAC 246-310-270(9)(iv).

⁹ Two facilities include Fremont Endoscopy Center and Seattle Endoscopy Center.

For the remaining eight ASCs, all are located within a solo or group practice (considered an exempt ASC) and the use of these ASCs is restricted to physicians that are employees or members of the clinical practices that operate the facilities. Therefore, none of these facilities meet the ASC definition in WAC 246-310-010. For exempt ASCs, the utilization, but not ORs, is included in the methodology for the planning area.

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

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

**Table 4
Department's Methodology Assumptions and Data**

Assumption	Data Used
Planning Area	North King County
Population Estimates and Forecasts	Age Group: 0-85+ Claritas Population Data released year 2015: Year 2014 – 306,977 Year 2019 – 359,494
Use Rate	Divide calculated surgical cases by 2014 population results in the service area use rate of 139.879/1,000 population
Year 2014 Total Number of Surgical Cases	34,968 – Inpatient or Mixed-Use; 12,613 – Outpatient 47,581 – Total Cases
Percent of surgery: ambulatory vs. inpatient	Based on DOH survey and ILRS data: 26.51% ambulatory (outpatient); 73.49% inpatient
Average minutes per case	Based on DOH survey and ILRS Data: Outpatient cases: 54.05 minutes Inpatient cases: 145.56 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes (per methodology in rule)
Existing providers/ORs	Based on listing of North King County Providers: 6 dedicated outpatient ORs 53 mixed use ORs
Department's Methodology Results	Numeric Need for an additional 4.46 outpatient ORs

Based on the assumptions described in the Table 4 above, the department's application of the numeric methodology indicates a need for 4.46 outpatient ORs in year 2019.

When comparing the applicant's and department's methodology, there are differences in the projection year (and consequently, the populations), the number of surgical cases, the use rate for the planning area, and the number of Certificate of Need approved outpatient ORs. The differences for these data points are highlighted in Table 5, below.

**Table 5
Applicant's and Department's Methodology Comparisons**

Data Points	Department's Numbers	Proliance Numbers
Available Data/Projection Year	2014 data 2019 projection year	2014 data 2018 projection year
Total Number of Surgical Cases	47,581 surgeries	46,347 surgeries
Calculated Use Rate	139.879/1,000	137.78/1,000
Projected Number of Outpatient ORs	6	4
Projected Planning Area Need	4.46 ORs	6.23 ORs

Projection Year

In their application, SOC assumed that 2016 would be the first full year of operation, and therefore used 2018 as the projection year. With the understanding that a decision would not be released until early 2016, the department has used 2017 as the first full year of operation and used year 2019 as the projection year. The difference in projection year affects the population and projected need.

Projected Number of Outpatient ORs

The applicant only assumed four Certificate of Need-approved ORs in the planning area, whereas the department recognizes six. The University of Washington Roosevelt location contains a hospital outpatient surgery department that is not physically attached to the main hospital campus, which was established in 1994. Prior to December 28, 1996, off-site hospital outpatient surgery departments did not require Certificate of Need review. Therefore, the ORs at the Roosevelt location are counted as Certificate of Need-approved under the hospital license, even though the site did not go through review or the exemption process. [sources: ILRS, CN historical files]

In some ASC projects, the differences described above can significantly affect the outcome of the methodology. The differences in this instance are not significant, as need is still shown in excess of the ORs proposed by the applicant. The applicant projected need for an additional six outpatient OR in the planning area and the department projected need for an additional four ORs. If not for the difference in the counted existing supply, the departments and applicants need projection for North King County would be nearly identical.

WAC 246-310-270(6)

WAC 246-310-270(6) requires a minimum of two ORs in an ASC. SOC is currently operating as a two-OR Certificate of Need exempt ASC. Based on that information, this standard is met. [source: application p. 8]

In summary, based on the department's numeric methodology, numeric need for additional OR capacity in the North King County planning area is demonstrated. The number of ORs proposed by the applicant does not exceed the planning area need. Further, SOC meets the standard under WAC 246-310-270(6). **This sub-criterion is met.**

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

Even though Seattle Orthopedic Center has been providing healthcare services for many years, for CN purposes, it is considered a new provider of health care services as it transitions from its status as a Certificate of Need-exempt to a Certificate of Need-approved facility. To demonstrate that all residents of the service area would have access to the services provided by SOC, the applicant must demonstrate availability to all residents of the service area, including low-income, racial and ethnic minorities, handicapped and other underserved groups. SOC must also participate in the Medicare and Medicaid programs and commit to

providing a percentage of charity care in the planning area. As a Proliance facility, the applicant is subject to Proliance policies.

Non-Discrimination Policy and Patient Rights and Responsibilities

To determine whether all residents of the planning area would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. 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 service area would have access to services. This is accomplished by providing a policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, Proliance provided copies of their current Non-Discrimination policy and their Patient Rights and Responsibilities Policy. Collectively, these two policies speak to the rights accorded to all patients upon their admission to any Proliance facility, including the applicant. These policies include the required non-discrimination language referenced above that assures access to treatment, and address the requirements in WAC 246-330-125. However, neither of the two policies identify appropriate candidates for outpatient surgery or clinical admitting criteria and associated admitting processes. Therefore, neither is considered an "admission policy." If approved, the department would attach conditions related to this sub-criterion, requiring that Proliance provide an admission policy specific to SOC. This policy must identify appropriate candidates for outpatient surgery and clinical admitting criteria and associated admitting process. [sources: application exhibit 17, November 23, 2015 supplemental information exhibit 18]

Medicare and Medicaid Programs

The department uses Medicare certification to determine whether the elderly would have access, or continue to have access to services. The department uses the facility's Medicaid certification to determine whether low-income residents would have access, or continue to have access to services. SOC is both Medicare (50C0001031) and Medicaid (1045762) certified.

The applicant has asserted that they currently provide services to Medicare and Medicaid patients, and if this project is approved, would continue to be accessible to these patients. To demonstrate compliance with this sub-criterion, SOC provided their current and projected payer mix in Table 6, below.

Table 6
Seattle Orthopedic Center Payer Distribution

Payer Group	Historical (2014)	Projected post-approval
Medicare	13.8%	13.8%
Medicaid	0.7%	3.0%
HMO	0.9%	0.9%
Commercial/Health Care Contractor	68.8%	66.5%
L&I/Other Government	15.9%	15.6% %
Self-Pay/Self-Insured	0.3%	0.2%

[sources: application p. 13, November 23, 2015 supplemental information p. 12]

Through screening, the department requested more information regarding the low percentage of Medicaid payers. The projected payer mix reflects a lower percentage of Medicaid patients than is typically expected for a Certificate of Need approved ASC. In response, SOC stated:

“Seattle Orthopedic Center accepts all persons, regardless of insurance coverage or ability to pay....it must be noted that Seattle Orthopedic Center is located in North King County Planning Area, which has a higher-than-average median income than King County’s average....While there are many residents who do qualify for Medicaid within this planning area, there are simply a greater number of patients who do not. Thus, we expect that the relatively low percentage of patients enrolled in Medicaid receiving care at Seattle Orthopedic Center is, in part, due to the demographics of the region in which SOC is located.” [source: November 23, 2015 screening response pp. 4-5]

Their analysis shows a median household income of \$72,967.50 in the North King County planning area. To ensure equitable access to surgical services at SOC, the department would attach a condition related to this sub-criterion requiring the ASC to maintain Medicare and Medicaid certification throughout the operation of this facility, regardless of ownership. [source: November 23, 2015 screening response pp. 4-5]

Charity Care

A facility’s charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

To demonstrate compliance with this sub-criterion, Proliance provided copies of their most recent Charity Care Policy, which is used at all Proliance facilities including SOC. While this policy provides the 2015 Federal Poverty Level guidelines and includes specific criteria for a patient to qualify for charity care, it does not identify the process one must use to obtain charity care. For these reasons, the department would consider this policy a draft. [source: November 23, 2015 supplemental information Exhibit 16]

If this project is approved, the department would attach conditions requiring SOC to provide a copy of their policy and procedure for notifying patients of charity care, specific to the facility. The policy must include references to the facility and include the process one must use to obtain charity care.

WAC 246-310-270(7)

WAC 246-310-270(7) requires that ASCs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC. For charity care reporting purposes, HPDS (Hospital and Patient Data Section) divides Washington State into five regions: King County, Puget Sound, Southwest, Central, and Eastern. SOC is located in North King County within the King County region. Currently, there are 21 hospitals operating in the region. Of those, two are acute care hospitals located in North King County and could be affected by approval of this project.¹⁰

For this project, the department reviewed the most recent three years of charity care data for the 21 existing hospitals currently operating within the King County Region and focused on the two affected general acute care hospitals located in North King County. The three years reviewed are 2012, 2013, and 2014.¹¹ Table 7, below, contains a comparison of the average charity care for the King County Region as a whole, the three hospitals combined average, and Seattle Orthopedic Center’s projected charity care for their project.¹²

**Table 7
Charity Care**

	% of Total Revenue	% of Adjusted Revenue
King County Region	1.73%	3.33%
Two Hospitals Combined	2.20%	4.09%
Seattle Orthopedic Center	2.50%	3.28%

[sources: HPDS Charity Care 2011-2013, November 23, 2015 supplemental information exhibit 19]

As shown in the table above, the charity care levels represented in the application exceeds the regional and two hospital average when measured as a percentage of total revenue. Based on a review of the applicant’s historical financial statements, it does not appear that the applicant currently provides charity care. Therefore, if this project is approved, the department would attach conditions related to the percentage of charity care to be provided at the ASC.

¹⁰ Includes UW Medicine/Northwest Hospital (and their associated Outpatient Medical Center), and University of Washington Medical Center (and their associated Roosevelt facility with hospital outpatient department). Swedish Ballard has been excluded, as their charity care is reported as a part of the Swedish First Hill license. Kindred Hospital has been excluded, as it is a long-term acute care hospital that does not provide surgical services.

¹¹ As of the writing of this evaluation, year 2015 charity care data is not yet available

¹² 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.

Based on the source documents reviewed in the application and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department concludes that all residents including low income, racial and ethnic minorities, handicapped, and other under-served groups would have access to the services provided by the applicant. Therefore, **this sub-criterion is met.**

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 Seattle Orthopedic Center has **met** the financial feasibility criteria in WAC 246-310-220.

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

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

To determine if SOC would meet its immediate and long range operating costs, the department reviewed the assumptions used as a basis for its financial projections. Additionally, the department reviewed Seattle Orthopedic Center's financial statements for its first three full years of operation. Summarized below are the assumptions used by SOC as the basis for projecting utilization and the number of procedures it expects.

- Since SOC received their exemption in 2005, only those physicians associated with the practice have been allowed to perform surgeries at the ASC. With Certificate of Need approval, SOC will be open to other surgeons that are credentialed by Proliance.¹³
- The applicant assumed growth in demand for outpatient surgery in North King County. In order to assume surgical volumes for the planning area, Proliance adapted findings regarding outpatient surgical use rates from the latest National Center for Health Statistics (NCHS) survey study: Ambulatory Surgery in the United States.¹⁴
- Surgeries included existing orthopedic services, and also included surgical services to be added after Certificate of Need approval: ENT, eye, endocrine, digestive, GYN, neurosurgery, plastic, urologic, vascular, and general surgery.
- Use rates derived from the NCHS survey were multiplied by the 2016-2020 planning area populations, and then divided by 10,000 to project total number of procedures for the North King County planning area, broken down by procedure type.

¹³ In order to practice in a Proliance facility, a physician must be approved to provide care by meeting the standards in the Proliance Credentialing Policy. These standards include, but are not limited to: a current, valid state license, an admitting coverage plan, DEA certification, board certification, and malpractice insurance. [source: November 23, 2015 supplemental information, Exhibit 22]

¹⁴ Number 11, January 28, 2009 – Revised September 4, 2009

- SOC’s market share percentage was calculated based on current and planned surgeries, and taking into account any addition of surgeons who wished to use the ASC if available, and inflated based on an assumed planning area average annual growth rate of 1.1% between 2015-2020.

Table 8, below, shows historical utilization at SOC:

**Table 8
Seattle Orthopedic Center Surgical Cases 2012-2014**

	2012	2013	2014
Orthopedic Surgical Cases ¹⁵	2,174	2,168	2,058

[source: application p. 11]

The applicant used this historical data in conjunction with the use rate assumptions and predictions from the NCHS report listed above. The utilization rates for each respective surgical type to be utilized at SOC post-Certificate of Need approval are listed below:

**Table 9
Procedure Types, Coding, National Utilization Rates**

Procedure Description	ICD9 CM Code	Utilization Rate / 10,000
Operations on the Nervous System	01-05	107.2
Operations on the Endocrine System	06-07, 40-41, 72-75	11.5
Operations on the Eye	08-16	237.6
Operations on the Ear	18-20	37.3
Operations on the Nose, Mouth, and Pharynx	21-29	96.0
Operations on the Digestive System	42-54	483.3
Operations on the Urinary System	55-59	59.6
Operations on the Male Genital Organs	60-64	21.2
Operations on the Female Genital Organs	65-71	83.7
Operations on the Musculoskeletal System	76-84, 00.70-00.73, 00.80-00.84	266.4
Operations of the Integumentary System	85-86	120.1

[source: application p. 25]

The applicant first projected the anticipated number of outpatient surgical procedures to be performed in North King County during the first three years of operation. Basing this on data acquired through the NCHS Report shown above, Proliance applied the applicable outpatient surgical use rates to the North King County population.

The applicant then assigned market shares for each type of surgical procedure. The market shares that SOC assumed for orthopedic (musculoskeletal system) were based on 2014 actual volumes and inflated with an assumed 1.11% annual population growth between 2015-2020. The market shares assumed for all other surgical procedure types were assigned based on the

¹⁵ These cases referred to under “Operations on the Musculoskeletal System” in the following tables.

experience of Proliance in operating other Certificate of Need-approved ASCs. These market shares are between 1.0% and 5.0% to start, and increase in conjunction with assumed 1.11% annual population growth between 2015 and 2020. Tables 10, 11, and 12 demonstrate the steps that SOC took to determine their anticipated surgical volumes. [source: November 23, 2015 supplemental information p. 9]

Table 10
North King County Outpatient Surgery Utilization Forecast

	2017	2018	2019
Operations on the Nervous System	3,728	3,769	3,810
Operations on the Endocrine System	400	404	409
Operations on the Eye	8,262	8,353	8,446
Operations on the Ear	1,297	1,311	1,326
Operations on the Nose, Mouth, and Pharynx	3,338	3,375	3,412
Operations on the Digestive System	16,805	16,991	17,179
Operations on the Urinary System	2,072	2,095	2,119
Operations on the Male Genital Organs	363	367	372
Operations on the Female Genital Organs	1,476	1,492	1,508
Operations on the Musculoskeletal System	9,263	9,366	9,469
Operations of the Integumentary System	4,176	4,222	4,269
Total:	51,180	51,745	52,319

Table 11
Seattle Orthopedic Center Market Share Assumptions

	2017	2018	2019
Operations on the Nervous System	1.0%	1.0%	1.1%
Operations on the Endocrine System	2.0%	2.1%	2.1%
Operations on the Eye	1.0%	1.0%	1.1%
Operations on the Ear	5.1%	5.2%	5.3%
Operations on the Nose, Mouth, and Pharynx	2.0%	2.1%	2.1%
Operations on the Digestive System	1.0%	1.0%	1.1%
Operations on the Urinary System	2.0%	2.1%	2.1%
Operations on the Male Genital Organs	3.1%	3.1%	3.2%
Operations on the Female Genital Organs	1.0%	1.0%	1.1%
Operations on the Musculoskeletal System	22.4%	22.9%	23.3%
Operations of the Integumentary System	2.0%	2.1%	2.1%
SOC Total North King Market Share:	4.4%	4.5%	4.6%

Table 12
Seattle Orthopedic Center Volume Assumptions

	2016	2017	2019
Operations on the Nervous System	38	39	40
Operations on the Endocrine System	8	8	9
Operations on the Eye	84	87	90
Operations on the Ear	66	68	70
Operations on the Nose, Mouth, and Pharynx	68	70	72
Operations on the Digestive System	171	177	182
Operations on the Urinary System	42	44	45
Operations on the Male Genital Organs	11	11	12
Operations on the Female Genital Organs	15	16	16
Operations on the Musculoskeletal System	2,079	2,144	2,211
Operations of the Integumentary System	85	88	91
Total:	2,668	2,752	2,838

The number of surgeries projected by the applicant per year appears to be reasonable when compared to existing volumes at the two-OR ASC. In the projection year, 2019, the applicant expects 2,838 surgeries, or 1,419 per OR per year. Between the years 2012 and 2014, SOC performed approximately 2,100 surgeries, or 1,050 per OR per year. In their application, Proliance asserted that they “*can typically perform 1,300 to 1,500 cases per year in an efficiently run OR.*” Based on their past volumes and assertion regarding efficient use of OR space and time, these surgical volume assumptions appear to be reasonable and can be substantiated. [source: application pp. 11, 28]

The department also recognizes that there are currently no Certificate of Need-approved ASCs in the planning area, and that all existing exempt facilities are single-specialty (with the exception of Puget Sound Surgical Center, which began operating in July 2015). The single-specialty facilities are limited to plastic surgery, gastroenterology (exclusively endoscopy), and ophthalmology. As none of the existing facilities are Certificate of Need-approved, none are required to provide care to Medicare and Medicaid patients, nor are they obligated to provide charity care. As such, the only options available to individuals in need of outpatient surgery are within a hospital at higher cost, or to travel outside the North King County Planning Area. [source: ILRS]

Seattle Orthopedic Center also provided their assumptions used to project revenue, expenses, and net income for the first three years following CON approval. Those assumptions are summarized below:

- Revenues were calculated using actual revenue figures observed by Proliance, based on the procedure groups involved.
- No inflation was assumed for gross or net revenues.
- Revenues exclude professional fees, as these are paid to physicians through the operation of the associated clinic, and are financially separate.

- Deductions were calculated based on actual reimbursement rates negotiated between Proliance and their payers (Medicare, Medicaid, Commercial, HMO, etc.).
 - Charity care to be provided at 2.5% of gross revenues
 - Bad debt is assumed at a constant of 1.5%, consistent with actuals
 - Wage and salary figures have been calculated on an hourly basis, based on actual wages and salaries at SOC in 2014
 - Benefits are assumed at 25% of total wages and salaries – consistent with actual Proliance figures
 - Depreciation on SOC 2014 actuals, extrapolated forward
 - Consistent with Proliance ASCs, the revenues over expenses for the ASF financials are paid to physicians as a bonus, per Proliance compensation plan.
- [source: application pp. 33-34, November 23, 2015 supplemental information pp.1-2]

Using the assumptions stated above, Proliance projected revenue, expenses, and net income for SOC. SOC is already operational as a Certificate of Need-exempt facility. The first full calendar year of operation will be 2017 and 2019 will be year three. The projections for years 2017-2019 are below in Table 13.

Table 13
Seattle Orthopedic Center
Projected Revenue and Expenses Years 2017 through 2019

	2017	2018	2019
Net Revenue	\$7,065,495	\$7,286,493	\$7,514,403
Total Expenses	\$4,439,925	\$4,502,613	\$4,634,321
Net Profit/(Loss)	\$2,625,570	\$2,783,880	\$2,880,082
Average Revenue per Procedure	\$2,647.80	\$2,647.80	\$2,647.80
Average Expenses per Procedure	\$1,663.86	\$1,636.18	\$1,632.96
Net Profit/(Loss) per Procedure	\$983.93	\$1,011.62	\$1,014.83

[source: November 23, 2015 supplemental information p. 62]

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 both operating and non-operating expenses, including salaries and wages, benefits, insurance, rentals and leases, and depreciation. As shown above, Seattle Orthopedic Center anticipates that Certificate of Need approval will contribute to greater profitability over time as services are able to expand.

SOC identified Dr. Mark Reed as the medical director, who is a Proliance surgeon shareholder. There is no associated medical director contract. SOC provided a narrative that outlined the role and rotation of medical director duties. [source: November 23, 2015 supplemental information p. 15]

Based on the source documents evaluated, the department concludes that the projected revenues and expenses at the proposed ASC are reasonable and can be substantiated for this application. The department concludes that the immediate and long-range operating costs of the project can be met. **This sub-criterion is met.**

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

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

There are no construction or equipment costs associated with this project. These costs were incurred prior to 2005 as part of the construction of the exempt ASC. The impacts of these costs are already included in the current operating revenue and expenses of the facility. Under these circumstances, converting the currently exempt ASC to an open Certificate of Need approved ASC is expected to have minimal impact on the costs and charges of surgeries performed at this ASC. Any increase in operating costs will be associated with the increase in the number of procedures being performed in the existing operating rooms and therefore are not expected to have an unreasonable impact on cost and charges. [sources: Certificate of Need historical files, November 23, 2015 supplemental information, pp. 61-67]

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

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 Seattle Orthopedic Center 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.

Seattle Orthopedic Center is currently operating under an exemption from Certificate of Need review. As an operational ASC, the applicant employs 17.4 FTEs in the facility. The applicant expects that staffing will increase incrementally over time as surgical volumes and workloads increase. Table 14 shows staffing levels for years 2014-2019:

Table 14
Seattle Orthopedic Center Staffing Incremental Increase 2014-2019

	2014	2015 Change	2016 Change	2017 Change	2018 Change	2019 Change	2019 Total
				Year 1	Year 2	Year 3	
Office/Clerical	0.71	0.26	0.15	0.56	0.00	0.00	1.68
Scheduler	1.05	(0.06)	0.13	0.56	0.00	0.00	1.68
Billing	1.29	0.18	0.21	0.56	0.00	0.00	2.24
Medical Records	0.00	0.00	0.28	0.00	0.00	0.00	0.28
Registered Nurses	6.95	1.21	0.80	0.56	0.00	0.56	10.08
OR Technicians	3.45	0.06	0.97	0.56	0.00	0.00	5.04
Materials Management	0.79	0.25	0.08	0.56	0.00	0.00	1.68
Manager	1.17	0.09	(0.26)	0.00	0.00	0.00	1.00
Total Increase	--	1.99	2.36	3.36	0.00	0.56	--
Total FTE's	15.41	17.40	19.76	23.12	23.12	23.68	23.68

[source: application p. 36, November 23, 2015 supplemental information p. 13]

The applicant does not anticipate facing any difficulty in recruiting and maintaining the needed staff to support surgical volume increases after Certificate of Need approval. The applicant stated: *“all necessary staff are already employed at the Seattle Orthopedic Center. This facility offers attractive work environment, hours and pay, attracting local residents who are highly qualified. We do not expect any staffing challenges that would disrupt our ability to achieve our goals and objectives relative to the Seattle Orthopedic Center.”*

[source: application p. 37]

Given that SOC is currently operating with the majority of key staff in place, and that staffing increases will be incremental, the department concludes that the ASC would be adequately staffed. Based on the source information reviewed, the department concludes **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.

Seattle Orthopedic Center is an exempt ASC that has been operating since year 2005, and has already established ancillary and support agreements with healthcare providers in the North King County planning area. SOC provided a copy of the existing transfer agreement between itself and Swedish – First Hill and UW Medicine/Northwest Hospital. The agreement identifies the roles and responsibilities of both entities. There is no indication that

this current relationship would be negatively affected if this exempt ASC obtains Certificate of Need approval. [source: application Exhibit 21]

Furthermore, SOC provided a list of their existing ancillary agreements and asserted that all contracts will be adequate to support the increased surgical volumes anticipated with Certificate of Need approval. [source: November 23, 2015 supplemental information pp. 15-16]

Therefore, the department concludes that there is reasonable assurance that SOC will continue its relationships with ancillary and support services and this project would not negatively affect those relationships. **This sub-criterion is met.**

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

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center has been a provider in North King County since 2005. As a part of this review, the department must conclude that the proposed services provided by SOC would be provided in a manner that ensures safe and adequate care to the public.¹⁶ To accomplish this task, the department reviewed the quality of care compliance history for SOC and all healthcare facilities that are either owned, operated, or managed by Proliance Surgeons, Inc., P.S. [source: Certificate of Need historical files]

Seattle Orthopedic Center

SOC is currently accredited by the Accreditation Association for Ambulatory Health Care (AAAHC).¹⁷ The applicant provided a copy of their most recent survey through the AAAHC. SOC is accredited through the AAAHC. Their last accreditation survey took place for 2014. AAAHC accreditation is awarded for three years for ASCs. Further, the last licensing survey conducted by Washington State Office of Investigation and Inspection revealed no substantial non-compliance issues for the ASC. No substantiated complaints

¹⁶ WAC 246-310-230(5)

¹⁷ The Accreditation Association for Ambulatory Health Care is a private, non-profit organization that accredits more than 6,000 organizations, including ambulatory surgery centers, community health centers, medical and dental group practices, medical home practices, and managed care organizations. The AAAHC develops standards to advance and promote patient safety, quality care, and value for ambulatory health care through a peer-based accreditation process, education, and research. With a single focus on the ambulatory care community, AAAHC offers organizations a cost-effective, flexible, and collaborative approach to accreditation. AAAHC accreditation for ASCs holds Medicare deemed status from the Centers for Medicare and Medicaid Services (CMS).[source: AAAHC website]

have been received by the department regarding SOC. [sources: ILRS, AAAHC website, November 23, 2015 supplemental information pp. 233-307]

The applicant provided the names and license numbers of all credentialed staff. The following physicians practice at SOC:

**Table 15
Seattle Orthopedic Center
Physicians and Surgeons and Other Staff**

Name	Credential Number	Recorded Sanctions?
Dan Bailes	MD.00036693	No
Herb Clark	MD.00020828	No
Phil Downer	MD.00041479	No
Jon Franklin	MD.00021811	No
Tim Higgins	MD.00024745	No
Kevin Kogut	MD.00035435	No
James Liberman	MD.00038663	No
Will Mondzac	MD.00031202	No
Greg Paul	MD.00029940	No
Charlie Peterson	MD.00033841	No
Michael Podell	MD.00037438	No
Mark Reed*	MD.60279136	No
Scott Ruhlman	MD.60144741	No
George Sarantinos	MD.00031222	No
Joel Shapiro	MD.00039921	No
Arooj Simmonds	MD.60164134	No
J Michael Watt	MD.00027295	No
Wayne Weil	MD.00043327	No
Susan Roys**	RN.00133519	No

[sources: MQAC, NQAC, SOC website, November 23, 2015 supplemental information pp. 14-15]

Dr. Mark Reed, highlighted above with an asterisk, currently serves as the medical director of SOC. The medical director duties rotate between the surgeons listed above, and services provided as the medical director are unpaid. As such, there is no medical director contract. Susan Roys, identified above with a double asterisk serves as the director of nursing. [source: November 23, 2015 supplemental information p. 15]

As shown above, all credentialed staff members associated with SOC are licensed in good standing. [source: November 23, 2015 supplemental information p. 15]

Proliance Surgeons, Inc., P.S.

The facilities listed in Table 16 are owned or operated by Proliance Surgeons, Inc., P.S. – facilities highlighted in bold are Certificate of Need-approved.

Table 16
Proliance Surgeons, Inc., P.S. Ambulatory Surgery Centers

Facility	License Number	CON Status	Owned/Operated
Cascade Ear Nose and Throat Surgery Center	ASF.FS.60442571	Exempt	Owned
Edmonds Center for Outpatient Surgery	ASF.FS.60101035	Approved	Owned
Everett Bone and Joint Surgery Center	ASF.FS.60101038	Exempt	Owned
Evergreen Surgical Clinic ASC ¹⁸	ASF.FS.60101044	Exempt	Owned
Lakewood Surgery Center	ASF.FS.60101047	Approved	Owned
Overlake Surgery Center	ASF.FS.60101029	Approved	Operated
Plastic & Reconstructive Surgeons ASC	ASF.FS.60572737	Exempt	Owned
Proliance Orthopedic Associates ASC	ASF.FS.60101083	Exempt	Owned
Proliance Eastside Surgery Center	ASF.FS.60101042	Approved	Owned
Proliance Highlands Surgery Center	ASF.FS.60101051	Approved	Owned
Puyallup Ambulatory Surgery Center	ASF.FS.60534460	Exempt	Owned
Seattle Orthopedic Center*	ASF.FS.60101053	Exempt	Owned
Seattle Surgery Center*	ASF.FS.60101072	Approved	Owned
Skagit Northwest Orthopedic ASC at Continental	ASF.FS.60442605	Exempt	Owned
Skagit Northwest Orthopedic ASC at LaVenture	ASF.FS.60101074	Approved	Owned
Southwest Seattle Ambulatory Surgery Center	ASF.FS.60101076	Approved	Owned
The Retina Surgery Center	ASF.FS.60278648	Approved	Owned
The Surgery Center at Rainier	ASF.FS.60101080	Approved	Owned
Tri-City Regional Surgery Center	ASF.FS.60100019	Approved	Operated

* – applicant

[sources: November 23, 2015 supplemental information p. 3, ILRS]

According to the Department of Health’s Office of Investigation and Inspections, all Proliance facilities are substantially in compliance with facility licensing standards. Furthermore, all Proliance facilities have, or are pursuing, Medicare and Medicaid certification.

In addition to verifying quality of care for Proliance facilities, the department also performed a quality of care check for 208 Proliance physicians and surgeons. All of the 208 physicians have active and unrestricted licenses with the State of Washington. Furthermore, Proliance

¹⁸ Change of ownership effective 9/29/2015. This facility is now owned by EvergreenHealth. [source: CN historical files]

provided a copy of their credentialing and privileging applications and procedures for disciplinary action in response to screening. [sources: DOH Provider Credential Search, November 23, 2015 supplemental information Exhibit 24]

Given the compliance history of the health care facilities owned and operated by Proliance, the staff compliance history and accreditation, there is reasonable assurance that the ASC would be operated and managed in conformance with applicable state and federal licensing and certification requirements.

Based on the above information, the department concludes that Proliance demonstrated reasonable assurance that SOC would continue to be operated in compliance with state and federal requirements. Therefore, **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.

To demonstrate compliance with this sub-criterion, SOC asserted that Certificate of Need approval "*will improve access to orthopedic care in the North King County Planning Area. CON approval of the Seattle Orthopedic Center will allow a greater number of licensed and skilled physicians, improving the overall scope and quality of care of services and ensuring current and future patient needs are met.*" [source: application p. 30]

The ASC is operational as an exempt facility, and working relationships with existing healthcare facilities have already been established. Since the ASC will not relocate, the department expects these relationships to continue. As discussed above under WAC 246-310-230(2), SOC has asserted that all ancillary and support agreements will not be affected by Certificate of Need approval.

As an existing provider, approval of this project will not result in a fragmentation of outpatient surgical services. Approval could result in increased continuity of care for patients of non-Proliance physicians as these physicians gain access to SOC ORs.

No public comment was received by any other providers of surgical services – hospitals or ASCs – which further supports that this project will not fragment existing services.

Based on this information, the department concludes that approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. Further, SOC demonstrated the ASC would have appropriate relationships to the service area's existing health care system within the planning 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.

WAC 246-310 does not contain specific WAC 246-310-230(5) 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 certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant. The department's review of this sub-criterion includes historical quality of care of the applicant to assess whether the applicant's history could be a positive indicator of the future.

This sub-criterion is evaluated in sub-section (3) above, and based on that evaluation; the department concludes that **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 Seattle Orthopedic Center has **met** the cost containment criteria in WAC 246-310-240.

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

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 through 230. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met the applicable criteria, the department would move to step two in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific criteria (tie-breaker) contained in WAC 246-310. The tiebreaker 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 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:

This application is not competing with any other applications. The department concluded that SOC's application meets the review criteria under WAC 246-310-210, 220, and 230. Therefore, further analysis of this project is provided in step two.

Step Two:

As this is an existing facility, the only alternative identified by SOC was to remain as a Certificate of Need-exempt facility rather than to seek Certificate of Need approval. SOC provided the following statement in support of this project versus continuing to operate under an exemption:

"In our analysis, we found the best option for Seattle Orthopedic Center, as well as Planning Area residents, would be CON approval. Doing nothing does not improve access and it would further fragment care. Further, a No Project option does not promote quality of care, nor does it help the efficient operation and cost-effectiveness of our two-OR ASF, and very importantly, No Project does nothing to address Planning Area outpatient OR shortages, as demonstrated above.

Seattle Orthopedic Center has already incurred all costs associated with constructing and equipping this facility. Planning Area residents (and physicians) face future shortages of outpatient operating suites...The Requested Project best meets access, quality/continuity of care, efficiency/cost-effectiveness, and has modest staffing and legal impacts. It is the preferred option. Approval of our two-OR ambulatory surgery facility best meets cost containment criteria." [source: application p. 41]

Department Evaluation

The department found need for an additional 4.46 ORs in the planning area. Proliance provided rationale to support that the continued operation of SOC as a Certificate of Need-exempt facility is not an efficient use of its existing OR space. While the department understands this rationale, it would not justify the approval of the project in the absence of numeric need.

Given that the only alternative to this project would be to do nothing (continuing operation as a Certificate of Need-exempt facility), and taking into account the numeric need for outpatient ORs in the planning area, the department concludes that the project as described in this evaluation is the best available alternative for the community.

Step Three:

As Proliance Surgeons, Inc., P.S. dba Seattle Orthopedic Center was the sole applicant, step three was not necessary

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

APPENDIX A



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

Facility	License Number	Zip Code	Special Procedure Rooms	Dedicated Inpatient ORs	Dedicated Outpatient ORs	Mixed Use ORs	Inpatient min/case	Inpatient Cases in Mixed Use ORs	2011 Inpatient Mins. In Mixed Use ORs	Outpatient Min/Case	Outpatient Cases	Outpatient Mins.	Data Source	
Seattle Childrens Hospital	HAC.FS.00000014	98105	0	0	0	13	123.6	12,180	1,505,421				2014 data from 2015 survey	
Swedish First Hill - BALLARD CAMPUS	HAC.FS.00000001	98107	2	0	0	4	80.2	1,953	156,569				2014 data from 2015 survey	
Kindred Hospital Seattle - Northgate	HAC.FS.00000148	98125	0	0	0	0							2014 data from 2015 survey	
UW Medicine/Northwest Hospital	HAC.FS.00000130	98133	3	0	0	12	111.9	7,375	825,237				2014 data from 2015 survey	
Northwest Hospital Outpatient Medical Center	HAC.FS.00000130	98133	0	0	4	0				87	1,621	140,784	2014 data from 2015 survey	
University of Washington Medical Center	HAC.FS.00000128	98195	0	0	0	24	193.4	13,460	2,602,776				2014 data from 2015 survey	
University of Washington Medical Center - Roosevelt	HAC.FS.00000128	98105	0	0	2	0				103	1,316	136,014	2014 data from 2015 survey	
<i>Ageless</i>	ASF.FS.60102702	98103	0	0	1	0				50.0	100	5,000	CLOSED - NO LONGER OPERATING (3/10/2014) per ILRS. Data from 2012 renewal, x 50 min/case	
Downey Plastic Surgery	ASF.FS.60101024	98133	0	0	2	0				50.0	275	13,750	Facility not licensed - used ILRS cases x 50 for minutes	
Fremont Endoscopy Center	ASF.FS.60101880	98103	ENDOSCOPY ORS AND MINUTES NOT COUNTED								#DIV/0!			(endoscopy)
Seattle Orthopedic Center - Surgery	ASF.FS.60101053	98103	0	0	2	0				65.8	2,060	135,585	2014 data from 2015 survey.	
Eye Associates Northwest Surgery Center	ASF.FS.60102711	98107	0	0	2	0				50.0	2,061	103,050	2014 data from 2015 survey. Surgery minutes not known - 50 x outpatient cases	
Northwest Eye Surgeons	ASF.FS.60101724	98133	0	0	4	0				17.0	3,379	57,443	2014 data from 2015 survey.	
Seattle Endoscopy Center	ASF.FS.60102743	98133	ENDOSCOPY ORS AND MINUTES NOT COUNTED								#DIV/0!			(endoscopy)
Pacific Dermatology and Cosmetic Center	ASF.FS.60103032	98133	0	0	2	0				50.0	400	20,000	Facility not licensed - used ILRS cases x 50 for minutes	
Puget Sound Surgical Center	ASF.FS.60501191	98155	0	0	2	0				#DIV/0!			Facility first opened 7/20/2015 - no data to report (same address as Hand and Wrist - below)	
Hand and Wrist Surgery Center of Washington	ASF.FS.60100931	98155	0	0	2	0				50.0	1,401	70,050	CLOSED - NO LONGER OPERATING (2014). Data from 2012 renewal x 50 min/case	
Totals			5	0	23	53	509.0	34,968	5,090,003	#DIV/0!	12,613	681,676		
							Avg min/case inpatient		145.56		Avg min/case outpatient	54.05		
ORs counted in numeric methodology					6	40								
ILRS: Integrated Licensing & Regulatory System														
Population data source: Claritas 2015														
Total Surgeries			47,581									47,581		
Area population 2014 [15+]			291,026									340,158		
Use Rate			163,494									139,879		
Planning Area projected 15+ population Year: 2019			306,977									359,494		
% Outpatient of total surgeries			26.51%											
% Inpatient of total surgeries			73.49%											



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

	Service Area Population: 2019	359,494	Claritas	Age:0-85+									
	Surgeries @ 139.879/1,000:	50,286											
a.i.	94,250	minutes/year/mixed-use OR											
a.ii.	68,850	minutes/year/dedicated outpatient OR											
a.iii.	6	dedicated outpatient OR's x 68,850 minutes =			413,100	minutes dedicated OR capacity	7,644	Outpatient surgeries					
a.iv.	53	mixed-use OR's x 94,250 minutes =			4,995,250	minutes mixed-use OR capacity	34,317	Mixed-use surgeries					
b.i.		projected inpatient surgeries =	36,956	=	5,379,340	minutes inpatient surgeries							
		projected outpatient surgeries =	13,330	=	720,425	minutes outpatient surgeries							
b.ii.		Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's											
		13,330	-		7,644	=	5,686	outpatient surgeries					
b.iii.		average time of inpatient surgeries		=	145.56	minutes							
		average time of outpatient surgeries		=	54.05	minutes							
b.iv.		inpatient surgeries*average time		=	5,379,340	minutes							
		remaining outpatient surgeries(b.ii.)*ave time		=	307,325	minutes							
					5,686,665	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.											
		4,995,250											
		- 5,686,665											
		-691,415	/	94,250	=	-7.34							
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											
		5,379,340											
		- 4,995,250											
		384,090	/	94,250	=	4.08							
		divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's											
		307,325	/	68,850	=	4.46							