



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

August 29, 2019

CERTIFIED MAIL # 7016 3010 0001 0575 0167

Erica Bustamante, Administrator
Northwest Neurosciences, PLLC
1110 North 35th Avenue
Yakima, Washington 98902

RE: CN Application #19-29 – Northwest Neurosciences, PLLC

Dear Ms. Bustamante:

We have completed review of the Certificate of Need application submitted by Northwest Neurosciences, PLLC, dba Northwest Surgery Center (NWSC) proposing to convert the existing two operating room CN-exempt ambulatory surgical facility (ASF) to a two operating room CN-approved ASF in Yakima, within the Yakima County secondary health services planning area. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Washington Administrative Code 246-310-210	Need
Washington Administrative Code 246-310-220	Financial Feasibility
Washington Administrative Code 246-310-240	Cost Containment

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

<u>Mailing Address:</u>	<u>Physical Address</u>
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

Erica Bustamante, Administrator
Northwest Neurosciences, PLLC
Certificate of Need Application #19-29
August 29, 2019
Page 2 of 2

Appeal Option 2:

You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:

Department of Health
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

Physical Address

Department of Health
Adjudicative Service Unit
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 29, 2019 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST NEUROSCIENCES PLLC D/B/A NORTHWEST SURGERY CENTER PROPOSING TO ESTABLISH AN AMBULATORY SURGICAL FACILITY IN YAKIMA COUNTY

APPLICANT DESCRIPTION

Northwest Surgery Center

Northwest Neurosciences PLLC is a professional limited liability company wholly owned by Eduardo Meirelles, MD PDH. Northwest Neurosciences owns and operates an existing Certificate of Need-exempt ambulatory surgical facility called Northwest Surgery Center (NWSC), which is licensed as an ambulatory surgical facility (ASF)¹ with the Washington State Department of Health. Northwest Surgery Center holds accreditation from the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). [source: Certificate of Need historical records and Application p9]

Northwest Neurosciences also operates three clinics under the name Northwest Spine Center located in Bellevue, Kennewick, and adjacent to NWSC in Yakima. Northwest Neurosciences does not perform surgeries in the three clinics. [source: Application, p9]

Northwest Surgery Center currently operates as a 2-operating room (OR) ASF providing spine surgery, neurosurgery, and interventional pain management procedures to patients aged 10 years and older that do not require overnight stay or hospitalization. [source: Certificate of Need Historical records and Application p7]

PROJECT DESCRIPTION

With this application, NWSC proposes to maintain its two operating room ASF and expand its service offerings to include: spine surgery, neurosurgery, interventional pain management, orthopedic, ENT, general surgery, and plastic surgery. NWSC would commence the project upon CN-approval. After Certificate of Need approval, NWSC would continue to operate at its current location at 1110 North 35th Avenue, Yakima, Washington 98902. [sources: Certificate of Need historical files, application, pp7-8]

The estimated capital expenditure associated with this project is \$182,933, which includes movable equipment necessary to accommodate the expanded range of services to be offered. [source: Application p33]

Based on the timing of this decision and the associated steps that an applicant must take in order to execute a Certificate of Need, the expected first full year of operation would be 2020, and 2022 would be year three [source: Application p13]

¹ For the purposes of Certificate of Need review, the terms “Ambulatory Surgical Facilities” (ASFs) and “Ambulatory Surgery Centers” (ASCs) are largely interchangeable, as CN-approved ASFs (the category of licensure) are almost always ASCs (an indicator of Medicare certification). The department’s review will consistently refer to these facilities as ASFs; however, the applicant does reference ASCs through the application, and quotations from the applicant will reflect as such.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This application is subject to review as the construction, development, or other establishment of 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	Date
Letter of Intent Submitted	October 16, 2018
Application Submitted	November 15, 2018
Department's pre-review activities <ul style="list-style-type: none">• DOH 1st Screening Letter• Applicant's Responses Received	December 10, 2018 December 28, 2018
Beginning of Review	February 11, 2019
Public Hearing Conducted	N/A ²
Public Comments accepted through end of public comment	March 18, 2019
Rebuttal Comments Due	April 1, 2019
Department's Anticipated Decision Date	May 16, 2019
Department's Actual Decision Date	XXX

AFFECTED PERSONS

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

"...an "interested person" who:

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

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

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

During the course of review, four entities requested interested person status. None qualified for affected person status, as none submitted comments.

² No public hearing was requested or conducted

SOURCE INFORMATION REVIEWED

- NWSC's Certificate of Need application
- NWSC's screening responses received December 28, 2018
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission and Nursing Quality Assurance Commission
- Compliance history for NSC from the Washington State Department of Health – Office of Health Systems Oversight (OHSO)
- 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 Office of Hospital/Finance and Charity Care (HFCC)
- Year 2018 Annual Ambulatory Surgery Provider Survey for Surgical Procedures Performed During Calendar Year 2017 for hospitals, ambulatory surgical facilities, or ambulatory surgical facilities located in Yakima County
- Year 2018 Claritas population estimates
- Department of Health internal database – Integrated Licensing & Regulatory Systems (ILRS)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) website: <http://aaaasf.org/>
- Northwest Spine Center website: <https://nwspinecenter.com>
- 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

CONCLUSIONS

For the reasons stated in this evaluation, the application submitted by Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center proposing to establish a two operating room ambulatory surgical facility in Yakima, within the Yakima County secondary service planning area is not consistent with the applicable criteria of the Certificate of Need Program.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes that North Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center has **not 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(6)

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

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

NSC has proposed that the ASF will have two ORs. [source: Application p12]

Public Comment

None

Rebuttal

None

Department Evaluation

WAC 246-310-270(6) requires a minimum of two ORs in an ASF. As NSC has proposed that their facility will have two ORs, **this standard is met.**

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. Northwest Surgery Center is located in Yakima, within the Yakima County secondary health service planning area.

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

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

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

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

NWSC determined the existing capacity in the Yakima County planning area to be 12 dedicated outpatient ORs and 20 mixed use ORs, shown on the following page. [source: Application Exhibit F]

**Department's Table 1
NWSC OR Count**

Facility Name	Outpatient OR	Mixed Use OR
Astria Sunnyside Hospital		3
Astria Toppenish Hospital		2
Astria Regional Medical Center		8
Virginia Mason Memorial Hospital		7
Virginia Mason Memorial Surgicenter at Ridgeview	5	
Virginia Mason Memorial Surgicenter	4	
Yakima Ambulatory Surgical Center (Astria)	3	
Yakima Gastroenterology Associates		
OR Count in Numeric Methodology	9	20

Based on 2017 utilization and population data, NWSC's methodology identified a use rate of 123.05/1,000 population. Focusing on year 2022, NWSC projected the Yakima population to be 27,315. Applying the use rate to the projected population and subtracting the existing number of ORs in the planning area, NWSC projected a surplus of 6.76 mixed use ORs in Yakima County for projection year 2022. [source: Application Exhibit 11]

Public Comment

None

Rebuttal

None

Department's Numeric Methodology and Evaluation

The numeric portion of the methodology requires a calculation of the annual capacity of the existing providers inpatient and outpatient OR's in a planning area – Yakima County.

According to the department's records, there are ten planning area providers with OR capacity. Of these providers, seven are hospitals or associated with hospitals and three are freestanding ambulatory surgical facilities.

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

For hospitals, all known OR capacity and procedures are included in the methodology calculations for the planning area, with the exception of ORs dedicated to endoscopy, pain management, or other specialized dedicated services.

Table 2 below, contains a listing of the 6 ASFs in the planning area.

**Department's Table 2
Yakima County ASFs**

Facility	CN Approved or Exempt?
Pacific Cataract and Laser Institute	Exempt
Northwest Surgery Center (the applicant)	Exempt
Virginia Mason Memorial Surgicenter	Approved
Virginia Mason Memorial Surgicenter at Ridgeview	Approved
Yakima Ambulatory Surgical Center (Astria)	Approved
Yakima Gastroenterology Associates	Approved

[source: ILRS, CN historical records]

Of the ASFs shown above, one includes ORs that are exclusively dedicated to endoscopy or pain management. Yakima Gastroenterology Associates has three total ORs, all of which are dedicated to endoscopy. The numeric methodology deliberately excludes this OR capacity and procedures from the numeric need methodology.³ As a result, the ORs and procedures for these operating rooms will not be counted in the numeric need methodology.

Out of the remaining ASFs within the planning area, two 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 – Pacific Cataract and Laser Institute and Northwest Surgery Center (the applicant) – 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 ORs, is included in the methodology for the planning area. In summary, OR capacity will be counted for four hospitals and three hospital-based ASFs.

The data points used in the department's numeric methodology are identified in Table 3. The methodology and supporting data used by the department is provided in the Appendix attached to this evaluation.

³ WAC 246-310-270(9)(iv)

Department's Table 3
Department's Methodology Assumptions and Data

Assumption	Data Used
Planning Area	Yakima County
Population Estimates and Forecasts	Age Group: 0+ OFM Population Data updated year 2017 Year 2017 – 255,137 Year 2022 – 267,706
Use Rate	Divide calculated surgical cases by 2017 population results in the service area use rate of 88.799/1,000 population
Year 2017 Total Number of Surgical Cases	14,627 – Inpatient or Mixed-Use; 8,924 – Outpatient 23,551– Total Cases
Percent of surgery: outpatient vs. inpatient	Based on DOH survey and application: 37.89% outpatient; 62.11% inpatient
Average minutes per case	Based on DOH survey and ILRS: Outpatient cases: 62.57 minutes Inpatient cases: 92.26 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 Yakima County Providers: 12 dedicated outpatient ORs 20 mixed use ORs
Department's Methodology Results	Surplus of 7.53 mixed use ORs

Based on the assumptions described in Table 3 above, the department's application of the numeric methodology indicates a surplus of 7.53 mixed use ORs in 2022.

When comparing the applicant's and department's methodology, there are differences in several data points. NSC identified all the same providers as the department, however because NSC proposes to only serve patients aged 15 and older, it based its use rate and population projections on the current and projected population of Yakima County in that age group only. As a result, both the current use rate and projected number of surgeries in 2022 differed from the Department's projections. The applicant's methodology returned a net surplus of mixed use ORs of 6.76, as opposed to the department's projection of a surplus of 7.53 mixed use ORs. Because both projections reach the same conclusion that numeric need is not demonstrated by the methodology, and both projections return very similar values for the surplus of ORs, the department need not examine the propriety of the population and use rate projections provided by the applicant.

The applicant requested consideration under WAC 246-310-270(4), which allows for the approval of additional operating rooms in a planning area absent numeric need if circumstances warrant it. NWSC offered the following rationale for disregarding the numeric need

methodology. Because NWSC made numerous and varied assertions, each is addressed individually below: [source: application, pp17-18]

Northwest Surgery Center

“We recognize that under WAC 246-310-270(4) “Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need.” And although the Department’s quantitative need methodology outlined under 246-310-270(9) does not show net need for additional outpatient ORs in the Yakima County planning area, there are several qualitative factors and supporting quantitative evidence that support CN approval of our requested project. These factors include the following:

“Patient/provider choice and cost-effective care

- *“In the past few years the Yakima community has experienced a tremendous rise in the absolute level of surgical volumes, as well as the relative proportion of surgeries performed in an outpatient setting rather than inpatient. In April 2016, the Department released its evaluation approving Yakima Gastroenterology Associate’s request to operate a CN-approved 3-operating suite endoscopy center. In that April 2016 evaluation, and relying on CY2014 utilization data, the Department calculated a use-rate of 91.3 procedures per 1,000 residents [15+ years old], of which 27% of procedures were provided in an outpatient setting and the remaining 73% were performed in an inpatient setting. 4 The current Yakima use rate, relying on CY2017 utilization data, is estimated to be 136.7 procedures per 1,000 residents [15+ years old]. This represents a growth of 45.4 procedures per 1,000 residents, or approximately a 50% growth from the CY2014 use rate. Further, the estimated proportion of the total number of surgeries performed in the Yakima Planning Area has risen from 27% outpatient, as calculated by the Department for CY2014, to 43% in CY2017.*

Department’s Evaluation

NSC’s assertion that the surgery use rate in the planning area has increased significantly in the three years since the department’s most recent ASF evaluation in Yakima is accurate. This statement is not, however, accompanied by any evidence that such an increase is likely to continue or that it is any reason to disregard or modify the results of the methodology. NSC makes no statements about the importance of this trend, and this observation alone does not indicate a greater need for OR capacity in the planning area than forecast by either the applicant’s or the department’s methodologies.

Northwest Surgery Center

- *“If approved, NWSC will be the only independent CN-approved ASF with no direct or indirect affiliation with a local hospital. This is a critical need in the community, Evaluation of CN App #16-13A. Washington State Department of Health. April 2016. Appendix A 18 especially in light of the evolving landscape shifting evermore procedures to an outpatient setting as described above. We believe that expanding our services to other surgical specialties will offer other physicians and their patients in the Yakima region a very important alternative in regard to independent surgical care. Freestanding facilities are more efficient and cost-effective in comparison to hospital outpatient surgery*

departments, thus, contractual rates for purchasers can be lower in a freestanding setting, which translates to cost savings for patients.

Department's Evaluation

The department agrees that freestanding ambulatory surgical facilities are generally a lower cost alternative to hospital based surgical services. The department has historically noted that providing lower cost options to patients is desirable in the effort to increase affordability of healthcare, but this alone should not be interpreted as a critical need for additional healthcare services.

Northwest Surgery Center

- *"Northwest Surgery Center serves a large patient population that are related to motor vehicle accidents (MVA). We are one of the few providers in Yakima, Bellevue, and the Tri Cities area that is willing to hold the bills until settlement.*

Department's Evaluation

The applicant provided a copy of its financial policy offering patients information about NSC's billing practices if patients are using out-of-network insurance benefits, motor vehicle insurance benefits, or an anticipated settlement to pay for services. The policy asks patients to initial if they are "...awaiting a settlement and have provided a letter of protection in order to hold (their) bills for a settlement." The policy does not explicitly state that NSC will honor such a letter of protection, but the representations made by NSC in the application indicate that it is its practice to do so. The applicant did not, however, substantiate its claim that it is "...one of the few providers..." that follows such a practice. Absent any information about other providers' billing practices in motor vehicle accident cases, the department cannot conclude that this is a unique practice. This is also not directly related to any CN review criteria.

Northwest Surgery Center

Access to specialized services

- *As the Department recognized in its February 2018 evaluation of Providence Surgery and Procedure Center in Spokane County: "Of the 23 ASFs currently operating in Spokane County, 18 ASFs do not meet the ASF definition in WAC 246-310-010. These ASFs are under no obligation to provide charity care, or to serve Medicare and Medicaid patients. Therefore, these ASFs may not be sufficiently available and accessible to all residents of the planning area." The same rationale is appropriate for review of need in Yakima County.*

Department's Evaluation

The Yakima and Spokane planning areas have very different numbers and types of surgery providers. As noted in the evaluation referenced by the applicant, 18 of 23 ASFs in Spokane were CN exempt. Yakima, however, currently has only three ASFs not operated under hospital licenses: the applicant, a facility dedicated to endoscopic procedures, and a facility dedicated to eye procedures. The three other ASFs in Yakima are operated under hospital licenses and are under the same requirements for access to patients who need financial assistance or are covered by Medicare or Medicaid. The department cannot conclude that outpatient surgery services are not sufficiently available and accessible to such patients in Yakima.

Northwest Surgery Center

- *“We would like to offer the community a new line of service in healthcare that has not been offered at any extent that is related to regenerative medicine to musculoskeletal injuries i.e., procedures introducing growth factors (platelet rich plasma-PRP) and stem cells and injured musculoskeletal structures (muscles and joints). This field is performed by orthopedic surgeons and physiatrists (physical medicine and rehabilitation physicians). Therefore we believe that our center should develop opportunities for these two specialties to better serve our community.*
- *“In addition, based on our extensive and successful experience performing complex spine surgeries with outstanding outcomes and no significant complications or infections as well as being able to discharge patients home within 12 hours without any hospital transfers, we strongly believe that our center is prepared to offer the infrastructure and management for patients to undergo more complex orthopedic procedures such as total joint replacements (knee, hip, and shoulder) in an ambulatory surgery setting without the costs and associated “negatives of hospital admission”. It has been well documented and presented at national conferences that these procedures have been frequently and routinely offered in ASC’s around the country.*
- *“The Yakima community previously had 2 plastic surgeons providing both cosmetic and reconstructive surgery. Over a year ago both surgeons left the Yakima area and the plastic surgeon who recently entered the market has yet to fill the need left behind by the previous providers.”*

Department’s Evaluation

It is not clear how the department should regard the three statements above. The applicant has not provided any evidence that physicians in the Yakima area wish to perform the procedures noted above or are unable to do so at the existing surgery locations. A review of the services purported to be offered by existing surgery centers in Yakima includes orthopedic and plastic surgery. The applicant also provided information about its quality of care and patient experience in its discussion of need. This information will be addressed later in this evaluation where appropriate.

The rule allows flexibility to approve operating rooms absent numeric need. In recent evaluations, the department has made such allowances when the need methodology has shown a small surplus of mixed-use ORs but, within the various calculations, indicated a need for outpatient ORs. In such instances, it may be inferred that a maldistribution of OR capacity might exist in a planning area, justifying approval of additional outpatient ORs. [source: Evaluation of CN application #18-33, June 6, 2019] In this case, however, the need methodologies performed by both the applicant and the department show surpluses of each type of OR.

In summary, based on the department's numeric methodology, numeric need for additional OR capacity in the Yakima County secondary health service planning area is not demonstrated.

Because the applicant has not demonstrated any maldistribution of OR capacity sufficient to overcome the existing OR surplus, nor has it identified any evidence that existing surgery facilities are not sufficiently available and accessible, the department cannot conclude that the remaining justification for approving this project – the lower overall cost of care in a freestanding ASF – is sufficient reason to add two more ORs to the Yakima planning area. Furthermore, all projected surgeries that would be performed by any physician other than Dr. Meirelles cannot be relied upon. NSC identified that the facility would be open to other surgeons, but did not provide any information supporting that outside physicians would seek an additional practice location. It is true, the department has approved new specialties in existing ASFs in the past without specific physician interest documented. However, these projects were overwhelmingly proposed by physician groups that included surgeons on their roster that matched the specialties proposed. In this case, Dr. Meirelles only performs a portion of the specialties proposed and no information in the application or screening response supports consideration of these volumes.

This sub criterion is not 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 and Medicaid patients, and to serve patients that cannot afford to pay for services.

The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and 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.

Northwest Neurosciences, PLLC. d/b/a Northwest Surgery Center

NSC provided copies of the following policies, along with the following comments.

- Admission Policy [source: Application Exhibit 14]
- Charity Care Policy [source: Application Exhibit 13]

“Charity Care shall be available without discrimination regarding race, color, national origin, handicap, sex, sexual orientation, religious or fraternal organization, are, or source of income” [source: Application Exhibit 13]

Medicare and Medicaid Programs

NSC is currently Medicare and Medicaid certified. NSC provided its existing and projected source of revenues by payer for the proposed ASF in Table 8. NSC stated:

“Northwest Surgery Center has historically received 90-95% of its revenues from commercial insurers, health maintenance organizations, and health service contractors. The remaining 5-10% of revenues are related to patients with motor vehicle accidents.

The projected payer mix is anticipated to be considerably different given the expanded scope of services, as well as the commitment to provide access to all patients including Medicare, and Medicaid. Table 3 below presents the forecasted payer mix based on cases and net revenues. It is based initially on 2017 inpatient CHARS payer mix statistics by discharges. These CHARS percentage figures, by payer, have been adjusted for the expected difference between inpatient and outpatient ambulatory surgery.” [source: Application p13]

“It is the practice of this facility to admit and treat all persons without regard to race, color, creed, religion, gender, age, ethnicity, disability status, national origin, sexual orientation, marital status, pre-existing condition or age. Patients are assigned without regard to race, color, national origin, handicap, sex, sexual orientation, religious or fraternal organization or age.” [source: Application Exhibit 14]

**Department’s Table 4
Historical and Projected Payer Mix***

Payer Group	Current/Historical	Projected
Commercial and HMO	99.7%	69.4%
Medicare	0.0%	19.3%
Medicaid	0.0%	5.2%
Self-Pay*	0.0%	0.0%
Other Gov’t. and L&I	0.3%	0.9%
Total	100%	100%

* Self-Pay sponsored patients are not assumed to pay for ASF-provided care, i.e., net revenues for these payer groups are assumed to be zero

**may not sum due to rounding

Public Comments

None

Rebuttal

None

Department Evaluation

NSC provided their admission, and charity care policies, stating that each are currently in use and would continue to be used at NSC. The admission policy that was provided includes the required information, including 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 financial data provided in the application does not show any Medicare and Medicaid revenues, although the facility is certified to participate in those programs. The department concluded that NSC intends for this proposed surgery center to be accessible and available to Medicare and Medicaid patients based on the information provided, although it has not historically served those patients.

The Charity Care policy includes the process one must use to access charity care.

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. NSC is located within Yakima County within the Central region. Currently, there are 21 hospitals operating in the region. Of those, four hospitals⁴ are within the planning area.

NSC projected that the ASF will provide charity care consistent with historical practice. For this project, the department reviewed the most recent three years of charity care data for the 22 existing hospitals currently operating within the Puget Sound Region and focused on the three potentially affected acute care hospital located in the planning area. The three years reviewed are 2015, 2016, and 2017.⁵ Table 5 on the following page is a comparison of the historical average charity care for the Central Region as a whole, the historical average charity care within the planning area, and the projected charity care to be provided at the ASF. The adjustments mentioned above are included.

⁴ Astria Regional Medical Center, Astria Sunnyside Hospital, Astria Toppenish Hospital, Virginia Mason Memorial Hospital

⁵ As of the writing of this evaluation, the year 2018 charity care report was available, but the three Astria hospitals had failed to report, rendering calculation of Yakima County charity averages impossible

Department's Table 5
Charity Care – Three Year Average and Projection

	% of Total Revenue	% of Adjusted Revenue
3-year Central	0.95%	2.54%
3-year Yakima County	0.81%	2.12%
Projected NSC-2022	1.19%	1.33%

[sources: Community Health Systems Charity Care 2015-2017, Application Exhibit 16A]

As shown above, the three year regional average proposed by NSC exceeds the regional and planning area average as a percentage of total revenue, but it does not meet the planning area or regional average as a percentage of adjusted revenue.

NSC has been providing health care services for several years. Charity care is health care provided at no cost or reduced cost to low income patients. Only people who meet certain income and asset criteria are eligible to receive charity care.

The focus of this sub-criterion is charity care percentages specific to NSC. In past ASF CN applications, the department has been attaching a charity care condition to the approvals, based, in part, on the fluctuation of charity care percentages since the passage of the Affordable Care Act in March 2010.

If this project were to be approved, the department concludes that NSC would be required agree to the charity care condition stated below.⁶

Northwest Neurosciences, PLLC. d/b/a Northwest Surgery Center will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent policies reviewed and approved by the Department of Health. Northwest Neurosciences, PLLC. d/b/a Northwest Surgery Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in Yakima County. Currently, this amount is 0.81% gross revenue and 2.12% of adjusted revenue. Northwest Neurosciences, PLLC. d/b/a Northwest Surgery Center will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires these records to be available upon request.

Based on the information provided in the application and with NSC's agreement to the condition, the department concludes **this sub-criterion would be 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

⁶ The condition related to the percentage of charity care and its impact on NSC's revenue and expense statement is further addressed in the financial feasibility section of this evaluation.

portion of their services or resources, or both to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

Department Evaluation

This criterion is not applicable to this application.

- (b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.*

Department Evaluation

This criterion is not applicable to this application.

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

Department Evaluation

This criterion is not applicable to this application.

- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:*

- (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.*

Department Evaluation

This criterion is not applicable to this application.

- (b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.*

Department Evaluation

This criterion is not applicable to this application.

- (5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.*

Department Evaluation

This criterion is not applicable to this application.

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

Based on the source information reviewed, the department concludes that Northwest Neurosciences, PLLC. d/b/a Northwest Surgery Center has not 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.

Northwest Neurosciences, PLLC. d/b/a Northwest Surgery Center

The assumptions used by NSC to determine utilization and the projected number of procedures during the projection period are summarized below. [source: December 27, 2018 screening response Exhibit 16B]

**Department's Table 6 (excerpted from applicant's revised projections)
Northwest Surgery Center Forecast Cases, 2019-2022**

		3Q-4Q 2019	2020	2021	2022
NWSC Total Cases	Total 'All Other' Cases	420	1,108	1,677	2,201
	Total Neurosurgery Cases	20	40	41	41
	Total (Excluding Pain Management)	440	1,148	1,718	2,242
	Interventional Pain Management Procedures	61	123	124	125
	Total (with Pain Management)	500	1,271	1,842	2,367

NSC provided detailed descriptions of its projected utilization: [source: application, pp25-28]

"The utilization forecast is comprised of three separate models: (1) neurosurgery, (2) pain management, and (3) 'All Other'.

"The neurosurgery forecast model assumes forty (40) neurosurgery cases in full-year 2019. This figure is well within our historical utilization experience. Because the project is anticipated to be completed by July 1, the forecast period for 2019 involves 6 months of volumes (July to December 2019). Therefore, the total number of neurosurgery cases for 3Q-4Q2019 is twenty (20). Subsequent growth from 2020 onward is based on the annual Yakima 10+ year old population growth according to the OFM's 2017 GMA Projections (Medium Series).

"The pain management forecast model assumes 121 interventional pain management procedures in full-year 2019. Again, because the project is anticipated to be completed by July 1, the forecast period for 2019 involves 6 months of volumes (July to December 2019). Therefore, the total number of pain management procedures for 3Q-4Q2019 is approximately sixty-one (61). Similar to the neurosurgery model, subsequent growth from 2020 onward is

based on the annual Yakima 10+ year old population growth according to the OFM's 2017 GMA Projections (Medium Series).

"The 'All Other' forecast model uses the following assumptions and methodologies:

- 1. "Surgical use rates for applicable services by ICD-9 procedure code group were derived from the latest National Center for Health Statistics ("NCHS") survey study, "Ambulatory Surgery in the United States."¹⁰ The report analyzed and presented summaries of data from the 2006 National Survey of Ambulatory Surgery ("NSAS").*

[APPLICANT'S TABLE 7 OMITTED – REPLACED BY REVISED UTILIZATION FORECAST]

"In this study, ambulatory surgery refers to surgical and nonsurgical procedures performed on an ambulatory basis in a hospital or freestanding center's general ORs, dedicated ambulatory surgery rooms, and other specialized rooms. This NCHS survey study is the principal source for published national data on the characteristics of visits to hospital-based and freestanding ambulatory surgery centers. The report was updated and revised in 2009 and contains the latest NCHS estimates on ambulatory surgery use rates.¹¹ Please see Table 7 for the NCHS utilization rates used in the forecast methodology

- 2. The NCHS use rates were multiplied by the 2019-2022 Yakima County population forecasts for residents 10 years and older (i.e. the intended patient population), and then divided by 10,000 in order to forecast planning area resident ambulatory surgeries by procedure type, by year. Table 8 includes these procedure estimates for the planning area.*

[APPLICANT'S TABLE 7 OMITTED – REPLACED BY REVISED UTILIZATION FORECAST]

- 3. "Table 9 below presents market share assumptions by service category. Modest market shares were assumed in the initial time period for the relevant areas of expanded operations proposed, allowing for a gradual increase throughout the forecast period.*

[APPLICANT'S TABLE 7 OMITTED – REPLACED BY REVISED UTILIZATION FORECAST]

- 4. "Estimated Yakima County surgeries were then multiplied by Northwest Surgery Center's presumed market share, yielding forecasted number of 'All Other' procedures, by year. These projections are included in Table 10. From an operations point of view, year one is 2020 since that is the first complete year after CON approval.*

[APPLICANT'S TABLE 7 OMITTED – REPLACED BY REVISED UTILIZATION FORECAST]

NSC replaced Table 10 from the evaluation with the table on the following page: [source: December 27, 2018, Screening responses, Exhibit 16B]

Northwest Surgery Center - Utilization Forecast

July 2019 to December 2022

Revised December 2018

Neurosurgery and Pain Management Forecast

	Service Type	3Q-4Q 2019	2020	2021	2022
Cases	Neurosurgery	20	40	41	41
	Pain Management	61	123	124	125
Total Minutes	Neurosurgery	7,462	15,110	15,259	15,410
	Pain Management	1,815	3,675	3,711	3,748

For description of methodology and assumptions, please see CN-App #19-29 application, pages 25-26 and footnote to Table 11.

"All Other" Forecast

	Service Type	3Q-4Q 2019	2020	2021	2022
Service Area* Case Volume	Operations on the Ear	400	812	820	828
	Operations on the Nose, Mouth and Pharynx	1,031	2,091	2,111	2,131
	Operations on the Digestive System	5,189	10,527	10,626	10,728
	Operations on the Musculoskeletal System	2,860	5,803	5,857	5,914
	Operations of the Integumentary System	1,289	2,616	2,641	2,666
	Subtotal	10,770	21,850	22,055	22,267
NWSC Market Share Assumptions	Operations on the Ear	3.0%	3.9%	5.9%	7.6%
	Operations on the Nose, Mouth and Pharynx	3.0%	3.9%	5.9%	7.6%
	Operations on the Digestive System	3.5%	4.6%	6.8%	8.9%
	Operations on the Musculoskeletal System	3.0%	3.9%	5.9%	7.6%
	Operations of the Integumentary System	8.5%	11.1%	16.6%	21.5%
NWSC "All Other" Case Subtotal	Operations on the Ear	12	32	48	63
	Operations on the Nose, Mouth and Pharynx	31	82	123	162
	Operations on the Digestive System	182	479	725	952
	Operations on the Musculoskeletal System	86	226	343	450
	Operations of the Integumentary System	110	289	438	574
	Total "All Other" Cases	420	1,108	1,677	2,201
	Yakima Planning Area Cases	10,770	21,850	22,055	22,267
	NWSC Market Share, Yakima Planning Area	3.9%	5.1%	7.6%	9.9%

*Yakima Planning Area, Residents 10+ years of Age

SUMMARY Forecast

		3Q-4Q 2019	2020	2021	2022
NWSC Total Cases	Total 'All Other' Cases	420	1,108	1,677	2,201
	Total Neurosurgery Cases	20	40	41	41
	Total (Excluding Pain Management)	440	1,148	1,718	2,242
	Interventional Pain Management Procedures	61	123	124	125
	Total (with Pain Management)	500	1,271	1,842	2,367

NWSC, Projected Utilization (Minutes) and Internal OR Need, By Type, 2019-2023

		3Q-4Q 2019	2020	2021	2022
NWSC Total Minutes	Surgery Minutes Per Year - 'All Other'	22,883	60,355	91,385	119,940
	Surgery Minutes Per Year - Neurosurgery	7,462	15,110	15,259	15,410
	Surgery Minutes Per Year - TOTAL (Excluding Pain Management)	30,346	75,465	106,644	135,350
	Interventional Pain Management Minutes	1,815	3,675	3,711	3,748
	Surgery Minutes Per Year - TOTAL (with Pain Management)	32,161	79,140	110,356	139,098
NWSC Internal OR Need	<i>Estimated Number of Operating Rooms Needed (WAC 246-310-270 (9) (ii) (Assumes 37.5 hours per week, 51 weeks per year, 25% loss for prep/clean-up and 15% loss for scheduling flexibility--results in 60% capacity) Results are the same if minutes are divided by 68,850.</i>				
		0.93	1.15	1.60	2.02

**'All Other' minutes per surgery (54.5 minutes per surgery) based on the outpatient average (54.5 minutes per surgery) calculated in the Yakima ASC Need Model.

**Neurosurgery minutes per surgery (373.1 minutes per surgery) based on January to June 2018 rates.

***Pain management minutes per surgery (30 minutes per surgery) based on January to August 2018 rates.

Note: Please note that estimated number of ORs needed is calculated by dividing surgery minutes by 68,850 minutes per year, the default figure in WAC 246-310-270(9)(ii).

NSC provided historical profit and loss statements as the basis for their financial projections as well as a detailed table of projected volumes. The remaining assumptions NSC used to project revenue, expenses, and net income for the proposed surgery center for the projection years are summarized below. [source: Application, pp33-35]

“Utilization

1. The methodology used to estimate the Northwest Surgery Center utilization projections is described above.

Capital Expenditures

2. As discussed above, there are estimated capital expenditures of \$182,933.22 associated with the project that consist entirely of moveable equipment. Depreciation associated with the project is calculated on a straight-line method depreciated over a 7-year time horizon.

Revenues

3. Inflation of gross and net revenues was excluded from the models.

4. Average Gross Revenue per case for services not currently provided by NWSC has been estimated by procedure group, where the procedure code groups, as defined in Table 7, have been "crosswalked" into a set of five surgical groups, as identified below. This allows for less complex models.

Crosswalk from groups to NCHS	
Operations on the Ear	ENT
Operations on the Nose, Mouth and Pharynx	ENT
Operations on the Digestive System	General surgery
Operations on the Musculoskeletal System	Orthopedics
Operations of the Integumentary System	Plastics

5. Gross revenue per case, by type of case, as identified for the five groups above, were modeled based on public documents for other ASCs similar to NWSC’s proposed project.

6. Payer mix, by case/gross charges is provided in Table 3, above. It is based on 2017 inpatient CHARS payer mix statistics, by payer, for discharges. These CHARS percentage figures, by payer, have been adjusted for the expected difference between inpatient and outpatient ambulatory surgery.

7. As demonstrated in Table 3, the percent of net revenues by payer is different from the respective mix of cases/gross charges given that different payers reimburse at different rates for the same care. Net revenues by payer have been prepared based on review of public documents for ASCs comparable to the proposed project. The Contractual Allowance assumption used for each payer are included in Exhibit 16.

8. It should be noted that in Table 3, Self-Pay sponsored patients are not assumed to pay for ASF-provided care, i.e., net revenues for these payer groups are assumed to be zero.

9. The difference between Gross Revenue and Net Revenue equals Deductions from Revenue, which includes Contractual Allowances and Charity Care. In this ASF model, Bad Debt is considered an operating expense, as detailed below. Forecasted Deductions From Revenue are included in Exhibit 16.

10. Charity care is assumed constant at 1.2% of Gross Revenue. It should be noted this figure is above the Central Washington regional charity care average of 1.1% over the 2014-2016 period (Table 12).

Expenses

11. Inflation was not included in any operating expense forecasts.

12. Detailed FTE tables are also included in Exhibit 16. Non-productive FTE figures, calculated at 10% of productive figures, add in the time spent for vacation or sick time on top of productive hours.

13. Wage and salary figures are specific to each group of FTEs, and are calculated on an hourly basis. It is assumed a FTE works 2,080 hours per year. These costs have been estimated per hour, based on current NWSC employees' costs, knowledge of the labor market and review of other publicly-available ASC CN requests similar to this ASF request.

14. Benefits were calculated as 18.0% of total wages and salaries.

15. Officer/Medical Director expenses were calculated based on historical compensation.

16. Medical supplies, purchased services, office supplies, and business and professional fees were calculated on a per case basis.

17. Employee education, meals and travel, banking fees, and insurance were assumed annual estimates based on historical rates but adjusted for anticipated requirements due to expanded operations.

18. Repairs and maintenance were calculated based on square footage.

19. Equipment and repair expenses were calculated based on 10% of movable equipment capital expenditures, where it is assumed year one expenses are covered by warranty.

20. B&O taxes were calculated at 1.5% of net revenue.

21. Bad debt expenses have been modeled at 1.0% of Gross Revenues.

22. Depreciation has been explained above.

NSC's projected revenue, expenses, and net income for the ASF are shown in Table 6 below.
[source: Screening 2 Exhibit A]

Department's Table 6
Projected Revenue and Expenses

	CY2020 (year one)	CY2021 (year two)	CY2022 (year three)
Net Revenue	\$5,730,782	\$7,086,794	\$8,337,460
Total Expenses	\$3,230,969	\$4,025,814	\$4,567,392
Net Profit/(Loss)	\$2,499,813	\$3,060,980	\$3,770,068

The "Net Revenue" line item is gross patient revenue, minus any deductions from revenue for contractual allowances, and charity care. The "Total Expenses" line item includes operating expenses, including salaries and wages, medical supplies, purchased services, rent, fees, repairs and maintenance, training and travel, insurance, taxes, and bad debt.

Public Comment

None

Rebuttal

None

Department Evaluation

To evaluate this sub-criterion, the department first reviewed the assumptions used by NSC to determine the projected number of procedures and occupancy of the ASF.

NSC used their historical volumes as baseline for neurosurgery cases, and used NCHS data from 2009 to estimate the types and numbers of surgeries likely to be needed in the Yakima Area. NSC then applied its assumed market share to those projections to derive its projected volumes.

As noted in the need section of this evaluation, NSC did not identify any physicians who have expressed a desire to use this facility. Similarly, NSC did not identify any physicians, payers, or patient who expressed any difficulty accessing surgical services from the existing providers in the planning areal. Finally, NSC provided no substantive basis for its projected market share assumptions. After reviewing NSC's utilization assumptions, the department concludes they are cannot be supported by the information provided. As a result, the department does not find NSC's utilization assumptions reasonable.

NSC provided a lease agreement for the site, between Northwest Business Enterprises and Northwest Surgery Center. The lease identifies the roles and responsibilities for each, and is effective until 2019 – NSC has options to renew and provided documentation to the department of their communication with their landlord to renew through November 10, 2022. All costs associated with the lease are substantiated in the revenue and expense statement.

NSC identified the medical director, Dr. Eduardo Meirelles, the owner of the facility. The role of medical director is described in the applicant's screening responses. The costs are substantiated in the pro forma.

The pro forma financial statements show revenues exceeding expenses within the first full year of operation and to continue doing so. These financial statements, however, are based on need and utilization projections that the department has concluded are not supported by information in the application and screening responses. Because the department has concluded that NSC has not demonstrated need for additional OR capacity in the planning area and has shown no evidence that it will be likely to attract the volumes in the projections, the department concludes that the financial statements cannot be relied upon as evidence of this project's financial feasibility.

Based on the information above, the department does not conclude that the immediate and long-range operating costs of the project can be met.

This sub-criterion is not 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.

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

The capital expenditure associated with the operation of NSC as a CN-approved ASF with two ORs is \$182,933, which is solely the cost of purchasing moveable equipment to accommodate additional specialties in the existing facility. No construction is proposed. [source: Application p33]

NSC provided list of the equipment proposed to be purchased. [source: Application, Exhibit 6]

Public Comment

None

Rebuttal

None

Department Evaluation

The proposed capital expenditure is limited to moveable equipment and far less than construction of a new facility.

Based on the information above, the department concludes that, contingent upon a demonstration of need, approval of this project would likely not have an unreasonable impact on costs and charges for healthcare services in Yakima County. The small capital cost of this project, even absent need, is not likely to result in an unreasonable impact on the costs and charges for healthcare services in the planning area. **This sub-criterion is met.**

- (3) *The project can be appropriately financed.*

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

NSC provided the following information related to the financing of this project:

"Northwest Surgery Center will fund the project from existing cash reserves. Please see Exhibit 19 for a letter of financial commitment from Northwest Surgery Center's CEO and President, Eduardo Meirelles, MD PhD."

As stated above, NSC intends to fund the project using existing cash on hand. NSC provided a letter of financial commitment from PNSC's CEO and President for the cash reserves. In addition to the financial commitment letter, NSC provided historical financial information for years 2015 through 2017. [source: Application, p35, Exhibits 17A-17D and 19]

Public Comments

None

Rebuttal

None

Department Evaluation

NSC intends to finance this project solely with cash on hand. This approach is appropriate, as NSC's cash assets are more than sufficient to cover this cost. Based on its review of NSC's financial statements, 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, the department concludes that Northwest Neurosciences, PLLC, d/b/a Northwest Surgery 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.

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

"Over the years, our organization focused on developing a culture centered around our patients and our employees. Therefore, as a consequence we place an emphasis on high quality patient care, excellent customer service, and strong teamwork. We also made sure that our employees were able to witness and participate in the outcomes that our patients obtained under our care. We frequently receive requests from every type of healthcare professional regarding job opportunities. We believe that the working conditions characterized by stability, continuous growth, opportunity for personal and professional development, and above-average compensation are some of the factors that health care professionals indicate to explain their reason to want to work in our organization.

"As a relatively small organization, we have never encountered significant difficulty hiring new healthcare professionals or maintaining our employees. Our records over the last four years support these statements." [source: Applicant's screening responses, p5]

NSC provided a listing of all existing staff as well as their projected staffing, on the following page:

**Department's Table 7
Historical and Projected Staffing**

	Current	Projected		
	2018	2020	2021	2022
Front Office	0.25	1.00	1.00	1.00
Medical Assistant	0.00	1.00	1.00	1.00
X-Ray Tech	0.25	1.50	2.00	2.00
Billing/Collection Manager	0.75	1.00	1.00	1.00
Billing/Collections Rep	0.00	1.00	1.00	1.00
Materials Manager/Admin	0.00	0.50	1.00	1.00
RNs	0.00	3.00	5.00	6.00
Surgical Tech	0.50	2.00	3.00	3.00
Director of Nursing	0.75	1.00	1.00	1.00
Medical Director	1.00	1.00	1.00	1.00
Admin Manager	0.75	1.00	1.00	1.00
TOTAL	4.25	14.00	18.00	19.00
Change		9.75	4.00	1.00

NSC also identified their key staff:

Medical Director: Eduardo Meirelles,, MD PhD (MD00047704)

Administrator: Erica Bustamente, MA (MR60418046)

Director of Nursing: Lorelee Almuetti, RN (RN60273501)

Public Comment

None

Rebuttal

None

Department Evaluation

As shown above, the applicant is projecting to grow from 4.25 FTEs in 2018 to 19 FTEs by the end of 2022. When asked for specific information about how it intends to staff this facility, NSC offered the statement quoted above.

Information provided in the application demonstrates that NSC is a well-established provider of healthcare services in Yakima County. NSC is currently operational with 2 ORs as a CN-exempt facility.

NSC proposes to increase their FTEs from approximately 4 to nearly 20 within three years, with the majority of staff being recruited in 2020. While this pace of recruitment is quicker than what is generally seen by the department, it is not necessarily unachievable. NSC provided information supporting that they do not struggle with recruitment and retention, and

identified that an ASF is an attractive work environment given the predictable hours and existing positive office culture.

Based on the above information, the department concludes that NSC is likely to be able to recruit a sufficient supply of qualified staff for this project. **This sub-criterion is met.**

- (2) *The proposed service(s) will have an appropriate relationship, including organizational relationship to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.*

WAC 246-310 does not contain specific WAC 246-310-230(2) 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.

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

NSC provided the following statement relating to ancillary and support services required for the proposed project. [source: Application p39]

“NWSC will leverage its existing network of vendors and service providers for the proposed project. However, final determination regarding which ancillary and support services will be provided on-site or from vendors for the full scope of the proposed project has not yet been made. It is our experience that such final determinations and subsequent contracts can be established well within the time frame of CN approval and anticipated project completion.”

Public Comment

None

Rebuttal

None

Department Evaluation

NSC has been providing healthcare services in Yakima County for five years. The ancillary and support required for the operation of the ASF are already in place and available.

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that NSC will maintain the necessary relationships with ancillary and support services to provide outpatient surgical services at the proposed ASF. The department concludes that there is no indication that the operation of this existing ASF would adversely affect the existing relationships. **This sub-criterion is met.**

- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.
WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare and Medicaid certified.

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

NSC provided the following statement related to this sub-criterion:

“Northwest Surgery Center does not have any such convictions as defined in WAC 246-310-230 (5) (a).

Northwest Surgery Center abides by all current laws, rules and regulations. All physicians performing surgeries at this ASF will be credentialed and privileged as a member of the medical staff roster and in good standing within the medical community.” [source: Application pp39-40]

Public Comment

None

Rebuttal

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.⁷ To accomplish this task, the department reviewed the quality of care and compliance history for NSC and the medical professionals that would practice there.

CMS Survey Data

The only licensed facility operated by Northwest Neurosciences, PLLC, is NSC – therefore this is the only facility by which the department can gauge compliance with this sub-criterion. NSC is accredited by the American Association for Accreditation of Ambulatory Surgery Facilities.⁸

⁷ WAC 246-310-230(5)

⁸ “AAAASF accreditation programs help facilities demonstrate a strong commitment to patient safety, standardize quality, maintain fiscal responsibility, promote services to patients and collaborate with other health care leaders.

AAAASF provides official recognition to facilities that have met 100% of its high standards. Accreditation assures the public that patient safety is top priority in a facility.

An accredited facility must comply with the most stringent set of applicable standards available in the nation and meet our strict requirements for facility directors, medical specialist certification and staff credentials. It also must pass a thorough survey by qualified AAAASF surveyors.

An accredited facility is re-evaluated through a self-survey every year, and an onsite survey every three years. Facilities must continuously comply with all AAAASF accreditation standards between surveys. Upon approval, an accredited facility must prominently display its accreditation certificate in public view. An accredited facility must be fully equipped to perform procedures in the medical specialties listed on its accreditation application.” [source: AAAASF website]

Using CMS Quality, Certification & Oversight Reports (QCOR), the department reviewed historical survey data for NSC. Within the last three years, NSC has not been surveyed by the department. The Office of Health Systems Oversight with the Department of Health has not taken action against NSC's license. [source: ILRS, QCOR Survey Activity Report for NSC]

In addition to the facilities identified above, the department also reviewed the compliance history of the physicians and other staff associated with NSC. The table below shows the 10 licensed health professionals listed as providers in the application and their credential status. [source: Application, p38; DOH Provider Credential Search]

**Department's Table 8
NSC Credentialed Staff**

Name	Credential Number	License Status
Loralee Almuetti, RN	RN60273501	Active
Erica Bustamante, MA	MR60418046	Active
Paul Ford, MA	CM60396186	Active
Paul Ford, RT	RT00008468	Active
Zach Grunig, Pa-C	PA60659920	Active
Amy Hernandez, MA	MR60831827	Active
Sandee Holland, ST	ST60440751	Active
Eduardo Meirelles, MD	MD00047704	Active
Laura Mendoza, MA	MR60418052	Active
Maricela Velazquez, MA	CM60664515	Active

As shown above, all providers associated with NSC have active credentials. The department did not find any restrictions on the above listed licensees within the last three years. Based on the information above, the department concludes that NSC demonstrated reasonable assurance that the facility would continue to operate in compliance with state and federal requirements if this project is approved. **This sub-criterion is met.**

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

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

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

NSC provided the following statement related to this sub-criterion:

"The project will include Northwest Surgery Center's two-suite operating room facility as a CN-approved ASF, allowing for increased access to the existing facility. Further, CN approval

is beneficial for patients in that assurance of greater access to high quality and cost effective care is improved.

Northwest Surgery Center is working with local inpatient health providers, as required. Please see Exhibit 18, which includes a copy of our transfer agreement with Virginia Mason Memorial (formerly Yakima Valley Memorial Hospital) and Astria Toppenish Hospital (formerly Toppenish Community Hospital).. [source: Application p40]

The signed transfer policies between NSC and Astria Toppenish and Virginia Mason Memorial hospitals were provided in Exhibit 18 in their application.

Public Comment

None

Rebuttal

None

Department Evaluation

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

- (5) *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, **is met**

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

Based on the source information reviewed, the department concludes that Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center has not 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.

Department Evaluation

Step One:

The department concluded that NSC did not meet the applicable review criteria under WAC 246-310-210 and -220. Therefore, the department need not move to step two.

Public Comment

None

Rebuttal

None

Department Evaluation

In earlier portions of this evaluation, the department concluded that the applicant had not demonstrated need for the project, and further concluded that the lack of need rendered the applicant's utilization and financial projections unsupportable.

Because there is no demonstrated need for the project, the department cannot conclude that approval of this facility is the superior alternative to meet the health care needs of the residents of the planning area.

This sub-criterion is not met.

(2) In the case of a project involving construction:

(a) The costs, scope, and methods of construction and energy conservation are reasonable;

Department Evaluation

The proposed project does not involve construction, therefore this criterion is not applicable to this evaluation

- (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

The proposed project does not involve construction, therefore this criterion is not applicable to this evaluation

- (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.

Northwest Neurosciences, PLLC, d/b/a Northwest Surgery Center

“An important benefit of the requested project is expanding patient access to high quality and cost-effective care. Without such access to freestanding ASFs in general, ambulatory surgeries would be limited to hospital-based ambulatory surgery facilities, which are higher cost. This was documented by the Department in a 2014 decision approving Providence Health Services’ ASF in Spokane Valley, where it stated in its decision:

“...PHS-W would be reimbursed at the ambulatory surgery rates, rather than hospital outpatient department rates. This action could reduce the overall costs of healthcare to the community. This conclusion is supported by a cost comparison review between ambulatory surgery and hospital outpatient 2014 CMS rates. ...the comparison showed that ambulatory surgery reimbursement rates are lower, and in some cases, significantly lower than hospital reimbursement rates.” (p. 16)

“Higher cost of care to both patients and insurers is increasingly important. As more and more patients move to high deductible health plans, this has become a greater hardship for both physicians and patients to find space in an ASF.” [source: application p44]

Public Comment

None

Rebuttal

None

Department Evaluation

Based on information provided within the application, and evaluated under WAC 246-310-210, -220, and -230, the department is concluded that the applicant had not demonstrated that the project was needed and financially feasible. The department cannot conclude that the approval of an additional ASF in Yakima will appropriately improve the delivery of health services in Yakima County. **This sub-criterion is not met.**

APPENDIX

Ambulatory Surgery Need Methodology
WAC 246-310-270

Facility	License Number	CN Approved?	ZIP Code	Special Procedure Rooms	Dedicated Inpatient ORs	Dedicated Outpatient ORs	Mixed Use ORs	Inpatient min/case	Cases in Mixed Use ORs	Minutes In Mixed Use ORs	Outpatient Min/Case	Outpatient Cases	Minutes in Outpatient ORs	Data Source
Virginia Mason Memorial	HAC.FS.00000058	yes	98902	3	0	0	7	90.75	8,522	773,392				2018 Survey for 2017 data
Virginia Mason Memorial - Surgery Center at Ridgeview	HAC.FS.00000058	yes	98902	0	0	5	0				41.99	3,562	149,551	2018 Survey for 2017 data
Virginia Mason Memorial Surgicenter	HAC.FS.00000058	yes	98902	0	0	4	0				73.45	3,023	222,041	2018 Survey for 2017 data
Astria Regional Medical Center	HAC.FS.60790591	yes	98902	0	0	0	8	83.56	3,816	318,883				2018 Survey for 2017 data
Astria Toppenish Hospital	HAC.FS.60790220	yes	98948	0	0	0	2	86.48	545	47,134				2017 Survey for 2016 data - no response to 2018 survey.
Astria Sunnyside Hospital	HAC.FS.00000198	yes	98944	1	0	0	3	120.49	1,744	210,141				2017 Survey for 2016 data - no response to 2018 survey.
Yakima Ambulatory Surgical Center - A. Sunnyside license	HAC.FS.00000198	yes	98902	0	0	3	0				119.41	895	106,869	2017 Survey for 2016 data - no response to 2018 survey.
Pacific Cataract and Laser Institutc	ASF.FS.60101096	no	98902	0	0	1	0				50.00	1,416	70,800	2018 Survey for 2017 data. Default minutes applied
Northwest Surgery Center	ASF.FS.60455333	no		1	0	1	0				326.11	28	9,131	
Yakima Gastroenterology Associates	ASF.FS.60514718	yes		3	0	0	0							2018 Survey for 2017 data. Endoscopy only - no procedures or minutes counted
Totals				8	0	14	20		14,627	1,349,550	62.57	8,924	558,392	
Outpatient ORs Counted in Methodology				12				Avg min/case inpatient		92.26	Avg min/case outpatient		62.57	
Total Surgeries				23,551										
Total Planning Area Population-2017				255,137										
Use Rate				92.307										
Total Planning Area Population-2022				267,706										
% Outpatient of total surgeries				37.89%										
% Inpatient of total surgeries				62.11%										

Ambulatory Surgery Need Methodology
WAC 246-310-270

Service Area Population-2022		267,706										
Use Rate		92.3072										
Projected Surgeries in Projection Year		24,711										
a.i.	94,250	minutes/year/mixed-use OR										
a.ii.	68,850	minutes/year/dedicated outpatient OR										
a.iii.	12	dedicated outpatient OR's x 68,850 minutes =			826,200	minutes dedicated OR capacity	13,204	Outpatient surgeries				
a.iv.	20	mixed-use OR's x 94,250 minutes =			1,885,000	minutes mixed-use OR capacity	20,430	Mixed-use surgeries				
b.i.	projected inpatient surgeries =		15,348	=	1,416,035	minutes inpatient surgeries						
	projected outpatient surgeries =		9,364	=	585,901	minutes outpatient surgeries						
b.ii.	Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's											
		9,364	-	13,204	=	-3,840	outpatient surgeries					
b.iii.	average time of inpatient surgeries			=	92.26	minutes						
	average time of outpatient surgeries			=	62.57	minutes						
b.iv.	inpatient surgeries*average time			=	1,416,035	minutes						
	remaining outpatient surgeries(b.ii.)*avg time			=	-240,299	minutes						
					1,175,736	minutes						
c.i.	if b.iv. < a.iv. , divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's											
	USE THIS VALUE											
		1,885,000										
		- 1,175,736										
		709,264	/	94,250	=	7.53						
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.											
		1,416,035										
		- 1,885,000										
		(468,965)	/	94,250	=	-4.98						
	divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's											
		-240,299	/	68,850	=	-3.49						