DEPARTMENT OF HEALTH

Olympia, Washington 98504

January 3, 2022

Lance Baldwin 3621 156th Place SE Bothell, WA 98012

Sent via email: Lance Baldwin lance@m-exec.com

RE: Certificate of Need Application #21-80 – Department's Evaluation and Decision

Lance Baldwin:

We have completed review of the Certificate of Need application submitted by Pain Care Physicians, PLLC proposing expansion of services and CN-approval of an existing two-operating room ambulatory surgical facility within the Thurston County Secondary Health Services Planning Area. Attached 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 246-310-230	Structure and Process of Care
Washington Administrative Code 246-310-240	Cost Containment
Washington Administrative Code 246-310-270	Ambulatory Surgery

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:

Lance Baldwin Certificate of Need Application #21-80 January 3, 2022 Page 2 of 2

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

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,

Eric Hernandez, Program Manager Certificate of Need Office of Community Health Systems

Attachment

cc: <u>Paul.Song@anesispain.com</u>

Esther.Kim@anesispain.com

EVALUATION DATED JANUARY 3, 2022 FOR THE CERTIFICATE OF NEED APPLCATION SUBMITTED BY PAIN CARE PHYSICIANS, PLLC PROPOSING TO ESTABLISH A CN-APPROVED, TWO-OPERATING ROOM AMBULATORY SURGICAL FACILITY, WITHIN THE THURSTON COUNTY SECONDARY HEALTH SERVICES PLANNING AREA

APPLICANT DESCRIPTION

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians, PLLC is a Washington State professional limited liability company¹ solely owned by Adam Burkey, M.D. Through Pain Care Physicians, PLLC, Adam Burkey, M.D. owns and operates five outpatient clinics, all in Washington State, listed below. These facilities are collectively known as Anesis Spine & Pain Care. The primary services of Pain Care Physicians, PLLC dba Anesis Spine & Pain Care are surgical services associated with pain management. [sources: Application, pdf4-5; Exhibit 10; July 19, 2021, screening response, pdf1; and Anesis Spine & Pain Care website]

Anesis Spine & Pain Care 3305 Nassau Street Everett, WA 98201 Anesis Spine & Pain Care 1414 N Vercier Road, Ste 5 Spokane, WA 99216

Anesis Spine & Pain Care 801 SW 16th Street, Ste 121 Renton, WA 98057 Anesis Spine & Pain Care 155 Lilly Road NE, Ste A & B Olympia, WA 98506

Anesis Spine & Pain Care 1628 Mildred Street, Ste 104 Tacoma, WA 98465

For reader ease in this evaluation, Pain Care Physicians, PLLC is the applicant and will be referred to as "Pain Care Physicians" the surgical facility under review is Sound Ambulatory Surgery Center and will be referred to as "Sound ASC."

PROJECT DESCRIPTION

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

With this project Pain Care Physicians proposes to establish a Certificate of Need (CN)-approved two-operating room (OR) ambulatory surgical facility (ASF) Sound Ambulatory Surgery Center,² by converting an existing facility from CN-exempt to CN-approved; and expand services offered to include pain management, plastic surgery, podiatry, and orthopedics. Currently, the facility is operational as CN-exempt³ and licensed as an ASF⁴ operating as Anesis Spine and Pain Care. It is located at 155 Lilly Road NE, in Olympia, within the Thurston County Secondary Health Services Planning Area (Thurston County). Services currently offered at the exempt facility are pain management surgical services. [sources: CN historical files and application pdf9]

² UBI 604 475 532

³ DOR#19-22 issued October 16, 2019

¹ UBI 604 032 151

⁴ ASF.FS.60979461, expiring August 27, 2024

Pain Care Physicians assumed a project completion date very shortly after the release of the CN decision, projected to be December 2021. Since the facility is already operational as CN-exempt under the authority of the CN Determination of Reviewability #19-22, issued October 16, 2019, this is a reasonable assumption. Consequently, the project's first full year is 2022 and third full year 2024 [source: Application, pdf6]

The estimated capital expenditure associated with this project is \$0. Since this project is to establish a CN-approved facility by converting an operational facility from CN-exempt to CN-approved and expanding surgical services that will not require additional equipment or construction, this is a reasonable assumption. [source: July 19, 2021, screening response, pdf2, 4, and 7]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This application is subject to Certificate of Need review as the construction, establishment, or other development of a health care facility under RCW 70.38.105(4)(a) and 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.

If 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.

To obtain Certificate of Need approval, an 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 ambulatory surgical facility (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 a regular review timeline. The following table shows a summary of the timeline used for the review of this project.

APPLICATION CHRONOLOGY

Action	Pain Care Physicians, PLLC
Letter of Intent Received	February 10, 2021
Application Received	June 10, 2021
Department's pre-review activities:	
DOH 1st Screening Letter	July 2, 2021
Applicant's Responses Received	July 19, 2021
DOH 2nd Screening Letter	August 9, 2021
Applicant's Responses Received	September 23, 2021
Beginning of Review	September 30, 2021
Public Hearing Conducted	None requested or conducted
Public Comments Deadline	November 4, 2021
Rebuttal Comments Deadline ⁵	November 19, 2021
Department's Anticipated Decision	January 3, 2021
Department's Actual Decision ⁶	January 3, 2021

AFFECTED PERSONS

"Affected persons" are defined under WAC 246-310-010(2). In order to qualify as an affected person someone must first qualify as an "interested person" defined under WAC 246-310-010(34). During the course of the review of this application two entities sought interested person status, only one of which qualifies as an interested person. However, neither testified at a public hearing nor submitted written evidence. Therefore, neither entity qualifies as an affected person.

Lori Aoyama, Health Facilities Planning & Development

Health Facilities Planning & Development is a consultant for multiple providers of health care services throughout the region and state. On June 30, 2021, Health Facilities Planning & Development submitted its request for interested person status. However, did not identify any specific person or organization it is representing that matches the criteria to be an interested person, WAC 246-310-010(34)(a) through (g). Consequently, Health Facilities Planning & Development does not qualify as an interested or affected person for this review.

Erin Kobberstad, Vice President of Strategy & Market Intelligence, MultiCare Health System

MultiCare Health System (MHS) is a not-for-profit health care organization that's been providing health services to communities in Washington State since the founding of Tacoma's first hospital in 1882. With more than 20,000 employees, MHS has grown from a hospital-based organization to offering a number of services including: inpatient care, primary care, virtual care, urgent care, dedicated pediatric care and specialty services. Some of its services are surgical and offered in the Thurston County Secondary Health Services Planning Area. On September 24, 2021, MHS submitted its request for interested person status. However, did not testify at a public hearing nor submit written evidence. Consequently, does not qualify as an affected person for this review.

⁵ No public comments were submitted for this project, as a result, no rebuttal comments were submitted.

⁶ The department's decision was delayed due to workload issues.

PUBLIC COMMENT AND REBUTTAL

There was no public comment submitted for this application; as a result, the applicant was precluded from providing rebuttal comments. This fact is stated here and will not be restated throughout this evaluation.

SOURCE INFORMATION REVIEWED

- Pain Care Physicians' Certificate of Need application received on June 10, 2021
- Pain Care Physicians' first screening response received July 19, 2021
- Pain Care Physicians' second screening response received on September 23, 2021
- Historical charity care data for years 2017, 2018, and 2019 obtained from the Department of Hospital/Finance and Charity Care.
- 2019 Charity Care in Washington Hospitals Report obtained from the Department of Hospital/Finance and Charity Care.
- Years 2018, 2019, and 2020 Annual Ambulatory Surgery Provider Surveys for surgical procedures performed during calendar years 2017, 2018, and 2019 for hospitals, ambulatory surgery centers, or ambulatory surgical facilities located in Thurston County.⁷
- Claritas population data 2021
- DOH Provider Credential Search website: http://www.doh.wa.gov/pcs
- CMS QCOR Compliance website: https://qcor.cms.gov/index new.jsp
- Department of Health internal database Integrated Licensing and Regulatory Systems (ILRS)
- Anesis Spine and Pain Care's website: https://anesispain.com/
- Washington State Secretary of State website: https://sos.wa.gov
- Center for Medicare and Medicaid Services website: https://www.cms.gov

CONCLUSION

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

For the reasons stated in this evaluation, the application submitted by Pain Care Physicians, PLLC proposing to establish a new certificate of need-approved surgical facility and expand available services within the Thurston County Secondary Health Services Planning Area; is not consistent with applicable criteria of the Certificate of Need Program and a Certificate of Need is denied.

⁷ For Certificate of Need purposes, "Ambulatory Surgery Centers" (ASCs) and "Ambulatory Surgical Facilities" (ASFs) are often used interchangeably – ASCs are Medicare-certified surgery centers, whereas ASFs are licensed facilities in the State of Washington.

CRITERIA DETERMINATIONS

A. NEED (WAC 246-310-210)

Based on the source information reviewed, the department concludes that the Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center project **has not met** the applicable need criteria in WAC 246-310-210 and **has not met** the applicable ambulatory surgery facility criteria in WAC 246-310-270.

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.
 To evaluate this sub-criterion, the department uses facility-specific criteria found in WAC 246-310-270.

WAC 246-310-270(6)

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

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians identified that the CN-exempt facility currently has two ORs and the proposed CN-approved facility will also have two ORs. Additionally, Pain Care Physicians provided a single line drawing which clearly designates the spaces of the two existing ORs. [sources: Application, pdf5 and Exhibit 3]

Department Evaluation

Pain Care Physicians provided statements to demonstrate the facility has a total of two ORs and at project completion will still have two ORs. **This sub-criterion is met.**

WAC 246-310-270(9) – Ambulatory Surgery Numeric Need 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 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. The facility which is the focus of this review is located in Olympia [98506] within the Thurston County Secondary Health Services Planning Area (Thurston County).

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 rooms 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 outpatient rooms is calculated.

Data used to make these projections specifically excludes special purpose and endoscopy rooms and corresponding procedures. Rooms dedicated to interventional pain management surgical services and corresponding procedures are also excluded.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided a detailed step-by-step account of the numeric methodology as well as a version similar to the one the department typically uses. Both demonstrate a numeric <u>surplus</u> of 0.73 ORs for both inpatient and outpatient surgery (mixed-use hospital ORs). However, the applicant mistakenly interpreted this to mean there to be a projected <u>shortage</u> of 0.73 mixed-use ORs and 4.47 dedicated outpatient ORs. [source: Application, pdf10-15 and Exhibit 2]

Applicant's Analysis

Ser	vice Area Po	pulation: 2024	308,533	Claritas	Age 0 - 8	5+						
Sur	geries @114	.157/1,000:	35,221									
a.i.	94,250	minutes/year/n	nixed-use OR									
a.ii.	68,850	minutes/year/d	ledicated outpa	tient OR								
a.iii	. 11	dedicated outp	atient OR's x 6	8,850 minut	tes =	757,350	minutes d	ledicated O	R capacity	13,696	Outpatient	surgeries
a.iv	. 21	mixed-use OR	's x 94,250 min	utes =		1,979,250	minutes n	nixed-use O	R capacity	19,707	Mixed-use	surgeries
b.i.	projecte	ed inpatient surg	eries =	15,954	=	1 602 313	minutes ir	npatient sur	neries			
D.1.		ed outpatient sur		19,267				utpatient su				
b.ii.	Forecas	st # of outpatient	surgeries - cap	acity of dec	dicated out	tpatient OR's						
		19,267	-	13,696	=	5,571	outpatien	surgeries				
b.iii		e time of inpatier			=		minutes					
	average	e time of outpation	ent surgeries		=	55.30	minutes					
b.iv		nt surgeries*aver		a tima	=	1,602,313						
	remaini	ng outpatient su	rgenes(b.ii.) av	e ume	_	1,910,360	minutes minutes					
C.İ.	if b.iv. <	a.iv., divide (a.i	vb.iv.) by 94,2	50 to deter	mine surpl	us of mixed-u	use OR's					
	USE TH	IIS VALUE										
		1,979,250										
	-	1,910,360										
-		68,890	1	94,250	=	0.73						
C.II.	if b.iv. >	a.iv., divide (inp	atient part of b.	iv - a.iv.) by	94,250 to	determine s	hortage of	inpatient OI	R's			
	Not Ap	plicable - Ignor	e the following	values an	d use res	ults of c.i.						
		1,602,313										
	-	1,979,250										
		(376,937)	1	94,250	=	-4.00						
	divide	outpatient part	of b.iv. By 68,8	50 to deter	rmine sho	rtage of dec	dicated ou	tpatient OF	l's			
		308.047	1	68.850	=	4.47						

[source: Application, Exhibit 2]

Applicant's Table

Table 4: Summary of data and assumptions used in numeric need methodology				
Planning area	Thurston County			
Population estimates and	Year 2019: 288,655 Year 2024 (Forecast Year): 308,533			
forecasts, all ages	Source: Claritas 2021			
Planning area surgeries	Inpatient or Mixed Use: 15,953 Outpatient: 19,267 Total: 35,221 Sources: 2019, 2020 ASC Surveys			
Planning area use rate	Surgeries/2020 Population*1,000 = 114.157 per 1,000 persons			
Surgery case mix	Outpatient: 54.70% Inpatient: 45.30%			
	Outpatient: 55.3 Inpatient: 100.43			
Average minutes per case	Sources: 2019, 2020 ASC Surveys			
OR annual capacity (in minutes)	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes			
	11 dedicated outpatient ORs, 21 mixed use ORs			
Existing OR capacity (in ORs)	See Table 3			
Summary of need calculations	2024 Overall Need. Projected Shortage of 0.73 Mixed Use ORs Projected Shortage of 4.47 Outpatient ORs			

[source: Application, pdf12]

Department Numeric Need Methodology and Evaluation

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. Sound ASC is located in Olympia, within Thurston County. No zip code analysis is necessary for this project since the planning area includes the entirety of Thurston County.

According to the department's historical records, there are ten planning area providers, including the applicant, with OR capacity. Of the ten providers, two are hospitals and eight are ASFs. The following table shows a listing of the two planning area hospitals. [source: ILRS database]

Department's Table 1 Thurston County Secondary Health Services Planning Area Hospitals

Hospitals	City
Capital Medical Center	Olympia
Providence St. Peter Hospital	Olympia

The following table contains a listing of the eight ASFs located in Thurston County. [source: ILRS database]

Department's Table 2 Thurston County Secondary Health Services Planning Area Ambulatory Surgical Facilities

Ambulatory Surgical Facilities	City
Foley Plastic Surgery Center	Olympia
Gastroenterology Associates Endoscopy Center	Olympia
Laser and Surgery Center LLC	Lacey
Olympia Multi Specialty Clinic Ambulatory Procedure Center	Olympia
Olympia Surgery Center	Olympia
Pacific Cataract and Laser Institute	Olympia
Pain Care Physicians PLLC	Olympia
Pearl Plastic Surgery	Olympia

Based on the services provided at a facility, the numeric methodology deliberately excludes the OR capacity and procedures of certain facilities from its calculations; such as facilities that only provide endoscopy services. Additionally facilities with services that are limited to a special population may be excluded if the services do not overlap with those proposed by the applicant. Of the eight ASFs shown in the preceding table, two facilities OR capacity and procedures will be excluded from the numeric methodology – rationale for exclusion is detailed in the following table.

Department's Table 3
Thurston County Secondary Health Services Planning Area
Ambulatory Surgical Facilities Excluded Based on Services

Ambulatory Surgical Facility	Exclusion Rationale
Gastroenterology Associates Endoscopy Center	Endoscopy only [source: 2020 CN utilization survey and CN#1810]
Olympia Multi Specialty Clinic Ambulatory Procedure Center	Endoscopy only [source: 2020 CN utilization survey]

Of the remaining six ASFs, four are exempt from Certificate of Need review, including the applicant. This means it is located within and owned by a solo or group practice, and the use of this surgical facility is restricted to physicians that are employees or members of the clinical practices that operate the facility; so, surgical services are not the primary purpose of the facility. Therefore, these facilities do not meet the definition of an ASF. ¹⁰ These exempt facilities' cases, but not ORs, are included in the methodology for the planning area.

⁸ WAC 246-310-270(9)(iv)

⁹ WAC 246-310-210(2)

¹⁰ WAC 246-310-010(5) and WAC 246-330-010(5)

Department's Table 4 Thurston County Secondary Health Services Planning Area CN-Exempt Ambulatory Surgical Facility

Ambulatory Surgical Facility	City	DOR#
Foley Plastic Surgery Center	Olympia	Predates DOR numbering, exemption granted 05/28/1985
Pacific Cataract and Laser Institute	Olympia	DOR#11-08, issued 10/15/2010
Pain Care Physicians PLLC	Olympia	DOR#19-22, issued 10/16/2019
Pearl Plastic Surgery	Olympia	DOR#20-01, issued 09/26/2019

The remaining two ASFs are Certificate of Need-approved facilities. For these ASFs, both the ORs and the number of cases are counted in the numeric methodology.

Department's Table 5
Thurston County Secondary Health Services Planning Area
CN-Approved Counted Facilities

Ambulatory Surgical Facilities	City	CN#
Laser and Surgery Center LLC	Lacey	CN#1303, issued 04/27/2005
Olympia Surgery Center	Olympia	CN#1520, issued 12/31/2013

There is no mandatory reporting requirement for the utilization of ASF or hospital ORs, so the department sends an annual utilization survey to all hospitals and known ASFs in Washington State. When this application was submitted in June 2021, the most recent utilization survey was soliciting data for year 2019. Not all providers submitted responses. The data provided in a utilization survey is used, if available. Otherwise the department uses the previous year's utilization survey information. If the provider did not respond with 2018 or 2017 data, the department relies on its internal data system known as the Integrated Licensing and Regulatory System (ILRS). Consistent with WAC 246-330-100(2), licensed ambulatory surgical facilities must submit to the department an annual update. The data provided in the 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 once it is internally reviewed. Per WAC 246-310-270(9)(a)(ii) ¹¹ the department uses the listed number of surgical procedures and multiplies that number by 50 minutes to approximate the total number of surgical minutes performed at the facility annually.

The data points used in the department's numeric methodology are identified in the following table. The entire methodology and supporting data used by the department are provided in Appendix A of this evaluation.

¹¹ If unknown, WAC 246-310-270(9)(a)(ii) identifies a default of 50 minutes per surgery.

Department's Table 6 The Department's Thurston County Secondary Health Services Planning Area

Methodology Assumptions and Data

Assumption	Data Used			
Planning area	Thurston County			
Population estimates and	Age Group	: All ages		
forecasts	Year 2019 -	- 287,770		
(Claritas Population Data 2021)	Year 2024 -	- 307,535		
Use rate	124.42 /1,000) population		
Year 2019 total number of	Inpatient or mixed use	Outpatient		
surgical cases in the planning	14,291 cases	21,512 cases		
area	Total case	s 35,803		
Percent of surgeries:				
outpatient vs. inpatient	39.92%	60.08%		
(based on DOH survey)				
Average minutes per case	104.90 minutes	55.33 minutes		
(based on DOH survey)	104.90 minutes	55.55 minutes		
OR annual capacity in minutes	04 250 surgary minutes	68,850 surgery minutes		
(per methodology in rule)	94,250 surgery minutes	08,830 surgery minutes		
Existing providers/ORs		14 dedicated		
(using DOH survey and	21 mixed-use ORs			
ILRS database)		outpatient ORs		
Department's Methodology	Surplus of 0.73 ORs used	_		
Results	outpatient surgery in Thurston County.			

As noted in the table, the department's numeric methodology calculates a surplus of 0.73 ORs used for both inpatient and outpatient surgery in Thurston County for projection year 2024. Although both the applicant's and department's methodologies show the same result, there are some differences. The differences between the methodologies include:

- Slight differences in population data
- The applicant did not include operating rooms of a CN-approved facility
- The applicant used out of date information for Capital Medical Center's inpatient cases
- The applicant excluded Pearl Plastic Surgery's volumes
- The applicant excluded its own exempt facility's volumes

In summary, numeric need for an ASF is not demonstrated for Thurston County.

WAC 246-310-270(4) and WAC 246-310-210

WAC 246-310-270(4) gives the department some flexibility when the methodology does not demonstrate numeric need for operating rooms. It states, "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." While WAC 246-310-210 requires in addition to demonstrating need for services within a planning area, an applicant must also demonstrate that existing services are not sufficiently available and accessible to meet that need.

In response to these criteria Pain Care Physicians provided the following statements to support its project.

"Market share figures were applied to each procedure code group based on current and planned surgeries. The historical usage of PCP's Pain Management procedures equate to a 9.49% and 6.8% market share of operations on the Nervous System and Miscellaneous outpatient cases respectively. The additional service lines represent a <1% of total market share decreasing impact to existing facilities." [source: Application, pdf20]

- "1. No Impact on Market Share. This ASF has been in operation since 2020 and continues to provide high quality outpatient surgical services to its patients. Allowing PCP to continue to operate as a CON-approved facility will not detrimentally impact the other providers of outpatient surgeries in the planning area.
- 2. Facility is Necessary to Provide Access to Specific Surgical Types. PCP has the necessary equipment to serve these patients in an outpatient setting. With the continued push by Medicare and private payers to free standing ambulatory surgery centers, PCP's facility is necessary to provide lower cost and high quality pain management, plastic, podiatry, and orthopedic surgeries.
- 3. Existing Healthcare System Supports Continued Operation of the Facility. Without the continued operation of PCP, patients requiring pain management would have no other option but to have the surgeries performed at a hospital or outside of the planning area. The existence of PCP as a free-standing ASF open to all surgeons is necessary to continue to provide patients access to care and choice of providers. The table below shows that the additional services represent ~1 % of the services currently being provided in the Thurston County planning area. The plastic, podiatry, and orthopedic services provided by PCP are similar to the primary pain management services provided currently." [source: July 19, 2021, screening response, pdf3]

Pain Care Physicians later provided additional clarity in response to a screening question, stating that "these patients" include plastic, podiatry, and orthopedic patients. [source: July 19, 2021, screening response, pdf4]

Department's Evaluation of WAC 246-310-270(4) and WAC 246-310-210

Pain Care Physicians provided a reasonable argument which supports its project's approval despite the lack of numeric need for outpatient ORs in the planning area. Primarily, that as a currently CN-exempt Thurston County operational ASF, much of its impact on other facilities has already occurred. Additionally, that new services proposed by this project are expected to be about 4% of the CN-approved facility's surgeries translating to less than 1% of the total market share of existing planning area facilities.

In addition to numeric need, the department must determine whether other services and facilities for the type proposed are not or will not be sufficiently available and accessible to meet that need. Pain Care Physicians provided information on the minimal impact the new additional services it proposes with this project will have on existing area providers.

The department also takes into consideration the lack of opposition for this project. None of the healthcare facilities with OR capacity in Thurston County submitted comments opposing this project during this review.

Based on the department's methodology assumptions described in the earlier table, the department's numeric methodology by itself, projects a surplus of dedicated outpatient ORs in Thurston County. However, given that this project is an existing CN-exempt facility seeking CN-approval, new service lines are a minority of projected services, and that no public comment from existing providers was submitted, the department finds that need for an ASF is demonstrated for this Thurston County project. **This sub-criterion is met.**

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

To evaluate this sub-criterion, the department evaluates an applicant's admission policies, willingness to serve Medicare and Medicaid patients, and willingness 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 assurances regarding access to treatment.

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 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 applicant's willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals aged 65 and over.

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

Charity care shows the 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. 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.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

In response to an application question asking if the proposed facility will meet the CN requirement to provide access to services for all planning area residents, Pain Care Physicians responded: "Yes our facility will meet this requirement" [source: Application, pdf21]

To further support its statement Pain Care Physicians states elsewhere in its application: "We have completed accreditation with the Joint Commission and have deemed status with CMS." [source: Application, pdf9]

Pain Care Physicians provided copies of the following policies, stating that all policies are reviewed annually, effective September 1, 2020, and are applicable to only this facility being reviewed. [source: July 19, 2021, screening response, pdf11]

- Admission Policy: Patient Admission, Assessment, and Discharge Policy
- Patient Rights and Responsibilities Policy: Abuse, Criteria and Reporting
- Patient Rights and Responsibilities Policy: Patient Privacy Practices
- Advanced Directive
- Nondiscrimination Policy
- Financial Assistance/Charity Care Policy Patient Rights and Responsibilities Policy: Abuse, Criteria and Reporting

[source: September 23, 2021, screening response, Exhibit 5]

In addition to the policies listed above, Pain Care Physicians provided its historical and projected sources of revenue by patient and payer, see the following tables for a breakdown by payer. Note that the first table is for all of its existing operations, while the second and third tables represent only the facility being reviewed.

Department's Table 7
Pain Care Physicians' Historical Payer Mix for
All Operations Percent of Revenue by Payer

Payer	CY 2018	CY 2019	CY 2020
Medicare	44.5%	49.4%	49.3%
Medicaid	23.3%	18.8%	15.8%
Commercial/Other*	32.2%	31.8%	34.9%
Total	100.0%	100.0%	100.0%

^{*} Other includes worker's compensation, motor vehicle accidents, self-pay [source: July 19, 2021, screening response, Exhibit 8]

Department's Table 8
Sound ASC Historical Payer Mix

Payer	Percent by Revenue	Percent by Patient
Medicare	94.8%	92.9%
Medicaid	3.9%	4.7%
Commercial	1.3%	2.4%
Self-Pay	0.0%	0.0%
Total	100%	100%

[source: Application, pdf27]

Department's Table 9 Sound ASC Projected Payer Mix

Payer	Percent by Revenue	Percent by Patient
Medicare	31.0%	35.0%
Medicaid	3.9%	5.0%
Commercial	65.0%	59.0%
Self-Pay	0.1%	1.0%
Total	100%	100%

[source: Application, pdf26-27]

When asked on what basis the projections were made, the applicant responded, "PCP's ASF became fully operational at the end of 2021, as a result historical payer data is heavily weighted to Medicare and Medicaid because of the process of contracting with commercial insurances. Therefore, until contracts are in place, we have been largely limited to cases with Medicare. This has started to change as we have executed commercial contracts and will continue to change to more closely reflect the payor mix of our patients. As more and more payers are added the payer mix will shift. The projected payer mix is based on PCP's over 5 years of experience providing healthcare in this region." [source: July 19, 2021, screening response, pdf7]

Department Evaluation

Pain Care Physicians provided policies currently in use at Sound ASC, and the ASF is Medicare and Medicaid-certified.

The Patient Admission, Assessment, and Discharge Policy describes the process and criteria that would be used to admit a patient. The Nondiscrimination and Accessibility Requirements and Nondiscrimination Statement states that Pain Care Physicians will not discriminate, exclude, or treat differently people because of race, color, national origin, age, disability, ability to pay, or sex. The combination of these policies provides a clear expectation that patients will be treated fairly. This document also provides contact information for patients who feel as though they have been discriminated against. [source: September 23, 2021, screening response, Exhibit 5]

The Patient Rights and Responsibilities Policies outline the rights of each patient as well as the ASF's expectations of a patient. The combination of these policies provides a clear understanding that patients can expect safe and transparent provision of services while their right to privacy is protected. Policies include a purpose statement, procedures, contact information, and examples. [source: September 23, 2021, screening response, Exhibit 5]

The applicant also provided a copy of its Financial Assistance/Charity Care Policy. The policy's stated purpose is: "Pain Care Physicians ASC is committed to ensuring our patients get the care they need regardless of ability to pay for that care. Providing health care to those who cannot afford to pay is part of our mission and state law requires facilities to provide free and discounted care to eligible patients. You may qualify for free or discounted care based on family size and income, even if you have health insurance.

If you think you may have trouble paying for your health care, please talk with us. When possible, we encourage you to ask for financial help before receiving medical treatment."

This policy includes what can be covered, a procedure on how to apply for charity care, as well as other services available. Although initial documentation provided the department budgets for charity care costs, the final revenue and expense statement provided on September 23, 2021, as Exhibit 4 does not include charity care costs. As stated in WAC 246-310-270(7) the department shall only approve projects which document and provide assurances of the implementation of policies to provide access to individuals unable to pay for services. This is demonstrated through inclusion of Medicaid payers and patients (demonstrated by the applicant) in addition to anticipated charity care

deductions in proforma revenue and expense statements (not demonstrated by the applicant). Because the applicant's final projected financial statements do not contain any charity care, the department cannot conclude whether Pain Care Physicians intends to provide adequate access to indigent patients. [sources: Application, Exhibit 9 and September 23, 2021, screening response, Exhibit 5]

Sound ASC is accredited with the Joint Commission and has deemed status with CMS. The ASF also holds an active state license as Pain Care Physicians, PLLC.¹²

Pain Care Physicians provided a table showing the percentages of current and projected sources of revenues at the surgical facility as well as the historical payer percentages for its entire operations. Further Pain Care Physicians stated that these amounts are expected to change with its further integration to the community and with establishment of commercial contracts. The applicant based its projections on its entire operation's historical patients and revenues. The anticipated amount of its combined Medicare and Medicaid revenues is approximately 35% of total revenues and commercial and self-pay are expected to make up the remaining approximate 65% of revenues.

The Medicaid and Medicaid payer mixes are in range of what is typically seen in CN applications for ASFs. However, since no charity care deductions were included in the final submission of the applicant's projected revenue and expense statement, the department cannot conclude whether Pain Care Physicians intends to provide adequate access to indigent patients. The program also cannot conclude that this proposed project will increase the availability and accessibility of outpatient surgical services equally to all populations of the Thurston County Secondary Health Services Planning Area. The department concludes **this sub-criterion is not met.**

WAC 246-310-270(7) – Charity Care Requirement

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.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided the following summary of the planning area's current charity care rates. [source: Application, pdf22]

Applicant's Table

2017	2018		2019
0.20%	0.97%		1.129
1.21%	1.51%		1.439
			1.079
	Charity Care	as a 1.07%	
	ntage of Total	1.07%	
	0.20% 1.21% 3-year Average	0.20% 0.97% 1.21% 1.51% 3-year Average Charity Care	0.20% 0.97% 1.21% 1.51% 3-year Average Charity Care as a 1.07% nue

When asked why a specific facility was not included in the above table that is in the planning area, the applicant responded: "The South Sound Behavioral Hospital is not included in the Washington

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¹² ASF.FS.60979461

Hospital Charity Care Report." [source: July 19, 2021, screening response, pdf4] Although South Sound Behavioral Hospital is not included in years 2017 and 2018 charity care reports one quarter is included in the year 2019 report. The department includes this facility in the Southwest Washington Hospital Charity Care Region average but excludes this facility's charity care amounts from the ASF Secondary Health Services Planning Area average because it does not provide surgical services.

To demonstrate compliance with this sub-criterion, Pain Care Physicians <u>initially included</u> in its original application proforms revenue and expense statement a line item for its projected charity care amounts; however it was left out of the final proforms revenue and expense statement submitted to replace the earlier version in response to screening. [sources: Application, Exhibit 9 and September 23, 2021, screening response, Exhibit 4]

Department Evaluation – Charity Care Requirement

For charity care reporting purposes, Washington State is divided into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. For this review, the department focuses on years 2017, 2018, and 2019 of available charity care data reported by the hospitals in the proposed ASF's region, Thurston County. Currently there are 15 hospitals operating within the Southwest Washington Hospital Charity Care Region.

There are three hospitals located in the Thurston County Secondary Health Services Planning Area; the two ¹³ which provide surgical services that would be affected by the proposed project are listed in the following table.

Department's Table 10
Thurston County Hospitals Affected by this ASF Project

Hospital	License Number
MultiCare Capital Medical Center	HAC.FS.00000197
Providence Saint Peter Hospital	HAC.FS.00000159

[source: Department of Health's Integrated Licensing & Regulatory System]

The next table compares the three-year historical average of charity care provided by the hospitals operating in the Southwest Washington Hospital Charity Care Region, those providing surgical services in the Thurston County Secondary Health Services Planning Area, and the applicant's projected charity care percentages.

Department's Table 11 Charity Care – Three Year Average

	% of Total Revenue	% of Adjusted Revenue		
3-year Southwest Washington Hospital Charity Care Region	1.50%	4.76%		
3-year Thurston County	1.07%	3.08%		
Pain Care Physicians – Projected	Not available 14	0.0%		

[sources: Department of Hospital/Finance and Charity Care Financial Review and Application, Exhibit 9]

¹³ The excluded hospital is South Sound Behavioral Hospital, which does not provide surgical services.

¹⁴ This applicant uses cash-based accounting not accrual. So, its revenues prior to deductions are not tracked.

As shown in the preceding table, there is no projected or historical charity care either proposed or demonstrated by the applicant.

The 2019 Report of Charity Care in Washington Hospitals offers the following analysis of charity care costs across Washington State Hospitals as impacted by the Affordable Care Act (ACA): "In 2013, as a result of the Affordable Care Act, Washington saw the first decline in the amount of charity care reported by hospitals since the department began gathering these data in 1989. That decline, however, has ceased and charity care has been increasing again. Charity care rates in Washington in 2019 have remained similar to levels in 2018, which includes slight increases in revenue and slight increases in charity care. Charity care charges increased 24 percent between 2017 and 2018, but only 9.3 percent between 2018 and 2019, so the rise may be slowing." [Source: 2019 Washington State Charity Care in Washington Hospitals]

The Certificate of Need Program recognizes that charity care in Washington State could be slowing in coming years. However, Pain Care Physicians' did not project any charity care deductions in its final submitted revenue and expense statement. Without sufficient documentation and assurances of implementation of its Financial Assistance/Charity Care Policy, the department is unable to determine that approval of this project would not adversely affect Thurston County hospitals. **This sub-criterion is not met.**

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.
 - (b) <u>The special needs and circumstances of biomedical and behavioral research projects</u> designed to meet a national need and for which local conditions offer special advantages.
 - (c) <u>The special needs and circumstances of osteopathic hospitals and non-allopathic services.</u>
- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:
 - (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.
 - (b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.
- (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

WAC 246-310-210(3), (4), and (5) do not apply to this project under review.

B. FINANCIAL FEASIBILITY (WAC 246-310-220)

Based on the source information reviewed, the department concludes that the Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center project **has not met** the applicable 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 evaluate this sub-criterion, the department reviews the assumptions provided by an applicant, projected revenue and expense (income) statements, and projected balance sheets. The assumptions are the foundation for the projected statements. The income statement is a financial statement that reports a company's financial performance over a specific period—either historical or projected. Projected financial performance is assessed by giving a summary of how the business expects its revenues to cover its expenses for both operating and non-operating activities. It also projects the net profit or loss incurred over a specific accounting period. ¹⁵

The purpose of the balance sheet is to review the financial status of company at a specific point in time. The balance sheet shows what the company owns (assets) and how much it owes (liabilities), as well as the amount invested in the business (equity). This information is more valuable when the balance sheets for several consecutive periods are grouped together, so that trends in the different line items can be viewed.

As a part of its review, the department must determine that a project is financially feasible – not just as a stand-alone entity, but also as an addition to its own existing operations, if applicable. To complete its review, the department may request an applicant to provide projected financial information of the parent corporation if the proposed business would be operated under the parent.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Following are the assumptions used by Pain Care Physicians to determine utilization for the first three full years of operation.

"The facility has been fully operational since September 18, 2020. The amounts below represent actual and not annualized volume. Due to credentialing delays the ASC has not utilized its full capacity. The current payer mix is >90% Medicare. When fully credentialed Medicare will represent 35% of patient volume. See Tables 12 and 13

¹⁵ One purpose behind the income statement is to allow key decision makers to evaluate the company's current situation and make changes as needed. Creditors use these statements to decide on loans it might make to the company. Stock investors use these statements to determine whether the company represents a good investment.

2020	Jan- May 2021			
85	129			
,				

In Table 5, we present projected surgical volumes for the first three full years of operations given project approval (2022 through 2024). Currently, PCP provides outpatient services for Pain Management in its ASC. Beginning in January 2022, given approval of the proposed project, it plans to add the specialties of Orthopedics, Podiatry, and Plastic Surgery.

The specialty-specific case counts presented in Table 5 reflect a mapping of procedures by ICD-9 group presented in Table 6.

Some ICD-9 groups have a straightforward correspondence to a certain specialty group, while others bridge multiple specialty groups. For this reason, we apply mapping assumptions regarding the expected proportion of procedures within a given ICD-9 group to fall within each of the different specialties for PCP. These mapping assumptions are based on review of CPT and ICD-9 procedural classifications and the specialties of PCP and its historical utilization. We emphasize that our mapping assumptions are distinct from our market share assumptions, which are outlined in Table 10. These mapping assumptions are:

- For ICD-9 group 'Operations on the Nervous System,' 50% are ENT procedures, 15% are Colon Rectal/Gastroenterology procedures, 30% are General Surgery procedures, and 5% are Pain Management procedures and 10% are pain management procedures.
- For ICD-9 group 'Operations on the Musculoskeletal System,' 30% are ENT procedures, 50% are General Surgery procedures, 10% are Orthopedics procedures and 10% are podiatry procedures.
- For ICD-9 group 'Operations of the Integumentary System,' 50% are ENT procedures, 20% are Colon Rectal/Gastroenterological Procedures, 15% are General Surgery procedures, 5% are Maxillofacial procedures, and 10% are Plastic Surgery procedures.
- For ICD-9 group 'Miscellaneous diagnostic and therapeutic procedures and new technologies,' 2% are ENT procedures, 87% are Colon Rectal/Gastroenterological procedures, 6% are General Surgery procedures, and 5% are Pain Management procedures." [source: Application, pdf17-18]

Applicant's Table

Updated Table 5:			
Projected Case Count			
	2022	2023	2024
Pain Management	779	790	800
Podiatry	36	37	37
Plastic Surgery	36	37	37
Orthopedics	36	37	37
Total Cases	889	901	913
Total Surgery Minutes (38.5 Minutes/case)	34,217	34,675	35,140
Estimated Number of Operating Rooms	0.5	0.5	0.5
Needed	0.5	0.5	0.5

[source: July 19, 2021, screening response, pdf4]

"The forecast model uses the following assumptions and methodologies:

Surgical use rates 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.' The report analyzed and presented summaries of data from the 2010 National Survey of Ambulatory Surgery ('NSAS'). This survey is included in our application as Exhibit 6. For utilization estimates by surgical specialty, please see Table 6, below.

Procedure Description (ICD-9-CM Code)	ICD9 CM Code	Utilization Rate / 10,000
All Operations		1560.3
Operations on the Nervous System	01-05	136.6
Operations on the Musculoskeletal System	76-84,00.70- 00.73,00.80-00. 84	228.8
Operations of the Integumentary System	85-86	140.3
Miscellaneous diagnostic and therapeutic procedures and new technologies	87-99,00	190.5
Sources: "Ambulatory Surgery in the Ur Department of Health and Human Servi Statistics, National Health Statistics Rep 2017; U.S. Census Annual Estimates of Single Year of Age and Sex for the Unit 2018	ices, National Ce ports, Number 10 f the Resident Po	enter for Health 02, February 28, opulation by
lotes: Utilization rates calculated by div ounts available in Table 3 of "Ambulato 010," by 2010 J.S. census population counts and mult	ory Surgery in the	United States,

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 ASFs. The report was updated and revised in 2017 and contains NCHS estimates on ambulatory surgery case counts for the year 2010. Estimates of population use rates were calculated by dividing the procedure case counts by 2010 U.S. Census population counts and multiplying by 10,000. Please see Exhibit 6 for a copy of the NCHS survey study used in the forecast methodology.

The NCHS use rates were multiplied by 2021-2024 Thurston County Planning Area population forecasts and divided by 10,000 to forecast Planning Area resident ambulatory surgeries by procedure type and year. Table 7 presents estimates of these case counts." [source: Application, pdf18-19]

These assumptions resulted in Pain Care Physicians assuming the following utilization for its ambulatory surgical facility. [source: Application, pdf19-20]

Applicant's Table

Table 7: Thurston County Ambulatory Surgery Forecasts, 2022-2						
Outpatient Cases	2022	2023	2024			
Number of Months	12	12	12			
Operations on the Nervous System	4,106	4,160	4,215			
Operations on the Musculoskeletal System	6,877	6,968	7,059			
Operations of the Integumentary System	4,217	4,273	4,329			
Miscellaneous diagnostic and therapeutic procedures and new technologies	5,726	5,802	5,878			
Total	20,926	21,203	21,480			

Pain Care Physicians provided the following information about its assumed market share. [source: Application, pdf20]

"Market share figures were applied to each procedure code group based on current and planned surgeries. The historical usage of PCP's Pain Management procedures equate to a 9.49% and 6.8% market share of operations on the Nervous System and Miscellaneous outpatient cases respectively. The additional service lines represent a <1% of total market share decreasing impact to existing facilities."

Applicant's Table

Table 8: PCP Projected M	Table 8: PCP Projected Market Share					
Service Area Volume of Outpatient Cases	2022	2023	2024			
Number of Months	12	12	12			
Operations on the Nervous System	9.49%	9.49%	9.49%			
Operations on the Musculoskeletal System	1.05%	1.06%	1.05%			
Operations of the Integumentary System	0.85%	0.87%	0.85%			
Miscellaneous diagnostic and therapeutic procedures and new technologies	6.80%	6.81%	6.81%			

[source: Application, pdf20]

Pain Care Physicians provided the following statement related to its project lack of capital expense or start-up funds. [source: July 19, 2021, screening response, pdf7]

"The PCP ASF is a fully operation surgery center with all the equipment needed to safely provide surgical care to pain management, podiatry, plastic, and orthopedic patients. Specialized supplies will be purchased based on service line. Disposable supplies are not included in capital expenditures."

Following are the assumptions Pain Care Physicians used to project revenue, expenses, and net income for the project.

"All expense items in the clinic budget are a continuations of actual expenditures from previous years that have been adjusted for inflation, employee raises and costs associated with increased revenue. All expense items on the ASC pro forma are based on expected costs." [emphasis added] [source: September 23, 2021, screening response, pdf11]

In response to screening questions Pain Care Physicians provided the following clarifications about the topics listed.

"Anesis is a management services organization (MSO) and provides all the management and administrative functions while Pain Care Physicians is the clinical entity that provides all the medical services. Anesis provided billing and management services for Covid 19 testing during the pandemic of 2020 and 2021. Those were categorized as MSO management and billing fee (when combined) or Billing fee (when stand-alone billing services were provided).

Contractor Expense is outside contractors such is IT service providers and occasionally, contractor costs associated with staffing companies for MA's and providers.

Employee Related Expense is for company meetings, picnics, Christmas parties, etc.

Miscellaneous income primarily represents stimulus funds from the federal government (Payroll protection program 'PPP'). Miscellaneous expense are nominal or one-time expenses not categorized elsewhere.

Philippines Operations Expense is for our outsourced team of 30+ people in the Philippines that provide call center, prior auth, referral coordination, billing. Payroll Expense Other is all payroll excluding officers/owners.

Medical supplies on [page] 230 are the same as Medical supplies in [page] 232. ASC supplies on page 230 are zero as the ASC was not operational until the end of 2020. The proforma on page 232 shows Medical Devices which represent the cost of implantable devices.

This was an account created but not used. CME is spread into dues, travel expenses, etc. There was limited CME during the pandemic as most conferences were canceled or held virtually.

Because we are using cash-based accounting, we do not accrue accounts receivable or accounts payable. We only show loans, liabilities to other companies, intercompany debt on the balance sheet. By 2022, the asset purchase (SPC Note) will have been completely paid off, the convertible notes will have been exercised, the Noridian Advance Loan would have been paid and intercompany loans

(MSO to PCP) would have been paid. Therefore many of the liability line items are expected to be at zero by end of 2022.

We use cash-based accounting, not accrual. Therefore we do not have receivables on our books and the associated had debt related to receivables.

The proforma includes the additional surgeries in its creation.

No allocations are made since the ASC and clinics are one entity. We do track divisional financials and the ASC is a separate division." [source: July 19, 2021, screening response, pdf13-15]

"With the new budget spreadsheet provided, medical supplies are the medical supplies used by the clinic. The ASC pro forma only includes medical supplies and also implantable devices ('ASC medical devices') used in the ASF." [source: September 23, 2021, screening response, pdf10]

When asked why some line items were not included in the proforma statement that were in the historical statement, Pain Care Physicians responded: "Lines excluded from the projected profit and loss pro forma is that they are not relevant to the ASC" [source: July 19, 2021, screening response, pdf12]

Pain Care Physicians clarified that only the last few columns of the historical statement included ASF revenues and expenses since the ASF has only been operational since September 2020. [source: July 19, 2021, screening response, pdf13]

Pain Care Physicians also provided actual and projected staffing amounts and assumptions in the following table and statement.

Applicant's Table

	Sep-Dec			
	2021	2022	2023	2024
	Actual	Projected	Projected	Projected
ASC Manager	1	1	1	1
Infection Control Nurse	0.2	0.2	0.2	0.2
Pre/Post Nurse 1	0.8	0.8	0.8	0.8
Pre/Post Nurse 2	0.5	0.5	0.5	0.5
OR RN 1	0.6	0.6	0.6	0.6
OR RN 2	0.6	0.6	0.6	0.6
Scrub tech 1	0.6	0.6	0.6	0.6
Scrub tech 2	0.6	0.6	0.6	0.6
Sterile Processing Tech	0.6	0.6	0.6	0.6
Front Desk/Reception	0.8	0.8	0.8	0.8

[source: July 19, 2021, screening response, pdf8]

"The ASC supports the staffing guide lines of AORN and ASPAN for care of patients in the operating room and pre/post-operative areas. These guidelines hold the following staffing: Operating Room 1 -RN and 1-Scrub tech per operating room, and Pre/Post area of a matrix of staff based on the of the patient." [source: Application, pdf28]

Since the proposed facility's operations are and will be tied to Pain Care Physicians' existing clinical operations, the applicant provided historical and projected financial statements for its entire

operations which includes five clinics for several historical years and for the exempt ASC for the period in which it operated. The applicant also provided proforma financial statements and utilization for the ASC alone. Based on the preceding assumptions, the following table shows the projected revenue, expenses, and net income of the proposed ASF. [source: September 23, 2021, screening response, Exhibit 4]

Department's Table 12
Pain Care Physicians' Sound Ambulatory Surgery Center
Projected Revenue, and Expenses

	2022	2023	2024
	Year 1	Year 2	Year 3
Net Revenue	\$6,425,920	\$7,777,100	\$9,672,000
Total Expenses	\$5,146,090	\$6,109,575	\$7,307,500
Net Profit/(Loss)	\$1,279,830	\$1,667,525	\$2,364,500

"Net Revenue" in the table is ASC revenue, other income, and patient refunds. "Total Expenses" includes all the facility's projected costs of goods sold, operating expenses, and depreciation.

To demonstrate the financial health of its organization, Pain Care Physicians also provided historical and projected balance sheets for the whole organization, including Sound ASC for the period in which it was operational. Projected balance sheets are summarized in the following table. [source: July 19, 2021, screening response, Exhibit 2]

Department's Table 13
Pain Care Physicians' Combined Operation's
Projected Balance Sheet Summary

Agasta	2022	2023	2024
Assets	Year 1	Year 2	Year 3
Current Assets	\$2,626,424	\$3,926,324	\$4,791,361
Property & Equipment	\$82,624	\$182,624	\$332,624
Other Assets	\$406,288	\$368,288	\$335,288
Total Assets	\$3,115,336	\$4,477,236	\$5,459,273

Liabilities	2022 Year 1	2023 Year 2	2024 Year 3
Current Liabilities	\$0	\$0	\$0
Long Term Liabilities	\$680,000	\$80,000	\$80,000
Total Capital	\$2,435,336	\$4,397,236	\$5,379,273
Total Liabilities & Capital	\$3,115,336	\$4,477,236	\$5,459,273

Department Evaluation

The department first reviewed the assumptions used by Pain Care Physicians to determine the projected number of procedures and utilization of the facility if the project is approved. An applicant's utilization assumptions are the foundation for the financial review under this subcriterion. The utilization assumptions (market share) for existing services, Pain Care Physicians based on the historical utilization of the existing exempt facility with projected increases that

incorporate Thurston County population statistics. The applicant modestly determined projected volumes (market share) for newly proposed services as <1% of the total market.

Pain Care Physicians provided in response to second screening revised financial statements. Due to the following notable inconsistencies and/or lack of substantiation, the proforma submitted as Exhibit 4 of the September 23, 2021 screening response is considered unreliable and the department cannot complete review of this project under this sub-criterion.

- The applicant adjusted budgeted expenses for inflation. It is clearly stated on the ASF application form, in the "Application Instructions" page, that an applicant "[should] not include a general inflation rate for any dollar amounts." This is a long-standing expectation of the department due to the fact that inflation rates are not reasonably predictable over several years.
- Although initial documentation provided to the department budgeted for charity care costs, the final revenue and expense statement provided on September 23, 2021, as Exhibit 4 did not budget for charity care costs. An approvable project includes charity care documentation and assurances. This is demonstrated partially through inclusion of charity care deductions in proforma revenues and expense statements. Without these assurances the department cannot conclude whether Pain Care Physicians intends to provide adequate access to indigent patients. Even if this applicant uses cash-based accounting, department needs to see that charity care costs are deducted from annual projected revenue amounts and at what percentage these deductions are assumed.
- Expense line items¹⁶ that inexplicably decrease over projection period. These expected changes could be attributed to sharing costs with already operational portions of the business. However, no explanation or assumption was provided.
- Expense line items¹⁷ that inexplicably decrease over the over the projection period. There is no assumption that the department could attribute to the expected decrease as volumes increase.
- On the revenue and expense statement for the ASC alone, the expense line item for "*Rent or Lease Expense*" is assumed to be:

For year 2022 \$161,000 For year 2023 \$167,400

For year 2024 \$174,130

[source: September 23, 2021, screening response, Exhibit 4]

However, the lease provides a base rent table ¹⁸ which shows the monthly rent by period for the premises confirmed as Suite 100 also known as Suite B. This table shows that annual rent even in year 2029 does not exceed \$160,000. The department calculates the following amounts for base rent using the amounts in the lease.

For year 2022 \$123,337.96 For year 2023 \$127,038.08 For year 2024 \$130,849.24

[sources: Application, Exhibit 8 and July 19, 2021, screening response, Exhibit 5]

¹⁶ Bank services charges, computer and IT, continuing education, dues and subscriptions, facilities services-other, moving expense, office supplies, accounting fees, legal fees, professional fees – other, and recruiting expense.

¹⁷ Office supplies and payroll – physicians.

¹⁸ Section 1.1 (k) of the lease.

There is "Additional Rent" required by the lease however, these costs¹⁹ appear to be accounted for in other projected expense line items. Further the department asked for a crosswalk which connects all costs associated with the lease (rent, additional rent, and utilities) to the corresponding projected expenses in financial statements. The applicant responded with the following.

For year 2022 \$160,992.00 For year 2023 \$167,431.68

For year 2024 \$174,128.95

[source: September 23, 2021, screening response, Exhibit 1]

Although the list the applicant provided is reasonably similar to that of the "Rent or Lease Expense" line item in its own proforma revenue and expense statement the department is unable to directly match it to any portion of the lease agreement.

Pain Care Physicians identified Dr. Adam Burkey²⁰ as Sound ASC's Medical Director. Dr. Burkey is the sole owner of the facility. There is no separate or additional compensation for the Medical Director position; as such, there is no corresponding cost in financial statements for this position. [source: Application, pdf4 and 29]

In summary, based on the information submitted, the department is unable to conclude whether the immediate and long-range operating costs of the project can be met. **This sub-criterion is not met.**

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

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

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided the following statements and tables related to this sub-criterion. "*There are no construction costs.*" [source: Application, pdf26]

"The service opportunities gained by PCP will result in increased cost savings for patients' due to the efficiency and cost-effectiveness of an ASF in comparison to hospital outpatient surgery departments. As evidenced in the National Health Statistics Reports (NHSR), the efficiency of an ASF can be measured by the time spent for the procedure to include the operating room, the actual surgery time and the postoperative care. Table 9 outlines the findings within the report.

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¹⁹ Operating expenses

²⁰ License MD60545557

Table 9 - Distribution of times for surgical visits	, by ambulatory surgery facility type; United States,
2010	

Calculated time of ambulatory surgical visit	Hospital Average Time (minutes)	Standard Error	ASF Average Time (minutes)	Standard Error	All Facilit Average Time (minutes)	cies Standard Error
Operating Room	63	2	50	4	57	2
Surgical	37	2	29	3	33	2
Postoperative Care	89	3	51	4	70	3
Total Time	189	•	130		160	

Source: "Ambulatory Surgery Data from Hospitals and Ambulatory Surgery Centers: United States, 2010", U.S. Department of Health and Human Services, National Center for Health Statistics, Report Number 102, February 28, 2017. Table C, page 6.

In an article in the Ambulatory Surgery Center Association (ASCA) a publication titled 'A Positive Trend in Health Care' identifies that the increase and rise of Ambulatory Care Facilities can be attributed to physicians, high-quality, cost-effective alternative to the inpatient hospital setting and the value an ASF adds to the economy.

'A Positive Trend in Healthcare' identifies the cost savings within an ASF compared to a hospital setting is substantial. The recent trend in how Medicare reimburses a procedure done in a hospital outpatient setting compared to reimbursement of that same procedure in an ASF has widened. In 2003 the difference in reimbursement was only 16%, at the time of the article's publication there was a difference of 72% in reimbursement. In an article titled 'Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up', explained that in 2003, the Medicare Prescription Drug, Improvement, and modernization Act froze ASF's payment updates. For the next couple of years, they phased in a new ASF's prospective payment based on the outpatient prospective payment system. This ASF fee schedule set rates for procedures done in an ASF to no more than 59% of payments to hospitals who provided the same procedure. This went into full effect in 2012.

ASC v. Hospital Outpatient Department											
	Patient Co	st	Medicare Cost								
	ASF Co-pay	HOPD Co-pay	Total Procedure Cost ASF	Total Procedure Cost HOPD							
Cataract	\$193.00	\$490.00	\$964.00	\$1,670.00							
Upper Gi Endoscopy	\$68.00	\$139.00	\$341.00	\$591.00							
Colonoscopy	\$76.00	\$186.00	\$378.00	\$655.00							

The economic growth that ASFs have added to our economy has been considerable. The following Table illustrates the impact witnessed in 2009.

United States, 2009	
Year 2009	
Total Tax Payments	\$5.8 Billion
Total FTE	117,700
Total Nationwide Economic Impact	\$90 Billion

'A Positive Trend in Healthcare' also identifies the top 'Medicare Case Volume by Specialty' that was derived from analyzing CMS claim data in 2010. The three main specialty services that are performed in an ASF are gastroenterology (31%), ophthalmology (28%) and pain management (22%). The article also provides the results of a survey that was taken on the satisfaction rate of patients having their procedures performed within an ASF coming in at 92% favorable.

Based on the analysis of physician preference, cost effectiveness, efficiency and quality of care, PCP, as a pain management surgical facility, will be in a position to continue to meet the current needs of the residents of Thurston County planning area with an approved CON." [source: July 19, 2021, screening response, pdf5-7]

Department Evaluation

In order to evaluate this sub-criterion, the department performed a calculation of net revenue per procedure after the project's completion to determine whether the applicant's projections are reasonable.

Department's Table 14
Department Calculation of Pain Care Physicians' Charges per Case

	2022	2023	2024
	Year 1	Year 2	Year 3
Net Revenue	\$6,240,358	\$7,552,530	\$9,392,700
Number of Procedures	34,217	34,675	35,140
Net Revenue (charges) per Procedure	\$182	\$218	\$267

As shown above, the anticipated net revenue per procedure is modest in year one and increases through the projection period, demonstrating the ASF's growing profitability as it becomes more highly utilized.

Because this facility was approved to operate under a CN exemption²¹ is fully operational, and does not propose additional operating rooms, Pain Care Physicians has confirmed that no construction is needed. Further, the ASF has already passed survey by the Joint Commission. This confirms the applicant's assertion that no construction is necessary and that there is no capital expense associated with this project.

However, since the department can't substantiate this applicant's commitment to offering charity care resulting in the project's issues related to availability and accessibility and the applicant's failure

²¹ DOR #19-22, decision issued on October 16, 2019.

to demonstrate compliance with 246-310-210(2), 270(7), and 220(1), the department cannot conclude that the establishment of Sound ASC is will have an unreasonable impact on the costs and charges for healthcare services in Thurston County. **This sub-criterion is not 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.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

This project has no capital expense since it was previously approved to operate under a CN exemption, ²² is fully operational, and does not propose additional operating rooms. Additionally, there are no losses anticipated by the applicant.

"There are no construction costs.

...

PCP does not anticipate the need to purchase any equipment because of the proposed project. Thus, this question is not applicable.

There are no capital expenditures or start-up costs associated with the proposed project. Thus, this question is not applicable." [source: Application, pdf26-27]

Department Evaluation

As stated above, this project does not have any estimated capital expense or losses anticipated in its first three years of operation. The department concludes that **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 the Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center project **has not met** the applicable structure and process (quality) of care criteria in WAC 246-310-230.

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

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

Page 29 of 37

²² DOR #19-22, decision issued on October 16, 2019.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided the following statements related to this sub-criterion.

"Staff members are recruited through online position posting services such as indeed." [source: Application, pdf29]

"Employee retention involves regular reviews, competitive pay and benefits and bonus/incentive plans. We believe that company culture and strong management are keys to retention.

PCP organization's large size allows for sharing of staff as needed between locations to diminish impact to the patients they serve. We have ARNP's and other provider staff that can be utilized when necessary to help when we experience staff shortage or turnover. We are also establishing relationships with nursing staffing companies for short term staffing gaps." [source: July 19, 2021, screening response, pdf9]

"PCP employs many general and specialty employees. Therefore, we can utilize shared staff within PCP, including selected administrative, clinical, and technical staff, as needed. PCP offers an 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 related to the ASF. Further, as stated in the application, the ASF is currently operational.

PCP has demonstrated a proven history of maintaining staff even in the worst of circumstances as evidenced by maintaining operations throughout the current pandemic." [source: September 23, 2021, screening response, pdf2-3]

Following is a table summarizing Pain Care Physicians' actual and projected FTEs for this facility under review. [source: July 19, 2021, screening response, pdf8]

Department's Table 15
Pain Care Physicians' Historical and Projected FTEs

	2021*	2022	2023	2024
Job Classification	Actual	Projected	Projected	Projected
ASC Manager	1.0	1.0	1.0	1.0
Infection Control Nurse	0.2	0.2	0.2	0.2
Pre/Post Nurse 1	0.8	0.8	0.8	0.8
Pre/Post Nurse 2	0.5	0.5	0.5	0.5
OR RN 1	0.6	0.6	0.6	0.6
OR RN 2	0.6	0.6	0.6	0.6
Scrub Tech 1	0.6	0.6	0.6	0.6
Scrub Tech 2	0.6	0.6	0.6	0.6
Sterile Processing Tech	0.6	0.6	0.6	0.6
Front Desk/Reception	0.8	0.8	0.8	0.8
Total FTEs	6.3	6.3	6.3	6.3

^{*} Year 2021 is a partial year, September through December.

In addition, Pain Care Physicians identified its Medical Director as Dr. Adam Robert Burkey²³ who is also the sole owner of the ASF. [source: Application, pdf4 and 29]

Department Evaluation

As stated by the applicant, Sound ASC already has staff in place at its exempt facility and has demonstrated a history of maintaining staff even in challenging circumstances such as the COVID-19 pandemic. Pain Care Physicians also already has a medical director in place, as evidenced in the application.

Information provided in the application demonstrates that Sound ASC is an established provider of healthcare services in Thurston County. Given that the facility is already operational with its staff in place, the department concludes that Pain Care Physicians has the ability to staff the ASF. **This subcriterion is met.**

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

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

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided the following list ancillary and support services already in place. [source: Application, Exhibit 5]

Applicant's Tables

Air gas (tanks)	Air Gas-Medical
Alarm system	ADT
Ambulance service	Olympic Ambulance of Lacey
Biohazard Waste	Stericycle
Biomed	NW Biomedical
Building Cleaners	JVA Commercial Cleaning
Compounding Rx	AIS Pharmacy
Drain cleaning	Bee Mechanical
Electrician	Tandem Electric
Fire - Monitoring	Pioneer Fire & Security
Fire - Panel	Pioneer Fire & Security
Garbage / Recycling	City of Olympia
General Contractor	Highmark Contractors
Generator	Power Systems West
HVAC	Universal Refrigeration

Ice machine	Food Service Equipment
Insurance	Propel Insurance
Internet	Xfinity / Comcast
	,,
Linen	Sterile Surgical - Laundry
Locksmith	Advantage Lock & Key
Medical Gas Systems	Cornell Plumbing & Heating
Pest control	Western Exterminators
Pharmacy Consulting	Premier Pharma
Plumber	Bee Mechanical
Power - Electric / Gas	PSE
Radiation/Dosimetry	Stanford Dosimetry
Sterilizer	NW Biomedical
Telephone	Sound Line Communications
Water	City of Olympia

In response to a question asking if existing ancillary or support agreements are expected to change as a result of this project, Pain Care Physicians stated: "None are expected to change." [source: Application, pdf30]

²³ Washington State license MD 60545557

Further, Pain Care Physicians submitted an executed transfer agreement for the ASF between itself and Providence Health & Services – WA dba Providence Saint Peter Hospital. The agreement is currently in effect and is in effect until terminated by either party. [source: July 19, 2021, screening response, Exhibit 1]

In response to a question asking if its existing transfer agreement is expected to change as a result of this project, Pain Care Physicians stated: "This relationship will not change with CN approval." [source: Application, pdf30]

Department Evaluation

Pain Care Physicians has been operating in Thurston County for just over a year. Pain Care Physicians has already established and intends to continue working relationships with its vendors and the existing healthcare infrastructure. None of these relationships is expected to change as a result of this proposed project.

Pain Care Physicians also provided a transfer agreement which outlines the terms and procedures agreed upon by participating facilities. The agreement is with Providence Health & Services – WA dba Providence Saint Peter Hospital; and is effective June 16, 2021 with no set termination date.

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that Pain Care Physicians will continue to maintain the necessary relationships with ancillary and support services for the ASF if this project is approved. **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.

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.²⁴ For surgical facilities, the department reviews two different areas when evaluating this sub-criterion. One is a review of the Centers for Medicare and Medicaid Services (CMS) "*Terminated Provider Counts Report*" covering years 2018 through current.²⁵ The department uses this report to identify surgical facilities that were involuntarily terminated from participation in Medicare reimbursement.

The department also reviews an applicant's conformance with Medicare and Medicaid standards, with a focus on Washington State facilities. The department uses the CMS "Survey Activity Report"

²⁴ WAC 246-310-230(5)

²⁵ In the context of this section of this evaluation "current" refers to data available on CMS' website, listed as "The data in these reports, including provider and supplier counts and percentages, are valid for the subset of providers or suppliers for which there are survey records in CASPER. Source: CASPER (12/26/2021)"

to identify Washington State facilities with a history of condition level findings. For CMS surveys, there are two levels of deficiencies: standard and condition.²⁶

• Standard Level

A deficiency is at the Standard level when there is noncompliance with any single requirement (or several requirements) within a particular standard that is not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

• Condition Level

Deficiency at the Condition level may be due to noncompliance with requirements in a single standard that, collectively, represent a severe or critical health or safety breach, or it may be the result of noncompliance with several standards within the condition. Even a seemingly small breach in critical actions, or at critical times, can kill or severely injure a patient, and such breaches would represent a serious or severe health or safety threat.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided the following statement related to this sub-criterion. [source: Application, pdf31]

"PCP does not have a history of any of the actions listed above. This question is not applicable."

Department Evaluation

As stated in the Applicant Description section of this evaluation, Pain Care Physicians, PLLC is the applicant; and according to this application Pain Care Physicians has five clinics and one surgical facility, which is the subject of this review. All its clinics and surgical facility are located in Washington State.

Department's Table 16 Pain Care Physicians' Ambulatory Surgery Center

Name	Location	State Credential	CCN
Sound Ambulatory Surgery Center	Olympia	60979461	50C0001329

Following is a summary of the areas reviewed for Pain Care Physicians and its surgical facility.

Terminated Provider Counts Report

Focusing on years 2018 through current Pain Care Physicians' single surgical facility was not involuntarily terminated from participation in Medicare and/or Medicaid reimbursement. [source: Centers for Medicare & Medicaid Services, Quality, Certification, and Oversight Reports as of December 26, 2021]

Conformance with Medicare and Medicaid Standards

Pain Care Physicians owns and operates one surgical facility therefore this is the only facility by which the department can gauge compliance with this sub-criterion. Using CMS Quality, Certification & Oversight Reports (QCOR), the department reviewed historical survey data for the surgical facility. Following is a summary of the survey data reviewed by the department. [source:

²⁶ Definitions of standard and condition level surveys: https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/

Centers for Medicare & Medicaid Services, Quality, Certification, and Oversight Reports as of December 26, 2021]

Department's Table 17 Pain Care Physicians' Surveys and Enforcement Year 2018 to Current

	C4 11	Commission	Number of Types	Surveys wit s of Deficien	-
Facility	Standard Complaint Surveys Surveys		No Deficiencies	Standard Only	Condition & Standard
Pain Care Physicians, PLLC 115 ²⁷ Lilly Road NE Ste B Olympia, WA 98506	1	0	0	0	0

Focusing on years 2018 through current, its one Medicare and Medicaid-certified surgical facility was surveyed once. The facility had no deficiencies cited and did not require a follow-up visit; therefore, currently is in compliance with CMS standards.

In addition to the facility identified above, the department also reviewed the compliance history of the credentialed owner/Medical Director, physicians, and other staff associated with the facility.

The department reviewed the credential status of its sole owner²⁸ and employees or physicians that will practice at the facility. This includes, three physicians, one advanced registered nurse practitioner, two registered nurses, one physician assistant, one medical assistant, two x-ray technologists, and two surgical technologists. Of these credentials reviewed, the department found them to all be active with no restrictions.

In review of this sub-criterion, the department considered the total compliance history of the facilities owned and operated by Pain Care Physicians. The department also considered the compliance history of the credentialed owner (which serves as the medical director), current credentialed employees, and prospective physicians who will use the surgical facility. Based on the information reviewed, the department concludes that Pain Care Physicians' surgical facility has been in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the approval of this facility and expansion of services offered at Sound ASC would not have a negative effect on Pain Care Physicians' overall compliance. **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

²⁷ Although the address is not an exact match (the actual address is 155 Lilly Road NE, Ste B) the other identifiers are enough for the department to confirm this is the facility being reviewed by this evaluation.

²⁸ The owner holds a physician and surgeon license.

and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided the following statement in response to a question about how the proposed project will promote continuity in the provision of health care services in the planning area. [source: Application pdf30]

"The 2 operating rooms are exclusively used for pain management procedures at this time. With the proposed project, PCP anticipates providing surgical services across all the aforementioned specialties. Furthermore, with the ability to open the ASC to additional physicians, PCP will also anticipate providing services related to Orthopedics, Podiatry, and Plastic Surgery."

Department Evaluation

Pain Care Physicians provided information within application materials to demonstrate it intends to continue established relationships with vendors and referrals at the existing exempt facility, and that these relationships are adequate to support the increase in services to be provided. This includes an executed transfer agreement with an area hospital. In addition, no relationships are expected to change with this proposed project.

Although these factors are a part of the basis confirming this sub-criterion, the department takes into consideration its own analysis and conclusions on this project related to WACs 246-310-210, 270, 220, and 230. With failures in other parts of this evaluation, the department does not have sufficient assurances of the applicant's ability to implement its policies and provide access to those without an ability to pay for services. Without evidence that they would have access to this facility's services, indigent patients would be forced to seek services at other Thurston County ASFs or hospitals, leaving those other area providers to shoulder more than their share of the indigent population.

Based on the failures in other portions of this evaluation, the department concludes there is no reasonable assurance that approval of this this project would promote continuity and avoid unwarranted fragmentation in the provision of health care services in the community. **This subcriterion is not 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.

This sub-criterion is addressed in sub-section (3) above and is met for this project under review.

D. COST CONTAINMENT (WAC 246-310-240)

Based on the source information reviewed, the department concludes that the Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center project **has not met** the applicable cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.</u>
To determine if a proposed project is the best alternative, the department takes a multi-step approach.
Step one determines if the application has met the other criteria of WAC 246-310-210 thru 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 has met the applicable criteria in WAC 246-310-210 through 230 criteria, in step two, the department 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.

Last, 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 in Step three. The 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 use 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.

<u>Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center</u> <u>Step One</u>

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center **did not meet** the applicable review criteria under WAC 246-310-210 through 230 and 270. Therefore, the department's evaluation under this sub-criterion is completed.

- (2) *In the case of a project involving construction:*
 - (a) The costs, scope, and methods of construction and energy conservation are reasonable;
 - (b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

Department Evaluation

There is no construction or capital expenditure associated with this project, this sub-criterion is not applicable to this project.

(3) The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.

Pain Care Physicians, PLLC dba Sound Ambulatory Surgery Center

Pain Care Physicians provided the following statement related to this sub-criterion.

"This project does not include construction, this question does not apply." [source: Application, pdf33]

Department Evaluation

Pain Care Physicians provided information supporting its proposal to establish a new surgical facility by converting its existing exempt facility to approved. However, since the proposed project did not

meet the applicable review criteria under WAC 246-310-210, 270, 220, and 230, the department cannot conclude that this project is the best available option for Thurston County residents. **This sub-criterion is not met.**

APPENDIX A

Ambulatory Surgery Need Methodology Source Data WAC 246-310-270 Thurston County

Facility	License Number	CN Approved or Exempt	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
Providence St Peter Hospital Capital Medical Center	HAC.FS.00000159 HAC.FS.60986502		98506-5133 98502-8654	3	0	5	11 10	108.71 97.57	9,402 4,889	1,022,063 477,017	51.99 #DIV/0!	3,651	,	OH 2020 Utilization Survey OH 2020 Utilization Survey
Foley Plastic Surgery Center	ASF.FS.60102721	Exempt	98506-5063			1					117.03	286	e	OH 2019 Utilization Survey, temption issued 05/28/1985, & SF website
Gastroenterology Associates En		•		Exclude - end	oscopy only	WAC 246-31	0-270(9)(a)(iv	7)			117.03	200	D &	OH 2020 Utilization Survey CN1810 issued 08/30/2019 OH 2020 Utilization Survey
Laser and Surgery Center LLC Olympia Multi Specialty Clinic		11	98503-1014 98502-8701	Exclude - end	oscopy only	3 WAC 246-31	0-270(9)(a)(iv	y)	_	_	50.00	5,019	250,950 &	CN1303 issued 04/27/2005 OH 2020 Utilization Survey
Olympia Surgery Center	ASF.FS.60320652	11	98502-8654			6					63.10	6,730	424,680 & D	OH 2020 Utilization Survey CN1520 issued 12/31/2013 OH 2020 Utilization Survey
Pacific Cataract and Laser Insti	t ASF.FS.60101112	Exempt	98506-5250			2					50.00	2,626	D	DOR11-08 issued 10/15/2010 OH 2020 Utilization Survey, OH License Renewal,
Pain Care Physicians PLLC	ASF.FS.60979461	Exempt	98506-5028			2					50.00	2,800	.,	DOR19-22 issued 10/16/2019 OH License Renewal
Pearl Plastic Surgery	ASF.FS.60927357	Exempt	98506-5028			1			11201	4 400 000	50.00	400	,	DOR20-01 issued 09/26/2019
Totals						14	21	Avg min/cas	14,291	1,499,080	Avg min/cas	21,512	1,190,227 55.33	
Outpatient ORs Counted in Me	thodology			14				Avg IIIII/cas	e inpatient	104.50	Avg IIIII/cas	e outpatient	33.33	
Total Surgeries Total Planning Area Population	i, 2019 (Claritas 2020))		35,803 287,770										

124.42

307,535

60.08% 39.92%

Use Rate

% Outpatient of total surgeries % Inpatient of total surgeries

Total Planning Area Population, 2024 (Claritas 2020)

Ambulatory Surgery Need Methodology WAC 246-310-270 Thurston County

Service Area Population, 2025 307,535
Use Rate 124.42
Projected Surgeries in Projection Year 38,262

	,			
a.i.	94,250 minutes/year/mixed-use OR			
a.ii.	68,850 minutes/year/dedicated outpatient	OR		
a.iii.	14 dedicated outpatient ORs x 68,850	minutes =		963,900 minutes dedicated OR capacity 17,421 Outpatient surgeries
a.iv.	21 mixed-use ORs x 94,250 minutes =	=		1,979,250 minutes mixed-use OR capacity 18,869 Mixed-use surgeries
b.i.	projected inpatient surgeries =	15,273	=	1,602,039 minutes inpatient surgeries
	projected outpatient surgeries =	22,989	=	1,271,973 minutes outpatient surgeries
b.ii.	Forecast # of outpatient surgeries - capacity of 22,989 -	dedicated of 17,421	outpatien =	t ORs 5,568 outpatient surgeries
b.iii.	average time of inpatient surgeries		=	104.90 minutes
	average time of outpatient surgeries		=	55.33 minutes
b.iv.	inpatient surgeries*average time		=	1,602,039 minutes
	remaining outpatient surgeries(b.ii.)*avg time		=	308,073 minutes
				1,910,112 minutes
c.i.	if b.iv. < a.iv., divide (a.ivb.iv.) by 94,250 to determine surplus of mixed-use ORs			
	USE THIS VALUE			
	1,979,250			
	- 1,910,112	04.250		0.72
	69,138	94,250	=	0.73

divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient ORs

94,250 =

68,850

-4.00

4.47

/

1,602,039 1,979,250 (377,211)

308,073