



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

March 19, 2019

CERTIFIED MAIL # 7017 3380 0000 0863 8680

Bryce Helgerson, President
Legacy Salmon Creek Medical Center
12211 Northeast 139th Street
Vancouver, Washington 98686

RE: Certificate of Need Application #18-27

Dear Mr. Helgerson:

We have completed review of the Certificate of Need application submitted by Legacy Health proposing to establish an adult elective percutaneous coronary intervention (PCI) program at Salmon Creek Medical Center in Vancouver. Enclosed is a written evaluation of the application.

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

Washington Administrative Code 246-310-210	Need
Washington Administrative Code 246-310-220	Financial Feasibility
Washington Administrative Code 246-310-230	Structure and Process of Care
Washington Administrative Code 246-310-240	Cost Containment

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

Appeal Option 1:

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

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

Bryce Helgerson, President
Legacy Salmon Creek Medical Center
Certificate of Need Application #18-27
March 19, 2019
Page 2 of 2

Appeal Option 2:

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

Mailing Address:

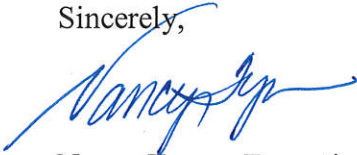
Department of Health
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

Physical Address

Department of Health
Adjudicative Service Unit
111 Israel Road SE
Tumwater, WA 98501

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

Sincerely,



Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure

EVALUATION DATED MARCH 19, 2019, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY LEGACY HEALTH PROPOSING TO ESTABLISH AN ADULT, ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT SALMON CREEK MEDICAL CENTER IN VANCOUVER, WITHIN CLARK COUNTY

APPLICANT DESCRIPTION

Legacy Health is a nonprofit organization based in Portland, Oregon that provides healthcare services to the residents of Oregon and southwest Washington through its hospitals and other healthcare facilities. Legacy Health currently operates six hospitals in the state of Oregon and one hospital in Washington State. [source: Legacy Health website] Below is a listing of the seven Legacy Health hospitals. [source: May 14, 2018, screening response, Attachment 1]

Hospital	City	State
Legacy Emanuel Medical Center	Portland	Oregon
Legacy Good Samaritan Medical Center	Portland	Oregon
Legacy Meridian Park Medical Center	Tualatin	Oregon
Legacy Mount Hood Medical Center	Gresham	Oregon
Randall Children’s Hospital at Legacy Emanuel	Portland	Oregon
Legacy Silverton Medical Center	Silverton	Oregon
Salmon Creek Medical Center	Vancouver	Washington

PROJECT DESCRIPTION

This project focuses on Salmon Creek Medical Center (SCMC) located in Vancouver. The hospital has held a Washington State hospital license since January 1, 2015 and provides a variety of healthcare services to the residents of Clark County and surrounding communities. As of the writing of this evaluation, SCMC is licensed for a total of 220 acute care beds and is located at 2211 Northeast 139th Street in Vancouver [98686]. Table 1 below shows the 220 beds broken down by service. [source: DOH hospital licensing files]

**Department’s Table 1
Salmon Creek Medical Center
Current Configuration of Licensed Acute Care Beds**

Services Provided	Total Beds
General Medical Surgical	198
Intermediate Care Nursery - Level II	7
Neonatal Intensive Care Nursery – Level III	15
Total	220

As of the writing of this evaluation, SCMC provides a variety of general medical surgical services, including intensive care, emergency services, and cardiac care. The hospital is currently a Medicare and Medicaid provider and holds a three-year accreditation from the Joint Commission¹. [source: DOH hospital licensing files]

¹ The Joint Commission accredits and certifies more than 20,000 health care organizations and programs in the United States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards. [source: Joint Commission website]

Legacy Health submitted this application proposing to establish an adult, elective percutaneous coronary intervention (PCI) program within space at SCMC. The project would increase the types of services provided at SCMC, but does not propose to increase the total number of acute care beds. [source: Application, p9]

Legacy Health states there is no capital expenditure associated with the addition of a PCI program and provided the following information to support this position. [source: May 14, 2018, screening response, p2] *“The catheterization labs are currently in place and perform a wide range of cardiac and peripheral procedures, including Peripheral Vascular Interventions (PVI). These procedures involve a similar technique and equipment to that needed to perform PCI.”*

Though SCMC has two operational cardiac cath labs, the hospital does not provide emergent PCI procedures and provided the following rationale for this approach in the planning area. [source: May 14, 2018, screening response, pp2-3]

“Legacy Salmon Creek has been extremely interested in establishing a comprehensive PCI program (elective and emergency) since at least 2008. As noted in this current CN application, we elected not to file in 2008 (or oppose) the application of PeaceHealth St. John (St. John) because the rules clearly gave preferential treatment to the provider located furthest away from the existing program (WAC 246-310-750). St. John’s CN was approved in 2009. In 2010, we began evaluating an emergency only program, but our emergency room was becoming increasingly busy (see Table 3) and the ability to divert emergency patients was deemed preferential to having them delivered to an emergency room that was operating above capacity.”

If approved, Legacy Health states that the adult, elective PCI program would be available in April 2020. Since there is no construction or capital costs associated with the program, the department asked Legacy Health to clarify why the PCI program could not become operational before April 2020. Legacy Health provided the following explanation for its implementation timeline. [source: May 14, 2018, screening response, p2]

“The response to question # 7 details that the current issue at Legacy Salmon Creek is a lack of capacity resulting from high volumes in the ED. Legacy Salmon Creeks’ emergency department sees nearly 75,000 patients annually, operating in excess of 150% capacity on the current 32 beds (assumes 1,600 visits per room, per year). While Legacy has put into place numerous procedures and protocols to assure patients are treated and triaged rapidly despite capacity constraints, the completion of the Emergency Department expansion provides the capacity needed to address emergency and elective PCI volumes.”

APPLICABILITY OF CERTIFICATE OF NEED LAW

Legacy Health’s application is subject to review as the establishment of a new tertiary service not previously provided by the hospital under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d).

EVALUATION CRITERIA

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

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

- (a) *In the use of criteria for making the required determinations, the department shall consider:*
- (i) *The consistency of the proposed project with service or facility standards contained in this chapter;*
 - (ii) *In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
 - (iii) *The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.”*

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

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

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

To obtain Certificate of Need approval, the applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment). Where applicable, the applicant must demonstrate compliance with the above general criteria by meeting the Adult Elective Percutaneous Coronary Interventions (PCI) Without On-Site Cardiac Surgery Standards and Forecasting Methodology outlined in WAC 246-310-700 through 755.

TYPE OF REVIEW

As directed under WAC 246-310-710, the department accepted this project under the year 2018 adult, elective PCI Concurrent Review Cycle. The purpose of the concurrent review process is to comparatively analyze and evaluate competing or similar projects to determine which of the projects may best meet the identified need. For PCI projects, concurrent review allows the department to review PCI applications proposing the serve the same PCI planning area [as defined in WAC 246-310-705(5)] simultaneously to reach a decision that serves the best interests of the planning area’s residents.

SCMC is located in planning area #5 as defined in WAC 246-310-705(5). The planning area includes the counties of Clark, Cowlitz, Skamania, and Wahkiakum. It also includes the following specific ZIP codes in west Klickitat County: 98650, 98619, 98672, 98602, 98628, 98635, 98617, and 98613.

During the year 2018 PCI concurrent review, no other application was submitted proposing to establish a PCI program in this planning area. As a result, the department reviewed this project under a regular review schedule as allowed under WAC 246-310-710(3). The review timeline is summarized on the following page.

APPLICATION CHRONOLOGY

Action	Legacy Health
Letter of Intent Submitted	January 31, 2018
Application Submitted	February 28, 2018
Department's pre-review activities <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant's Responses Received • DOH 2nd Screening Letter • Applicant's Responses Received 	<p>March 30, 2018</p> <p>May 14, 2018</p> <p>May 31, 2018</p> <p>July 16, 2018</p>
Beginning of Review	July 23, 2018
End of Public Comment/No Public Hearing Conducted <ul style="list-style-type: none"> • Public comments accepted through end of public comment 	August 27, 2018
Rebuttal Comments Received ²	September 11, 2018
Department's Anticipated Decision Date	October 26, 2018
Department's Anticipated Decision Date with 150-day Extension	March 25, 2019
Department's Actual Decision Date	March 19, 2019

AFFECTED PERSONS

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

“...an “interested person” who:

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

WAC 246-310-010(2) requires an affected person to first meet the definition of an ‘interested person.’

WAC 246-310-010(34) defines “interested person” as:

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

During the review of this project, two entities sought interested person status, and of those, one sought affected person status. A brief description of each entity is below.

Providence Health & Services Washington

Providence Health & Services Washington submitted a request for interested and affected person status for this application. In Washington State, Providence Health & Services operates a variety of healthcare

² Two letters of support and no letters of opposition were submitted during the review of this project. As a result, Legacy Health did not provide rebuttal comments.

facilities. Providence Health & Services does not operate any healthcare facilities in PCI planning area #5, but does operate St. Peter Hospital in Lacey, within Thurston County. While Providence St. Peter Hospital may provide healthcare services to residents Clark County, this does not meet the interested person criteria outlined in WAC 246-310-010(34) above. Further, Providence Health & Services did not provide public comment on this project. As a result, neither Providence Health & Services nor Providence St. Peter Hospital qualifies as an interested person and cannot qualify as an affected person for this project.

SEIU 1199NW

A representative from SEIU (Services Employees International Union) 1199NW requested interested person status. SEIU 1199NW is a statewide union of nurses and healthcare workers. According to its website, SEIU 1199NW represents more than 30,000 nurses and healthcare workers across Washington State. [source: SEIU 1199NW website] Though SEIU 1199NW may represent employees at Salmon Creek Medical Center in Vancouver, it is not located within the applicant's health service area. SEIU 1199NW meets the definition of an 'interested person,' but does not qualify as an "affected person." As an interested person, SEIU 1199NW could provide public comments on the application. Since SEIU 1199NW does not meet the definition of an affected person, it could not provide rebuttal comments. SEIU 1199NW did not submit either public comments or rebuttal comments for this project.

SOURCE INFORMATION REVIEWED

- Legacy Health's Certificate of Need application received February 28, 2018
- Legacy Health's first screening responses received May 14, 2018
- Legacy Health's second screening responses received July 16, 2018
- Public comments received by the end of public comment on August 27, 2018
- Department of Health's Hospital and Patient Data Systems' Comprehensive Hospital Abstract Reporting System data for year 2016
- Department of Health PCI outpatient survey responses for 2016
- Office of Financial Management population estimates release August 2017
- Hospital/Finance and Charity Care (HFCC) Financial Review dated March 5, 2015
- Department of Health Integrated Licensing and Regulatory System database [ILRS]
- Compliance history for Salmon Creek Medical Center Health obtained from the Washington State Department of Health – Office of Health Systems and Oversight
- DOH Provider Credential Search website: <http://www.doh.wa.gov/pcs>
- Legacy Health's and Salmon Creek Medical Center's websites at www.legacyhealth.org
- Joint Commission website at www.qualitycheck.org
- COAP (Clinical Outcomes Assessment Program) website at www.coap.org
- Certificate of Need historical files

CONCLUSIONS

For the reasons stated in this evaluation, the application submitted by Legacy Health proposing to establish an adult, elective percutaneous coronary intervention program at Salmon Creek Medical Center is not consistent with applicable review criteria of the Certificate of Need Program and a Certificate of Need is denied.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210) Need Forecasting Methodology (WAC 246-310-745), and Standards (WAC 246-310-715(1), (2))

Based on the source information reviewed, the department determines that Legacy Health does not meet the applicable need criteria in WAC 246-310-210.

(1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

WAC 246-310-700 requires the department to evaluate all adult elective PCI applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The adult, elective PCI specific numeric methodology applied is detailed under WAC 246-310-745. WAC 246-310-210(1) criteria is also identified in WAC 246-310-715(1), and (2).

PCI Methodology WAC 246-310-745

The determination of numeric need for adult, elective PCI programs is performed using the methodology contained in WAC 246-310-745(10). The method is a five-step process of information gathering and mathematical computation. The first step examines historical PCI use rates at the planning area level to determine a base year PCI use rate per 1,000 population. The remaining four steps apply that PCI use rate to future populations in the planning area. The numeric net need for additional PCI programs is the result of subtracting current capacity from projected need. The completed methodology is Appendix A attached to this evaluation.

For PCI programs, Washington State is divided into 14 separate planning areas.³ SCMC is located in Vancouver, within Clark County, identified as PCI planning area #5. The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation is limited to Planning Area #5.

Legacy Health

Legacy Health applied the five-step numeric need methodology for the PCI planning area #5. The numeric methodology outlined in WAC 246-310-745(10) is restated below along with Legacy Health's information as it applied the numeric methodology. [source: Application, pp13-15]

Step 1: Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient PCI case counts.

- (a) *Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.*
- (b) *Divide the total number of PCIs performed on the planning area residents over fifteen years of age⁴ by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.*

³ WAC 246-310-705.

⁴ Residents 15 years of age and older.

Applicant's Table

Step 1: Planning Area PCI Use Rate
Base Year = 2016

Population Age 15+ (1a)	Divide by 1,000	Resident Inpatient PCI (CHARS)	Resident Inpatient PCI (Oregon)	Resident Observation PCI CHARS	Resident Outpatient PCI²	Total PCIs	Use Rate (1b)
477,319	477.3	482	205	2	371	1,060	2.22

Source: Population, Claritas; Inpatient, CHARS database, Outpatient, CHARS observation database, Oregon and PCI survey. PeaceHealth Southwest Medical Center did not complete a 2016 survey, Therefore, Legacy Salmon Creek estimated outpatient volume for PeaceHealth Southwest at 37.2% which is the statewide average. In addition, Legacy Salmon Creek assumed that 100% of the outpatient cases for PeaceHealth Southwest were from PCI planning area 5 (this is consistent with the latest PeaceHealth survey).

- Step 2:** *Forecasting the demand for PCIs to be performed on the residents of the planning area.*
- (a) *Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.⁵*

Applicant's Table

Step 2: Planning Area Forecasted PCI
Forecast Year = 2021

Use Rate from Step 1	Population Age 15+	Divide by 1,000	Projected Demand (2a)
2.22	523,513	523.5	1,163

Source: Population, Claritas; Rate derived from Claritas, CHARS database and PCI survey.

- Step 3:** *Compute the planning area's current capacity.*
- (a) *Identify all inpatient procedures at CON approved hospitals within the planning area using CHARS data;*
- (b) *Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data; or*
- (c) *Calculate the difference between total PCI procedures by CON approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.*
- (d) *Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.*

⁵ Residents 15 years of age and older.

Applicant's Table

Step 3: Current PCI Capacity (3d) all providers in Planning Area 5

Provider	Current Capacity
PeaceHealth Southwest Medical Center ³	672
PeaceHealth St. John	185
	858

Source: WA State CHARS Database and Department Outpatient PCI Surveys.

Step 4: Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than three hundred, the department will not approve a new program.

Applicant's Table

Step 4: Planning Area Net Need for PCI Procedures

Projected Demand (Step 2)	Current Capacity (Step 3)	Projected Net Need
1,163	858	305

Source: Rate derived from Claritas, CHARS database, and PCI survey.

Step 5: If Step 4 is greater than three hundred, calculate the need for additional programs.
 (a) *Divide the number of projected procedures from Step 4 by three hundred.*
 (b) *Round the results down to identify the number of needed programs. (For example: $575/300 = 1.916$ or 1 program.)*

Applicant's Table

Step 5: Planning Area Need for Additional PCI Program

Projected Need/300 (5a)	# of New Programs (5b)
301	1.00

Source: Rate derived from Claritas, CHARS database and PCI survey.

WAC 246-310-720 provides the following guidance for minimum volume standards for hospitals with an elective PCI program. It states:

- “(1) Hospitals with an elective PCI program must perform a minimum of three hundred adult PCIs per year by the end of the third year of operation and each year thereafter.*
- (2) The department shall only grant a certificate of need to new programs within the identified planning area if:*
 - (a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and*
 - (b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.”*

The table included in Step 3 of Legacy Health’s numeric methodology identifies the current capacity of the planning area and shows PeaceHealth St. John Medical Center performed 185 PCIs in year

2016. For this reason, during the review of this project, the department asked questions about Legacy Health’s approach to the numeric methodology. Below is a restatement of the exchange between the department and Legacy Health. [source: Certificate of Need Program March 30, 2018, screening and Legacy Health’s May 14, 2018, screening response, pp6-8]

Certificate of Need Program Question #13

Step 3 of the numeric methodology identifies 185 PCIs for PeaceHealth St. John Medical Center, which is below the 300 threshold. Provide a detailed discussion of why PeaceHealth St. John Medical Center should not be considered available and accessible to the residents of the PCI planning area.

Legacy Health Screening Response

“When the CN Program adopted its elective PCI rules in 2008, and despite comment from Legacy Salmon Creek about the illogicality of the Service Area, Clark County was co-located in a Planning Area with Cowlitz, Skamania and Western Klickitat. At the time of rule adoption, Southwest Washington Medical Center (SWMC) was the only PCI program located in the Planning Area. The rules identified need for one additional provider and gave explicit priority to the location furthest away from the existing provider. St. John applied, and was approved and started a PCI program in 2009. Legacy did not oppose PeaceHealth’s application for PCI, even though it precluded us from applying for Legacy Salmon Creek because we understood the benefit of hospitals like St. John performing these procedures locally.

Since the time that PeaceHealth St. Johns has had their CON approval, they have not met the minimum volume threshold of 300 cases. In fact, as depicted in CHARS and Survey data provided in Table 6, it has never attained 200 cases annually, and it is operating out of compliance.

Applicant’s Table

**Table 6
PeaceHealth St. John Medical Center
PCI Volume Over Time**

	2010	2011	2012	2013	2014	2015	2016
Inpatient	28	51	58	99	99	95	88
Outpatient	40	55	102	NR	NR	NR	96
Total	68	106	160	99	99	95	184

Source: WA State CHARS database and DOH Outpatient PCI Surveys

In addition, we understand that St. John has in the past and does not currently meet the General Requirements of WAC 246-310-715 which states in section (5) “Be Prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to scheduled PCIs.” The lack of staffing and availability has resulted in cases that are either sent to Oregon by Air Ambulance or transferred to the closest ED or PCI enabled facility.

St. John is a sole community provider, providing safety net services for residents of Cowlitz County. Having an elective PCI Program is likely a benefit for residents of Cowlitz County, and Legacy Salmon Creek is not opposed to it retaining its CN approval. However, WAC 246-310-755 states:

WAC 246-310-755 Ongoing compliance with standards.

If the department issues a certificate of need (CON), it will be conditioned to require ongoing compliance with the CON standards. Failure to meet the standards may be grounds for revocation or suspension of a hospital's CON, or other appropriate licensing or certification actions.

(1) Hospitals granted a certificate of need must meet:

(a) The program procedure volume standards within three years from the date of initiating the program; and

(b) QA standards in WAC 246-310-740.

(2) The department may reevaluate these standards every three years.

Related to quality, WAC states:

WAC 246-310-740 Quality Assurance

The applicant hospital must submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application. At minimum, the plan must include:

(1) A process for ongoing review of the outcomes of adult elective PCIs. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.

(2) A system for patient selection that results in outcomes that are equal to or better than the benchmark standards in the applicant's plan.

(3) A process for formalized case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases.

(4) A description of the hospital's cardiac catheterization laboratory and elective PCI quality assurance reporting processes for information requested by the department or the department's designee. The department of health does not intend to require duplicative reporting of information

More importantly, CHARS data along with the Department's outpatient survey data demonstrates beyond any doubt that residents of Clark County do not seek PCI services in Cowlitz County. Table 7 identifies Clark County resident's location for PCI over the course of 2012 to 2016; less than 1% have availed themselves of the Program in Cowlitz, and in fact 34% of Cowlitz residents choose to have a PCI in a County other than Cowlitz.

Applicant's Table

Table 7

Clark County Residents, Location of PCI Procedures 2012-2017

Year	PeaceHealth St. John, Cowlitz	PeaceHealth Southwest, Clark County	Other WA	Oregon ³	Total Clark County Residents
2012	1	471	16	107	595
2013	0	411	8	101	520
2014	0	384	22	112	519
2015	1	314	11	113	439
2016	1	430	8	150	589

Source: WA State CHARS Database for Inpatient Procedures and OR Hospital Association for Inpatient procedures, DOH PCI Outpatient Survey Data for 2012-2017, no DOH survey in 2016 (2015 data), no PeaceHealth St. John outpatient survey 2014 or 2015. 2016 outpatient data includes Legacy Good Sam and Legacy Emanuel data

In the end, the Cowlitz community needs access, and St. John provides that access. We do not seek to have its CN revoked, unless the continued existence of a low volume program prohibits Legacy from addressing the needs of Clark County residents.”

Public Comments

During the review of this project, the department received two letters of support and no letters of opposition. Both letters of support focus on this sub-criterion. Below are the letters of support.

Andrew Shepard, MD, FACEP Medical Director, SCMC Emergency Department

“I am writing this letter in support of the Certificate of Need application submitted by Legacy Salmon Creek Medical Center (Legacy Salmon Creek) to establish an elective PCI program. I serve as the Medical Director of the Legacy Emergency Department (ED) and have practiced Emergency Medicine for more than 16 years. I am board certified and a member of the Faculty of the American College of Emergency Physicians. I also serve as an oral board examiner for the American Board of Emergency Physicians.

The Legacy Salmon Creek ED serves more than 75,000 patients annually, making it one of the busiest in the State. Last year, Legacy Salmon Creek transferred almost 400 patients annually from our ED to existing PCI programs, primarily to PeaceHealth Southwest Medical Center. The nearly 400 transferred cases are a conservative representation of the number of PCI procedures given it does not take into consideration emergency vehicles that bypassed Legacy Salmon Creek because we do not have a PCI program. The impact on the patient and the family cannot be overstated: the time delays, transports and additional costs add stress to an already major event for most families. The additional transport time for EMS is also a real factor.

I understand that the Department of Health has a methodology for determining when an additional provider should be added in a Planning Area. I further understand that the methodology has identified a net need for more than 300 additional PCI's in our region. Legacy Salmon Creek is well-equipped to address this unmet need.

The hospital already operates two state of the art catheterization labs, has a highly skilled staff and is supported by Legacy Medical Group cardiologists experienced in performing elective and emergent PCI. Legacy Salmon Creek also enjoys close access to, and the support and expertise of, our sister hospitals in Oregon that perform PCI-both with and without open heart surgery capability. Importantly, Legacy Salmon Creek is in the process of a significant expansion of our ED. This expansion will assure that we can rapidly accept cardiac patients and get them to revascularization with door to balloon time that will meet or exceed best practices.

I have no question that Legacy Salmon Creek will be able to meet the required volume of PCIs and all other quality standards required by Washington State WAC. Just in the patients that we currently transfer from our ED, we will exceed the required volumes. These patients will also be much better served and be put at less risk by being able to be treated faster locally and avoiding transfer.

With the only other program serving Clark County operating at or near capacity, and patients are increasingly waiting and/or being transferred (after a wait) to Oregon, Legacy Salmon Creek submits this application now because the volume of transfers is simply not in the best interest of patient quality, outcomes and costs.”

Amish Desai, MD Medical Director, Cardiovascular Services Legacy Health

“As a board-certified interventional cardiologist practicing in the Legacy Medical Group, I fully support the Legacy Salmon Creek Medical Center Certificate of Need application, for the establishment of an elective percutaneous coronary intervention (PCI) program. Growing patient volumes and an aging population are highlighting a progressive unmet need for additional PCI services in Clark County. Legacy Salmon Creek can combine state of the art facilities and provider expertise to provide a PCI program focused on delivering focused population care and excellent clinical outcomes.

Legacy Medical Group cardiologists currently perform PCI in the catheterization labs at Legacy Emanuel, Legacy Good Samaritan and Legacy Meridian Park hospitals. In 2010, Legacy Salmon Creek Medical Center investigated the creation of an emergency PCI program, however, due to the already high patient volumes in their Emergency Department, the decision was made to divert these patients to other facilities that offer PCI.

Today, Legacy Salmon Creek Medical Center is transferring more than 400 patients annually for PCI, most frequently to PeaceHealth Southwest, which, itself, is increasingly operating at capacity. As a result, many patients have to be transferred twice, from Legacy Salmon Creek to PeaceHealth Southwest, and to Portland from PeaceHealth Southwest.

These transfers delay initiation of definitive therapy, which may pose an increased risk to the patient. After a cardiac diagnosis is made and the need for a diagnostic and invasive therapeutic procedure determined, having to transfer the patient to an outside facility is not in their best interest. This is especially true when the cardiologist making the diagnosis is trained and fully capable of performing PCI. As the Department of Health's own methodology has identified the need for an additional PCI provider in Clark County, the combined analytics, demographic changes and population growth all reinforce the creation of a PCI program at Legacy Salmon Creek. In sum, I appreciate the opportunity to provide public comment on this extremely important issue and urge the Department to approve this initiative.”

Rebuttal Comments

None

Department Evaluation

For this project, the department calculated the PCI methodology using two different data sets. One set uses CHARS data for inpatient PCIs and survey responses for outpatient PCIs. The other set uses COAP data⁶, which is reported by each Washington State hospital and identifies the total number of PCIs performed, but does not distinguish between inpatient and outpatient procedures. The numeric methodology uses the total number of PCIs in all of its calculations; therefore a separation of inpatient and outpatient PCIs is unnecessary.

⁶ COAP is an acronym for Clinical Outcomes Assessment Program, a regional quality collaborative that leverages medical and clinical, administrative, and financial data to establish and drive best practices in cardiac care. One purpose is to support all hospitals and clinicians in achieving the highest levels of patient care and outcomes. COAP operates under the auspices of the Foundation for Health Care Quality (FHCQ), a nationally recognized not-for-profit 501(c)3 corporation which is the sponsor for, and home of, a number of programs addressing patient safety, variability, outcomes and quality in various medical and surgical services. All hospitals in Washington State that provide adult cardiac surgery and/or percutaneous coronary interventions (PCI) participate in COAP, producing a rigorous database that allows the State to identify areas for quality improvement and collaborate on improvement efforts.

This portion of the evaluation will describe, in summary, the calculations the department made at each step of the methodology and the assumptions and adjustments, if any, made in that process. This section will also include a discussion of any differences between the applicant’s and the department’s numeric methodologies. For the department’s methodology, the discussion below will address the results of each data set used. The methodology using both CHARS and survey response will be referenced as #1; the COAP methodology will be referenced as #2.

The titles for each step are excerpted from WAC 246-310-745.

Step 1: Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient PCI case counts.

- (a) Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.*
- (b) Divide the total number of PCIs performed on the planning area residents over fifteen years of age⁷ by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.*

Specific sections of WAC 246-310-745 defines specific terms used in the methodology. Base year is defined in WAC 246-310-750 as the most recent calendar year for which December 31 data is available as of the first day of the application submission period for the department’s CHARS reports or successor reports. Since this application was submitted on February 28, 2018, year 2017 data was not yet available. For this project, base year is 2016.

Using the base year of 2016, the department calculated the use rate as described above. The table below compares the use rates calculated by both the department and Legacy Health.

Department’s Step One Table

	Department Methodology #1	Department Methodology #2	Legacy Health Methodology
Year 2016 Population 15+	479,469	479,469	477,319
Divide by 1,000	479.47	479.47	477.3
Year 2016 PCIs	731	468	1,060
Use Rate Calculated	1.52	0.98	2.22

As shown in the Step One Table above, the 2016 population of residents 15 years and older is similar in all three methodologies. The significant difference in the table is the year 2016 PCIs, which when divided by the population results in a use rate. Since the calculated use rate is multiplied by the projected population step two below, any differences in the use rate are carried throughout the methodology.

Step 2: Forecasting the demand for PCIs to be performed on the residents of the planning area.

- (a) Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.⁸*

⁷ Residents 15 years of age and older.

⁸ Residents 15 years of age and older.

In this step, the forecast year is defined as the fifth year after the base year. For this project, the forecast year is 2021. The table below is a summary of step two.

Department’s Step Two Table

	Department Methodology #1	Department Methodology #2	Legacy Health Methodology
Forecast Year Population	525,704	525,704	523,513
Divide by 1,000	525.70	525.70	523.5
Use Rate (calculated from step 1)	1.52	0.98	2.22
Projected Demand for Planning Area Residents	801	513	1,163

As shown in the Step Two Table above, the forecast year populations are not significantly different in the methodologies. However, once the use rate calculated from step 1 is applied, the resulting ‘projected demand’ is significantly different.

Step 3: Compute the planning area's current capacity.

- (a) Identify all inpatient procedures at CON approved hospitals within the planning area using CHARS data;*
- (b) Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data; or*
- (c) Calculate the difference between total PCI procedures by CON approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.*
- (d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.*

In this step, "current capacity" is defined as “*the sum of all PCIs performed on people (aged fifteen years of age and older) by all certificate of need approved adult elective PCI programs, or department grandfathered programs within the planning area. To determine the current capacity for those planning areas where a new program has operated less than three years, the department will measure the volume of that hospital as the greater of:*

- (a) The actual volume; or*
- (b) The minimum volume standard for an elective PCI program established in WAC [246-310-720](#).”*

As defined above, the current capacity of planning area #5 the total number of PCIs performed in Southwest Washington Medical Center located in Clark County and St. John Medical Center located in Cowlitz County. The table below shows a comparison of the current capacity.

Department’s Step Three Tables

Southwest Washington Medical Center in Clark County

Inpatient PCIs (CHARS)	Outpatient PCIs (Survey)	Total	Combined Inpatient & Outpatient (COAP)
422	112	534	607

St. John Medical Center in Cowlitz County

Inpatient PCIs (CHARS)	Outpatient PCIs (Survey)	Total	Combined Inpatient & Outpatient (COAP)
88	96	184	196

The number of PCIs performed by the two hospitals are added together and the sum represents the current capacity in the planning area as defined in the numeric methodology. The calculations are shown in the table below.

Department’s Planning Area #5 Capacity

Inpatient PCIs (CHARS)	Outpatient PCIs (Survey)	Total	Combined Inpatient & Outpatient (COAP)
510	208	718	803

Applicant’s Calculated Current Capacity

Provider	Current Capacity
Southwest Washington Medical Center	672
St. John Medical Center	195
Current Capacity of Planning Area #5	858

As shown in step three above, the applicant’s calculated current capacity of 858 is higher than the department’s methodology #1 of 718 or methodology #2 of 803. A closer look at the breakdown in PCIs by hospital reveals the differences are in the number of PCIs performed by Southwest Washington Medical Center located in Clark County. Without more detailed information about the source data used by the applicant, the department is unable to explain the applicant’s current capacity for Southwest Washington Medical Center.

Step 4: Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than three hundred, the department will not approve a new program.

Step 5: If Step 4 is greater than three hundred, calculate the need for additional programs.
(a) Divide the number of projected procedures from Step 4 by three hundred.
(b) Round the results down to identify the number of needed programs. (For example: 575/300 = 1.916 or 1 program.)

For Steps 4 and 5, the department will show the calculations and the results in one table.

Department’s Step Four and Step Five Table

	Step	Department Methodology #1	Department Methodology #2	Legacy Health Methodology
Step 2-Forecasted Demand	4	801	513	1,163
Step 3-Current Capacity	4	718	803	858
Net Need in Planning Area	4	83	-290	305
Divide Net Need by 300	5	0.28	0	1.05
Round Down	5	0	0	1

Step 5 shown in the table above shows the department projects no need for an additional PCI program during this 2018 concurrent review cycle using a base year of 2016 and projecting to year 2021. In contrast, the applicant’s methodology project’s need for one new PCI program.

When each step in the numeric methodology is broken down, the significant differences are shown in the use rate and the number of PCIs performed by hospitals in the planning area, which is the current capacity.

As acknowledged by the applicant, WAC 246-310-720(2) provides the following guidance for the addition of a new PCI program in a planning area. It states:

- (2) *The department shall only grant a certificate of need to new programs within the identified planning area if:*
 - (a) *The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and*
 - (b) *All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.”*

The numeric methodology does not calculate need for an additional PCI program in planning area #5 for the 2018 review cycle. Further, both the department and the applicant show St. John Medical Center located in Cowlitz County operating well below the minimum volume standard of 300. For these reasons, the department concludes that the numeric methodology does not demonstrate need for an additional PCI program in planning area #5. **This sub-criterion is not met.**

Further criteria are subject to review under this section of the evaluation. According to General Requirements in WAC 246-310-715, the applicant hospital must submit a detailed analysis regarding the effect that an additional PCI program will have on the University of Washington (UWMC) program and how the hospital intends to meet the minimum number of procedures. The criteria and applicant’s responses are addressed below.

WAC 246-310-715(1) Submit a detailed analysis of the impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington, and allow the university an opportunity to respond. New programs may not reduce current volumes at the University of Washington fellowship training program.

Legacy Health

“Approval of the Legacy Salmon Creek’s program will not reduce the volume at the University of Washington Medical Center UWMC. In 2016, UWMC performed a total of 10 PCIs on residents of PCI Planning Area 5, equating to a 1.6% share of the all PCIs from the area. The patient origin of UWMC’s Planning Area 5 patients is shown in Table 12.

Applicant's Table

Table 12

UWMC PCIs Performed on Planning Area 5 Residents

Zip	City	County Name	Inpatient	Outpatients	Observation	Total
98604	Battle Ground	Clark		1	0	1
98626	Kelso	Cowlitz	1	2	0	3
98642	Ridgefield	Clark		1	0	1
98664	Vancouver	Clark		1	0	1
98671	Washougal	Clark		1	0	1
98683	Vancouver	Clark		1	0	1
98632	Longview	Cowlitz	2		0	2
Total			3	7	0	10

Source: CHARS Age 15+, MS-DRGs 250, 251, 248, 249, 246, 247. WA Department of Health survey of PCI hospitals 2016 data, also includes observation data.

We have verified with our cardiologists that they did not refer any patients to UWMC for PCI in 2016 or 2017. As such, UWMC's volumes from our service area will not be impacted, and we do not expect any reduction in cases performed at UWMC based on the commencement of elective services at Legacy Salmon Creek.

Nonetheless, because Legacy fully recognizes the valuable resource that an academic tertiary center provides to Washington State and its essential role in the training of new cardiologists, we pledge to support the UWMC. A letter to the University of Washington Medical Center documenting this data and supporting the UWMC program is included in Exhibit 1." [source: Application, p19]

The letter referenced in Exhibit 1 above is dated February 27, 2018, and addressed to the director of the Regional Heart Center at University of Washington Medical Center. The letter provides a summary of the PCI project submitted and includes the projected number of PCIs proposed to be performed at SCMC. The letter also acknowledges that ten PCI patients from planning area #5 were referred to University of Washington Medical Center in calendar year 2016, but none of the ten patient referrals were from Legacy Health cardiologists. The letter concludes that approval of SCMC's PCI application would not reduce the number of patients in planning area #5 that may choose to obtain PCI services from the University of Washington Medical Center. The letter includes contact information in case further discussion is necessary.

Within the application, Legacy Health states that the "*University of Washington has not responded to the letter.*" [source: May 14, 2018, screening response, p12]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

University of Washington Medical Center did not provide comments specific to this application. Information provided in the application states that no patients were referred to University of Washington Medical Center from physicians at SCMC.

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

WAC 246-310-715(2) submit a detailed analysis of the projected volume of adult elective PCIs that it anticipates it will perform in years one, two and three after it begins operations. All new elective PCI programs must comply with the state of Washington annual PCI volume standards (three hundred) by the end of year three. The projected volumes must be sufficient to assure that all physicians working only at the applicant hospital will be able to meet volume standards of seventy-five PCIs per year.

Legacy Health

Legacy Health provided a table showing the projected number of PCIs it expects to perform through the first three years of the proposed program. The table below summarized the information provided by the applicant. [source: Application, p10]

Applicant's Table

Table 7

Year 1	Year 2	Year 3
100	200	305

Source: Applicant.

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Legacy Health clarified in the application that the majority of patients expected to be served by SCMC's PCI program are those Washington State patients currently being referred to Oregon hospitals owned by Legacy Health. This project assumes that a high number of those patients would no longer be referred; instead would obtain PCI services at SCMC. However, Legacy Health did not provide documentation to substantiate the number of patients it referred to Oregon hospitals. As a result, the department cannot substantiate its projected number of PCIs shown in the table above.

In the 'need' section of this evaluation, the department's methodology concluded no need for an additional PCI program in planning area #5. Further one of the providers in the planning area is not performing at the minimum of 300 adult PCIs as required under WAC-310-720(2)(b). For these reasons, the department concludes that **this sub-criterion is not met.**

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

To evaluate this sub-criterion, the department evaluates an applicant's admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services.

The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and 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 age 65 and over. It is also recognized that women live longer than men and therefore more likely to be on Medicare longer.

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

Charity care shows a willingness of a provider to provide services to individuals who do not have private insurance, do not qualify for Medicare, do not qualify for Medicaid, or are underinsured. With the passage of the Affordable Care Act in 2010, the amount of charity care decreased over time. However, with recent federal legislative changes affecting the ACA, it is uncertain whether this trend will continue.

Legacy Health

Legacy Health provided copies of the following policies currently used at all of its hospitals, including SCMC. [source: Application, Exhibit 2]

- Patient Rights and Responsibilities, which includes the Admission Policy, Non-Discrimination Policy, End of Life Policy, and Reproductive Health Policy – updated March 2014
- Financial Assistance (Charity Care Policy) – updated March 2016

The above policies are also posted to the Department of Health website along with the Nurse Staffing Policy – updated December 2018.

SCMC is currently Medicare and Medicaid certified. Legacy Health provided its current source of revenues by payer for SCMC as a whole and for the cardiac catheterization services currently provided at the hospital. Legacy Health stated that the addition of an adult, elective PCI program would not change the payer mix for the hospital or the cardiac catheterization cost center. [source: Application, p10; May 14, 2018, screening response, p5; and July 16, 2018, screening response, pdf5]

Current and projected hospital-wide and cardiac catheterization cost center payer mix is shown below.

**Department’s Table 2
Salmon Creek Medical Center Current and Projected Percentages of Revenue**

Revenue Source	Current and Projected Hospital-Wide	Current and Projected Cardiac Catheterization Cost Center
Medicare	42.2%	55.5%
Medicaid	21.4%	13.0%
Self Pay (no insurance)	1.6%	2.0%
HMO/PPO/Commercial	34.8%	29.5%
Total	100.0%	100.0%

In addition to the policies and payer mix information, Legacy Health provided the following information related to access to healthcare services provided by SCMC. [source: Application, p20]

“Both Legacy Health and Legacy Salmon Creek are committed to providing health care services to all individuals based on need; we prohibit discrimination on the basis of income, race, ethnicity, sex, or handicap.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

SCMC has been providing healthcare services to the residents of Clark County and surrounding areas since it became operational in year 2005. Healthcare services are stated to be available to low-income, racial and ethnic minorities, handicapped and other underserved groups. [source: Application, p20]

The Admission Policy provided in the application is used for all Legacy Health hospitals, including SCMC in Vancouver, Washington. The Admission Policy describes the process SCMC uses to admit a patient and outlines rights and responsibilities for both SCMC and the patient. Included with the Admission Policy is the Patient Rights and Responsibilities Policy. This policy includes the following non-discrimination language.

“Legacy Health recognizes and respects the diversity and individuality of each person admitted to or treated within our facilities. All members of our workforce (employees, volunteers, medical staff, residents, students, contracted personnel and vendors) are expected to provide considerate and respectful care, meeting the cultural, spiritual, emotional, lifestyle and personal dignity needs of each patient and each patient’s family.

You have the right to...Receive care based on medical need, without regard to race, color, creed, religious background, national origin, sexual orientation, gender identity or the nature of the source of payment for care.”

Also within the Patient Rights and Responsibilities Policy, is a section on non-discrimination. This section ensures that all patients, employees, and contractors can expect fair and respected treatment with no discrimination.

SCMC currently provides services to both Medicare and Medicaid patients. Legacy Health does not anticipate any changes in Medicare or Medicaid percentages resulting in approval of this project. SCMC’s current Medicare revenues are approximately 42.2% of total revenues; Medicaid revenues are currently 21.4%; commercial/HMO/self pay, and other revenues are expected to remain at 36.4%. Financial data provided in the application also shows both Medicare and Medicaid revenues.

The Financial Assistance Policy (Charity Care) provided in the application has been reviewed and approved by the Department of Health's Hospital Financial/Charity Care Program (HFCCP). The policy outlines the process one would use to obtain financial assistance or charity care. The policy was approved in March 2016. This is the same policy posted to the department’s website for SCMC.

The pro forma financial documents provided in the application include a charity care 'line item' as a deduction of revenue

Charity Care Percentage Requirement

For charity care reporting purposes, Washington State is divided into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. SCMC is located in Vancouver, within the Southwest Region. Currently there are 14 hospitals operating within the region and all 14 hospitals reported charity care data for years reviewed—years 2015, 2016, and 2017.

Table 3 below compares the three-year historical average of charity care provided by the hospitals currently operating in the Southwest Region and SCMC’s historical charity care percentages for years 2015-2017. The table also compares the projected percentage of charity care. [source: Application, Exhibit3 and HFCCP 2015-2017 charity care summaries]

**Department’s Table 3
Charity Care Percentage Comparisons**

	Percentage of Total Revenue	Percentage of Adjusted Revenue
Southwest Region Historical 3-Year Average	1.03%	3.26%
Salmon Creek Medical Center Historical 3-Year Average	1.90%	5.57%
Salmon Creek Medical Center Projected Average	2.02%	5.56%

As noted in Table 3 above, the three-year historical average shows SCMC has been providing charity care above both the total and adjusted regional averages. For this project, Legacy Health projects that SCMC would continue to provide charity care above the regional average for both total and adjusted revenues.

In past hospital CN applications, the department has been attaching a charity care condition to the approvals, based, in part, on the fluctuation of charity care percentages since the passage of the Affordable Care Act in March 2010. Additionally, the department would typically attach a charity care condition on a hospital project that is proposing a new service, including a tertiary service.

For these reasons, if this project is approved, the department would attach a condition that requires Legacy Health to agree to the following charity care condition for SCMC.

Salmon Creek Medical Center will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent policies reviewed and approved by the Department of Health. Salmon Creek Medical Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Southwest Region. Currently, this amount is 1.03% gross revenue and 3.25% of adjusted revenue. Salmon Creek Medical Center will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires these records to be available upon request.

Based on the information provided in the application and with Legacy Health’s agreement to the condition, the department concludes **this sub-criterion is 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.

Department Evaluation

This sub-criterion is not applicable to this application.

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

Department Evaluation

This sub-criterion is not applicable to this application.

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

Department Evaluation

This sub-criterion is not applicable to this application.

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

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

Department Evaluation

This sub-criterion is not applicable to this application.

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

Department Evaluation

This sub-criterion is not applicable to this application.

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

Department Evaluation

This sub-criterion is not applicable to this application.

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

Based on the source information reviewed, the department determines that Legacy Health does not meet 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.

Legacy Health

Legacy Health provided the following assumptions to project adult, elective PCI volumes, patient mix, and payer mix at SCMC. [source: Application, p21 and May 14, 2018, screening response, pp8-9]

“PCI Project Assumptions:

- 1. Volume: As noted in earlier sections of this application, Legacy Salmon Creek assumed: 100 cases in year 1, 200 cases in year 2, and 305 cases in year 3.*
- 2. Patient mix: Legacy Salmon Creek assumed that the PCI cases would be 50% inpatient, and 50% outpatient.*
- 3. Payor mix: Used the current/actual Legacy Salmon Creek diagnostic catheterization lab payor mix*

Legacy Health currently operates three PCI programs, including programs at Legacy Emanuel Medical Center, Legacy Good Samaritan Medical Center and Legacy Meridian Park Medical Center. From a community, demographic and program scope perspective, the program at Good Samaritan is most comparable to the proposed program at Legacy Salmon Creek and we elected to use actual data from that program (specifically the mix of inpatient to outpatient) for this application.

In terms of volume by year, we are aware of the unmet need (greater than 300), the number of cases being referred to Portland, and the actual experience of our programs in start-up and the volumes of those Washington hospitals that received CN approval in 2009 that are located in larger urban areas (including Evergreen Hospital Medical Center, Valley Medical Center, Good Samaritan Hospital). The experience of each of these hospitals, coupled with the unmet need, resulted in the volumes we identified for the first three years of operation.”

Legacy Health operates SCMC on an April 1 through March 30 fiscal year. Legacy Health’s projections are shown in Tables 4 and 5 below beginning in fiscal year 2021 through fiscal year 2023. [source: Application, p21]

**Department’s Table 4
Salmon Creek Medical Center
Adult, Elective PCI for Years 2020 through 2022**

	FY 2021	FY 2022	FY 2023
Patient Volume	100	200	305
Patient Mix	Inpatient 50% Outpatient 50%		

Department’s Table 5

Adult, Elective PCI Payer Mix

Revenue Source	Current and Projected Cardiac Catheterization Cost Center
Medicare	55.5%
Medicaid	13.0%
Self Pay (no insurance)	2.0%
HMO/PPO/Commercial	29.5%
Total	100.0%

The assumptions Legacy Health used to project revenue, expenses, and net income for SCMC’s adult, elective PCI cost center for fiscal years 2021 through 2023 are below. [source: Application, p21 and May 14, 2018, screening response, p13]

Revenues and Expenses

“Baseline financial data for inpatient PCI from Legacy Good Samaritan was used as baseline, including:

- a. Charges per case*
 - b. Expenses per case*
 - c. Charges, expenses, and reimbursements per case by payor type (Medicare, Medicaid, commercial, etc.) and patient type (inpatient, outpatient)*
- *Reimbursement rate is blended between Legacy Good Samaritan and Legacy Meridian Park in an effort to be more reflective of inpatient/outpatient mix.*
 - *PCI Project Specific Only tab: Current year \$0, since project start date 4/1/2020*
 - *Without project: Current year = FY19 budget (starting 4/1/2018), and assumed flat for 3 years*
 - *With Project: Is the sum of the PCI Project Specific Only + Without Project”*

PCI Cost Center Expense Line Items

- *Purchased Services-other: Repairs and maintenance for equipment and medical devices, contract service*
- *Other Direct Expenses: Travel, training, dues and subscriptions, education, food, printing and equipment rentals*

Hospital Aggregate Line Items

- *Other operating revenue: Cafeteria and coffee bar revenue, gift shop revenue, etc.*
- *Professional fees: Medical Director fees, medical professional physician fees, ED call fees, interpretation fees, consulting fees, legal fees, audit fees, etc.*
- *Management fees: These are only inter-company expenses for administration services (allocations of shared services across hospitals in the system)*
- *Purchased services-other: Repairs and maintenance, contract services*
- *Other direct expenses: Travel, training, recruitment, rent, taxes, events, education, food, equipment rentals, dues and subscriptions, etc.*
- *Non-operating revenue net of expenses: Rental revenue, property taxes, miscellaneous other non-operating expenses (courier, printing, non-op depreciation, etc.)*

Legacy Health also provided its revenue by payer source for the hospital and the PCI cost center, which is included in this evaluation as Table 2 and is restated in the table below.

Revenue Source	Current and Projected Hospital-Wide	Current and Projected Cardiac Catheterization Cost Center
Medicare	42.2%	55.5%
Medicaid	21.4%	13.0%
Self Pay (no insurance)	1.6%	2.0%
HMO/PPO/Commercial	34.8%	29.5%
Total	100.0%	100.0%

Based on the assumptions above, Legacy Health provided the following revenue and expense statement for SCMC’s adult, elective PCI cost center. The statement shows fiscal years 2021 through 2023. [source: Application, Exhibit 3]

**Department’s Table 6
Salmon Creek Medical Center Adult, Elective PCI Cost Center
Projections for Fiscal Years 2021 through 20232**

	FY 2021	FY 2022	FY 2023
Net Revenue	\$2,007,766	\$4,015,532	\$6,126,713
Total Expenses	\$1,089,924	\$2,139,847	\$3,266,395
Net Profit / (Loss)	\$917,842	\$1,875,685	\$2,860,318

Net revenue includes both inpatient and outpatient revenue, minus any deductions for contractual allowances, bad debt, and charity care. Total expenses include all expenses specific to the PCI cost center, such as staffing, supplies, and any purchased services.

In addition to providing the adult, elective PCI cost center revenue and expense statement, Legacy Health also provided a projected revenue and expense statement for SCMC as a whole with the PCI program. The statement below shows fiscal year 2019 (current) and projection years 2021 through 2023. [source: Application, Exhibit 3]

**Department’s Table 7
Salmon Creek Medical Center Hospital with Adult, Elective PCI Service
Projections for Current Year FY 2019 and Fiscal Years 2021 through 20232**

	FY 2019	FY 2021	FY 2022	FY 2023
Net Revenue	\$368,729,276	\$370,737,042	\$372,744,808	\$374,855,989
Total Expenses	\$307,856,105	\$308,946,028	\$309,995,952	\$311,122,500
Net Profit / (Loss)	\$60,873,171	\$61,791,014	\$62,748,856	\$63,733,489

Net revenue includes both inpatient and outpatient revenue for the entire hospital, minus any deductions for contractual allowances, bad debt, and charity care. Total expenses include all expenses for the hospital, including purchased services, professional fees, staff wages and benefits, and management fees (allocations of shared services across hospitals in the Legacy Health system).

Public Comments

None

Rebuttal Comments

None

Department Evaluation

To evaluate this sub-criterion, the department first reviewed the assumptions used by Legacy Health to determine the projected number of patient volumes and patient mix for the PCI program at SCMC. Legacy Health states that it currently operates three PCI programs in Oregon. Community, demographic, and program scope perspective, the program at Good Samaritan in Portland is most comparable to the proposed program at SCMC. For this project, the inpatient / outpatient PCI mix and the PCI payer mix is based on Legacy Good Samaritan's actual mix.

For its projected number of patients by year, Legacy Health relied on its internal knowledge of the number of patients SCMC referred to Legacy's Portland area hospitals for elective and emergent PCI services. Legacy Health also relied on its experience of its existing programs related to start-up and the volumes. Using actual experience is a reliable assumption. Further, Legacy Health relied on the experiences of the following three Washington hospitals that received CN approval in 2009, located in larger urban areas, and are currently operational.

- Evergreen Hospital Medical Center in Kirkland
- Valley Medical Center in Renton
- Good Samaritan Hospital in Puyallup

Based on the above information, the department can substantiate Legacy Health's assumptions and concludes they are reasonable.

For its projected PCI cost center revenue and expenses, Legacy Health also based its projections on Legacy Good Samaritan's actual experience. Since SCMC will continue to be operational during establishment of the PCI program, Legacy Health provided its patient days and discharge projections beginning with fiscal year 2019 and then focused on fiscal years 2021 through 2023 for the PCI program. The projected revenue and expense statement for SCMC shows revenues covering expenses for all years shown. A review of SCMC's fiscal year historical data reported to the Department of Health substantiates that Legacy Health operated SCMC at a profit for fiscal years 2014 through 2016. [source: DOH Hospital and Patient Data Systems' Hospital Census and Charges Report-year 2014, 2015, and 2016]

To assist in the evaluation of this sub-criterion, the Department of Health's Hospital/Finance and Charity Care Program (HFCCP) reviewed the pro forma financial statements submitted by Legacy Health for SCMC. To determine whether Legacy Health would meet its immediate and long range capital costs, HFCCP reviewed fiscal year 2017 balance sheet for both Legacy Health and SCMC. The information shown in Table 8 is for Legacy Health as a whole. [source: HFCCP analysis, p2]

**Department's Table 8
Legacy Health Balance Sheet for Year 2017**

Assets		Liabilities	
Current Assets	\$ 441,027,000	Current Liabilities	\$ 280,833,000
Board Designated Assets	\$ 175,369,000	Other Liabilities	\$ 191,824,000
Property/Plant/Equipment	\$ 836,433,000	Long Term Debt	\$ 589,164,000
Other Assets	\$ 998,076,000	Equity	\$ 1,389,084,000
Total Assets	\$ 2,450,905,000	Total Liabilities and Equity	\$ 2,450,905,000

The information shown in Table 9 is the 2017 historical balance sheet for SCMC alone. [source: HFCCP analysis, p2]

**Department's Table 9
Salmon Creek Medical Center
Balance Sheet for Current Year 2017**

Assets		Liabilities	
Current Assets	\$ 44,892,000	Current Liabilities	\$ 24,891,000
Board Designated Assets	\$ 0	Other Liabilities	\$ 0
Property/Plant/Equipment	\$ 172,470,000	Long Term Debt	\$ 12,536,000
Other Assets	\$ 193,883,000	Equity	\$ 373,818,000
Total Assets	\$ 411,245,000	Total Liabilities and Equity	\$ 411,245,000

For hospital projects, HFCCP provides a financial ratio analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically analyzed are **1)** long-term debt to equity; **2)** current assets to current liabilities; **3)** assets financed by liabilities; **4)** total operating expense to total operating revenue; and **5)** debt service coverage. Historical and projected balance sheet data is used in the analysis. Legacy Health's 2017 balance sheet and SCMC's 2017 balance sheets were both used to review applicable ratios and pro forma financial information.

Table 10 compares statewide data for historical year 2017, Legacy Health's historical data and SCMC's PCI program for projected fiscal years 2021 through 2023. [source: HFCCP analysis, p3]

**Department's Table 10
Current and Projected Debt Ratios
Legacy Health and Salmon Creek Medical Center**

Category	Trend*	State 2017	Legacy Health 2017	SCMC FY2021	SCMC FY2022	SCMC FY2023
Long Term Debt to Equity	B	0.443	0.424	0.024	0.024	0.024
Current Assets/Current Liabilities	A	3.326	1.570	2.299	2.372	2.488
Assets Funded by Liabilities	B	0.372	0.355	0.071	0.071	0.071
Operating Expense/Operating Revenue	B	0.980	0.971	0.831	0.829	0.827
Debt Service Coverage	A	4.753	6.784	N/A	N/A	N/A
Definitions:	Formula					
Long Term Debt to Equity	Long Term Debt/Equity					
Current Assets/Current Liabilities	Current Assets/Current Liabilities					
Assets Funded by Liabilities	Current Liabilities + Long term Debt/Assets					
Operating Expense/Operating Revenue	Operating expenses / operating revenue					
Debt Service Coverage	Net Profit+Depr and Interest Exp/Current Mat. LTD and Interest Exp					

* A is better if above the ratio; and B is better if below the ratio.

After reviewing the financial ratios above, staff from HFCCP provided the following statements. [source: HFCCP analysis, pp2-3]

“All ratios except current assets to current liabilities are in the preferred range. The one ratio out of range is demonstrating an improving trend throughout the projection period. The hospital PCI program and the hospital as a whole are breaking even at the end of the third year and the hospital has the reserves to sustain this project. Review of the financing and ratios show that the immediate and long-range capital needs can be met. The criterion is satisfied.

“I conclude that Legacy has the financial capacity to proceed with this project and that the project is financially feasible if the projected volumes can be met.”

In the ‘need’ section of this evaluation, the department discussed that one of the two providers in the planning area is not performing at the minimum of 300 adult PCIs as required under WAC-310-720(2)(b). Therefore, a new provider in planning area #5 cannot be approved. Further, the numeric methodology outlined in WAC 246-310-745 calculates no need for an additional provider in the planning area. For those reasons, the department concludes that the immediate and long-range operating costs of the project may not be reliable. . **This sub-criterion is not met.**

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

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

Department Evaluation

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

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

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

Department Evaluation

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

C. Structure and Process (Quality) of Care (WAC 246-310-230), General (PCI Program) Requirements (WAC 246-310-715(3), (4), and (5); Physician Volume Standards (WAC 246-310-725; Staffing Requirements (WAC 246-310-730); Partnering Agreements (WAC 246-310-735) and Quality Assurance (WAC 246-310- 740)

Based on the source information reviewed, the department determines that Legacy Health does not meet the applicable cost containment criteria in WAC 246-310-230.

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

For adult, elective PCI projects, specific WAC 246-310-230(1) criteria is identified in WAC 246-310-715(3), (4) and (5); WAC 246-310-725; and WAC 246-310-730 (1) and (2).

WAC 246-310-715(3) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists without negatively affecting existing staffing at PCI programs in the same planning area.

Legacy Health

Legacy Health provided the following information regarding recruitment of staff necessary for the adult, elective PCI program. [source: Application, p26]

“Though Legacy Salmon Creek does not currently provide emergency or elective PCI, we do have the necessary infrastructure in place to perform PCI, with two state of the art catheterization labs and a highly skilled staff. No conversion or renovation is required, and no changes to other hospital support operations are necessary.

Legacy Salmon Creek intends to use interventional cardiologists employed by the Legacy Medical Group to perform emergent and elective PCI. At this time, Amish Desai, MD will be the primary provider of elective PCI and the other cardiologists will refer elective cases to him. Until volumes exceed 200 total cases, other Legacy Medical Group providers will cover the Program 24/7 and will perform emergent only cases. After the Program achieves 200, another fully qualified interventional provider will begin performing elective cases.

Legacy Salmon Creek currently operates its medical cardiology program and diagnostic catheterization program with a highly-qualified, trained, and experienced team of nurses, and catheterization laboratory technicians. These same individuals will staff the elective PCI program.”

It is noted that Legacy Health provided clarification regarding the primary provider of elective PCI at the hospital. In its May 14, 2018, screening response, Legacy Health provided the following statements. [source: May 14, 2018, screening response, p11]

“In the CN application, Dr. Desai was listed as the cardiologist that would perform the elective PCI procedures for Legacy Salmon Creek’s program. The decision has since been made that Dr. Wu will support the elective PCI program. An attestation and supporting documentation of Dr. Wu’s historical volumes is included in Attachment 3.”

SCMC currently provides cardiac catheterization services and is fully staffed to provide the services. The proposed adult, elective PCI services would be operated within the same cost center. Table 11 provides a breakdown of current and projected FTEs [full time equivalents] for the cost center. For this table, current year is fiscal year 2019 and projection years begin with fiscal year 2021. Year three of the projection years is fiscal year 2023. [source: Application, p25]

Department's Table 11
Salmon Creek Medical Center
Current and Proposed FTEs for Cardiac Catheterization Cost Center

FTE by Type	CY 2019 Current	CY 2021 Increase	CY 2022 Increase	CY 2023 Increase	Total FTEs
Technologists FTEs	3.6	0.0	0.5	0.5	4.6
Nursing FTEs	3.6	0.0	1.0	1.0	5.6
Management FTEs	0.5	0.0	0.0	0.0	0.5
Total FTEs	7.7	0.0	1.5	1.5	10.7

In addition to the table above, Legacy Health provided the following statements related to this sub-criterion. [source: Application, p25 and May 14, 2018, screening response, pp10-11]

“There are no other cost centers in which additional staff will be added as a result of this project.

The physicians are not in the FTE table, because they are employees of Legacy Medical Group, not Legacy Salmon Creek. The hospital related expenses associated with these providers are in the professional fee line item, not the salary and benefits line item. As reflected in the organizational chart included in Attachment 1, Legacy Salmon Creek and Legacy Medical Group share the same parent. Qualified Legacy Medical Group providers are privileged to perform cardiac catheterizations at Legacy Salmon Creek.

Legacy Salmon Creek and Legacy Medical Group have the same parent; therefore, an MOU is not required.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

This section of the evaluation focuses on the staffing of the proposed project. SCMC is currently licensed for 220 acute care beds, which includes a 7-bed level II intermediate care nursery and a 15-bed level III neonatal intensive care unit. The addition of adult, elective PCI program does not require the addition of acute care beds, but does requires an increase in staff appropriate to the program.

Legacy Health intends to use the strategies for recruitment and retention of staff it has successfully used in the past. The strategies identified by Legacy Health are consistent with those of other applicants reviewed and approved by the department for general hospital projects and specific adult elective PCI projects.

Information provided in the application demonstrates that Legacy Health is a well-established provider of healthcare services Clark County and surrounding areas. The application demonstrates that Legacy Health has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **This sub-criterion is met.**

WAC 246-310-715(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital

imaging systems, life sustaining apparatus, intra-aortic balloon pump assist device (IABP). The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.

Legacy Health

To demonstrate compliance with this sub-criterion, Legacy Health provided the following information and specific line drawings of the catheterization labs at related to the infrastructure of SCMC. Legacy Health also noted that the current and proposed line drawings are identical because there are no alterations required to implement the proposed project. [source: Application, p9 and May 14, 2018, screening response, p1 and Attachment 2]

“Though Legacy Salmon Creek does not currently provide emergency or elective PCI, we do have the necessary infrastructure in place to perform PCI, including two state of the art catheterization labs and a highly skilled staff. No construction or renovation is required, and no changes to other hospital support operations are necessary.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Documentation provided demonstrates that catheterization laboratory staff and equipment meet the standards outlined in WAC 246-310-730(2). **This sub-criterion is met.**

WAC 246-310-715(5) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.

Legacy Health

Legacy Health provided the following information related to this sub-criterion. [source: Application, p26]

“Legacy Salmon Creek’s PCI program will be staffed to perform emergency PCIs twenty-four hours per day, seven days per week. Legacy Salmon Creek will provide on-site staffing of the cath lab from 7:00 a.m. – 5:00 p.m. Monday through Friday. A call team will cover after hours and on weekends. The on-call staff will be required to be in-house within 30 minutes of call. Table 14 identifies Legacy PCI’s staffing plan detailing the twenty-four-hour coverage.

Applicant’s Table 14
Legacy Salmon Creek Current Cardiac Catheterization Lab Staffing

Hours	Staffing
0700 to 1700 Monday – Friday	4 Registered Nurses 2 Technicians
On-Call 1700-0700 Monday – Friday 24 hours Saturday and Sunday	2 Registered Nurses 2 Technicians

Source: Applicant

In terms of interventional cardiologists, Legacy Salmon Creek will utilize the Legacy Medical Group’s interventional cardiologists to provide 24/7 coverage.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Based on the documentation provided, the department concludes that all identified staff will be available 24/7 and will be appropriately trained as required by the standards. **This sub-criterion is met.**

WAC 246-310-725 Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of seventy-five PCIs per year. Applicant hospitals must provide documentation that physicians performed seventy-five PCI procedures per year for the previous three years prior to the applicant's CON request.

Legacy Health

It is noted that Legacy Health provided clarification regarding the primary provider of elective PCI at the hospital. In its May 14, 2018, screening response, Legacy Health provided the following statements. [source: May 14, 2018, screening response, p11]

“In the CN application, Dr. Desai was listed as the cardiologist that would perform the elective PCI procedures for Legacy Salmon Creek’s program. The decision has since been made that Dr. Wu will support the elective PCI program. An attestation and supporting documentation of Dr. Wu’s historical volumes is included in Attachment 3.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

This standard requires documentation of historical volumes for the physicians that would perform PCI procedures at the applying hospital. Based on the information above and documents provided in the application, the department concludes that **this sub-criterion is met.**

WAC-246-310-730(1) Employ a sufficient number of properly credentialed physicians so that both emergent and elective PCIs can be performed

Legacy Health

Legacy Health provided the following information for this sub-criterion. [source: Application, p29]

“Legacy Salmon Creek will utilize interventional cardiologists employed by Legacy Medical Group to initially staff its PCI program. Table 16 details the required information on these providers. At this time, Amish Desai, MD will be the primary provider of elective PCI. Until volumes exceed 200 total cases, other Legacy Medical Group providers will cover the Program 24/7 and will perform emergent only cases. After the Program achieves 200, another fully qualified interventional provider will begin performing elective cases.

**Applicant's Table 16
Cardiologists Qualified to Perform PCI at Legacy Salmon Creek**

Physician	DOH Professional License Number	Board Certification
Amish J. Desai, MD, FACC	MD00045340	Cardiology -Cardiovascular Disease, Interventional Cardiology
Eli Rosenthal, MD, FACC, FSCAI	MD60036889	Cardiology -Cardiovascular Disease, Interventional Cardiology and Internal Medicine
David E. Wu, MD, PhD, FACC	MC00039765	Cardiology -Cardiovascular Disease, Interventional Cardiology

Source: Applicant

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Documentation provided by Legacy Health demonstrated SCMC will employ a sufficient number of cardiologists to meet its projected number of PCIs. **This sub-criterion is met.**

WAC 246-310-730(2) Staff its catheterization laboratory with a qualified, trained team of technicians experienced in interventional lab procedures.

- a. Nursing staff should have coronary care unit experience and have demonstrated competency in operating PCI related technologies.
- b. Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary

Legacy Health

Legacy Health provided the following description and qualification detail for the FTEs referenced in its FTE table. [source: May 14, 2018, screening response, p10]

FTE by Type	Description	Qualifications
Technologists FTEs	Cath Lab and Radiologic Technologists	Washington State RT Certification Registered with American Registry of Radiologic Technologists (ARRT) Minimum of 2 years' experience in a Cardiac Cath Lab
Nursing FTEs	Registered Nurses	Washington State RN License Coronary Care Unit Experience Minimum of 2 years' experience in a Cardiac Cath Lab
Management FTEs	Registered Nurses	Washington State RN License, Coronary Care Unit Experience, Minimum of 2 years' experience in a Cardiac Cath Lab

For sub-section (b) under this sub-criterion, Legacy Health provided the following statements. [source: Application, p28]

“Each of Legacy Salmon Creek’s current cath lab nurses are advanced cardiac life support (ACLS) certified and have demonstrated balloon pump placement and management competency. ACLS certification ensures that training in performing endotracheal intubation and ventilator management has occurred. In addition, all nursing staff has completed training and certification in conscious sedation. However, Legacy Salmon Creek will not rely on the cath lab staff to perform these procedures in an emergent in-lab situation. Rather, the protocol requires that 24/7 in-house board-certified emergency room physicians and respiratory therapists be stat called to immediately respond to a respiratory code.

If a patient needs ventilator management during transfer, our cath lab nurses and/or respiratory therapists will be available to accompany patients during transfer.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Documentation provided demonstrated that catheterization laboratory staff meets the standards outlined in WAC 246-310-730(2). **This sub-criterion is met.**

For the entire sub-criterion of 246-310-230(1), the department concludes that if there is need for the additional PCI services at SCMC, the application meets the sub-criterion.

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

As an operating facility, SCMC has long-established and well-functioning relationships with health and social service providers in the area. For PCI projects, specific WAC 246-310-230(2) criteria is identified in WAC 246-310-735(1)-(13).

WAC 246-310-735(1) Coordination between the nonsurgical hospital and surgical hospital's availability of surgical teams and operating rooms. The hospital with on-site surgical services is not required to maintain an available surgical suite twenty-four hours, seven days a week.

Legacy Health

Legacy Health provided its Draft Elective PCI Partnering Agreement between Salmon Creek Medical Center in Vancouver and Legacy Emanuel Medical Center in Portland. Page 1 of the draft agreement includes a stated purpose, which is quoted below. [source; May 14, 2018, screening response, Attachment 6]

“The purpose of this Elective PCI Partnering Agreement is to:

- *Facilitate the care and timely transfer of elective PCI patients and records to Legacy Emanuel Medical Center from Legacy Salmon Creek Medical Center in the case of a complication; and*
- *Ensure ongoing coordination and quality review between Legacy Salmon Creek Medical Center and Legacy Emanuel Medical Center related to Legacy Salmon Creek’s Elective PCI Program.”*

Page 1 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek and Legacy Emanuel will coordinate the availability of surgical teams and operating rooms, and Legacy Salmon Creek will only perform elective PCIs when Legacy Emanuel is available to provide cardiac surgery.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Legacy Health provided a draft Elective PCI Partnering Agreement to meet many of the PCI standards. If this project is approved, the department would attach a condition requiring Legacy Health to submit a copy of the executed Elective PCI Partnering Agreement. The executed agreement must be consistent with the draft agreement provided in the application that was reviewed by the Certificate of Need Program. While many of the standards in this evaluation rely on the draft agreement, this condition will not be repeated throughout this evaluation.

Specific to this sub-criterion, the draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.

Legacy Health

Page 1 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek and Legacy Emanuel will coordinate the availability of surgical teams and operating rooms, and Legacy Salmon Creek will only perform elective PCIs when Legacy Emanuel is available to provide cardiac surgery.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard.

WAC 246-310-735(3) Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek will send with each patient at the time of transfer, or in the case of emergency as promptly as possible after the transfer, all clinical data, including images and videos to continue the patient's treatment without interruption, together with essential, identifying and administrative information.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(4) Communication by the physician(s) performing the elective PCI to the backup hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.

Legacy Health

Page 1 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek will monitor to assure that the physician performing the elective PCI communicates immediately and directly with Legacy Emanuel cardiac surgeon(s) about the clinical reasons for the urgent transfer and patient's clinical condition.

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(5) Acceptance of all referred patients by the backup surgical hospital.

Legacy Health

Page 1 of the Draft Elective PCI Partnering Agreement states:

“Legacy Emanuel will accept all elective PCI patients experiencing complications referred by Legacy Salmon Creek. When a patient's need for transfer has been determined and substantiated by the patient's physician, Legacy Emanuel agrees to admit the patient as promptly as possible, provided that admission requirements in accordance with federal and state laws and regulations are met.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(6) The applicant hospital's mode of emergency transport for patients requiring urgent transfer. The hospital must have a signed transportation agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery.

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek will develop a signed agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCI’s that require transfer to a backup hospital with on-site surgery to ensure the appropriate and safe transportation and care of the patient during the transfer. This emergency transportation will begin within twenty minutes of the initial identification of a complication by an emergency transport staff certified in advanced cardiac life support (ACLS) and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard.

WAC 246-310-735(7) Emergency transportation beginning within twenty minutes of the initial identification of a complication.

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek will develop a signed agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCI’s that require transfer to a backup hospital with on-site surgery to ensure the appropriate and safe transportation and care of the patient during the transfer. This emergency transportation will begin within twenty minutes of the initial identification of a complication by an emergency transport staff certified in advanced cardiac life support (ACLS) and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).”

Legacy Salmon Creek will ensure that the transport time from the decision to transfer the patient to arrival in the operating room is 120 minutes or less. Legacy Salmon Creek will document the transportation time for each patient.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(8) Evidence that the emergency transport staff are certified. These staff must be advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek will develop a signed agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCI’s that require transfer to a backup hospital with on-site surgery to ensure the appropriate and safe transportation and care of the patient during the transfer. This emergency transportation will begin within twenty minutes of the initial identification of a complication by an emergency transport staff certified in advanced cardiac life support (ACLS) and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(9) The hospital documenting the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of the backup hospital. Transportation time must be less than one hundred twenty minutes.

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek will ensure that the transport time from the decision to transfer the patient to arrival in the operating room is 120 minutes or less. Legacy Salmon Creek will document the transportation time for each patient.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard.

WAC 246-310-735(10) At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek and Legacy Emanuel will conduct at least two annual timed emergency transportation drills and Legacy Salmon Creek will report the outcomes of those drills to Legacy Salmon Creek's quality assurance program.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(11) Patient signed informed consent for adult elective (and emergent) PCIs. Consent forms must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements

Legacy Health

Page 1 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek will receive patient signed informed consent for adult elect PCI's that will communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements.”

Legacy Health also provided a copy of a Draft Patient Informed Consent form that will be used at SCMC. The form provides the following information. [source: Application, Exhibit 7]

“Consent, Additional Information (e.g. risks, benefits, alternatives, anesthesia).

- The procedures, benefits, material risks, and reasonable alternatives were explained to me and all of my questions about the procedures, benefits, material risks and reasonable alternatives were answered to my satisfaction.*
- I understand that, during the course of the procedures, unforeseen circumstances may necessitate additional or different procedures than those discussed with me.*
- I authorize the practitioners to perform such other procedures as are, in their judgment, necessary and appropriate.*
- I acknowledge that no warranty or guarantee was made to me as to result or cure.*
- For PCI Balloon/Stenting there is generally less than 1% risk of heart attack, death, or need for emergency transfer to another hospital for open heart surgery. Open heart surgery is not available at Legacy Salmon Creek Medical Center.*
- Should emergency transfer to an open-heart surgery hospital be needed, Legacy Salmon Creek Medical Center has an established agreement with a qualified emergency transport agency that will ensure a total transportation time of less than 120 minutes, which is the ideal standard. I understand that a transport team will be en route with me that include staff certified in advance cardiac life support who have the skills, experience, and equipment to monitor and treat me and to manage an intra-aortic balloon pump. Legacy Salmon Creek will immediately*

notify both the open-heart hospital and the emergency transport in the rare case a complication should arise. Emergency transport occurs in less than 3 out of 1,000 cases.

- *I have chosen to undergo this procedure after considering alternative forms of diagnosis and/or treatment and/or location for my condition, including non-treatment, or other procedures or tests such as: bypass surgery or the scheduling of PCI procedure at a hospital that performs open heart surgery. Open heart surgery is not performed at Legacy Salmon Creek Medical Center. Patient selection criteria approved by the Society of Cardiovascular Angiography and Interventions is used to determine whether to perform the above stated procedure at Legacy Salmon Creek Medical Center or at an open-heart hospital. In the rare event that I may need emergency open-heart surgery because of the PCI procedure, it might be performed more quickly if the procedure was scheduled at such facility first. Each of these alternative forms of diagnosis or treatment has its own potential benefits, risks and complications.”*

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard.

Legacy Health also provided a draft Patient Informed Consent Form to meet the PCI standard. If this project is approved, the department would attach a condition requiring Legacy Health to submit a copy of the adopted Patient Informed Consent Form. The adopted form must be consistent with the draft form provided in the application that was reviewed by the Certificate of Need Program.

This sub-criterion is met.

WAC 246-310-735(12) Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases.

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Conferences between Legacy Emanuel and Legacy Salmon Creek will be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(13) Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).

Legacy Health

Page 2 of the Draft Elective PCI Partnering Agreement states:

“Legacy Salmon Creek shall have a policy for addressing peak volume periods that may impact the ability to perform elective PCIs.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard.

For the entire sub-criterion of 246-310-230(2), the department concludes that if there is need for the additional PCI services at SCMC, approval of this project would not negatively affect existing healthcare relationships within the planning area. Provided that Legacy Health agrees to conditions related to the draft agreements in the application, **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.

Legacy Health

The specific question in the application form related to this sub-criterion requests the applicant to identify if the owner, operator, or physician(s) identified in this application has had any of the following in this state or other states:

- a. Decertification from Medicare
- b. Decertification from Medicaid
- c. Convictions related to the competency to practice medicine or own or operate a hospital.
- d. Denial of a license
- e. Revocation of a license
- f. Voluntary withdrawal from Medicare or Medicaid while decertification processes were pending.

In response to the specific question above, Legacy Health provided the following statement. [source: Application, p35]

“Neither Legacy Health, Legacy Salmon Creek nor any physician identified in this application has had any sanctions or notifications related to the above items referenced in (a)-(f).”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

As part of this review, the department must conclude that the proposed services provided by an applicant would be provided in a manner that ensures safe and adequate care to the public.⁹ To accomplish this task, the department reviewed the quality of care compliance history for the healthcare facilities owned, operated, or managed by Legacy Health or its subsidiaries.

Legacy Health is a health system based in Portland, Oregon that operates six hospitals Oregon and one hospital in Washington.

Washington State Survey Data

SCMC is the sole Washington State based hospital owned and operated by Legacy Health. The hospital is Joint Commission accredited through June 2019. Since year 2015, SCMC three surveys have been conducted and completed by Washington State surveyors.¹⁰ All surveys demonstrated substantial compliance with both state and federal regulations. [source: Joint Commission website, CN historical files]

Out-of-State Compliance

In addition to a review the Washington State facility, the department also examined all six of the Oregon facilities owned and operated by Legacy Health. The department reviewed information from the licensing authorities for each of the facilities listed, and concluded that these facilities are substantially compliant with state licensure and Medicare conditions of participation. The department did not identify facility closures or decertification.

Oregon Hospital Name	City	Joint Commission Accredited?
Legacy Emanuel Medical Center	Portland	Yes
Legacy Good Samaritan Medical Center	Portland	Yes
Legacy Meridian Park Medical Center	Tualatin	Yes
Legacy Mount Hood Medical Center	Gresham	Yes
Randall Children’s Hospital at Legacy Emanuel	Portland	Yes
Legacy Silverton Medical Center	Silverton	Yes

[sources: Joint Commission website]

In addition to the facility review above, Legacy Health provided the names and provider credential numbers for known cardiology and/or PCI staff. The listing includes physicians, registered nurses, and radiology technicians, for a total of 11 known staff. A summary of the departments review of known staff is shown in Table 12 below. A review of each provider’s credential revealed no sanctions.

⁹ WAC 246-310-230(5).

¹⁰ Surveys conducted February 5, 2015, August 26, 2016, and August 8, 2017.

**Table 12
Salmon Creek Medical Center PCI Staff Credential Information**

Last Name	First Name	Middle Name	Credential #	Status	Comments
Desai	Amish	J	MD00045340	Active	Cardiologist
Rosenthal	Eli	A	MD60036889	Active	Cardiologist
Wu	David	E	MD00039765	Active	Cardiologist & Medical Director
Edwards	Kevin	S	RN00116998	Active	
Funches	Martha	Ross	RN00106621	Active	
Milligan	Matthew	W	RN00148119	Active	
Tower	Katrina	Joleen	RN60018705	Active	
Schneldewind	Jeffrey	S	RT00007932	Active	
Jodoin	Larry	Patrick	RT00000232	Active	
Buchholz	David	Paul	RT00000113	Active	
Crockett	Debra	C	RT00003198	Active	

Based on the above information, the department concludes that Legacy Health demonstrated reasonable assurance that its existing facilities operating in both Oregon and Washington would continue to operate in compliance with state and federal guidelines if this project is approved. Legacy Health further demonstrated that known staff of its proposed PCI program at SCMC are in compliance with state requirements. **This sub-criterion is met**

In addition to the general quality of care sub-criterion above, WAC 246-310-740(1)-(4) identify specific quality assurance/quality improvements requirements for adult, elective PCI programs.

WAC 246-310-740(1) A process for ongoing review of the outcomes of adult elective PCI's. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.

Legacy Health

In response to this standard, Legacy Health states that page 2 of the draft PCI Continuous Quality Improvement Plan addresses this standard. [source: May 14, 2018, screening response, Attachment 7]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

Legacy Health provided a draft PCI Continuous Quality Improvement Plan to meet many of the PCI standards. If this project is approved, the department would attach a condition requiring Legacy Health to submit a copy of the executed PCI Continuous Quality Improvement Plan. The executed plan must be consistent with the draft plan provided in the application that was reviewed by the Certificate of Need Program. While many of the standards in this evaluation rely on the draft plan, this condition will not be repeated throughout this evaluation.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-740(2) A system for patient selection that results in outcomes that are equal to or better than the benchmark standards in the applicant's plan

Legacy Health

In response to this standard, Legacy Health states that page 3 of the PCI Continuous Quality Improvement Plan addresses this standard. [source: May 14, 2018, screening response, Attachment 7]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft PCI Continuous Quality Improvement Plan submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-740(3) A process for formalized case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases

Legacy Health

In response to this standard, Legacy Health states that page 4 of the PCI Continuous Quality Improvement Plan addresses this standard. The standard is further addressed on page 2 of the Elective PCI Partnering Agreement. [source: source: May 14, 2018, screening response, Attachment 7 and Application, Exhibit 5]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft PCI Continuous Quality Improvement Plan submitted by Legacy Health demonstrated compliance with this standard.

The draft Elective PCI Partnering Agreement submitted by Legacy Health demonstrated compliance with this standard.

WAC 246-310-740(4) A description of the hospital's cardiac catheterization laboratory and elective PCI quality assurance reporting processes for information requested by the department or the department's designee. The department of health does not intend to require duplicative reporting of information.

Legacy Health

In response to this standard, Legacy Health states that page 5 of the PCI Continuous Quality Improvement Plan addresses this standard. The revised Continuous Quality Improvement Program is included in Attachment 7. Page 5 of the revised document specifies the process for handling

requests by the department or its designee. [source: source: May 14, 2018, screening response, Attachment 7]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The draft PCI Continuous Quality Improvement Plan submitted by Legacy Health demonstrated compliance with this standard. **This sub-criterion is met**

For the entire sub-criterion of 246-310-230(3), the department concludes that if there is need for the additional PCI services at SCMC, Legacy Health has demonstrated the services would be operated in compliance with both state and federal guidelines. **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 directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Legacy Health

Legacy Health provided the following statements related to this review criteria. [source: Application, p30]

“Legacy Salmon Creek has established a partnership agreement with Legacy Emanuel Medical Center in Portland, OR. This agreement is included as Exhibit 5. Legacy Emanuel Medical Center, is a nationally recognized tertiary/quaternary provider serving Portland and the Pacific Northwest region with expertise in critical health conditions. Emanuel provides a full range of interventional and cardiac surgical services.

Adding elective PCI to the continuum of cardiology services currently performed Legacy Salmon Creek will enhance the continuity of care and reduce the current fragmentation of PCI services in Planning Area 5. Under the current delivery system, patients undergoing a diagnostic procedure at Legacy Salmon Creek that are found to be in need of an elective PCI must be transferred or rescheduled at another hospital. This requires transport, a second groin or radial artery puncture, second dye contrast, etc. Some of these patients ultimately elect not to receive treatment at another hospital. This care model is inefficient, costly, and fragmented.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

This evaluation takes into consideration the letters of support provided for the project. It also takes into consideration the numeric methodology and rules related to the establishment of a new adult, elective PCI program within a planning area.

However, one of the two providers in the planning area is not performing at the minimum of 300 adult PCIs as required under WAC-310-720(2)(b). Therefore, a new provider in planning area #5 cannot be approved. Further, the numeric methodology outlined in WAC 246-310-745 calculates no need for an additional provider in the planning area. For those reasons, the department concludes that approval of this project during this review cycle may result in unwarranted fragmentation of PCI services in the planning area. **This sub-criterion 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.**

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

Based on the source information reviewed, the department determines that Legacy Health does not meet the applicable cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.
To determine if a proposed project is the best alternative, in terms of cost, efficiency, or effectiveness, the department takes a multi-step approach. First the department determines if the application has met the other criteria of WAC 246-310-210 thru 230. If the project has failed to meet one or more of these criteria then the project cannot be considered to be the best alternative in terms of cost, efficiency, or effectiveness as a result the application would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, the department then assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type. The adopted superiority criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility type superiority criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Legacy Health

Step One

For this project, Legacy Health did not meet the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department concludes **this sub-criterion is not met.**

- (2) In the case of a project involving construction:
(a) The costs, scope, and methods of construction and energy conservation are reasonable;
(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 are no costs 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.

Legacy Health

Legacy Health provided the following information in support of its adult, elective PCI program for this sub-criterion. [source: Application, p37]

“... being able to perform elective PCI at Legacy Salmon Creek will allow our already highly trained and competent cath lab staff to perform elective and emergent PCI, such that their proficiency, as well as their productivity is enhanced.

In addition, our emergency department staff spends thousands of hours each year preparing cardiac patients for transfer and the region’s EMS staff incur additional time when transporting patients beyond Legacy Salmon Creek. The redeployment of emergency room staff to direct patient care (as opposed to transfer) and better use of EMS will improve overall efficiency of the delivery system.

The current delivery system is costly and impacts patient quality and outcomes. The efficiencies that will be realized will be significant for patients, for the hospitals and cardiologists, for payers and for the health of the community.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation

For this project, Legacy Health did not meet the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department concludes **this sub-criterion is not met.**

APPENDIX A

Department of Health
 2017-2018 Percutaneous Coronary Intervention Numeric Need Methodology
 Using COAP data only



Planning Area	County	2016 15+ Population	2016 PCI Population/1,000	Resident PCI - COAP	WA Patients in OR Hospitals	Total Resident PCIs	2016 Use Rate	2021 15+ Population	2021 PCI Population/1,000	2021 Use Rate	2021 Projected Demand for Planning Area Residents	2016 Planning Area Capacity	2021 Projected Net Need	Projected Need for New Programs	Number of Possible New Programs
PSA 1	Adams	13,279		15	0	15		14,520							
	Asotin	18,305		4	0	4		18,972							
	Ferry	6,582		4	0	4		6,681							
	Grant	71,924		90	0	90		78,923							
	Lincoln	8,949		11	0	11		9,070							
	Pend Oreille	11,303	610.17	12	0	12	0.96	11,912	644.12	0.96	621	1,546	-925	-3.08	0
	Spookane	401,183		390	0	390		423,095							
	Stevens	36,888		40	0	40		38,795							
	Whitman	41,758		22	0	22		42,159							
	Total:		610,170		588	0	588		644,125						
PSA 2	Benton	149,803		71	0	71		160,587							
	Columbia	3,450		3	0	3		3,395							
	Franklin	64,428		13	0	13		74,119							
	Garfield	1,910	269.50	3	0	3	0.64	1,909	290.96	0.64	186	595	-409	-1.36	0
Total:	49,907		82	0	82		50,952								
PSA 3	Chelan	60,838		114	0	114		63,890							
	Douglas	32,201	127.01	52	0	52	1.77	35,385	134.24	1.77	238	282	-44	-0.15	0
	Okanogan	33,970		59	0	59		34,962							
	Total:	127,010		225	0	225		134,237							
PSA 4	Killias	36,982		73	0	73		39,844							
	Klickitat East	6,557		1	0	1		6,844							
	Yakima	186,817	230.36	411	0	411	2.11	197,706	244.39	2.11	515	273	242	0.81	0
	Total:	230,356		485	0	485		244,394							
PSA 5	Clark	369,008		243	12	255		409,608							
	Cowlitz	85,588		197	3	200		89,787							
	Klickitat West	11,684	479.47	3	3	3	0.98	12,413	525.70	0.98	513	803	-290	-0.87	0
	Shamania	9,719		3	0	3		10,377							
	Wahkiakum	3,469		7	0	7		3,518							
	Total:	479,469		450	18	468		525,704							
PSA 6	Grays Harbor	60,753		242	0	242		61,593							
	Lewis	63,451		204	0	204		66,323							
	Mason	53,207	418.96	181	0	181	3.15	58,067	449.19	3.15	1,414	1,033	381	1.27	1
	Total:	18,241		34	1	35		18,250							
PSA 7	Thurston	223,305		657	0	657		244,954							
	Total:	418,958		1,318	1	1,319		449,187							
	Pierce East	305,257	305.26	582	0	582	1.91	328,651	328.65	1.91	627	304	323	1.08	1
	Total:	305,257		582	0	582		328,651							
PSA 8	Pierce West	375,651	375.65	727	0	727	1.94	395,447	395.45	1.94	765	1,336	-571	-1.90	0
	Total:	375,651		727	0	727		395,447							
PSA 9	King East	968,907	968.91	1,909	0	1,909	1.97	1,048,606	1,048.61	1.97	2,066	1,806	260	0.87	0
	Total:	968,907		1,909	0	1,909		1,048,606							
PSA 10	King West	819,171	819.17	1,315	0	1,315	1.61	878,415	878.42	1.61	1,410	2,635	-1,225	-4.08	0
	Total:	819,171		1,315	0	1,315		878,415							
PSA 11	Shoemish	626,356	626.36	1,569	0	1,569	2.50	689,882	689.88	2.50	1,728	1,305	423	1.41	1
	Total:	626,356		1,569	0	1,569		689,882							
PSA 12	Island	67,448		191	0	191		70,507							
	San Juan	14,547	181.80	30	0	30	2.78	15,227	193.92	2.78	540	277	263	0.88	0
	Skaquit	99,802		285	0	285		105,186							
	Total:	181,797		506	0	506		193,922							
PSA 13	Olliam	62,565		200	0	200		64,450							
	Jefferson	27,876	305.77	80	0	80	2.83	29,449	322.83	2.83	914	657	257	0.86	0
	Kitsap	215,332		586	0	586		228,935							
	Total:	305,773		866	0	866		322,833							
PSA 14	Whatcom	178,095	178.10	363	0	363	2.04	193,399	193.40	2.04	394	450	-56	-0.19	0
	Total:	178,095		363	0	363		193,399							

Source: County_Age Pop. Projections OFM August 2017
 Sub county Pop. Charitas 2016-2021
 PCI Data Survey By COAP
 PCI Inpatient CHARS Data for 2016

Department of Health
 2017-2018 Percutaneous Coronary Intervention Numeric Need Methodology
 Using CHARS and Survey data



Planning Area	County	2016 15+ Population	2016 PCI Population/1,000	Resident PCIs - CHARS	Resident PCIs - Survey	WA Patients in OR Hospitals	Total Resident PCIs	2016 Use Rate	2021 15+ Population	2021 PCI Population/1,000	2021 Use Rate	2021 Projected Demand for Planning Area Residents	2016 Planning Area Capacity	2021 Projected Net Need	Projected Need for New Programs	Number of Possible New Programs
PSA 1	Adams	13,279		15	18	0	33		14,520							
	Asotin	18,305		2	7	0	9		18,972							
	Ferry	6,592		5	8	0	13		6,681							
	Grant	71,924		95	30	0	125		78,923							
	Lincoln	8,949		18	8	0	26		9,070							
	Pend Oreille	11,303	610.17	18	11	0	29	2.09	11,912	644.12	2.09	1,349	1,347	2	0.01	0
	Spokane	401,183		566	312	0	878		423,095							
	Stevens	36,888		66	37	0	103		38,795							
	Whitman	41,758		28	12	0	40		42,159							
	Total:		610,170		835	443	0	1,278		644,125						
PSA 2	Benton	149,803		219	115	0	334		160,587							
	Columbia	3,450		6	4	0	10		3,395							
	Franklin	64,428		55	39	0	94		74,119							
	Garfield	1,910	269.50	2	1	0	3	2.04	1,909	290.96	2.04	595	430	165	0.55	0
PSA 3	Walla Walla	49,907		83	27	0	110		50,952							
	Total:	269,498		365	186	0	551		290,962							
PSA 4	Chelan	60,838		76	29	0	105		63,890							
	Douglas	32,201		40	10	0	50		35,385							
	Okanogan	33,970		50	17	0	67		34,962							
	Total:	127,010		166	56	0	222		134,237							
PSA 5	Kittitas	36,982		31	18	0	49		39,844							
	Klickitat East	6,557		8	4	0	12		6,844							
	Yakima	186,817	230.36	238	92	0	330	1.70	197,706	244.39	1.70	415	192	223	0.74	0
	Total:	230,356		277	114	0	391		244,394							
PSA 6	Clark	369,009		331	120	12	463		409,608							
	Cowlitz	85,689		139	106	3	248		89,787							
	Klickitat West	11,684		0	3	3	6		12,413							
	Skamania	9,719	479.47	8	2	0	10	1.52	10,377	525.70	1.52	801	718	83	0.28	0
	Wahakum	3,469		4	0	0	4		3,518							
	Total:	479,469		482	231	18	731		525,704							
	Grays Harbor	60,753		126	98	0	224		61,593							
PSA 7	Lewis	63,451		132	60	0	192		66,323							
	Masson	53,207		97	73	0	170		58,067							
	Pacific	19,241	418.96	19	8	1	28	2.86	18,250	449.19	2.86	1,286	939	347	1.16	1
	Thurston	223,305		386	199	0	585		244,954							
	Total:	418,958		760	438	1	1,199		449,187							
	Pierce East	305,257	305.26	406	257	0	663	2.17	328,651	328.65	2.17	714	279	435	1.45	1
PSA 8	Total:	305,257		406	257	0	663		328,651							
	Pierce West	375,651	375.65	426	317	0	743	1.98	395,447	395.45	1.98	782	1,238	-456	-1.52	0
PSA 9	Total:	375,651		426	317	0	743		395,447							
	King East	968,907	968.91	1,046	730	0	1,776	1.83	1,048,606	1,048.61	1.83	1,922	1,647	275	0.92	0
PSA 10	Total:	968,907		1,046	730	0	1,776		1,048,606							
	King West	819,171	819.17	739	480	0	1,219	1.49	878,415	878.42	1.49	1,307	2,167	-860	-2.87	0
PSA 11	Total:	819,171		739	480	0	1,219		878,415							
	Snohomish	626,356	626.36	926	558	0	1,484	2.37	689,882	689.88	2.37	1,635	1,218	417	1.39	1
PSA 12	Total:	626,356		926	558	0	1,484		689,882							
	Island	67,448		110	63	0	173		70,507							
PSA 13	San Juan	14,547		16	2	0	18		15,227							
	Skagit	99,802	181.80	66	66	0	226	2.29	108,188	193.92	2.29	445	236	209	0.70	0
	Total:	181,797		286	131	0	417		193,922							
	Clallam	62,565	305.77	102	76	0	178	2.48	64,450	322.83	2.48	801	548	253	0.84	0
PSA 14	Jefferson	27,876		43	28	0	71		29,449							
	Kitsap	215,332		268	252	0	510		228,935							
Total:	305,773		403	356	0	759		322,833								
Total:	178,095	178.10	191	37	0	228	1.28	193,399	193.40	1.28	248	251	-3	-0.01	0	

Source: County_Age Pop. Projections OFM August 2017
 Sub county Pop. Clients 2016-2021
 PCI Outpatient 2016 Data Survey By DOH
 PCI Inpatient CHARS Data for 2016