

STATE OF WASHINGTON DEPARTMENT OF HEALTH Olympia, Washington 98504

January 16, 2020

CERTIFIED MAIL # 7019 1640 0000 8194 1069

Jon Hersen, President Legacy Salmon Creek Medical Center 2211 Northeast 139th Street Vancouver, Washington 98686

RE: Certificate of Need Application #19-63

Dear Mr. Hersen:

We have completed review of the Certificate of Need application submitted on behalf of Legacy Salmon Creek Medical Center proposing to establish an adult percutaneous coronary intervention (PCI) program at the hospital in Clark County. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Legacy Health agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of an adult, elective percutaneous coronary intervention program at Salmon Creek Medical Center.

Conditions:

- 1. Approval of the project description as stated above. Legacy Health further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. 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 1.99% gross revenue and 5.76% 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.
- 3. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide a copy of the final Emergency Transport Agreement Elective PCI Addendum consistent with the draft agreement provided in the application.

Jon Hersen, Legacy Salmon Creek Medical Center Certificate of Need Application #19-63 January 16, 2020 Page 2 of 2

- 4. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide a copy of the final (Patient) Informed Consent for Legacy Health hospitals, including Salmon Creek Medical Center in Vancouver consistent with the draft document provided in the application.
- 5. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide a copy of the final Draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center consistent with the draft document provided in the application.
- 6. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide documentation to demonstrate David Wu, MD has an active Washington State physician credential.

Approved Costs:

There is no capital expenditure associated with this project.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response to the Certificate of Need Program, at one of the following addresses.

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

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

Sincerely,

Nancy Tyson, Executive Director Health Facilities and Certificate of Need

Enclosure

EVALUATION DATED JANUARY 16, 2020, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY LEGACY HEALTH PROPOSING TO ESTABLISH AN ADULT, ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM IN 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: Application, p4] Below is a listing of the seven Legacy Health hospitals.

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, year 2019]

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 20, 2019, screening response, p7] *"The catheterization laboratories 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 catheterization laboratories, the hospital does not provide emergent PCI procedures and provided the following rationale for this approach in the planning area. [source: May 20, 2019, screening response, pp2-3]

"Legacy Salmon Creek began providing diagnostic services in the cardiac catheterization lab when the hospital opened on August 15, 2005. 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."

Since there is no construction or capital costs associated with the program, Legacy Health states that the adult, elective PCI program would be available at SCMC in April 2020. [source: Application, p11] Under this timeline, year 2020 would be a partial year of operation, year 2021 is full calendar year one and 2023 is full calendar year three.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project 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, an applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment). Where applicable, each 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 2019 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 2019 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).

Consistent with historical practice, the department calculated the statewide PCI numeric need methodology and posted it to its website prior to the end of January 2019, which is when letters of intent are due. Simultaneous to calculating the numeric methodology, the department continued to work toward obtaining data from hospitals within the state of Oregon. The data requested from Oregon included inpatient PCI procedures performed within an Oregon hospital on Washington residents. If available, this data would be included in the department's numeric need methodology. Although requested, the Oregon data could not be obtained before the numeric need methodology must be posted.

The Oregon data was received at the Department of Health in early September 2019 and in October 2019, the department re-calculated the numeric methodology that included the Oregon data. To ensure

a fair concurrent review, the department re-opened the public comment and rebuttal portions of this review. The table below shows the initial and the re-opened review timelines.

Action	Legacy Health
Letter of Intent Submitted	January 31, 2019
Application Submitted	February 28, 2019
Department's pre-review activities	
• DOH 1 st Screening Letter	March 29, 2019
Applicant's Responses Received	May 20, 2019 ²
Beginning of Review	June 27 2019
 End of Public Comment No Public Hearing Conducted and public comments accepted through end of public comment 	August 1, 2019
Rebuttal Comments Due	August 15, 2019
Department's Anticipated Decision Date	September 30, 2019
Department Posts Revised Numeric Methodology to its website	October 3, 2019
Department of Health Re-Opened Public Comment	October 10, 2019
End of Public Comment	November 14, 2019
No Public Hearing Requested or Conducted	November 14, 2019
Rebuttal Comments Due	December 2, 2019
Department's Anticipated Decision Date	January 16, 2020
Department's Actual Decision Date	January 16, 2020

APPLICATION CHRONOLOGY

Public Comments

After the department re-opened the public comment on October 10, 2019, two entities submitted comments related to the process used by the department for obtaining Oregon data, reopening the public comment and rebuttal portions of this review, which ultimately extended the decision date from September 2019 to January 2020. Excerpts from those comments are below.

<u>Providence Health & Services</u> [source: Providence Health & Services November 14, 2019 public comments] "In accordance with its standard practice, the Department issued a 2018-2019 PCI need calculation in advance of the 2019 concurrent review cycle. Based upon the Department's need calculation, CN applications were submitted in four PCI Planning Areas in February 2019. [footnote #6 identifies planning areas, 2, 4, 5, and 9] The Department commenced the annual PCI application review cycle in each of the Planning Areas.

On October 3, 2019, the Department announced that it had "updated" the 2018-2019 PCI need calculation "in order to include recently acquired data from the State of Oregon." The Department further stated: "CHARS recently executed a contract with the State of Oregon to provide us with inpatient data, which we incorporated into this methodology in calculating need for adult elective PCI programs." On the same date, the Department issued an "updated" 2018-2019 need calculation. The "updated"

² On May 13, 2019, Legacy Health requested, and was granted, a ten day extension to provide screening responses. The due date for screening responses was extended from May 13 to May 23. Within its screening responses submitted on May 20, Legacy Health requested a second screening of the project. The department notified Legacy Health on June 21 that it had no further questions and review of the project would begin on June 27, 2019.

calculation changed the "2022 Projected Net Need" for PCI procedures (Step 4 of the PCI need forecasting methodology) in 13 of the 14 PCI Planning Areas.

Providence objects to the Department's "updating" of the PCI need calculation during the pendency of the 2019 PCI CN application review cycle. As noted above, the Department's standard practice is to issue its annual PCI need calculation prior to the commencement of the PCI review cycle. As also noted above, this standard practice enables potential CN applicants to evaluate whether to submit an application in one of the Planning Areas during the annual review cycle.

The Department's "updating" of the 2018-2019 PCI need calculation in the midst of the 2019 review cycle is prejudicial to potential applicants for the 2019 review cycle who, based upon the Department's original PCI need calculation, decided not to submit a CN application: their decision may have been different had the "updated" need calculation been available at the time that letters of intent were due in January 2019.

We believe that, if the Department wishes to include Oregon data in the PCI need calculation, it should have waited to do so when issuing the 2019-2020 PCI need calculation, in advance of the 2020 PCI CN application review cycle. This is the only fair and equitable course of action, for it.

The Department has made a significant revision to its annual PCI need calculation by deciding to include Oregon PCI data in the calculation. A change of this magnitude should not be implemented in the midst of the current PCI CN application review cycle, but rather should be implemented in the upcoming 2020 review cycle. Thank you for your consideration of our comments."

<u>Health Facilities Planning and Development, a consultant company</u> [source: November 14, 2019, public comments]

"... The latest version included the addition of Oregon inpatient data as well as outpatient volume data provided via unsolicited survey responses by several hospitals. While the inclusion of the inpatient data and unsolicited survey responses is a very positive step, the record should still reflect that the Program has not sought (as it historically did) outpatient data from all PCI providers in border States.

The Program's recognition that the Oregon inpatient data should be included in the methodology is appreciated. That said, and while in the case of PCI Planning Area # 5, these cases are sufficient to demonstrate need for a new provider, it is incumbent on the Program to actively request and secure the data to understand how many Washington residents are seeking PCI in our border states."

Rebuttal Comments

Legacy Health provided rebuttal comments that focus on the Providence Health & Services public comments above. The rebuttal comments are restated below. [source: Legacy Health November 27, 2019, rebuttal comments]

"Providence's view is that potential applicants for a CN related to percutaneous coronary intervention (PCI) services were prejudiced by the Department's decision to incorporate Oregon data into its 2019 methodology after review had begun. Providence does not dispute that Oregon data is rightfully included in the Department's methodology, but contends that the Department should have waited to include the data until the 2020 application cycle. But inclusion of the data in the 2019 methodology did not actually impact potential applicants in the way described by Providence. Letters of intent for the 2019 cycle were due in January 2019, before the Department issued its first methodology on February 8, 2019.1 Thus, all interested hospitals had to decide whether to apply for a PCI CN before they knew

whether the Department would include Oregon data in its methodology. Legacy opted to submit a letter of intent in anticipation that the Department would include Oregon data/ consistent with the Department's past practice and as required by the rules/ but Legacy had no assurances this would occur.

Providence observes that the Department typically issues need calculations for each planning area before the concurrent review cycle starts. Even so, this is not explicitly required by the rules; rather it has been the Department s practice to do so, which also makes good common sense. Nevertheless/ nothing in the rules prevents the Department from updating its methodology after the initial publication. Had the Department not updated the 2019 methodology to include Oregon data/the methodology would have remained incomplete and inaccurate as to the PCI use rate in planning area five. The Department appropriately incorporated Oregon data into its 2019 calculation as soon as the data became available.

It is also worth noting that Legacy did include appropriate Oregon inpatient and outpatient data in the need methodology that it prepared and submitted as part of its application.

To conclude, the Department's late inclusion of the Oregon data in its version of the need methodology for 2019 did not prejudice any party in the 2019 application concurrent review cycle because any interested applicant was forced to file a letter of intent prior to the Department publishing its 2019 methodology on February 8, 2019. Furthermore, Legacy, and any other applicant in the 2019 concurrent review cycle, would be unreasonably prejudiced as a matter of fact had the Department failed to include Oregon data when the need methodology requires that data to be included in order to produce any meaningful results."

Department's Evaluation of Public and Rebuttal Comments Related to the Review Process Used

Comments provided focus on the process used by the department to ensure incorporation of the Oregon data. Providence clarifies that it does not disagree that Oregon PCI data should be included in the Washington State PCI methodology, rather Providence objects to the process and 'updating' of the methodology well into the concurrent review process. The department concedes that the process used in this concurrent review cycle is unusual. The department re-opened the public comment on this project to ensure adequate opportunity for public comments on the numeric methodology from community members or existing hospitals. The department has established a contract to obtain this data in the future and anticipates receiving the data well before it is needed for the Washington State PCI numeric methodology.

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, one entity sought affected person status—Providence Health & Services, Washington.

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 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. 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. This lack of qualification for interested or affected person does not preclude Providence Health & Services from providing public comment on this project, which was provided on November 14, 2019.

SOURCE INFORMATION REVIEWED

- Legacy Health's Certificate of Need application received February 28, 2019
- Legacy Health's first screening responses received May 20, 2019
- Public comments received by the end of public comment on August 1, 2019
- Public comments received between October 10, 2019 and November 14, 2019, during the re-opening of the public comment
- Legacy Health's rebuttal comments received on or before December 2, 2019
- Department of Health's Hospital and Patient Data Systems' Comprehensive Hospital Abstract Reporting System data for year 2017
- Department of Health PCI outpatient survey responses for 2017
- Office of Financial Management population estimates released August 2017
- Legacy Health DOH financial review dated December 24, 2019, using data obtained from the Hospital/Finance and Charity Care Program
- Department of Health Integrated Licensing and Regulatory System database [ILRS]
- Compliance history for facilities owned and operated by Legacy Health obtained from the Washington State Department of Health Office of Health Systems Oversight
- DOH Provider Credential Search website: <u>https://www.doh.wa.gov/pcs</u>
- Legacy Health's website at <u>https://www.legacyhealth.org</u>
- CMS QCOR Compliance website: <u>https://qcor.cms.gov/index_new.jsp</u>
- COAP (Clinical Outcomes Assessment Program) website: <u>www.coap.org</u>

CONCLUSION

Legacy Health

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 consistent with applicable review criteria of the Certificate of Need Program, provided the applicant agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of an adult, elective percutaneous coronary intervention program at Salmon Creek Medical Center.

Conditions:

- 1. Approval of the project description as stated above. Legacy Health further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. 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 1.99% gross revenue and 5.76% 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.
- 3. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide a copy of the final Emergency Transport Agreement Elective PCI Addendum consistent with the draft agreement provided in the application.
- 4. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide a copy of the final (Patient) Informed Consent for Legacy Health hospitals, including Salmon Creek Medical Center in Vancouver consistent with the draft document provided in the application.
- 5. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide a copy of the final Draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center consistent with the draft document provided in the application.
- 6. Prior to providing elective percutaneous coronary intervention program at Salmon Creek Medical Center, Legacy Health will provide documentation to demonstrate David Wu, MD has an active Washington State physician credential.

Approved Costs:

There is no capital expenditure associated with this project.

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 and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that the Legacy Health application meets the applicable need criteria in WAC 246-310-210.

(1) <u>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.</u>
 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. 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.

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, pp12-14]

- 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.

<u>Applicant's Step I Table</u>						
Step 1: Planning Area PCI Use Rate						
Base Year = 2017						
Population Age 15+ (1a)	Divide by 1,000	Resident Inpatient PCI (CHARS)	Resident Inpatient PCI (Oregon)	Resident Outpatient PCI ²	Total PCIs	Use Rate (1b)

Source: Population, Claritas; Inpatient, WA CHARS database & OAHHS Oregon database, and DOH Outpatient PCI 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

<u>Applicant's Step 2 Table</u> Step 2: Planning Area Forecasted PCI Forecast Year = 2022			
Use Rate from Step 1 Population Age 15+ Divide by 1 000 Projected			Projected Demand (2a)
1.99	532,899	532.9	1,062

Source: Population, Claritas; Rate derived from Claritas, CHARS Database, OAHHS database and DOH Outpatient 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.

Step 3: Current PCI Capacity (3d) all providers in Planning Area 5		
Provider	Current Capacity	
PeaceHealth Southwest Medical Center	611	
PeaceHealth St. John	216	
Total	827	

Applicant's Step 3 Table

Source: For PeaceHealth Southwest: WA State CHARS Database and DOH Outpatient PCI Surveys. For PeaceHealth St. John, COAP data as reported by the CN Program.

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.

⁵ Residents 15 years of age and older.

Step 4: Planning Area Net Need for PCI Procedures		
Current Capacity (Step 3)	Projected Net Need	
827	235	
	Area Net Need for PCI P Current Capacity (Step 3)	

<u>Applicant's Step 4 Table</u>

Source: Rate derived from Claritas, CHARS Database, OAHHS database and DOH Outpatient PCI survey. Current Capacity from Step 3.

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 Step 5 Table

Step 5: Planning Area Need for Additional PCI Program

Projected Need/200 (5a)	# of New Programs (5b)
1.12	1.00

Source: Rate derived from Claritas, CHARS Database, OAHHS database and DOH Outpatient PCI survey

As noted in the step-by-step methodology identified above, Legacy Health projected a need for one PCI program in the planning area.

Public Comments None

Rebuttal Comments
None

Department Evaluation of Numeric Need

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. 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.

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.

- Compute each planning area's PCI use rate calculated for persons fifteen years of age and Step 1: older, including inpatient and outpatient PCI case counts.
 - Take the total planning area's base year population residents fifteen years of age and (a)older and divide by one thousand.
 - Divide the total number of PCIs performed on the planning area residents over fifteen *(b)* 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 submitted on February 28, 2019, year 2018 data was not yet available. As a result, the base year is 2017.

Using the base year of 2017, the department calculated the use rate as described above. The table below shows both use rates calculated by the department.

	Department Methodology #1	Department Methodology #2
Year 2017 Population 15+	489,064	489,064
Divide by 1,000	489.06	489.06
Year 2017 PCIs	1,003	441
Use Rate Calculated	2.05	0.90

Department's Step One Table

As shown in the Step One Table, even though the projected population is the same, when the number of PCI's counted in the planning area is divided by the population (divided by 1,000), the resulting use rate is different. 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.
 - Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning (a)area's corresponding forecast year population of residents over fifteen years of age.⁸

In this step, the forecast year is defined as the fifth year after the base year. For this project, the forecast year is 2022. The table below is a summary of step two.

Department's Step	Department Methodology #1	Department Methodology #2
Forecast Year Population	534,133	534,133
Divide by 1,000	534.1	534.1
Use Rate (calculated from step 1)	2.05	0.90
Projected Demand for Planning Area Residents	1,095	482

⁷ Residents 15 years of age and older.

⁸ Residents 15 years of age and older.

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.*

- Identify all inpatient procedures at CON approved hospitals within the planning area *(a)* using CHARS data;
- *(b)* Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data; or
- Calculate the difference between total PCI procedures by CON approved hospitals (c)within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.
- Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the (d)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 counties of Clark, Cowlitz, Skamania, and Wahkiakum plus specific ZIP codes in west Klickitat County: 98650, 98619, 98672, 98602, 98628, 98635, 98617, and 98613. There are two providers in the planning area— 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		
Combined Inpatient & Outpatient Combined Inpatient & Outpatient		
(CHARS) (COAP)		
552	558	

St. John Medical Center in Cowlitz County

St. John Medical Center in Cowniz County		
Combined Inpatient & Outpatient Combined Inpatient & Outpati		
(CHARS)	(COAP)	
191	216	

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 Plai	nning Area #5 Capacity
nnationt & Outnationt	Combined Innetient & O

Combined Inpatient & (CHARS	A	Combine	d Inpatient & Outpatient (COAP)
743			774

As shown in step three above, the CHARS data source shows that each hospital performed more than 200 PCIs in the planning area.

- 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 two 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 two 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	Sup rou	ii and Sup Five Ta	
	Step	Department Methodology #1	Department Methodology #2
Step 2-Forecasted Demand	4	1,095	482
Step 3-Minus Current Capacity	4	802	774
Net Need in Planning Area	4	293	(292)
Divide Net Need by 200	5	1.47	(1.46)
Round Down	5	1	0

Department's Step Four and Step Five Table

As shown in the table above, using CHARs and outpatient survey data, Step 5 shows need for an additional PCI program during this 2019 concurrent review cycle using a base year of 2017 and projecting to year 2022. COAP data projects a surplus of providers in the planning area.

CHARS and survey data show relatively constant values from year to year. However, COAP data decreased by more than 100 PCI for year 2017 when compared to 2016. The decrease seems less reliable than the consistent year-to-year reporting observed in the CHARS and survey data. For this reason, the department considers the CHARS and survey data to be more reliable.

The department concludes that the numeric methodology demonstrates need for an additional PCI program in planning area #5 and this **sub-criterion is met for Legacy Health's project**.

Public Comments

During the review of this project, the department received three letters of support and no letters of opposition. While all three letters were submitted by a representative of Legacy health System, each letter provides a different perspective related to availability and accessibility for PCI services in the planning area. Below are the letters of support.

Andrew Shepard, MD, FACEP Medical Director, Salmon Creek Hospital Emergency Department

"I serve as the Medical Director of the Legacy Emergency Department (ED) and offer this letter in full support of the Certificate of Need application submitted by Legacy Salmon Creek Medical Center (Legacy Salmon Creek) to establish an elective PCI program. The Legacy Salmon Creek ED serves about 75,000 patients annually, making it one of the busiest in the State. Last year, Legacy Salmon Creek transferred almost 400 patients annually from the 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 that it does not take into consideration emergency vehicles that bypassed Legacy Salmon Creek because we do not have a PCI program. With the PeaceHealth Southwest program operating at or near capacity, patients are increasingly waiting and/or being transferred a second time, (after a wait) to Oregon. 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, and the current delivery system is simply not in the best interest of patient quality, outcomes and costs.

Legacy Salmon Creek operates two state of the art catheterization labs, has a highly skilled staff and is supported by Legacy Medical Group interventional 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 al so be much better served and be put at less risk by being able to be treated faster locally and avoiding transfer."

Amish Desai, MD Medical Director, Cardiovascular Services Legacy Health

"As a Board-certified interventional cardiologist practicing in the Legacy Medical Group, I offer my full support to the approval of the Legacy Salmon Creek Medical Center Certificate of Need application proposing the establishment of an elective Percutaneous Coronary Intervention (PCI) program. I know first-hand the magnitude and extent of the need for an additional provider in Clark County. I also know that Legacy Salmon Creek has the facilities, staff and expertise to operate a high quality, excellent outcome PCI program.

Legacy Medical Group cardiologists currently perform diagnostic cardiac catherization procedures in the catheterization labs at Legacy Salmon Creek Medical Center. Over the past few years, high hospital and Emergency Department patient volumes have necessitated that patients be diverted to not further burden to an emergency room that was operating above capacity. However, today, Legacy Salmon Creek Medical Center is transferring about 400 patients annually for PCI to PeaceHealth Southwest which itself is increasingly operating at capacity. As a result, too many patients are transferred from Salmon Creek to PeaceHealth Southwest and then sent to various Portland hospitals because of capacity issues, increasing costs to the patient.

These transfers delay care initiation and increase risk. Diagnosing a patient, determining the need for intervention, and then having to transfer the patient elsewhere is not in the best interest of the patient, especially when the cardiologist making the diagnosis is trained and fully capable of performing the procedures Legacy Salmon Creek. When the Department's own methodology identifies the need for an additional provider, giving residents of Clark County an additional option for PCI is the only answer. As Clark County continues to grow and age, it even more imperative to

expand access to PCI services. It is in the best interest of all who reside in the planning area for Legacy Salmon Creek Medical Center to be granted the ability to perform elective PCI."

Kelly Espinoza, PhD, RN, President, Interim Legacy Salmon Creek Hospital

"Consistent with WAC 246-310-160, please accept this letter as public comment on Legacy Salmon Creek Hospital's certificate of need application to establish an elective PCI Program. Legacy Salmon Creek is located in Clark County, which is one of five Counties included within the in the Department of Health's (Department) PCI Planning Area 5. The other Counties include Cowlitz, Skamania, Wahkiakum, and portions of Western Klickitat County. Skamania and Wahkiakum are very small rural Counties and neither has a hospital. The hospital in Western Klickitat is a critical access hospital.

There are a number of extraordinary or exceptional circumstances in Clark County that warrant timely approval of the Legacy Salmon Creek application. These include:

1) When complete data is entered into the PCI methodology in WAC 246-310-45, there is need for an additional PCI provider in PCI Planning Area 5. The Only Logical Location for that **Department is at Legacy Salmon Creek.** Because the Department neglected to include the large outmigration to Oregon for PCI from the Planning Area, it has understated volumes and found no need for an additional provider. When data on the use of Oregon by PCI Planning Area residents generally, and by Clark County specifically is appropriately included, there is need is for one program.

With all due respect, the methodology posted to the Department's website in February of 2019 is incomplete and inaccurate. The posted information is missing inpatient data from the Oregon Association of Hospitals and Health Systems' Inpatient Database and outpatient survey data from Oregon hospitals. Legacy provided the raw data from the Oregon inpatient data base in our screening response submitted on May 20, 2019. We also previously provided outpatient PCI data for Clark County residents using the DOH form for the Oregon Legacy hospitals with Clark County PCI volume.

2) The PCI Program in Cowlitz is Not Available or Accessible to Clark County Residents: WAC 246-31-210 (1) requires that the Department determine that 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. The 15+ population of PCI Planning Area 5, according to the Department's PCI methodology, is 489,064 and, of this, 77.2% or 377,303 reside in Clark County, and 17.7% or 86,477 reside in Cowlitz County. According to data collected by the Program, in 2017, only one (1) Clark County patient had a PCI performed in Cowlitz County; the rest went either to Clark County or Oregon. As depicted in Table 1, the bottom line is that capacity in Cowlitz is not available or accessible to residents of Clark County.

Year	Total Clark County Resident Inpatient Cases ¹	Clark County Resident Cases Performed in Clark County	Clark County Resident Cases Performed in Oregon	Clark County Resident Inpatient Cases Performed in Cowlitz County
2010	560	456	90	0
2011	538	429	98	0
2012	544	432	102	0
2013	462	355	92	0
2014	446	322	110	0
2015	437	314	112	1
2016	469	327	134	1
2017	490	370	113	1

Applicant's Table 1 Table 1 Clark County Resident PCIs By Location As a Percentage of All PCIs

Source: Oregon Association of Hospitals and Health Systems, 2007-2017, Age 15+ and WA State CHARS database, excludes OP cases as DOH has not conducted an outpatient survey consistently each year between 2010 and 2017.

3) Legacy Transfers a Large Volume of Patients and the Existing Clark County Provider Does Not Have Capacity to Timely Accept All Patients: Legacy Salmon Creek is transferring almost 400 patients annually from our ED to existing PCI programs, predominantly at PeaceHealth Southwest Medical Center (PHSW). 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 automatically transport patients past Legacy Salmon Creek because we do not have a PCI program. Importantly, the PHSW program appears to be operating at or near capacity and patients are increasingly waiting and/or being transferred (after a wait) to Oregon, and /or diverted directly to Oregon.

In closing, Legacy Salmon Creek does 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. In addition, and as part of Legacy Health, Legacy Salmon Creek enjoys access to more than a decade of experience with PCI at hospitals without on-site open-heart surgery as two such sites already operate within the Legacy system. Legacy Salmon Creek submits this application now because the volume of transfers is not in the best interest of patient quality, outcomes and costs and is fully inconsistent with the State's transformation activities." (all bold type is in the original comments.)

<u>Rebuttal Comments</u> None

Department Evaluation

The numeric methodology outlined above objectively addresses the availability and accessibility of existing providers in the planning area by requiring existing hospitals providing PCI services provide

a minimum of 200 PCI's before a new provider can be approved. This standard ensures sufficient PCI volumes for the existing provider, as well as the proposed new provider.

Public comments in support of Legacy Health's project express the desire for another PCI provider in the planning area and surrounding communities and suggest that patient choice of providers is a factor that should be considered in this review. There was no comments submitted in opposition to this project.

Based on the information provided in the application, including public comments, the department concludes that Legacy Health provided sufficient documentation to demonstrate that the existing provider of PCI services may not be available and accessible to meet the projected need in the planning area. **This sub-criterion is 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 Medical Center (UWMC) program and how the hospital intends to meet the minimum number of procedures. The criteria and each 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.

<u>Legacy Health</u>

"Approval of the Legacy Salmon Creek's program will not reduce the volume at the University of Washington Medical Center UWMC. In 2017, UWMC performed a total of 10 PCIs on residents of PCI Planning Area 5, equating to a 1% share of the all PCIs from the area. The patient origin of UWMC's Planning Area 5 patients is shown in Table 10." [source: Application, pp17-18]

Legacy Health provided a table showing the number of planning area #5 residents that obtained PCI services at UWMC in Seattle for year 2017. The table is not recreated here, but shows one inpatient resident and nine outpatient residents, for a combined total of 10.

"We have verified with our cardiologists that they did not refer any patients to UWMC for PCI in 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 2." [source: Application, p18 and Exhibit 2]

In its letter to University of Washington Medical Center (UWMC), Legacy Health identified the counties and ZIP codes in planning area #5 and provided an analysis of the expected impact on the existing UWMC program. The letter concluded with an offer to discuss the analysis or provide comments.

Documentation provided in the application demonstrates that UWMC did not submit comments on the Legacy Health analysis or provide a response to the letter.

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 ten patients were referred to University of Washington Medical Center from physicians in planning area #5. 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 (two 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 fifty PCIs per year.

Legacy Health

"Legacy Salmon Creek's anticipated volume during the first three years of expanded operation is detailed in Table 8.

Applicant's Table Table 8 Legacy Salmon Creek l Projected Total PCI Volumes

Year	Total
Year 1	100
Year 2	200
Year 3	305
Source: Applicant.	

Legacy Salmon Creek employed a straightforward methodology to develop these conservative volume projections, the key features of which include:

- Consideration of the current and future total service area PCI volumes performed in Planning *Area 5, and*
- Use of actual data regarding the number of patients transferred from Legacy Salmon Creek for PCI and cases performed on Planning Area 5 patients in an existing Oregon Legacy hospital.

The Department's numeric need methodology shows that today, there is an unmet need for 235 PCIs in Planning Area 5, and this number is conservative, because it does not account for outpatient volumes occurring in non-Legacy hospitals in Oregon. Given that Legacy Salmon Creek currently refers nearly 400 patients annually from its Emergency Department, achieving and sustaining the at least 200 cases is a non-issue.

Initially, cardiologists employed by the Legacy Medical Group will perform PCI procedures at Legacy Salmon Creek. Dr. David E. Wu will be the primary provider of elective PCI and other cardiologists will refer elective cases to him. Until volumes exceed 200 total cases, the 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." [source: Application, pp16-17]

Public Comments None

Rebuttal Comments
None

Department Evaluation

Legacy Health clarified in the application that the basis for its projection is the historical number of PCIs transferred to an Oregon hospital within the Legacy Health system. For year 2017, this number was more than 400. This project assumes that approximately 75% of the transferred patients, or 300 patients, would be recaptured and receive PCI services at SCMC. This approach of projecting the number of PCI's performed at the hospital can be substantiated and is both reliable and reasonable.

Specific to the number of PCIs performed by each of the physicians, Legacy Health provided the table showing that the physician already performs more than the minimum volume required (50) at a Legacy Health hospital in Oregon. This approach of demonstrating that the number of PCI's to be performed by the physician is both reliable and reasonable.

Based on the information provided above and the documentation provided in the application, the department concludes that **this sub-criterion is met**.

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

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

The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and assurances regarding access to treatment. The admission policy 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 3]

- 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 polices 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, p20]

Current and projected hospital-wide and cardiac catheterization cost center payer mix is shown below. [source: Application, p9]

Revenue Source	Current Hospital-Wide	Current Cardiac Cost Center	Project Hospital-Wide With Elective PCI
Medicare	42.2%	55.5%	42.2%
Medicaid	21.4%	13.0%	21.4%
Private Payers	1.6%	2.0%	1.6%
Other Insurance (HMO)	34.8%	29.5%	34.8%
Total*	100.0%	100.0%	100.0%

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

* = Numbers may not add due to rounding

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, p19] *"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.*

For hospital charity care reporting purposes, the Department divides Washington State into five regions. Legacy Salmon Creek is located in the Southwest Washington Region. According to 2015-2017 charity care data produced by the Department (the latest data available), the three-year charity care average for the Southwest Washington Region was 1.03% of gross revenue and 3.27% of adjusted revenue. During the same time frame, Legacy Salmon Creek's charity care was 1.92% and 5.61%, respectively. The percentage of charity care included in the pro forma is higher than Legacy Salmon Creek's 2015-2017 average (2.0%)."

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.

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 2016, 2017, and 2018.

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, Exhibit 4 and HFCCP 2016-2018 charity care summaries]

· · ·	Percentage of Total Revenue	Percentage of Adjusted Revenue
Southwest Region Historical 3-Year Average	1.18%	3.80%
Salmon Creek Medical Center Historical 3-Year Average	1.99%	5.76%
Salmon Creek Medical Center Projected Average	2.04%	5.59%

Department's Table 3 Charity Care Percentage Comparisons

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 provide charity care at or near 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 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 1.18% gross revenue and 3.80% 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) <u>The special needs and circumstances of entities such as medical and other health professions</u> <u>schools, multidisciplinary clinics and specialty centers providing a substantial portion of their</u> <u>services or resources, or both, to individuals not residing in the health service areas in which the</u> <u>entities are located or in adjacent health service areas.</u>
 - (b) <u>The special needs and circumstances of biomedical and behavioral research projects designed</u> to meet a national need and for which local conditions offer special advantages.
 - (c) <u>The special needs and circumstances of osteopathic hospitals and non-allopathic services.</u>

Department Evaluation

This sub-criterion is not applicable to this application.

- (4) <u>The project will not have an adverse effect on health professional schools and training programs.</u> <u>The assessment of the conformance of a project with this criterion shall include consideration of:</u>
 - (a) <u>The effect of the means proposed for the delivery of health services on the clinical needs of health</u> <u>professional training programs in the area in which the services are to be provided.</u>
 - (b) <u>If proposed health services are to be available in a limited number of facilities, the extent to</u> which the health professions schools serving the area will have access to the services for training <u>purposes.</u>

Department Evaluation

This sub-criterion is not applicable to this application.

(5) <u>The project is needed to meet the special needs and circumstances of enrolled members or</u> 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 and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that the Legacy Health application meets the applicable financial feasibility criteria in WAC 246-310-220.

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

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 direct 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, p20, and May 20, 2019, screening response, p7]

"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, p16]

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% Outpa	tient 50%

Department's Table 5 Adult Elective PCI Paver Mix

Revenue Source	Projected Hospital with Cardiac Catheterization and PCI Cost Cent	
Medicare	42.2%	
Medicaid	21.4%	
Self Pay (no insurance	1.6%	
HMO/PPO/Commercial	34.8%	
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, p20 and May 20, 2019, screening response, p14]

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

- Professional fees: Medical Director fees, medical professional physician fees, and ED call fees.
- 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 Cardiac Cost Center
Medicare	42.2%	55.5%
Medicaid	21.4%	13.0%
Private Payers	1.6%	2.0%
Other Insurance (HMO)	34.8%	29.5%
Total*	100.0%	100.0%

Salmon Creek Medical Center urrent and Projected Percentages of Revenue

* = Numbers may not add due to rounding

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 4]

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

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

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 4]

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	\$62,748,857	\$63,733,490

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. Based on community, demographic, and program scope perspective, Legacy Health asserts that 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.

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 2019 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]

	Legacy nearly balance sheet for Fiscal Year 2019					
Assets		Liabilities				
Current Assets	\$ 504,529,000	Current Liabilities	\$ 301,640,000			
Board Designated Assets	\$ 140,854,000	Other Liabilities	\$ 553,531,000			
Property/Plant/Equipment	\$ 810,959,000	Long Term Debt	\$ 204,892,000			
Other Assets	\$ 1,185,543,000	Equity	\$ 1,581,822,000			
Total Assets	\$ 2,641,885,000	Total Liabilities and Equity	\$ 2,641,885,000			

Department's Table 8 Legacy Health Balance Sheet for Fiscal Year 2019

The information shown in Table 9 is the fiscal year 2019 historical balance sheet for SCMC alone. [source: HFCCP analysis, p2]

Salmon Creek Medical Center Balance Sheet for Fiscal Year 2019						
Assets		Liabilities				
Current Assets	\$ 57,978,000	Current Liabilities	\$ 29,615,000			
Board Designated Assets	\$ 0	Other Liabilities	\$ 0			
Property/Plant/Equipment	\$ 155,641,000	Long Term Debt	\$ 482,000			
Other Assets	\$ 287,968,000	Equity	\$ 471,490,000			
Total Assets	\$ 501,587,000	Total Liabilities and Equity	\$ 501,587,000			

Department's Table 9 Salmon Creek Medical Center Balance Sheet for Fiscal Year 2019

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 fiscal year 2019 balance sheet and

SCMC's fiscal year 2019 balance sheets were both used to review applicable ratios and pro forma financial information.

Table 10 compares statewide data for historical year 2018, Legacy Health's historical data and SCMC's PCI program for projected fiscal years 2021 through 2023. [source: HFCCP analysis, p3]

Current and Projected Debt Ratios Legacy Health and Salmon Creek Medical Center						
Category	Trend*	State 2018	Legacy Health 2019	SCMC FY2021	SCMC FY2022	SCMC FY2023
Long Term Debt to Equity	В	0.457	0.350	0.024	0.024	0.024
Current Assets/Current Liabilities	А	2.699	1.673	2.299	2.372	2.488
Assets Funded by Liabilities	В	0.396	0.324	0.071	0.071	0.071
Operating Expense/Operating Revenue	В	0.976	0.973	0.831	0.829	0.827
Debt Service Coverage	А	5.031	5.626	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					

Department's Table 20 Current and Projected Debt Ratios Legacy Health and Salmon Creek Medical Center

* 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, p3]

"CON year 3, (third full year following addition of elective PCI services) fiscal year end ratios for Legacy Health are either within or nearly within preferred range of the 2018 State average. Each ratio, except current assets to current liabilities (current ratio), is within the preferred range. The current ratio measures an entity's ability to pay short term liabilities with liquid assets or assets that can easily be turned into cash. A ratio above one indicates that there are sufficient current assets to satisfy the current liabilities. While both Legacy Salmon Creek's and Legacy Health's current ratios are lower than the statewide average, they are above one and may simply be indicative of management practices such as maintaining lower inventory levels than the industry average or maintaining some current assets in the board-designated asset category, which is not used in the current ratio. Legacy Salmon Creek's current ratio is very nearly the same as the statewide average. The debt service coverage ratio for Legacy Salmon Creek cannot be calculated for 2019 because Legacy did not report values for two of the components of that equation – interest expense and current maturities of long term debt – for the hospital in fiscal year 2019.

The Legacy Salmon Creek PCI program is breaking even at the end of the third year and 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."

HFCCP also provided a financial analysis of the revenue and expense statement for the PCI program. The statement shows revenue covering expenses in all three years of the project. HFCCP provided the following analysis of the statement. [source: HCCFDP analysis, pp3-4]

"In reviewing PCI procedures in the 2018 Comprehensive Hospital Abstract Reporting System (CHARS) there is variation among hospitals in the billed charges based on the healthcare common procedure coding system (HCPCS). I also reviewed the 0481 Cardiac Catheterization Lab cost

center in 2018 CHARS and there is variation among hospitals in this category also. The financial database does not have a cost center that is exclusive to cardiac catheterization. Contingent upon a demonstration of need, this project should not result in an unreasonable impact on the costs and charges for health services. This criterion is satisfied."

In the 'need' section of this evaluation, the department concluded that need for an additional PCI program was demonstrated. The assumptions used as a basis for the financial projections are considered reasonable and reliable. The HFCCP financial analysis also concludes a sound financial health for both Legacy Health and SCMC.

For those reasons, the department concludes that the immediate and long-range operating costs of the project are reliable. **This sub-criterion is met**.

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

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

Department Evaluation for Legacy Health

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)(i) 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 for Legacy Health

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 and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that the Legacy Health application meets the applicable structure and process of care criteria in WAC 246-310-230 and associated standards.

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

<u>Legacy Health</u>

In response to this sub-criterion, Legacy Health provided the following statements. [source: Application, p25]

"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, David E. Wu, MD will be the primary provider of elective PCI and the other cardiologists will refer elective cases to him.

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."

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, p24 and May 20, 2019, screening response, p13]

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		

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

Legacy Health provided the following explanation of the type of staff identified in the table above. [source: May 20, 2019, screening response, p9]

Applicant's Table Table 4 Legacy Salmon Creek Cardiac Catheterization Laboratory Current and Incremental FTEs by Year

Current and incremental FIEs by Year Year Year					Total	
Staff Position	Qualifications	FTEs	1 tear	2	1 car	FTE
Cath Lab Radiologic Technologists	Washington State RT Certification, Registered with American Registry of Radiologic Technologists (ARRT), Minimum 2 years' experience in a Cardiac Cath Lab	3.6	0	0.5	0.5	4.6
Registered Nurses	Washington State RN License, Coronary Care Unit Experience, Minimum 2 years in a Cardiac Cath Lab	3.6	0	1.0	1.0	5.6
Management	Washington State RN License, Coronary Care Unit Experience, Minimum 2 years in a Cardiac Cath Lab	0.5	0	0	0	0.5
Total		7.7	0	1.5	1.5	10.7

Source: Applicant

In addition to the table above, Legacy Health provided the following statements related to this subcriterion. [source: Application, p25 and May 20, 2019, screening response, pp9-10]

"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. As stated in the project description section of this evaluation, SCMC is currently licensed for 220 acute care beds and provides a variety of health care services. The addition of adult, elective PCI program does not require the addition of acute care beds, but could require an increase in staff appropriate to the program. Given that SCMC currently operates a cardiac catheterization lab, the addition of PCI to the hospital does not require additional FTEs in year one, and a combined 3.0 FTEs for years to and three. The proposed staffing is reasonable when compared to the projected number of PCIs in years two and three.

Information provided in the application demonstrates that SCMC is a well-established provider of healthcare services in Vancouver and surrounding communities within Clark County. With the small addition of FTEs necessary, the department concludes 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 apparati, 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. The line drawings provided show the location of the existing catheterization laboratory and the existing two operating rooms. [source: Application, p6, p10, and Exhibit 1]

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, pp24-25]

"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 12 identifies Legacy *PCI's staffing plan detailing the twenty-four-hour coverage.*

Hours	Staffing
0700 to 1700	4 Registered Nurses
Monday – Friday	2 Technicians
Dn-Call	2 Registered Nurses
700-0700 Monday – Friday	2 Technicians
24 hours Saturday and Sunday	

Applicant's Table 12 Recreated

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 fifty PCIs per year. Applicant hospitals must provide documentation that physicians performed fifty PCI procedures per year for the previous three years prior to the applicant's CON request.

<u>Legacy Health</u>

In response to this sub-criterion, Legacy Health provided the following information. [source: Application, p29 and May 20, 2019, screening response, p11 and Attachment 4]

"The cardiologists referenced in Table 14 will be responsible for performing all emergent cases at Legacy. Only Dr. David E. Wu will provide elective PCI during the start-up of the PCI program. Dr. Wu has performed more than a minimum of 50 cases per year over the last three years and can be identified in the Washington CHARS and OAHHS databases.

Dr. Wu has been identified as the cardiologist performing the elective PCI procedures at Legacy Salmon Creek, with the other referenced providers supporting the 24/7 coverage of the emergency program. All three of the physicians identified in the application comply with the volume requirement per the table below. Included in Attachment 4 is a letter from Legacy Medical Group attesting to these volumes."

The letter referenced in Attachment 4 of the screening responses identifies the total number of PCI cases for years 2016 through 2018. The table included with the letter is below.

	Applicant's	ladie		
	PCI	Volume Perform	ned	
Cardiologist	2016	2017	2018	
Amish J. Desai, MD	102	100	111	
Eli A. Rosenthal	122	119	113	
David E. Wu, MD	149	116	90	

Applicant's Table

All PCI's identified above were provided in a Legacy Health hospital located in Oregon.

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**.

<u>WAC-246-310-730(1)</u> Employ a sufficient number of properly credentialed physicians so that both emergent and elective PCIs can be performed⁹

Legacy Health

In response to this requirement, Legacy Health provided the following statements and Table 14 showing each of the cardiologist that would provide PCI services at SCMC. [source: Application, p28] "Legacy Salmon Creek will utilize interventional cardiologists employed by Legacy Medical Group to initially staff its PCI program. Table 14 details the required information on these providers. At this time, David E. Wu, MD will be the primary provider of elective PCI."

Applicant's Table

Table 14 Cardiologists Qualified to Perform PCI at Legacy Salmon Creek

Physician	Department of Health Professional License No.	Board Certification				
David E. Wu, MD, PhD, FACC	MD00039765	Cardiology -Cardiovascular Disease				
David E. Wu, MD, ThD, TACC	WID00039703	and Interventional Cardiology				
Amish J Desai, MD, FACC	NTD00045240	Cardiology -Cardiovascular				
Amisi J Desai, MD, FACC	MD00045340	Disease, Interventional Cardiology				
		Cardiology -Cardiovascular				
Eli Rosenthal, MD, FACC, FSCAI	MD60036889	Disease, Interventional Cardiology				
		and Internal Medicine				

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.

⁹ The term "employ" is interpreted to mean traditional employment relationships and traditional privileging practices that formally allow physicians to practice in a hospital.

b. Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary

<u>Legacy Health</u>

Legacy Health provided the following responses to this standard. [source: Application, 27]

"Legacy Salmon Creek's existing cath lab nursing staff has current and direct experience and competencies working in an interventional laboratory. The nursing staff all has coronary care unit experience or equivalent. As a comprehensive acute care facility, Legacy Salmon Creek operates post-procedure units that are staffed with qualified nurses with direct experience and competencies in coronary care. The job descriptions and competencies are included as Exhibit 5. Any nursing staff assigned to the cath lab will be required to demonstrate competencies in PCI related technologies and have direct coronary care, critical care, or equivalent experience.

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

<u>Rebuttal Comments</u> 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 in the planning area, the Legacy Health application meets the sub-criterion.

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

Salmon Creek Medical Center is currently operating in Vancouver and has long-established and wellfunctioning 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). Many sections of this sub-criterion require documentation from an applicant to demonstrate compliance with the standard. In this section, the department will first identify the documents provided by Legacy Health then reference those documents in specific areas throughout the sub-criterion. There were no public comments submitted that focus on the documents referenced below.

Documents provided by Legacy Health include:

- Staff Job Descriptions and Competencies [source: Application, Exhibit 5]
- Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon. [source: Application, Exhibit 6]
- Draft Emergency Transport Agreement Elective PCI Addendum [source: Application, Exhibit 7]
- Draft (Patient) Informed Consent for Legacy Health hospitals, including Salmon Creek Medical Center in Vancouver [source: Application, Exhibit 8]
- Draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center [source: Application, Exhibit 9]

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.

<u>Legacy Health</u>

The information for this standard is in section 1 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon.

Department Evaluation

Legacy Health provided a five documents as referenced above. Of the five, two are in draft format. If this project is approved, the department would attach a condition requiring Legacy Health to submit a copy of the <u>executed</u> Emergency Transport Agreement Elective PCI Addendum and a copy of the <u>executed</u> Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center. The executed agreements must be consistent with the draft agreements 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 agreements, this condition will not be repeated throughout this evaluation.

Specific to this sub-criterion, the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon is not in draft format. The agreement demonstrated compliance with this standard. **This sub-criterion is met**.

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

<u>Legacy Health</u>

The information for this standard is in section 1 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon.

Department Evaluation

Specific to this sub-criterion, the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. **This sub-criterion is met**.

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

Legacy Health

The information for this standard is in section 8 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon 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

The information for this standard is in section 3 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon 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

The information for this standard is in section 4 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon 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.

The information for this standard is in section 5 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon. It is also addressed in the Draft Emergency Transport Agreement Elective PCI Addendum.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. The draft Emergency Transport Agreement Elective PCI Addendum also demonstrated compliance with this standard. **This sub-criterion is met**.

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

<u>Legacy Health</u>

The information for this standard is in section 5 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon. It is also addressed in the Draft Emergency Transport Agreement Elective PCI Addendum.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. The draft Emergency Transport Agreement Elective PCI Addendum also 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

The information for this standard is in section 5 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon. It is also addressed in the Draft Emergency Transport Agreement Elective PCI Addendum.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. The draft Emergency Transport Agreement Elective PCI Addendum also 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.

<u>Legacy Health</u>

The information for this standard is in section 6 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical

Center in Portland Oregon. It is also addressed in the Draft Emergency Transport Agreement Elective PCI Addendum.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. The draft Emergency Transport Agreement Elective PCI Addendum also demonstrated compliance with this standard. **This sub-criterion is met.**

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

The information for this standard is in section 7 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon. It is also addressed in the Draft Emergency Transport Agreement Elective PCI Addendum.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. The draft Emergency Transport Agreement Elective PCI Addendum also 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

The information for this standard is in section 2 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon. It is also addressed in the (Patient) Informed Consent for Legacy Health hospitals, including Salmon Creek Medical Center in Vancouver.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. The (Patient) Informed Consent for Legacy Health hospitals, including Salmon Creek Medical Center in Vancouver, also demonstrated compliance with this standard. 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.

The information for this standard is in section 12 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon 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

The information for this standard is in section 11 of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon.

Department Evaluation

The Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon demonstrated compliance with this standard. **This sub-criterion is met**.

Summarized Conclusion for Legacy Health for WAC 246-310-230(2)

For the entire sub-criterion of 246-310-230(2), the department concludes that if there is need for the additional PCI services in the planning area, 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 two draft agreements provided in the application, **this sub-criterion is met for the Legacy Health project**.

(3) <u>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.</u> WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-

wAC 246-310 does not contain specific wAC 246-310-250(3) criteria as identified in wAC 246-310-200(2)(a)(i) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

As part of this review, the department must also conclude that the proposed services provided by an applicant would be provided in a manner that ensures safe and adequate care to the public.¹⁰ To accomplish this task, the department reviews the quality of care compliance history for all Washington State and out-of-state healthcare facilities owned, operated, or managed by an applicant, its parent company, or its subsidiaries.

¹⁰ WAC 246-310-230(5).

In response to this sub-criterion, Legacy Health provided the following statement. [source: Application, p34]

"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. 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 and Oregon 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 2021. Since year 2015, SCMC five surveys have been conducted and completed by Washington State surveyors, including three Joint Commission surveys in August 2016, August 2017, and August 2019.¹¹ All surveys demonstrated substantial compliance with both state and federal regulations. [source: DOH ILRS database]

As stated in the applicant description section of this evaluation, Legacy Health is based in Portland, Oregon and currently operates six hospitals in the state of Oregon. Below is a listing of the six Legacy Health hospitals.

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

For theses six hospitals, the department reviewed the survey history using the Center for Medicare and Medicaid Services Quality, Certification & Oversight Reports (QCOR) website and focused on years 2015 through 2019. Given that SCMC is also included in the QCOR data that was reviewed, the table below also includes SCMC.

¹¹ Surveys conducted February 5, 2015, August 26, 2016, and August 8, 2017.

Facility Name/State nanuel Medical Center, Randall Children's Hospital, Good Samaritan Medical regon	Type of Survey Complaint	Citations Issued Condition and Standard Citations Issued Two Follow Up Visits No Citations Issued
Randall Children's Hospital, Good Samaritan Medical		Citations Issued Two Follow Up Visits
	Complete	1
Ugun	Complaint	No Follow Up Visits
eridian Park Medical Center,	Complaint	Two Condition Citations Issued One Follow Up Visit
lount Hood Medical Center,	Complaint	Standard Citations Issued No Follow Up Visits
March 2015 Legacy Silverton Medical Center, Oregon		Two Condition Citations Issued One Follow Up Visit
lmon Creek Medical Center,	Complaint	No Citations Issued No Follow Up Visits
	Silverton Medical Center,	Iount Hood Medical Center, Complaint Silverton Medical Center, Complaint Ilmon Creek Medical Center, Complaint

As noted in the table above, for the six hospital surveys, four of the six resulted in citations and two of the four identified condition level citations that required follow up visits. For Legacy Emanuel Medical Center (including Randall Children's Hospital) the condition level citations were cited in May 2018 and focused on governing body, patient rights, and physical environment. The citations were corrected and follow up visits were conducted in July and October 2018.

Legacy Meridian Park Medical Center's August 2016 survey resulted in two condition level citations that focused on governing body and infection prevention control. The citations were corrected and one follow up visit was conducted in November 2016.

Legacy Silverton Medical Center's March 2015 survey resulted in two condition level citations that focused on patient rights and physical environment. The citations were corrected and one follow up visit was conducted in May 2015.

For these three facilities whose survey's resulted in citation level conditions, the department did not identify facility closures or decertification. Currently all of the six hospital identified above are operating in compliance with state and federal requirements.

In addition to the facilities identified above, Legacy Health also provide the name and credential numbers for each of the staff currently associated with cardiology services at SCMC and the physicians that would be associated with the proposed PCI services. The department reviewed the credential history for each of the current staff shown in the table below.

	Saimon Creek Medical Center Current and Projected PCI Staff									
LName	F Name	MName	Credential #	Status	Comments					
Desai	Amish	J	MD00045340	Active	Cardiologist					
Rosenthal	Eli	А	MD60036889	Active	Cardiologist					
Wu	David	Е	MD00039765	Expired	Cardiologist and Medical Director					
Denham	Tamara	Jill	RN60248322	Active	Registered Nurse					
Edwards	Kevin	S	RN00116998	Active	Registered Nurse					

Department's Table 12 Salmon Creek Medical Center Current and Projected PCI Staff

LName	F Name	MName	Credential #	Status	Comments
Milligan	Matthew	W	RN00148119	Active	Registered Nurse
Tower	Katrina	Joleen	RN60018705	Active	Registered Nurse
Polley	Mary	Helena	RN00176715	Active	Registered Nurse
Jodoin	Larry	Patrick	RT0000232	Active	Radiologic Technologist
McCarthy	Brian	S	RT00005829	Active	Radiologic Technologist
Buchholz	David	Paul	RT00000113	Active	Radiologic Technologist
Crockett	Debra	С	RT00003198	Active	Radiologic Technologist

Using data from the Washington State Department of Health Office of Customer Service, the department found that all but one staff are compliant with state licensure and there are no enforcement actions on any of the staff licenses.

It is noted that Dr. David Wu's Washington State credential has expired on June 10, 2018.¹² Since Dr. Wu is identified as the medical director and the primary physician for SCMC's PCI program, it is essential that Dr. Wu have an active Washington State credential. If this project is approved, the department would require Dr. Wu to obtain an active physician credential prior to implementation of the PCI program.

Given the compliance history of the facilities own or operated by the applicant, the department concludes there is reasonable assurance the proposed PCI services would be operated in conformance with applicable state and federal licensing and certification requirements.

Given the compliance review of the identified staff and provided that Legacy Health agree to the condition for Dr. David Wu, the department also concludes there is reasonable assurance the proposed PCI services would be provided in conformance with applicable standards outlined in the PCI rules.

Based on the information reviewed and the previously stated condition, the department concludes **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.

<u>Legacy Health</u>

The draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center provided information related to the four standards under WAC 246-310-740. Legacy Health provided the following statements related to this standard. [source: Application, Exhibit 9 and Application p33]

"Legacy Salmon Creek fully intends to participate in national and state data registries including:

- ACC Cath/PCI registry NCDR (National Cardiovascular Data registry) (Active)
- ACC ACTION registry NCDR (National Cardiovascular Date registry) (Future)
- Washington State COAP (Future)

¹² Documentation provided in the application demonstrated that Dr. Wu met the minimum volume standard required by WAC 246-310-725; the 50 PCIs were performed in one of the Legacy Health hospitals located in the state of Oregon.

Elective PCI outcomes will be benchmarked against statewide and national outcome data and included in the PCI QA joint case review meetings between Legacy Salmon Creek and Legacy Emanuel Medical Center, our heart surgery partner hospital.

Details on the process for benchmarking outcomes against the state and national quality indicators is included in the Quality Program in Exhibit 9."

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 <u>executed</u> 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

The draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center provided information related to this standard under WAC 246-310-740.

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**.

<u>WAC 246-310-740(3)</u> 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

The draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center provided information related to the four standards under WAC 246-310-740. Legacy Health provided the following statements related to this standard. [source: Application, Exhibit 9 and Application p33]

"As identified in the Quality Program established in Exhibit 9, review of data and data collection practices will be reviewed at two levels of frequency:

- Planned and systematic:
 - Monthly Cath Conference will involve formal case review with partnering surgical backup hospital(s), at this time namely Legacy Emanuel Medical Center (LEMC). The review will include jointly treated LSCMC and LEMC patients who receive a continuum of care between the two sites. All transferred cases will be reviewed.
 - Quarterly service line meetings will be established for presentation of data, course corrections and new initiatives for the PCI or Cardiac interventional program.
- *Periodic and as needed:*
 - Assessments conducted as indicated by practice issues, incident or variance reporting, concerns raised through Medical Staff Committees and other sources of information about service problems."

Public Comments None

Rebuttal Comments None

Department Evaluation

The draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center demonstrated compliance with this standard. This sub-criterion is met.

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.

<u>Legacy Health</u>

The draft Elective PCI Continuous Quality Improvement Program for Legacy Salmon Creek Medical Center provided information related to the four standards under WAC 246-310-740. Legacy Health provided the following statements related to this standard. [source: Application, Exhibit 9 and Application p34]

"The Interventional Cardiology Section will report in writing all findings, data and performance improvement activities from all the QA/PI activities. The report will be forwarded to the Department or the Department's designee as requested."

Public Comments None

Rebuttal Comments
None

Department Evaluation

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

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

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.

<u>Legacy Health</u>

In response to this sub-criterion, Legacy Health provided a copy of the Elective PCI Partnering Agreement between Legacy Salmon Creek Medical Center in Vancouver Washington and Legacy Emanuel Medical Center in Portland Oregon. [source: Application, Exhibit 6] Legacy Health also provided the following statements related to continuity of care and unwarranted fragmentation of services related to this project. [source: Application, p29]

"Legacy Salmon Creek has established a partnership agreement with Legacy Emanuel Medical Center in Portland, OR. This agreement is included as Exhibit 6. 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 considers the letters of support provided for this project. It also considers the need assessment and rules related to the establishment of a new adult, elective PCI program within the planning area. Legacy Health provided documentation to demonstrate compliance with the patient transfer standards within the PCI rules.

For these reasons, the department concludes that approval of this project would not result in unwarranted fragmentation of PCI services in the planning area. **This sub-criterion is met**.

(5) <u>There is reasonable assurance that the services to be provided through the proposed project will be</u> provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

Department Evaluation for Legacy Health

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 and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that the Legacy Health application meets the applicable need 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 or tiebreaker criteria contained in WAC 246-310-750. Since Legacy Health is the only applicant that submitted a project for the planning area, the superiority criteria will not be evaluated for this project.

Legacy Health

Legacy Health provided the following statements under this sub-criterion. [source: Application, pp35-36]

"After nearly ten years of waiting, after years of formally requesting and advocating for rule changes, and as transfers out of our emergency department for PCI approach 400 cases annually Legacy Salmon Creek determined that no other alternative exists. While the Department's 2018 data collection and PCI methodology applied to PCI Planning Area 5 is still not correct, Legacy Salmon Creek has run the methodology using all data sources that have historically been used and is confident that the unmet need is for well more than 200 cases. With the Department's confirmation that PeaceHealth St. John is operating above the provider volume threshold, Legacy Salmon Creek elected to submit a CN application at this time because of the need to address the health access issues in the Planning Area."

Legacy Health further states that the option for the community is to submit an application for a PCI program at SCMC because of the burden on patients, costs, and outcomes. Legacy Health provided the following advantages of establishing a program at SCMC.

- Legacy Salmon Creek, through Legacy Health and Legacy Medical Group has access to high quality PCI protocols and providers.
- Having an elective program will allow for the initiation of a 24/7 emergency program as well. Not having an elective PCI program has greatly impacted the Legacy's ability to establish an emergent program. Recruiting and retaining providers to perform procedures in a program that does not provide the full range of PCI services is challenging to say the least. Additionally, PeaceHealth Southwest's program was previously able to better support the community need for emergent PCI. With the recent and very significant population growth one program is just not

enough to support resident need for emergent PCI in Clark County, and it is well documented that patients from Clark County just simply do not go to Cowlitz County for care. Case in point, according to Washington CHARS data, almost 98% of Clark County residents currently go to either Clark County or Oregon hospitals for PCI (inpatient and observation). Being able to establish an elective program at Legacy Salmon Creek will ensure immediate access to both life-saving emergent and elective PCI.

• Patients will no longer be diverted in large numbers from our emergency room, care will be delivered timelier, risks associated with transfer will be reduced, and costs will decrease as well.

No disadvantages to establishing an elective program were identified."

Public Comments None

Rebuttal Comments
None

Department Evaluation

The department did not identify any alternative that was superior in terms of cost, efficiency, or effectiveness that is available or practicable. Taking into account the results of the numeric need methodology, Legacy Health provided information within the application and supplemental documents that its project is reasonable and the best available option for the planning area and surrounding communities. **This sub-criterion is met.**

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

- (a) <u>The costs, scope, and methods of construction and energy conservation are reasonable;</u>
- (b) <u>The project will not have an unreasonable impact on the costs and charges to the public of</u> providing health services by other persons.

Department Evaluation for Legacy Health

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

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

Department Evaluation for Legacy Health

This sub-criterion is evaluated in conjunction with WAC 246-310-240(1) above and is considered met.

APPENDIX A

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Intervention Numeric Need Methodology Using CHARS and DOH survey data Updated 2018-2019 Percutaneous Coronary

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Source: County_Age Pop. Projections OFM August 2017 Sub county Pop Clarinas 2017-2022 PCI Outpatient 2017 Dais Survey Washingtan + Oregon inpatient Data for 2017

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Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology Using CHARS and DOH survey data Department of Health

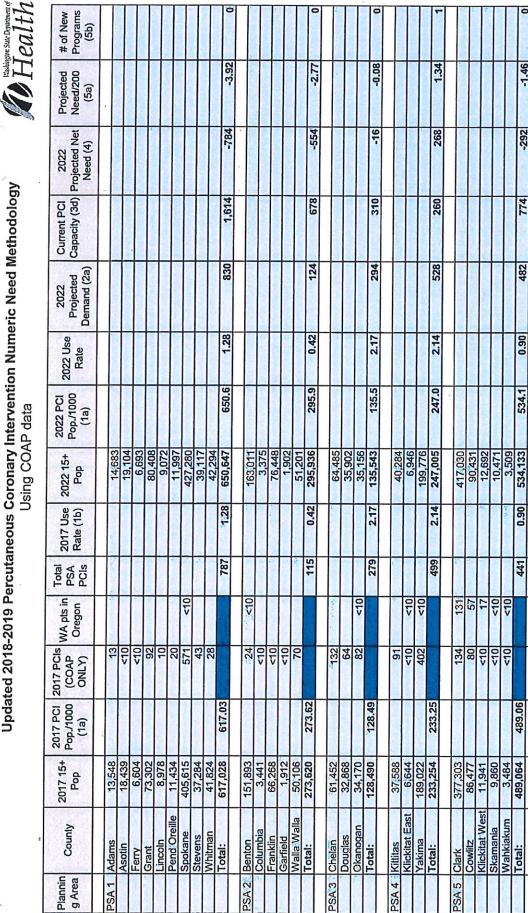
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2022 PCI Pop./1000 (1a)	Chine Reality	336.8		404.4	Contraction of the second of t	1063.2	C Statement of the	895.5	Carlored and the second	700.2	and the second se	and a second and	C. more Color and	196.0	and the second se	and the second		325.8	and the second second	196.0
2022 15+ Pop	336.832	336,832	ADA ADO	404,409	1 063 175	1,063,175	805,401	895,491	700 160	700,169	74 0.4.4	15.370	10.01	195,978	64 830	102,70	231 228	325,778		195,977
2017 Use Rate (1b)		2.00		1.92	the second	1:87		1.40	1	2.33	and the second second	and the second s		2.18				2:60	17 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2.23
Total PSA PCIs		627	a second s	738	State of the state	1849	1	1169	and the second second	1493	the second second second		and there is a	401	Contraction of the		14-1	805	a international and	405
WA pts in Oregon	<10		<10		<10		<10		<10				A Distance and		<10		Section 1		<10	
2017 Outpatient PCIs SURVEY	254		264		919		478		546		48	<10	47		104	30	258		135	
2017 Inpatient PCIs CHARS	372		472		924		689		945		130	15	153		66	65	247		269	
2017 PCI Pop./1000 (1a)		313.63		383:94	and the second	987.72		837.53	and the second se	639.67			a state of the	184.31		The second second		309:30		181.28
2017 15+ Pop	313,630	313,630	383,943	383,943	987,724	987,724	837,532	837,532	639,666	639,666	68:078	14,679	101,557	184,314	62,941	28,201	218,159	309,302	181.277	181,277
County	Pierce East	Total:	Pierce West	Total:	King East	Total:	PSA 10 King West	Total:	Snohomish	Total:	Island	SanJuan	Skagit	Total:	Clallam	Jefferson	Kitsap.	Total:	Whatcom.	Total:
Planning Area	PSA 7	•	PSA 8		PSA 9		PSA 10		PSA 11		PSA 12 Island		1		PSA 13 Clallam		a manual		PSA 14 Whatcom	

Source: County_Age Pop. Projections OFM August 2017 Sub county Pop Canina 2017 2022 PCI County Pop Canina 2017 2018 Survey Washington + Oregon Inpaulen Data for 2017

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Department of Health	Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology	Using COAP data
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Source: County_Age Pop. Projections OFM August 2017 Sub county Pop Clainsa 2017-2022 COAP data for 2017 PCI Inpatient Cregon Data for 2017 PCI Inpatient Cregon Data for 2017

2.07

415

1,093

1,508

3.31

454.9

3.31

1409

425.09

Thurston Total:

19<10

<10

271 208 229 26 645

60,899 64,035 54,211 18,237 18,237 227,712 227,712 425,094

Mason

PSA 6 Grays Harbor

Lewis

61,848 66,860 58,910 18,277 248,976 248,976 454,871

-1.46

-292

774

482

06.0

534.1

0.90

441

489.06

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Washington State Department of	Health
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Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology

Department of Health

Programs (5b) # of New -2.12 2.24 1.89 -6.85 2.39 1.36 1.33 Projected Need/200 (5a) Current PCI 2uzz Capacity (3d) Projected Net Need (4) 448 -424 -1,370 378 478 266 271 313 1,386 1,767 2,651 1,372 273 674 2022 Projected Demand (2a) 2,145 761 962 1,281 1,850 940 544 2.26 2:02 2.64 2.78 2.38 1.43 2.88 2022 Use Rate 336.8 404.4 196.0 325.8 2022 PCI Pop./1000 (1a) 1063.2 700.2 895.5 Using COAP data 336,832 336,832 404,409 1,063,175 895,491 895,491 700,169 71,044 15,379 109,554 195,978 231,228 325,778 195,977 64,830 29,721 2022 15+ Pop 2017 Use Rate (1b) 2.26 2.38 2.02 1.43 2.64 2.78 2.88 709 913 1993 1198 1690 892 512 Total PSA PCIs <10 Oregon . WA pts in <10 <10 <10 <10 <10 10 (COAP ONLY) 2017 PCIs 911 1196 1688 205 24 283 220 112 558 389 708 1987 2017 PCI Pop./1000 383.94 639.67 987.72 837.53 181.28 184.31 309.30 313.63 (1a) 383,943 987,724 987,724 14,679 101,557 184,314 62,941 28,201 218,159 313,630 313,630 639,666 639,666 2017 15+ 837,532 68,078 309,302 181,277 Pop PSA 8 Pierce West PSA 10 King West PSA 14 Whatcom Total: PSA 7 Pierce East Snohomish Total: County PSA 9 King East San Juan Jefferson Skagit PSA 13 Clallam Total: Total: Kitsap Total: Total: Total: Island Total: Plannin g Area PSA 11 SA 12

Source: County_Age Pop. Projections: OFM August 2017 Sub county Pop Cartains 2017-2022 COAP data for 2017 PCI Inpatient Oregon Data for 2017

-0.23

45

467

422

2.15

196.0

2.15

390

181,277

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