Dear Ms. Aylsworth:

We have completed review of the Certificate of Need application submitted by Swedish Health Services proposing to establish an elective percutaneous coronary intervention (PCI) program at Swedish Issaquah. Enclosed is a written evaluation of the application.

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

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

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

**Appeal Option 1:**
You or any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

**Mailing Address:**
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

**Physical Address:**
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501
Appeal Option 2:
You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

<table>
<thead>
<tr>
<th>Mailing Address:</th>
<th>Physical Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health</td>
<td>Department of Health</td>
</tr>
<tr>
<td>Adjudicative Service Unit</td>
<td>Adjudicative Service Unit</td>
</tr>
<tr>
<td>Mail Stop 47879</td>
<td>111 Israel Road SE</td>
</tr>
<tr>
<td>Olympia, WA 98504-7879</td>
<td>Tumwater, WA 98501</td>
</tr>
</tbody>
</table>

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 OCTOBER 23, 2019 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY SWEDISH HEALTH SERVICES PROPOSING TO ESTABLISH A PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT SWEDISH MEDICAL CENTER – ISSAQUAH CAMPUS, WITHIN KING COUNTY.

APPLICANT DESCRIPTION
Swedish Health Services (Swedish) is a not-for-profit health system serving the residents of King and Snohomish Counties and the surrounding areas. Swedish Health Services oversees operations of five hospital campuses, two free-standing emergency rooms, eight urgent care clinics, and a variety of primary and specialty care clinics, among others. [sources: Application pdf3-5, Swedish website]

Swedish Health Services affiliated with Providence Health & Services in 2011, which merged with St Joseph Health System in 2016 to form Providence St. Joseph Health (PH&S). Swedish currently operates through Western HealthConnect – a branch of Providence Ministries that is separate from Providence hospital operations. For ease of reference, the applicant will simple be referred to as “Swedish” throughout this evaluation. [source: CN Historical files]

PROJECT DESCRIPTION
This project focuses on Swedish Medical Center – Issaquah Campus, located in Issaquah. The hospital has been in operation since 2011 and provides a variety of healthcare services to the residents of East King County and surrounding communities. For reader ease, the hospital will be referred to as “Swedish Issaquah” throughout this evaluation. As of the writing of this evaluation, Swedish Issaquah is licensed for a total of 175 beds located at 751 Northeast Blakely Drive in Issaquah [98029]. Table 1 shows 175 beds broken down by service. [source: CN historical files]

<table>
<thead>
<tr>
<th>Services Provided</th>
<th>Beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Medical Surgical</td>
<td>160</td>
</tr>
<tr>
<td>Intermediate Care Nursery - Level II</td>
<td>15</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>175</strong></td>
</tr>
</tbody>
</table>

As of the writing of this evaluation, Swedish Issaquah provides a variety of general medical surgical services, including intensive care, emergency services, and a Level II intermediate care nursery. The hospital is currently a Medicare and Medicaid provider and maintains accreditation through Det Norske Veritas¹ (DNV). [sources: ILRS, and CN historical files]

Swedish submitted this application proposing to establish an adult, elective percutaneous coronary intervention (PCI) program within existing space at Swedish Issaquah. The project would increase the types of services provided at Swedish Issaquah, but does not propose to increase the total number of acute care beds. [source: Application, pdf1 1]

¹ “The requirements of the DNV GL - International Healthcare Accreditation...have been approved by the US Government's Centers for Medicare and Medicaid (CMS). [This] accreditation program is designed to support the development and continual improvement of healthcare quality and patient safety in healthcare organizations. It also addresses general safety for workers, patients and other visitors.” [source: DNV website]
Swedish states there is no capital expenditure associated with the addition of a PCI program and provided the following information to support this position. [source: Application pdf17]

“The proposed program will be operational beginning January 2020 or upon CN approval, whichever comes first. Since there is no construction and the facility currently provides emergent PCIs, the elective PCI program can begin immediately following CN approval.”

There is no estimated capital expenditure, as Swedish Issaquah already operates cardiac catheterization labs for emergent PCIs.

**APPLICABILITY OF CERTIFICATE OF NEED LAW**

This application is subject to review as the addition of a tertiary service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(G).

**EVALUATION CRITERIA**

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

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

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

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

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

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

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

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

(i) Nationally recognized standards from professional organizations;

(ii) Standards developed by professional organizations in Washington State;

(iii) Federal Medicare and Medicaid certification requirements;

(iv) State licensing requirements;

(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and

(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.”

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

**TYPE OF REVIEW**
As directed under WAC 246-310-710, the department accepted this project under the year 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.

Swedish Issaquah is located in planning area #9 as defined in WAC 246-310-705(5). The planning area includes ZIP codes on the east side of King County.

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). The review timeline is summarized on the following page.

**APPLICATION CHRONOLOGY**

<table>
<thead>
<tr>
<th>Action</th>
<th>Swedish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Intent Submitted</td>
<td>January 30, 2019</td>
</tr>
<tr>
<td>Application Submitted</td>
<td>February 28, 2019</td>
</tr>
<tr>
<td>Department’s pre-review activities</td>
<td></td>
</tr>
<tr>
<td>• DOH 1st Screening Letter</td>
<td>March 29, 2019</td>
</tr>
<tr>
<td>• Applicant's Responses Received</td>
<td>May 13, 2019</td>
</tr>
<tr>
<td>• DOH 2nd Screening Letter</td>
<td>June 4, 2019</td>
</tr>
<tr>
<td>• Applicant's Responses Received</td>
<td>June 5, 2019</td>
</tr>
<tr>
<td>Beginning of Review</td>
<td>June 20, 2019</td>
</tr>
<tr>
<td>End of Public Comment/No Public Hearing Conducted</td>
<td>July 25, 2019</td>
</tr>
<tr>
<td>• Public comments accepted through end of public comment</td>
<td></td>
</tr>
<tr>
<td>Rebuttal Comments Received</td>
<td>August 8, 2019</td>
</tr>
<tr>
<td>Department's Anticipated Decision Date</td>
<td>September 23, 2019</td>
</tr>
<tr>
<td>Department's Actual Decision Date with 30-day Extension</td>
<td>October 23, 2019</td>
</tr>
</tbody>
</table>

**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;

2 30-day extension letter sent on September 25, 2019.
(b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;
(c) Third-party payers reimbursing health care facilities in the health service area;
(d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;
(e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;
(f) Any person residing within the geographic area to be served by the applicant; and
(g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

During the review of this project, two entities qualified for affected person status – EvergreenHealth Medical Center and Overlake Hospital Medical Center. Both providers are located in the King East planning area and are CN-approved providers of PCI. Both submitted comments and requested to be informed of the department’s decision.

SOURCE INFORMATION REVIEWED
- Swedish’s Certificate of Need application received February 28, 2019
- Swedish’s first screening responses received May 13, 2019
- Swedish’s second screening responses received June 5, 2019
- Public comments received by the close of business on July 25, 2019
- Rebuttal comments received by close of business on August 8, 2019
- Hospital/Finance and Charity Care (HFCC) Financial Review
- Department of Health Integrated Licensing and Regulatory System database [ILRS]
- Licensing and/or survey data provided by the Department of Health’s Investigations and Inspections Office
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Swedish Health Services’ website at swedish.org
- Joint Commission website at www.qualitycheck.org
- Washington Courts website at www.courts.wa.gov
- Certificate of Need historical files

CONCLUSIONS
For the reasons stated in this evaluation, the application submitted by Swedish proposing to establish an adult, elective percutaneous coronary intervention program at Swedish Medical Center – Issaquah is not consistent with applicable review criteria of the Certificate of Need Program and a Certificate of Need is denied.
CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Swedish Health Services did not meet the applicable need criteria in WAC 246-310-210.

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

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

PCI Methodology WAC 246-310-745

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

For PCI programs, Washington State is divided into 14 separate planning areas. Swedish Issaquah is located in Issaquah, within East King County, identified as PCI planning area #9. The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation is limited to Planning Area #9.

Swedish Health Services

Swedish Health Services applied the five-step numeric need methodology for the PCI planning area #9. The numeric methodology outlined in WAC 246-310-745(10) is restated below along with Swedish Health Services’ information as it applied the numeric methodology. [source: Application, pdf 18, 22-27]

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 age by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

---

3 WAC 246-310-705.
4 Residents 15 years of age and older.
**Applicant's Table**

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

<table>
<thead>
<tr>
<th>Resident PCIs, 2017</th>
<th>Inpatient</th>
<th>Outpatient</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td></td>
<td></td>
<td>1,828</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Residents Age 15+, 2017</th>
<th>Population</th>
<th>Pop/1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td>966,842</td>
<td>966.84</td>
</tr>
</tbody>
</table>

**PCI Use Rate, 2017**

<table>
<thead>
<tr>
<th>East King</th>
<th>Rate/1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.891</td>
</tr>
</tbody>
</table>

Sources: ¹CHARS and ²Washington Department of Health PCI Survey ³Oregon Health Policy and Research Hospital Discharge Data. ⁴Population Source: Claritas

**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.

**Applicant's Table**

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

<table>
<thead>
<tr>
<th>PCI Use Rate, 2017</th>
<th>Rate/1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td>1.891</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Residents Age 15+</th>
<th>2017 ⁴</th>
<th>2022 ⁴</th>
<th>Ave. An. Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td>966,842</td>
<td>1,048,733</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Residents Age 15+, 2022</th>
<th>Population</th>
<th>Pop/1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td>1,048,733</td>
<td>1048.73</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resident PCIs, 2022</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td>1,983</td>
</tr>
</tbody>
</table>

⁴Population Source: Claritas

**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;

³ Residents 15 years of age and older.
(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.

**Applicant’s Table**

<table>
<thead>
<tr>
<th>PCI Providers, 2017</th>
<th>Inpatient and Observation</th>
<th>Outpatient</th>
<th>Total PCIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overlake Medical Center</td>
<td>227</td>
<td>242</td>
<td>469</td>
</tr>
<tr>
<td>UW Medicine/Valley Medical Center</td>
<td>232</td>
<td>73</td>
<td>305</td>
</tr>
<tr>
<td>EvergreenHealth Kirkland</td>
<td>200</td>
<td>329</td>
<td>529</td>
</tr>
<tr>
<td>MultiCare Auburn Medical Center</td>
<td>74</td>
<td>10</td>
<td>84</td>
</tr>
<tr>
<td>St. Francis Hospital</td>
<td>158</td>
<td>126</td>
<td>284</td>
</tr>
<tr>
<td><strong>Planning Area Total</strong></td>
<td><strong>891</strong></td>
<td><strong>780</strong></td>
<td><strong>1,671</strong></td>
</tr>
</tbody>
</table>

Sources: ¹CHARS and ²Washington Department of Health PCI Survey

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.

**Applicant’s Table**

<table>
<thead>
<tr>
<th>Resident PCIs, 2022</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td>1,983</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PCI Providers, 2017</th>
<th>Inpatient and Observation</th>
<th>Outpatient</th>
<th>Total PCIs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Planning Area Total</strong></td>
<td><strong>891</strong></td>
<td><strong>780</strong></td>
<td><strong>1,671</strong></td>
</tr>
</tbody>
</table>

**Net Need for PCIs, 2022**

<table>
<thead>
<tr>
<th>East King</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>312</td>
</tr>
</tbody>
</table>

Sources: ¹CHARS and ²Washington Department of Health PCI Survey

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

**Applicant’s Table**

<table>
<thead>
<tr>
<th>Net Need for PCIs, 2022</th>
<th>Total</th>
<th>Programs</th>
<th>200 Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>East King</td>
<td>312</td>
<td>+200</td>
<td>≈ 1 program</td>
</tr>
</tbody>
</table>

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

“(1) Hospitals with an elective PCI program must perform a minimum of three hundred adult PCIs per year by the end of the third year of operation and each year thereafter.

(2) The department shall only grant a certificate of need to new programs within the identified planning area if:

(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and

(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard."

The table included in Step 3 of Swedish Health Services’ numeric methodology identifies the current capacity of the planning area, and shows MultiCare Auburn Regional Medical Center performed 84 PCIs in year 2017. For this reason, during the review of this project, the department asked questions about Swedish Health Services’ approach to the numeric methodology. Below is a restatement of the exchange between the department and Swedish Health Services. [source: Certificate of Need Screening 1, Screening 1 Response pdf2-5]

Certificate of Need Program Question

[WAC 246-310-720(2) restated]

Though there is need in the planning area, there is one facility that is not meeting the volume standard. The rule does not include any provisions for an exception to this standard. Please confirm your understanding of this section of rule. Contact me if you would like to discuss your options.

Swedish Health Services Screening Response

Swedish Health Services dba Swedish Issaquah has reviewed and understands the volume standards for adult percutaneous coronary intervention ("PCI") programs that are identified in WAC 246-310-720(2). However, respectfully, we want to remind the Department of Health Certificate of Need Program ("the CN Program") of the PCI volume standards in WAC 246-310-720(1), which states [emphasis added]:

(1) Hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter.

In the East King Planning Area, Auburn Regional Medical Center ("Auburn Regional") and Franciscan Health System - St. Francis Hospital ("St. Francis") filed a CN application on February 26, 2009, proposing to establish a joint elective adult PCI program at their facilities. [FN1: Auburn Regional and St. Francis CN Application (February 26, 2009).]
Auburn Regional and St. Francis stated in their CN application:[FN2: Auburn Regional and St. Francis CN Application (February 26, 2009), p. 66.]

In addition to the joint application now in front of the Department, Auburn and St. Francis both considered filing independent applications to provide elective PCI services. In a joint meeting to explore options, it quickly became clear that there were numerous and compelling reasons to pursue a joint application. These include, but are not limited to:

- we share a single cardiology staff;
- our service areas overlap;
- our shared commitment to the long-term viability of our emergency programs; and
- our reliance on Tacoma tertiary hospitals for back-up and support.

The "joint" aspects of the Auburn Regional and St. Francis elective PCI programs were focused on staffing and operational decisions, not a combination of PCI volumes for a single program. In their CN application, Auburn Regional and St. Francis identified each hospital program would exceed the minimum 300 adult PCIs by the end of the third year of operations:[FN3: Auburn Regional and St. Francis CN Application (February 26, 2009), p. 18. The projected PCI volumes for Auburn Regional and St. Francis also were repeated in Table 12, p. 26.]

**Applicant's Table**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
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<td>70</td>
<td>70</td>
<td>68</td>
<td>69</td>
<td>70</td>
<td>137</td>
<td>139</td>
<td>140</td>
</tr>
<tr>
<td>Scheduled</td>
<td>69</td>
<td>155</td>
<td>235</td>
<td>70</td>
<td>155</td>
<td>234</td>
<td>139</td>
<td>310</td>
<td>469</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>138</td>
<td>225</td>
<td>305</td>
<td>138</td>
<td>224</td>
<td>304</td>
<td>276</td>
<td>449</td>
<td>609</td>
</tr>
</tbody>
</table>

Source: Applicant

The CN Program issued its evaluation on October 23, 2009, and identified the application was consistent with applicable criteria of the CN Program if the applicants agreed to meet certain terms and conditions. [FN4: CN Program Evaluation (October 23, 2009).] [FN5: In 2012, the CN Program issued CN #12-40 to approve the purchase of Auburn Regional Medical Center by MultiCare Health System. In the evaluation, the CN Program stated: "Auburn Regional Medical Center also operates a joint PCI program with St. Francis Hospital, a Franciscan Health System hospital located in Federal Way" (August 31, 2012, p. 1). In its PCI evaluation for Auburn Regional and St. Francis, the CN Program included this condition: "In the event this PCI program ceases to operate as a joint venture as described in the application and approved by the department, neither Auburn Regional Medical Center or FHS-St. Francis Hospital may continue to operate a PCI program without first obtaining a new Certificate of Need" (CN Program Evaluation (October 23, 2009, p. 4). It is unknown whether following the sale of Auburn Regional to MultiCare whether the joint venture has continued to operate or whether the Auburn Regional program is still permitted to operate.] However, Auburn Regional has not, in fact, met the conditions associated with the minimum volume standards.

Since receiving its CN in October 2009, Auburn Regional has failed to meet or exceed the minimum volume standards for its elective PCI program. At no point during the almost decade that
Auburn Regional has sought to establish and operate an elective PCI program has it met the minimum volumes standards. In their CN application, Auburn Regional projected it would provide a total of 138 cases in 2010, 225 cases in 2011, and 305 cases in 2012. [FN6: Auburn Regional and St. Francis CN Application (February 26, 2009), p. 18.] Historical data demonstrates Auburn Regional has never met even its first year projection of 138 cases (see Table 26). In fact, the program has been in steady decline from its high of 133 cases in 2011. In 2017, Auburn Regional provided just 84 total cases, representing 28% of the required minimum volume of 300 PCIs [FN7: When Auburn Regional was approved on October 23, 2009 to establish an adult elective PCI program, the minimum volume standard was three hundred (300) adult PCIs per year by the end of the third year of operation and each year thereafter. On March 20, 2018, the Department adopted amended rules under WSR #18-07-102 that changed WAC 246-310-715, WAC 246-310-725 and WAC 246-310-745 to state that hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter.] See Table 26 for the 2008-2016 PCI volumes at Auburn Regional, as well as the percentage of required volumes at the hospital.

**Applicant’s Table**

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ispatient PCI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MultiCare Auburn Regional Medical Center</td>
<td>89</td>
<td>80</td>
<td>144</td>
<td>148</td>
<td>129</td>
<td>125</td>
<td>90</td>
<td>86</td>
<td>81</td>
<td>74</td>
</tr>
<tr>
<td></td>
<td>Outpatient PCI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>24</td>
<td>131</td>
<td>133</td>
<td>103</td>
<td>127</td>
<td>101</td>
<td>104</td>
<td>97</td>
<td>84</td>
</tr>
<tr>
<td>Total PCI</td>
<td>106</td>
<td>104</td>
<td>275</td>
<td>281</td>
<td>232</td>
<td>252</td>
<td>201</td>
<td>190</td>
<td>178</td>
<td>160</td>
</tr>
<tr>
<td>% of required volume (300)</td>
<td>43.7%</td>
<td>44.3%</td>
<td>43.3%</td>
<td>43.3%</td>
<td>42.3%</td>
<td>43.3%</td>
<td>39.7%</td>
<td>39.7%</td>
<td>32.3%</td>
<td>28.0%</td>
</tr>
</tbody>
</table>

Source: CHARS 2008-2017 and DOH Outpatient PCI Surveys

When applicants fail to meet the annual volume standards, the Department may conduct a review of the CN approval for the elective PCI program under WAC 246-310-755 [emphasis added]:

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

1. Hospitals granted a certificate of need must meet:
   1. The program procedure volume standards within three years from the date of initiating the program; and
   2. QA standards in WAC 246-310-740.
2. The department may reevaluate these standards every three years.

To our knowledge, the CN Program has not conducted a review of the Auburn Regional program. Based on historical volumes and trend, it is highly unlikely that Auburn Regional will ever attract enough patients to achieve the current 200 minimum volume standard. Considering that the need methodology in the Planning Area projects a need for 1.56 additional programs, the failure of Auburn Regional to achieve the minimum volume standard during almost a decade of operations should not preclude another elective PCI program in the Planning Area. Approving an elective PCI program at Swedish Issaquah would provide local residents with much needed access to services and would serve to address a significantly unmet need.”

Public Comments
During the review of this project, the department received two letters of opposition and no letters of support. Both letters of opposition focus on this sub-criterion. Below are applicable excerpts of the letters from affected persons:

**Jonathan Duarte, Chief Strategy Office – Overlake Medical Center & Clinics**

"Swedish's application is inconsistent with WAC 246-310-720 (2) which states explicitly that the department only grant a certificate of need to new programs within the identified planning area if (b) all existing PC/ programs in that planning area are meeting or exceeding the minimum volume standard. MultiCare Auburn has not met the minimum volume standard of 200 PCI annually, and Swedish's proposal should be denied.

Swedish's application provides data demonstrating that MultiCare Auburn performed 84 PCIs in in the most recent year of data being used in this 2019 concurrent review cycle; well below the 200 annual volume requirement. Yet, Swedish suggests that its application should be approved because transportation corridors between eastside residents and MultiCare Auburn Hospital's location shows its location is not easily accessible to Issaquah, Bellevue, and other planning area residents.

Swedish further suggests that MultiCare Auburn's underutilization should not prevent King East residents who live on the eastside access, and that without the approval of its project, residents will not have access and outmigration will continue, particularly to Swedish Cherry Hill. WAC 246-310-210 (1) requires that a determination of need be based on a demonstration that services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

Swedish's application contains no data indicating why it bypasses the high quality, accessible program at Overlake and send its patients further, over bridges and into downtown Seattle. According to Google Maps, Overlake is located 12.5 miles and 18 minutes from Swedish Issaquah. We have capacity to serve additional patients. In contrast, Swedish Cherry Hill is located 17.4 miles and approximately 29 minutes from Swedish Issaquah. Swedish has failed to demonstrate that other PCI Planning Area providers, and particularly, Overlake, are not available and accessible.

In closing, the proposal of Swedish to establish a new adult elective PCI Program in PCI Planning Area 9 is not consistent with CN requirements, and should be denied. As an affected party, Overlake requests to be informed in writing of the Department's decision in the matter."

**Jeff Friedman, Senior Vice President – Hospital & Medical Group Operations at EvergreenHealth**

Swedish’s application fails to meet applicable standards. As detailed below, one PCI Planning Area 9 provider has not met the minimum volume standard of 200 PCI annually. Under rule, even in the presence of numeric need, no new provider can be approved until all existing providers are operating at the minimum threshold.

In its application materials, Swedish states that MultiCare Auburn’s volumes are irrelevant and that the Department should ignore the requirement that all providers in the planning area must meet or exceed the minimum volume standards.

The standard in WAC 246-310-720 is not only relevant, but mandatory and binding, and the Department and Swedish are both aware of this fact. In its request to Swedish for supplemental information, the Department wrote:
Though there is need in the planning area, there is one facility that is not meeting the volume standard. The rule does not include any provisions for an exception to this standard. Please confirm your understanding of this section of rule. Contact me if you would like to discuss your options.

Swedish responded to this statement by asserting that there is another subsection of the WAC that requires applicants to achieve the minimum volume by the third year of operation and provides permissive language to the Department to review programs that do not meet this standard, and hence the Department should approve the Swedish CN so as not to preclude another elective program:

Considering that the need methodology in the Planning Area projects a need for 1.56 additional programs, the failure of Auburn Regional to achieve the minimum volume standard during almost a decade of operations should not preclude another elective PCI program in the Planning Area.

The WAC language’s mandatory and absolute standard prohibiting approval of a program in a planning area wherein an existing provider is performing under 200 is separate and distinct from the WAC’s permissive authority or prerogative to review programs and potentially enforce for volume and quality. If at some point the Department decides to use its prerogative to review MultiCare Auburn and rescind its CN, and if MultiCare Auburn does not prevail in any appeal, then Swedish could apply when MultiCare Auburn no longer has an approved elective PCI CN application. In the meantime, the rules are clear and binding.

Of final note, Swedish’s current attempt to guide the Department to disregard its WAC established Planning Area definitions is inconsistent with the historical position of Swedish and its affiliate Providence Health Services. As recently as 2015, and related to a petition to remove elective PCI from CN review as a tertiary service, Providence (including Peter Casterella, MD, Department Chair of Cardiovascular Services, Swedish Health Services) submitted public comment stating that adding programs in urban areas already served by providers is an economically motivated, not need motivated (Swedish Issaquah is located within 10 miles of Overlake and 17 miles of Evergreen and Valley Medical Center). In that same public comment, Swedish also noted and supported the mandatory nature of the requirement for existing providers within the planning area to reach minimum volumes prior to a new program being established stating:

...four of the five hospitals proposing to remove PCI procedures from the list of tertiary services are located in urban areas already served by PCI providers… These facts are consistent with the clinical literature, which has found the addition of PCI services is an economic response, not a response driven by the need for greater access.

Patient access will not be improved by this proposal, and costs per unit of service will necessarily increase as falling volumes are divided across more providers. This is contrary to proper delivery of high quality, low cost care, a foundation of the Department of Health’s certificate of need policy objectives.

Further, all existing PCI programs in the planning area must be meeting or exceeding this minimum volume standard prior to approval of a new facility.
For each of the above reasons, the proposal of Swedish to establish a new adult elective PCI Program in PCI Planning Area 9 is not consistent with CN requirements, and should be denied.

**Rebuttal Comments**
Swedish provided combined rebuttal that responds to both Overlake and EvergreenHealth:

“As noted in Swedish’s screening response 1 (5/13/19), Auburn Regional Medical Center (“Auburn Regional”) and Franciscan Health System – St. Francis Hospital (“St. Francis”) filed a CN application on February 26, 2009, proposing to establish a joint elective adult PCI program at their facilities in the East King County.

The CN Program issued its evaluation on October 23, 2009, and identified the application was consistent with applicable criteria of the CN Program if the applicants agreed to meet certain terms and conditions. However, Auburn Regional has not, in fact, met the conditions associated with the minimum volume standards.

As noted further in Swedish’s screening response 1 (5/13/19), since receiving its CN in October 2009, Auburn Regional has failed to meet or exceed the minimum volume standards for its elective PCI program. At no point during the almost decade that Auburn Regional has sought to establish and operate an elective PCI program has it met the minimum volumes standards. In their CN application, Auburn Regional projected it would provide a total of 138 cases in 2010, 225 cases in 2011, and 305 cases in 2012. Historical data demonstrates Auburn Regional has never met even its first year projection of 138 cases (see Table 26). In fact, the program has been in steady decline from its high of 133 cases in 2011. In 2017, Auburn Regional provided just 84 total cases, representing 28% of the required minimum volume of 300 PCIs. See Table 26 for the 2008-2016 PCI volumes at Auburn Regional, as well as the percentage of required volumes at the hospital.

**Applicant’s Table**

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Inpatient PCI</th>
<th>Outpatient PCI</th>
<th>Total PCI</th>
<th>% of required volume (300)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MultiCare Auburn Regional Medical Center</td>
<td>89/80</td>
<td>17/24</td>
<td>131/133</td>
<td>43.7%</td>
</tr>
</tbody>
</table>

Source: CHARS 2008-2017 and DOH Outpatient PCI Surveys

When applicants fail to meet the annual volume standards, the Department may conduct a review of the CN approval for the elective PCI program under WAC 246-310-755 [emphasis added]:

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

(1) Hospitals granted a certificate of need must meet:
(a) The program procedure volume standards within three years from the date of initiating the program; and
(b) QA standards in WAC 246-310-740.
(2) The department may reevaluate these standards every three years.

To our knowledge, the CN Program has not conducted a review of the Auburn Regional program. Based on historical volumes and trend, it is highly unlikely that Auburn Regional will ever attract
enough patients to achieve the current 200 minimum volume standard. Considering that the need methodology in the Planning Area projects a need for 1.56 additional programs, the failure of Auburn Regional to achieve the minimum volume standard during almost a decade of operations should not preclude another elective PCI program in the Planning Area.

Applying an elective PCI program at Swedish Issaquah would provide local residents with much needed access to services and would serve to address a significantly unmet need. Without approval of an elective PCI program, the planning area residents will continue to face shortage of PCI programs.

In addition, Overlake makes reference to the distance travelled for patients seeking elective PCIs that live near Swedish Issaquah in East King County but currently travel to Swedish Cherry Hill. Swedish's application contains no data indicating why it bypasses the high quality, accessible program at Overlake and send its patients further, over bridges and into downtown Seattle. According to Google Maps, Overlake is located 12.5 miles and 18 minutes from Swedish Issaquah. We have capacity to serve additional patients. In contrast, Swedish Cherry Hill is located 17.4 miles and approximately 29 minutes from Swedish Issaquah.

As noted in the Swedish CN application, in 2017 32.5% of outpatient and inpatient PCIs for East King residents were performed Non-King East Hospitals. This indicates that East King residents are migrating out of East King for PCI services. Overlake has the greatest market share for outpatient and inpatient PCIs in the East King at 19.4% and Overlake claims they have capacity but clearly Overlake is not addressing the need in East King as nearly one-third of residents in 2017 sought PCI services outside of East King.

Given the significant outmigration and the demonstrated need for an elective PCI program, the DOH should approve the Swedish Issaquah elective PCI program to meet the need in East King and allow residents to seek care locally.

Finally, Evergreen references a 2015 position paper where they note the joint authors, (including Providence Health & Services and Swedish Health Services) stating the following:

Patient access will not be improved by this proposal, and costs per unit of service will necessarily increase as falling volumes are divided across more providers. This is contrary to proper delivery of high quality, low cost care, a foundation of the Department of Health's certificate of need policy objectives.

Clearly Evergreen does not address this statement in context of the current CN application submitted by Swedish. Swedish’s proposal to operate an elective PCI program in East King will meet documented unmet need in the East King Planning Area. As noted above, 32.5% of Planning Area residents out-migrated for PCIs in 2017. Such high outmigration suggests need for an additional program. Without the proposed project, there will be continued outmigration, and Planning Area residents will continue to travel unnecessarily long distances for an elective PCI procedure.

The proposed Swedish PCI program projects it will add elective PCI volume capacity of 76 in 2020, 92 in 2021, and 111 in 2022. For comparison, the total outmigration of elective PCIs to Non-King East Hospitals in 2017 was 374 cases. Therefore given the high outmigration to Non-King East
Hospitals, an elective PCI program at Swedish Issaquah will help retain volumes in the planning area contrary to Evergreen’s suggestions that volumes will fall among East King providers. With documented significant outmigration and the documented numeric need for an elective PCI program, the DOH should approve the Swedish Issaquah elective PCI program.

**Department Evaluation**

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

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

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

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

(a) Take the total planning area’s base year population residents fifteen years of age and older and divide by one thousand.

(b) Divide the total number of PCIs performed on the planning area residents over fifteen years of age⁷ by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Specific sections of WAC 246-310-745 defines specific terms used in the methodology. Base year is defined in WAC 246-310-750 as the most recent calendar year for which December 31 data is available as of the first day of the application submission period for the department’s CHARS reports or successor reports. Since this application was submitted on February 28, 2019, year 2018 data was not yet available. For this project, base year is 2017.

Using the base year of 2017, the department calculated the use rate as described above. The table below compares the use rates calculated by both the department and Swedish Health Services.

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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.

⁷ Residents 15 years of age and older.
As shown in the Step One Table above, the 2017 population of residents 15 years and older is similar in all three methodologies. The significant difference in the table is the year 2017 PCIs, which when divided by the population results in a use rate. Since the calculated use rate is multiplied by the projected population step two below, any differences in the use rate are carried throughout the methodology.

**Step 2:** Forecasting the demand for PCIs to be performed on the residents of the planning area.
(a) Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.\(^8\)

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.

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 different.

**Step 3:** Compute the planning area's current capacity.
(a) Identify all inpatient procedures at CON approved hospitals within the planning area using CHARS data;
(b) Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data; or
(c) Calculate the difference between total PCI procedures by CON approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.

\(^8\) Residents 15 years of age and older.
(d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.

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

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

As defined above, the current capacity of planning area #9 the total number of PCIs performed in EvergreenHealth Medical Center, MultiCare Auburn Medical Center, Overlake Hospital Medical Center, St Francis Hospital, and Valley Medical Center. The table below shows the current capacity by facility. Note that the sum of CHARS and Survey data does not always equal the total reported by COAP. This could be due to a variety of factors, though the total of CHARS and Survey data is generally consistent with the COAP figures, with some exceptions.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Inpatient PCIs (CHARS)</th>
<th>Outpatient PCIs (Survey)</th>
<th>Total</th>
<th>Combined Inpatient &amp; Outpatient (COAP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EvergreenHealth Medical Center</td>
<td>195</td>
<td>329</td>
<td>524</td>
<td>553</td>
</tr>
<tr>
<td>MultiCare Auburn Medical Center</td>
<td>74</td>
<td>10</td>
<td>84</td>
<td>90</td>
</tr>
<tr>
<td>Overlake Hospital Medical Center</td>
<td>227</td>
<td>242</td>
<td>469</td>
<td>515</td>
</tr>
<tr>
<td>St Francis Hospital</td>
<td>158</td>
<td>126</td>
<td>284</td>
<td>295</td>
</tr>
<tr>
<td>Valley Medical Center</td>
<td>232</td>
<td>73</td>
<td>305</td>
<td>314</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>886</strong></td>
<td><strong>780</strong></td>
<td><strong>1,666</strong></td>
<td><strong>1,767</strong></td>
</tr>
</tbody>
</table>

The number of PCIs performed by the hospitals above 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 above as well. The applicant’s calculation of current capacity is below:

<table>
<thead>
<tr>
<th>Provider</th>
<th>Current Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overlake Medical Center</td>
<td>469</td>
</tr>
<tr>
<td>UW Medicine/Valley medical Center</td>
<td>305</td>
</tr>
<tr>
<td>EvergreenHealth Kirkland</td>
<td>529</td>
</tr>
<tr>
<td>MultiCare Auburn Medical Center</td>
<td>84</td>
</tr>
<tr>
<td>St Francis Hospital</td>
<td>284</td>
</tr>
<tr>
<td><strong>Planning Area Total</strong></td>
<td><strong>1,671</strong></td>
</tr>
</tbody>
</table>

As shown in step three above, the applicant’s calculated current capacity of 1,674 is higher than the department’s methodology #1 of 1,666 but is lower than methodology #2 at 1,767. A closer look at the breakdown in PCIs by hospital reveals the differences are in the number of PCIs performed by
the hospitals. Without more detailed information about the source data used by the applicant, the department is unable to explain the applicant’s current capacity. That being said, the applicant’s calculation of Step 3 is generally consistent with the Department’s methodology #1, and the difference of five PCIs does not significantly impact the outcome.

**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 two 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: 375/200 = 1.875 or 1 program.)

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Department Methodology #1</th>
<th>Department Methodology #2</th>
<th>Swedish Health Services Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2-Forecasted Demand</td>
<td>4</td>
<td>2,145</td>
<td>1,983</td>
</tr>
<tr>
<td>Step 3-Current Capacity</td>
<td>4</td>
<td>1,666</td>
<td>1,767</td>
</tr>
<tr>
<td>Net Need in Planning Area</td>
<td>4</td>
<td>324</td>
<td>378</td>
</tr>
<tr>
<td>Divide Net Need by 200</td>
<td>5</td>
<td>1.62</td>
<td>1.89</td>
</tr>
<tr>
<td>Round Down</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Step 5 shown in the table above shows the department projects need for an additional PCI program during this 2019 concurrent review cycle using a base year of 2017 and projecting to year 2022. This need is present in methodologies #1, #2, and in the applicant’s methodology.

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

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

The numeric methodology does calculate need for an additional PCI program in planning area #9 for the 2019 review cycle, which satisfies (2)(a). However, both the department and the applicant show MultiCare Auburn Medical Center operating well below the minimum volume standard of 200. As a result, no applicant for this planning area can satisfy (2)(b). This fact was pointed out by both Overlake Medical Center and EvergreenHealth Medical Center in their public comments. Both entities are PCI providers in the planning area and qualify as affected persons.
WAC 246-310-720(2) has two components, both of which must be met based on a plain read of this rule. Regardless of numeric need identified in the methodology, the Certificate of Need program is not in a position to violate its own rules to approve a new program if both components are not met. Both EvergreenHealth and Overlake identify that the department does not have a mechanism for approving an additional elective PCI program under these circumstances.

Furthermore, there is case law supporting the department’s interpretation of WAC 246-310-720(2). In Swedish Health Services v. The Department of Health9 the Court of Appeals upheld the department’s action in denying a Certificate of Need to a hospital in a planning area where providers were not meeting the minimum volume standard. Relevant excerpts from the Opinion are below:

“...if the Department were to grant a certificate of need to Swedish, despite the plain language of its regulation that specifies minimum volume standards for existing PCI programs, it is fair to assume prejudice to those existing programs. Otherwise, minimum volume levels of existing programs would be irrelevant to forecasting need.” [source: Swedish v. Department of Health p12]

“Swedish points to the Department's regulations for certificates of need for different procedures or services. Swedish argues that these regulations "contain[] numerous exceptions, exemptions, and caveats which allow for[the] approval of various types of projects which may not otherwise satisfy applicable criteria." But the fact that those other regulations contain exemptions is not material to the issues before us.

The PCI regulations lack such language, indicating that their standards are mandatory and not subject to exemption. We reject the argument that the fact that other certificates of need may be granted without meeting all the identified criteria establishes that PCI certificates of need can also be granted without meeting the governing criteria.” [source: Swedish v. Department of Health pp13-14]

“Swedish appears to argue that the Department failed to decide whether the special circumstances that Swedish cites merited issuance of a certificate of need, despite the failure to meet an essential criterion for issuance. Because the regulation clearly requires fulfillment of the minimum volume criterion, and it is undisputed that this criterion is not met in this case, the Department did not need to decide whether the special circumstances advanced by Swedish merited issuance of a certificate of need. Swedish’s arguments to the contrary are unpersuasive for the reasons we explained earlier in this opinion.” [source: Swedish v. Department of Health pp15-16]

“Moreover, even assuming the Department could have issued an order inconsistent with its rules, nothing indicates that it was required to consider doing so before denying Swedish’s application. Thus, the Department did not fail to decide all issues requiring resolution.” [source: Swedish v. Department of Health p16]

“In sum, the Department did not erroneously interpret or apply the law when it denied Swedish's application for a certificate of need.” [source: Swedish v. Department of Health p15]

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Swedish’s rebuttal comments do not refute the department’s position, but instead advocate for an exception based on another section of WAC. EvergreenHealth accurately identified this language as permissive, not mandatory. Conversely WAC 246-310-720 is mandatory, not permissive.

For the reasons above reason, the department concludes that the department cannot approve a new PCI program in planning area #9 without violating the rule under WAC 246-310-720(2)(b). **This sub-criterion is not met.**

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

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

**Swedish Health Services**

“Importantly, the University of Washington provided a total of 709 PCIs in 2017, and of these, 483 were outpatient and 226 were provided on an inpatient basis. Thus, it provides a very large number of PCI cases for education and training purposes.

Further, in 2017, only 80 of the University of Washington's 483 outpatient PCIs came from the King East Planning Area. There are only three King East zip codes from which the University of Washington drew more than five outpatient PCI cases in 2017:

- 98002 (Auburn) which is south of Auburn Regional Medical Center
- 98030 and 98042 (Kent), which is south of Valley Medical Center

None of the three King East zip codes from which the University of Washington draws a significant number of patients is near Swedish Issaquah, and each is much closer to another existing program. Furthermore, Valley Medical Center is an affiliate of UW so current referral volumes to UW are not likely to change. Therefore, it is very unlikely that an elective PCI program at Swedish Issaquah will have a material impact on the University of Washington's volumes.

In addition, there are essentially five zip codes within a 5-mile radius of Swedish Issaquah - 98006, 98027, 98029, 98059, and 98075 - and these zip codes are closer to Swedish Issaquah than any other hospital facility. Although together they represented 191 total inpatient and outpatient PCIs in 2017, these zip codes represented only 10 inpatient and outpatient PCIs occurring at UWMC, which was 1.4% of UWMC's 2017 PCIs.

As stated above, there were 144 East King Planning Area resident PCIs performed at Swedish Cherry Hill (Table 10). The program in Issaquah expects to receive a fair amount of those PCIs as physicians move part of their elective PCI practice to Issaquah. Thus, the program at Swedish Issaquah is not likely to take a material number of PCIs from the University of Washington as such, but rather provide a Swedish facility in Issaquah where Swedish cardiologists may perform much of their current volume of elective PCIs.”
Swedish provided documentation of their correspondence with UWMC. UWMC acknowledged receipt, but did not provide any other response.

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**
University of Washington Medical Center did not provide comments specific to this application. Information provided in the application states that Swedish expects to have little to no impact on the UWMC program if approved. UWMC’s reports to the department and COAP indicate their program has consistently exceeded the minimum volume of 200 PCIs per year.

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.

**Swedish Health Services**
Swedish Health Services provided a table showing the projected number of PCIs it expects to perform through the first three years of the proposed program. The table below summarized the information provided by the applicant. [source: Screening 1 Response, pdf6]

**Applicant’s Table**

<table>
<thead>
<tr>
<th>Type of PCIs</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergent Baseline</td>
<td>91</td>
<td>91</td>
<td>91</td>
<td>91</td>
</tr>
<tr>
<td>Emergent Incremental</td>
<td>-</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Scheduled Incremental</td>
<td>-</td>
<td>74</td>
<td>89</td>
<td>107</td>
</tr>
<tr>
<td>Incremental Total</td>
<td>-</td>
<td>76</td>
<td>92</td>
<td>111</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>91</td>
<td>166</td>
<td>182</td>
<td>202</td>
</tr>
</tbody>
</table>

Source: Swedish

Swedish’s assumptions supporting the volume projections are below. [source: Application pdf29-30]

**Methodology—Emergent Cases**

1. 2019 emergent volumes set to 2016-2018 average with 1.5% estimated annual growth factor. The 1.5% annual growth factor is based on projected population growth (see Table 12).
2. 2020-2022 emergent volumes based on previous year’s emergent cases with 1.5% emergent population growth factor.
3. All sub-calculations are rounded to the hundredths place at each step of the process.
Methodology-Schedule Cases

1. 2020 scheduled outpatient volumes set to 50% of 2017Q3 - 2018Q2 inpatient non-emergent PCI outmigration from patients in East King to PCI centers outside East King Planning Area (total OP outmigration: 103).
2. 2020 scheduled inpatient estimated to be approximately 25% of 2019 emergent volumes.
3. 2021 scheduled volumes estimated at 20% growth over 2020 volume projections.
4. 2022 scheduled volumes estimated at 20% growth over 2021 volume projections.
5. 2021 & 2022 Scheduled IP/OP ratio determined using historic three year averages experienced at Swedish Cherry Hill Campus (2016-2018 CH IP/OP PCI ratio = ~31.1% OP, ~68.9% IP)
6. All sub-calculations are rounded to the hundredths place at each step of the process

A discussion regarding physician volumes was also included. [source: Application pdf30]

“Many cardiologists on Swedish Issaquah’s active Medical Staff are by Swedish Medical Group, working within the Swedish Heart and Vascular Institute. These cardiologists, while they have their current, principal practice in Seattle, rotate through Swedish Heart and Vascular Institute and, therefore, perform the majority of their PCIs at Swedish Cherry Hill.

In addition, Swedish’s Elective PCI Performance Improvement Plan addresses this issue of physician volume requirements. On an annual basis, the Swedish PCI Performance Improvement Committee will evaluate case counts by physician. If a situation arises where a physician’s annual volume, across all sites where the physician practices, is less than 50 cases, the Committee will evaluate potential corrective measures. In addition, the Committee will evaluate outcomes of each provider, and this information will also be used to evaluate physician volume standards.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Swedish Health Services clarified in the application that a large percentage of patients expected to be served by Swedish Issaquah’s PCI program are patients currently being served in an emergent capacity.

Swedish identified that the physicians who would perform PCI at Swedish Issaquah are one and the same with Cherry Hill staff, and therefore foresee no issue with meeting the minimum volume standards. For these reasons, the department concludes that this sub-criterion is met.

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.
To evaluate this sub-criterion, the department evaluates an applicant’s admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services.
The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the planning area would have access to the proposed services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

Medicare certification is a measure of an applicant’s willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals age 65 and over. It is also recognized that women live longer than men and therefore more likely to be on Medicare longer.

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

Charity care shows a willingness of a provider to provide services to individuals who do not have private insurance, do not qualify for Medicare, do not qualify for Medicaid, or are under insured.10

**Swedish Health Services**

Swedish provided copies of the following policies currently in use at Swedish Issaquah. [source: Screening Response 1 Exhibits 7 & 8]

- Admission Policy
- Patient Rights and Responsibilities
- Charity Care Policy

Swedish Issaquah is currently Medicare and Medicaid certified. Swedish provided its current source of revenues by payer for the existing PCI volumes. Swedish did not anticipate it would change with the project. Swedish also provided the current and projected sources of revenue by payer for the hospital as a whole – these are not expected to change as a result of the project, as the PCI program does not have a payer mix consistent with the hospital as a whole. The payer mixes are shown below. [source: Application pdf15, Screening Response 1 pdf6]

<table>
<thead>
<tr>
<th>Revenue Source</th>
<th>Entire Hospital</th>
<th>PCI Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>36.1%</td>
<td>31.09%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>10.28%</td>
<td>9.05%</td>
</tr>
<tr>
<td>Private Self Pay</td>
<td>3.67%</td>
<td>2.57%</td>
</tr>
<tr>
<td>Commercial</td>
<td>49.96%</td>
<td>57.29%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.00%</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

In addition to the policies and payer mix information, Swedish provided the following information related to uncompensated care provided by Swedish. [source: Application, pdf34-35]

“Swedish has provided charity care at the regional average (King County less Harborview) during the last three years, when calculated as a percent of total revenue and as a percent of adjusted revenue.

Importantly, when examined at the aggregate financial level, Swedish provides a significant portion of the charity care in King County. Swedish comprised 27.3% of the aggregate charity care in King County. 10 WAC 246-453-010(4)
County (less Harborview) in 2015, 29.1% in 2016, and 22.9% in 2017. During the period of 2015-2017, Swedish has provided more than 26% of the charity care in King County (less Harborview). Please see Table 16.”

**Applicant’s Table 15**

<table>
<thead>
<tr>
<th>Region/Hospital</th>
<th>% of Total Revenue</th>
<th>% of Adjusted Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overlake Hospital Medical Center</td>
<td>0.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>EvergreenHealth/Kirkland</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td>MultiCare/Auburn Regional Medical Center</td>
<td>1.1%</td>
<td>1.6%</td>
</tr>
<tr>
<td>UW Medicine/Valley Medical Center</td>
<td>0.6%</td>
<td>0.4%</td>
</tr>
<tr>
<td>CHI/Saint Francis Community Hospital</td>
<td>0.9%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Providence/Swedish - Cherry Hill</td>
<td>0.9%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Providence/Swedish - First Hill</td>
<td>0.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Providence/Swedish - Issaquah</td>
<td>0.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Swedish Health Services - Total</td>
<td>0.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>King County Region (Less Harborview Medical Center)</td>
<td>0.7%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

Source: DOH Charity Care Statistics

**Applicant’s Table 16**

<table>
<thead>
<tr>
<th>Region/Hospital</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>3 Year Total 2015-2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swedish Health Services - Total*</td>
<td>$42,608,698</td>
<td>$55,122,755</td>
<td>$57,469,886</td>
<td>$155,201,339</td>
</tr>
<tr>
<td>King County (Less Harborview)</td>
<td>$154,714,071</td>
<td>$189,405,776</td>
<td>$250,800,656</td>
<td>$594,920,503</td>
</tr>
<tr>
<td>Swedish Health Services - Percent</td>
<td>27.5%</td>
<td>29.1%</td>
<td>22.9%</td>
<td>26.1%</td>
</tr>
</tbody>
</table>

Source: DOH Charity Care Statistics

*Includes Swedish – Cherry Hill, Swedish – First Hill, Swedish – Issaquah

“Swedish is committed to providing healthcare services to all persons, without regard to income, race, ethnicity, sex, handicap, or any other factor. Swedish also is committed to caring for each person needing care, regardless of his or her ability to pay.

In addition to the charity care discussed above, Swedish also devotes substantial resources to health-related research, community health activities, and medical education. As a charitable, nonprofit 501(c)(3) organization, Swedish invests its resources in programs and services that improve the health of the community and region, from building partnerships with community clinics that serve the underprivileged to providing free and low-cost health-education classes to the public.” [source: Application pdf35]

Public Comments
None

Rebuttal Comments
None
Department Evaluation
Swedish Health Services has been providing healthcare services to the residents of King County through its hospitals and medical clinics for many years. Healthcare services are stated to be available to low-income, racial and ethnic minorities, handicapped and other underserved groups.
[source: Swedish Health Services website]

The Admission Policy describes the process Swedish uses to admit a patient and outlines rights and responsibilities for both Swedish and the patient. Swedish also provided the Patient Rights and Responsibilities Policy. This policy includes the following non-discrimination language:

“As a patient at Swedish, you have the right: … Not to be discriminated against because of race, color, religion, sex, age, national origin, sexual orientation, disability or source of payment and other factors in admission, treatment or participation in its programs, services and activities. This statement is informed by a variety of federal and state regulations.”

Swedish Issaquah currently provides services to both Medicare and Medicaid patients. Swedish does not anticipate any significant changes in Medicare or Medicaid percentages resulting in approval of this project.

Swedish Issaquah’s current Medicare revenues are approximately 36% of total revenues, likewise, Medicaid revenues are currently 11%. Other revenues are expected to remain the same as well. 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 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. Swedish proposes to establish a PCI program in Issaquah located in the King County Region. Currently there are 23 hospitals operating within the region. Of the 23 hospitals, some did not report charity care data for years reviewed.11

Table 7 on the following page compares the three-year historical average of charity care provided by the hospitals currently operating in the King County Region, less Harborview,12, and Swedish Issaquah’s historical charity care percentages for years 2016-2018. The table also compares the projected percentage of charity care. [source: Application and HFCCP 2016-2018 charity care summaries]

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11 For year 6, USS/BHC Fairfax Hospital North did not report data.
12 Harborview Medical Center is subsidized by the state legislature to provide charity care services. Charity care percentages for Harborview make up almost 50% of the total percentages provided in the King County Region. Therefore, for comparison purposes, the department excluded Harborview Medical Center's percentages.
Table 7
Charity Care Percentage Comparisons

<table>
<thead>
<tr>
<th></th>
<th>Percentage of Total Revenue</th>
<th>Percentage of Adjusted Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>King Region Historical 3-Year Average</td>
<td>0.99%</td>
<td>2.19%</td>
</tr>
<tr>
<td>Swedish Issaquah 3-Year Average</td>
<td>0.83%</td>
<td>1.49%</td>
</tr>
<tr>
<td>Swedish Issaquah Projected Average</td>
<td>1.10%</td>
<td>--</td>
</tr>
</tbody>
</table>

As noted in Table 7 above, the three-year historical average shows Swedish Issaquah has been providing charity care below both the total and adjusted regional averages. For this project, Swedish projects that Swedish Issaquah would provide charity care exceeding the regional average for total revenues and adjusted revenues. The pro forma demonstrate that Swedish expects to provide charity care within the PCI program at a rate consistent with the rest of the hospital.

Swedish has been providing health care services at the Issaquah campus for several years. Charity care is health care provided through the hospital at no cost or reduced cost to low income patients. Charity care is a state-mandated and partially state-funded program that allows uninsured or underinsured people to receive inpatient and outpatient care at a reduced cost. Only people who meet certain income and asset criteria are eligible to receive charity care.

If this project were to be approved, Swedish would be required to agree to the charity care condition stated below.

Swedish Issaquah 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. Swedish Issaquah will use reasonable efforts to provide charity care in an amount comparable to or exceeding the amount of charity care identified in the application or average amount of charity care provided by hospitals in the King County Region, less Harborview. Currently, this amount is 0.99% gross revenue and 2.19% of adjusted revenue. Swedish Issaquah 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 Swedish’s agreement to the condition, the department concludes this sub-criterion is met.

(3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.

(a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

Department Evaluation
This sub-criterion is not applicable to this application.

(b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.
(c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.

Department Evaluation
This sub-criterion is not applicable to this application.

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

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

Department Evaluation
This sub-criterion is not applicable to this application.

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

Department Evaluation
This sub-criterion is not applicable to this application.

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

Department Evaluation
This sub-criterion is not applicable to this application.
B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Swedish did not meet the applicable financial feasibility criteria in WAC 246-310-220.

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

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant’s pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

Swedish Health Services

Swedish provided the following assumptions to determine the projected number of PCIs during the projection period. [source: Application pdf38-39]

- 2019 emergent volumes set to 2016-2018 average with 1.5% estimated annual growth factor. The 1.5% annual growth factor is based on projected population growth (see Table 12).
- 2020-2022 emergent volumes based on previous year’s emergent cases with 1.5% emergent population growth factor.
- 2020 scheduled outpatient volumes set to 50% of 2017Q3 - 2018Q2 inpatient non-emergent PCI outmigration from patients in East King to PCI centers outside East King Planning Area (total OP outmigration: 103).
- 2020 scheduled inpatient estimated to be approximately 25% of 2019 emergent volumes.
- 2021 scheduled volumes estimated at 20% growth over 2020 volume projections.
- 2022 scheduled volumes estimated at 20% growth over 2021 volume projections.
- 2021 & 2022 Scheduled IP/OP ratio determined using historic three year averages experienced at Swedish Cherry Hill Campus (2016-2018 CH IP/OP PCI ratio = ~31.1% OP, ~68.9% IP)
  - Note: All sub-calculation are rounded to the hundredths place at each step of the process.
  - Note: 'With Project' model, the Outpatient Ratio, defined as total revenue/inpatient revenue, which is used to calculate adjusted patient days and adjusted admissions, falls slightly over the forecast.

Using the assumptions stated above, Swedish projected the number of PCIs with the addition of an elective program. The projections shown below begins with calendar year 2019. [source: Application pdf29, Screening 1 Response pdf6]
Applicant’s Table

<table>
<thead>
<tr>
<th>Year</th>
<th>Emergent A</th>
<th>Incremental Emergent B</th>
<th>Scheduled IP C</th>
<th>Scheduled OP D</th>
<th>Scheduled Total E = C + D</th>
<th>Incremental Total F = B + E</th>
<th>Grand Total E = A + E</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-2018 Avg</td>
<td>89.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>89.3</td>
</tr>
<tr>
<td>2019</td>
<td>90.7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>90.7</td>
</tr>
<tr>
<td>2020</td>
<td>92.0</td>
<td>1.4</td>
<td>22.7</td>
<td>51.5</td>
<td>74.2</td>
<td>75.5</td>
<td>166.2</td>
</tr>
<tr>
<td>2021</td>
<td>93.4</td>
<td>2.7</td>
<td>27.7</td>
<td>61.3</td>
<td>89.0</td>
<td>91.7</td>
<td>182.4</td>
</tr>
<tr>
<td>2022</td>
<td>94.8</td>
<td>4.1</td>
<td>33.2</td>
<td>73.6</td>
<td>106.8</td>
<td>110.9</td>
<td>201.6</td>
</tr>
</tbody>
</table>

Source: Swedish – Issaquah
Scheduled IP & OP ratio based on average of 2016-2018 experience at Swedish Cherry Hill for Non-Emergent PCIs

The assumptions Swedish used to project revenue, expenses, and net income for the PCI cost center are below. [source: Application pdf39]

**Revenue**

- Inflation of gross and net revenues was excluded from the model.
- For the project, the gross and net revenues were based on actual revenues of the existing PCI volumes at Swedish Issaquah.
- Payer mix for the project is based on Swedish Issaquah’s 2017 historical payor mix for PCI cases.
- Payer mix for without the project is based on 2019 budget, which is based on recent historical Swedish Issaquah hospital wide payer mix.

**Expenses**

- Salaries and Wages is estimated at an average of $4,685 per case based on actuals from another PCI program within the Swedish system.
- Benefits as a percentage of salaries and wages is estimated at 16.3%.
- Supplies are estimated at an average of $3,728 per case based on actuals from another PCI program within the Swedish system.
- Purchased Services are estimated at $1,093 per case based on actuals from another PCI program within the Swedish system.
- Corporate services allocation for the project is based on forecast percentage of total expenses of the proposed PCI project compared to Swedish Issaquah total expense.
- Corporate services allocation for without the project is based on 40% of total expenses with a 0.5% net increase year over year.
- There is no incremental depreciation projected as there are no new costs requested.

Based on the assumptions above, Swedish provided the following revenue and expense statement for the hospital with and without the project. The “with” scenario is shown below. [source: Screening Response 1, Exhibit 9]
Table 8
Swedish Issaquah WITH Project

<table>
<thead>
<tr>
<th></th>
<th>CY 2019</th>
<th>CY 2020</th>
<th>CY 2021</th>
<th>CY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenue</td>
<td>$222,486,729</td>
<td>$225,596,289</td>
<td>$227,456,307</td>
<td>$229,375,959</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$234,970,221</td>
<td>$238,538,683</td>
<td>$241,285,565</td>
<td>$244,112,897</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
<td>($12,483,492)</td>
<td>($12,942,394)</td>
<td>($13,829,258)</td>
<td>($14,736,938)</td>
</tr>
</tbody>
</table>

The ‘Net Revenue’ line item is gross inpatient and outpatient hospital revenue, plus any non-operating revenue. The ‘Total Expenses’ line item includes all expenses related to hospital operations, including all staff salaries/wages and allocated costs from Providence St. Joseph Health to Swedish Issaquah.

Public Comments
None

Rebuttal Comments
None

Department Evaluation
To evaluate this sub-criterion, the department first reviewed the assumptions used by Swedish to determine the projected PCIs. The incremental growth based on current emergent performance along with recapturing out-of-planning area referrals is an appropriate approach.

Swedish based its revenue and expenses for Swedish Issaquah on the assumptions referenced above. Swedish also used its current operations as a base-line for the revenue and expenses projected for Issaquah as a whole with the proposed elective PCI program. A review of Swedish Issaquah’s fiscal year historical data reported to the Department of Health shows that Swedish operated the Issaquah hospital at a profit for fiscal years 2014, but at a loss in subsequent years. [source: DOH Hospital Finance and Charity Care Income Statement Reports, 2014-2018]

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 Swedish for Swedish Issaquah. To determine whether Swedish would meet its immediate and long range capital costs, HFCCP reviewed the 2018 historical balance sheet for Providence St. Joseph Health and 2018 data for Swedish Issaquah. The information shown in Table 9 below shows both balance sheets. [source: HFCCP analysis, p2]
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. PH&S 2017 balance sheet and Swedish Issaquah 2018 balance sheets were both used to review applicable ratios and pro forma financial information.

Table 10 compares statewide data for historical year 2018, PH&S historical year 2018, and projected years 2020 through 2022. [source: HFCCP analysis, p3]

### Table 10
**Current and Projected Debt Ratios**

<table>
<thead>
<tr>
<th>Swedish Issaquah</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio Category</td>
<td>State 2018</td>
<td>PH &amp; S 2017</td>
<td>Swedish Issaquah</td>
</tr>
<tr>
<td>Long Term Debt to Equity</td>
<td>B 0.442</td>
<td>0.440</td>
<td>3.113</td>
</tr>
<tr>
<td>Current Assets/Current Liabilities</td>
<td>A 2.729</td>
<td>1.305</td>
<td>5.609</td>
</tr>
<tr>
<td>Assets Funded by Liabilities</td>
<td>B 0.389</td>
<td>0.387</td>
<td>0.768</td>
</tr>
<tr>
<td>Operating Expense/Operating Revenue</td>
<td>B 0.973</td>
<td>1.000</td>
<td>1.060</td>
</tr>
<tr>
<td>Debt Service Coverage</td>
<td>A 5.376</td>
<td>26.756</td>
<td>1.187</td>
</tr>
</tbody>
</table>

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, pp3-4]
“Swedish provided revised pro-forma income statements in its first screening responses. Two versions were provided – without the project, with the project. A summarized version of the two whole-hospital projections is presented below:

<table>
<thead>
<tr>
<th>Swedish Issaquah</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>WITHOUT Project</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Net Revenue</td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total Expenses</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Swedish Issaquah</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>WITH Project</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Net Revenue</td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total Expenses</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
</tr>
</tbody>
</table>

Each of the projected income statements provided by the applicant, show the hospital losing money with or without the project. The projected income statements with the project indicate a slightly smaller loss – $14.7 million in calendar year 2022 – than the $15.5 million loss projected for the facility without the project.

This program recognizes that not all reviewable medical services are, on their own, self-supporting. In some reviews, this program has concluded that adding services that might lose money to an otherwise financially viable facility is acceptable when they not damage the financial health of the hospital and meet a need that would be more costly to the community if not addressed.

In this case, the service proposed to be provided is expected to return a positive margin in each year of the projection period, but Swedish projects increasing losses for Issaquah with or without the project. I cannot conclude that the long-range operating costs of this project can be met and, therefore this criterion is not satisfied.”

The Certificate of Need program concurs with the HFCCP analysis. Based on the financial performance of the hospital, the department cannot conclude that the immediate and long-range operating costs of the project can be met. **This sub-criterion is not met.**

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

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

**Department Evaluation**

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

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

C. Structure and Process (Quality) of Care (WAC 246-310-230)
Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Swedish Health Services did not meet the applicable structure and process of care criteria in WAC 246-310-230.

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

Swedish Health Services
Swedish Health Services provided the following table and discussion regarding recruitment of staff necessary for the adult, elective PCI program. [source: Screening 1 Response pdf8-9]

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Technologists</td>
<td>6.0</td>
<td>0.0</td>
<td>6.0</td>
<td>0.5</td>
<td>6.5</td>
<td>0.0</td>
<td>6.5</td>
<td>0.5</td>
<td>7.0</td>
</tr>
<tr>
<td>Nurses</td>
<td>3.0</td>
<td>0.0</td>
<td>3.0</td>
<td>0.0</td>
<td>3.0</td>
<td>0.5</td>
<td>3.5</td>
<td>0.0</td>
<td>3.5</td>
</tr>
<tr>
<td>Management</td>
<td>0.3</td>
<td>0.0</td>
<td>0.3</td>
<td>0.2</td>
<td>0.5</td>
<td>0.0</td>
<td>0.5</td>
<td>0.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Other</td>
<td>0.3</td>
<td>0.0</td>
<td>0.3</td>
<td>0.0</td>
<td>0.3</td>
<td>0.0</td>
<td>0.3</td>
<td>0.0</td>
<td>0.3</td>
</tr>
<tr>
<td>Total</td>
<td>9.6</td>
<td>0.0</td>
<td>9.6</td>
<td>0.7</td>
<td>10.3</td>
<td>0.5</td>
<td>10.8</td>
<td>0.5</td>
<td>11.3</td>
</tr>
</tbody>
</table>

Source: Swedish

“We do not anticipate any staffing challenges. As noted in Table 17 (Revised), Swedish Issaquah will only need to add the equivalent of 1.7 FTE over the 2020-2022 period in order to meet the additional elective PCI volumes.

The on-site staffing model during business hours (7:00 a.m.-4:30 p.m.) includes 3 registered nurses, 6 cath lab technologists, 0.3 FTE scheduler, and 0.3 FTE management. The Cath Lab is currently staffed to cover both elective interventional radiology cases and Emergency STEMI procedures concurrently during business hours. Incremental increases are related to overall combined growth of interventional radiology and Cardiac Catheterization at Swedish Issaquah. Staffing increases will be implemented as volumes grow through 2022, accounting for a 1.7 FTE increase. The incremental
The Catheterization Lab at Swedish Issaquah is currently staffed for emergency PCI both during business hours and on-call. Staffing increases will be implemented as volumes grow through 2022, accounting for a 1.7 FTE increase. The incremental FTE increase by 2022 includes 1.0 technologist, 0.5 nurse, and 0.2 in management. Thus given the limited increase in FTEs, the new elective PCI program will not harm existing PCI programs in the planning area.

Public Comments
None

Rebuttal Comments
None

Department Evaluation
This section of the evaluation focuses on the staffing of the proposed project. Swedish Issaquah is currently licensed for 175 acute care beds, which includes a 15-bed level II intermediate care nursery. The addition of adult, elective PCI program does not require the addition of acute care beds, but does require an increase in staff appropriate to the program.

Swedish Health Services intends to use the strategies for recruitment and retention of staff it has successfully used in the past. The strategies identified by Swedish Health Services are consistent with those of other applicants reviewed and approved by the department for general hospital projects and specific adult elective PCI projects.
Information provided in the application demonstrates that Swedish Health Services is a well-established provider of healthcare services King County and surrounding areas. The application demonstrates that Swedish Health Services has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **This sub-criterion is met.**

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

**Swedish Health Services**

To demonstrate compliance with this sub-criterion, Swedish Health Services provided the following information and specific line drawings of the catheterization labs at related to the infrastructure of Swedish Issaquah. Swedish Health Services also noted that the current and proposed line drawings are identical because there are no alterations required to implement the proposed project. [source: Application pdf17, Screening 1 Response Exhibit 20]

“The proposed program will be operational beginning January 2020 or upon CN approval, whichever comes first. Since there is no construction and the facility currently provides emergent PCIs, the elective PCI program can begin immediately following CN approval.”

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.*

**Swedish Health Services**

Swedish Health Services provided the following information related to this sub-criterion. [source: Application, pdf43-44]

“Swedish Issaquah is currently staffed to perform emergency PCIs twenty-four hours per day, seven days per week. Swedish Issaquah currently has cardiac teams that provide staffing of the Cath Lab from 7:00 a.m. to 4:30 p.m., Monday through Friday. Weekdays after 4:30 p.m. and weekends, the call team is already available for on-call emergent/emergency cases. The on-call team is always available by pager and/or cell phone and is expected to arrive at the hospital within 30 minutes of being contacted. The call team consists of two technologists, one RN, and one credentialed physician during nonbusiness hours.

The current call model places strain on hospital resources and contributes to escalating costs of providing emergency/emergent care for East King County. For example, the total number of ST-Elevation Myocardial Infarction (STEMI) procedures performed last year during call hour’s (4:30
p.m.-7:00 a.m., non-business hours) total 20 cases. A total of 25,584 hours of on-call time was dedicated to the emergent/emergency PCI program between doctors, registered nurses, and technologists resulting in 1,280 call hours per case. Elective PCI would assist in covering the costs associated with the emergency PCI service provided to residents of East King County.

The on-site staffing model during business hours (7:00 a.m.-4:30 p.m.) includes 3 registered nurses, 6 cath lab technologists, 0.3 FTE scheduler, and 0.3 FTE management. The Cath Lab is currently staffed to cover both elective interventional radiology cases and Emergency STEMI procedures concurrently during business hours. Incremental increases are related to overall combined growth of interventional radiology and Cardiac Catheterization at Swedish Issaquah.”

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.

Swedish Health Services
Swedish provided a table showing the number of PCIs performed by their physicians in the last three years. [source: Application pdf46]

Applicant’s Table

<table>
<thead>
<tr>
<th>Physician</th>
<th>Physician License Number</th>
<th>2016 PCIs</th>
<th>2017 PCIs</th>
<th>2018 PCIs</th>
<th>3-Year Total PCIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peter A. Demopoulos, MD</td>
<td>MD00026532</td>
<td>93</td>
<td>118</td>
<td>76</td>
<td>287</td>
</tr>
<tr>
<td>Ming Zhang, MD</td>
<td>MD0216278</td>
<td>89</td>
<td>109</td>
<td>115</td>
<td>313</td>
</tr>
<tr>
<td>Howard S. Lewis, MD</td>
<td>MD0028676</td>
<td>96</td>
<td>77</td>
<td>104</td>
<td>277</td>
</tr>
<tr>
<td>John E. O'Mara, MD</td>
<td>MD0320133</td>
<td>72</td>
<td>81</td>
<td>88</td>
<td>241</td>
</tr>
<tr>
<td>Roger J Westcott, MD</td>
<td>MD00012583</td>
<td>78</td>
<td>60</td>
<td>47</td>
<td>185</td>
</tr>
<tr>
<td>Paul P. Huang, MD</td>
<td>MD00037376</td>
<td>47</td>
<td>60</td>
<td>67</td>
<td>174</td>
</tr>
</tbody>
</table>

Source: SHS

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, some, but not all physicians affiliated with the Swedish PCI program meet this standard. Therefore, if this project were approvable, the department would attach a condition identifying that only physicians meeting the 50 PCIs per year standard would be permitted to perform PCIs at Swedish Issaquah. With agreement to this condition, the department concludes that **this sub-criterion would be met.**

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

**Swedish Health Services**
Swedish Health Services provided the following information for this sub-criterion. [source: Application, pdf29]

“Swedish Issaquah will employ the same cardiologists who perform emergent and elective PCIs at Swedish Cherry Hill and emergent PCIs at Swedish Issaquah, thus if the program is approved the Swedish Cherry Hill cardiologists will be providing elective PCIs in Issaquah they would otherwise perform in Seattle.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
Documentation provided by Swedish Health Services demonstrated Swedish Issaquah will employ a sufficient number of cardiologists to meet its projected number of PCIs, with limited net increase of PCIs in the planning area. **This sub-criterion is met.**

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

a. **Nursing staff should have coronary care unit experience and have demonstrated competency in operating PCI related technologies.**

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

**Swedish Health Services**
Swedish Health Services provided job descriptions for their staff, along with the following information. [source: Application pdf44-46]

“All RNs are ACLS certified through the American Heart Association. All registered nurses have extensive experience (at least 2 years) in a critical care environment. They also have at least one-year of experience in a cath/interventional radiology lab that performs interventional and
diagnostic cardiovascular/vascular imaging procedures. They also have the capability for managing critically-ill patients requiring advanced life support measures—ventilators; transcutaneous/transvenous pacing; intra-aortic balloon pump; vasoactive medications; and invasive monitoring (arterial, pulmonary, Central Venous Pressure).

All technologists are required to have either a Surgical Technologist Registration (RST) with the Department or a Washington State Certified Radiologic Technologist Diagnostic License (AART). All technologists also are required to have BLS-CPR certification. Technologists must have the ability to participate in the on-call schedule with a response time of 30 minutes. Staff members are trained and evaluated annually on many life-saving and sustaining therapies, such as IABP (“intra-aortic balloon pump) counter pulsations. In addition, the technologist staff rotate to Swedish Cherry Hill where they are able to maintain their skills by working in a very high volume cath lab with complex cases and advanced circulatory support devices.

Swedish Issaquah respiratory therapists are licensed with the Department of Health under Chapter 18.89 RCW. Registered Respiratory Therapist (RRT) credentials are preferred. They must have a minimum of six months hospital-based work experience, and have knowledge of adult ventilator management.

In addition, it is Swedish Issaquah policy that hospitalists, who are on-site 24 hours/day, each day, are responsible for, and will manage all airway “codes” in the hospital. Thus, if an intubation emergency arises in the hospital, on-site hospitalists will take responsibility for patient care.

Please see Exhibit 12 for job descriptions of registered nurses, interventional radiology technologists and respiratory therapists. Exhibit 13 also includes orientation checklists for the cardiac Catheterization Interventional Lab.”

“RNs are required to have an equivalent of two years as a staff nurse in a critical care unit and one year in a Cath/IR lab that performs interventional and diagnostic cardiovascular/vascular imaging procedures. They also must have demonstrated competency in PCI-related technologies and have knowledge of computer-based cath lab monitoring equipment. RNs also must have knowledge of sterile procedures and must have experience in caring for critically ill patients requiring advanced life support measures.”

“Respiratory therapists are available 24/7 and are capable of ventilator management. Respiratory Therapists must be registry eligible with the National Board for Respiratory Care (NBRC) and must be a licensed Respiratory Care Practitioner with the State of Washington Department of Health. Swedish Issaquah will provide necessary clinical staff, including hospitalists, who are trained in endotracheal intubation and ventilator management to ride with patients during transport, if necessary. Further, at the discretion of the treating cardiologist, there may be a cardiologist who also accompanies critically-ill patients.

As noted above, it is Swedish Issaquah policy that hospitalists, who are on-site 24 hours/day, each day, will manage all airway “codes” in the hospital. If an intubation emergency arises in the hospital, hospitalists will take responsibility for patient care. Respiratory therapists also can provide ventilator management if that care management is required.”

Public Comments
None
None

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

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

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

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

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

**Swedish Health Services**
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf13; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 3.1”

Item 3.1 states: “**Coordination. The Transferring Hospital and Receiving Hospital shall coordinate the availability of surgical teams and operating rooms. The Transferring Hospital and the Receiving Hospital shall each designate a person who is responsible to coordinate patient transfers under this Agreement.**”

None

**Department Evaluation**
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services demonstrated compliance with this standard. **This sub-criterion is met.**
WAC 246-310-735(2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.

**Swedish Health Services**

Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf13; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 2.2”

Item 2.2 states: “Hours of Operation. The Receiving Hospital shall ensure that it is available to provide cardiac surgery during the hours that elective PCIs are available at the Transferring Hospital.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**

Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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.

**Swedish Health Services**

Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf13; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 1, Item 1.3. Both the Transferring Hospital and the Receiving Hospital share the same electronic medical record system, providing the same access for clinical data, including images and videos.”

Item 1.3 states: “Transfer of Clinical Data. The Transferring Hospital shall transfer all clinical data, including images and videos, with the patient to the Receiving Hospital.”

Public Comments
None

Rebuttal Comments
None
**Department Evaluation**
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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.*

**Swedish Health Services**
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf13; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 1.5.”

Item 1.5 states: “*Communications between Physicians. The Transferring Hospital shall coordinate communications between the physician performing the elective PCI and the cardiac surgeon at the Receiving Hospital regarding the reasons for the patient's transfer and clinical condition.*”

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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.*

**Swedish Health Services**
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf13; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 2.1.”

Item 2.1 states: “*Acceptance of Transfers. The Receiving Hospital agrees to accept all patients referred by the Transferring Hospital under this Agreement.*”

**Public Comments**
None
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards. Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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.

**Swedish Health Services** Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf13; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 1.2.”

Item 1.2 states: **Emergency Transport.** The Transferring Hospital shall arrange for appropriate and safe transportation to the Receiving Hospital. Before the Effective Date, the Transferring Hospital shall have an agreement with a transport vendor. The emergency transport staff shall be advanced cardiac life support certified and have the skills, training, and equipment necessary to monitor and treat the patient during transport and to manage an intra-aortic balloon pump. The Emergency transport shall commence within twenty (20) minutes of the initial identification of a complication.”

**Public Comments** None

**Rebuttal Comments** None

**Department Evaluation** Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards. Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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.

**Swedish Health Services** Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf14; Application Exhibit 15]
“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 1.2.”

Item 1.2 states: “Emergency Transport. The Transferring Hospital shall arrange for appropriate and safe transportation to the Receiving Hospital. Before the Effective Date, the Transferring Hospital shall have an agreement with a transport vendor. The emergency transport staff shall be advanced cardiac life support certified and have the skills, training, and equipment necessary to monitor and treat the patient during transport and to manage an intra-aortic balloon pump. The Emergency transport shall commence within twenty (20) minutes of the initial identification of a complication.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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).**

**Swedish Health Services**
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf14; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 1.2.”

Item 1.2 states: “Emergency Transport. The Transferring Hospital shall arrange for appropriate and safe transportation to the Receiving Hospital. Before the Effective Date, the Transferring Hospital shall have an agreement with a transport vendor. The emergency transport staff shall be advanced cardiac life support certified and have the skills, training, and equipment necessary to monitor and treat the patient during transport and to manage an intra-aortic balloon pump. The Emergency transport shall commence within twenty (20) minutes of the initial identification of a complication.”

Swedish also provided staff job descriptions demonstrating adherence to this sub-criterion. [source: Application Exhibit 12]

Public Comments
None
Rebuttal Comments
None

Department Evaluation
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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._

Swedish Health Services
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf14; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 1.4.”

Item 1.4 states: “**Documentation of Transfer.** The Transferring Hospital shall document the reason(s) for recommending the transfer in the patient's medical record, a copy of which shall be sent with the patient to the Receiving Hospital. The Transferring Hospital shall document the transport time from the decision to transfer the patient to arrival in the operating room of the Receiving Hospital, which under no circumstances shall be longer than two (2) hours.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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._

Swedish Health Services
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf14; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 2, Item 1.7.”
Item 1.7 states: “*Transportation Drills. The Transferring Hospital shall conduct two (2) timed emergency transport drills per year. The outcomes of these transport drills shall be reported to the Transferring Hospital's quality assurance program for review.*”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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* 

**Swedish Health Services**
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening I Response pdf14; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 1, Item 1.1.”

Item 1.1 states: “*Informed Consent. The Transferring Hospital shall secure the patient's signed informed consent for the PCI. The consent form shall indicate that the Transferring Hospital does not have on-site surgical backup and shall address the risks associated with transfer and urgent surgery under this Agreement and the transfer agreement in place with the Receiving Hospital.*”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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.

**Swedish Health Services**
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf14; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 3, Item 3.2.”

Item 3.2 states: “Conferences. Representatives of the Transferring Hospital’s PCI program and the Receiving Hospital's surgical program shall hold quarterly conferences during which preoperative and postoperative cases are reviewed, including all transport cases occurring during that quarter. Case reviews shall include review of the quality measures and outcomes more fully described in Exhibit A attached to this Agreement.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards. Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services 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.).

**Swedish Health Services**
Swedish Health Services provided its executed Elective Patient Transfer Agreement between Swedish Issaquah in Issaquah and Swedish Cherry Hill in Seattle. [sources: Screening 1 Response pdf15; Application Exhibit 15]

“This requirement is addressed in Exhibit 15: Swedish Issaquah and Swedish/Cherry Hill Patient Transfer Agreement, page 3, Item 3.3.”

Item 3.3 states: “Peak Volume Periods. The parties shall address peak volume periods, as necessary, if capacity issues arise.”

Public Comments
None

Rebuttal Comments
None
Swedish Health Services provided a Transfer Agreement to meet many of the PCI standards. Specific to this sub-criterion, the executed transfer agreement submitted by Swedish Health Services demonstrated compliance with this standard. **This sub-criterion is met.**

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

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

**Swedish Health Services**

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

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

In response to the specific question above, Swedish provided the following statement. [source: Application, pdf50]

"There have been no such occurrences."

**Public Comments**

None

**Rebuttal Comments**

None

**Department Evaluation**

As a part of this review, the department must conclude that the proposed services provided by an applicant would be provided in a manner that ensures safe and adequate care to the public. To accomplish this task, the department reviewed the quality of care and compliance history for Swedish and their parent corporation, Providence St. Joseph Health.

**Washington State Survey Data**

The eight Providence hospitals currently operating include Providence Holy Family Hospital, Providence St Joseph’s Hospital, Providence Mount Carmel Hospital, Providence Centralia Hospital,

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13 WAC 246-310-230(5)
Providence Sacred Heart Medical Center and Children’s Hospital, Providence St Mary Medical Center, Providence St Peter Hospital, and Providence Regional Medical Center Everett. Swedish Health Services and Western Health Connect also operate under the Providence umbrella – their Washington State hospitals include Swedish Edmonds, Swedish First Hill, Swedish Issaquah, Swedish Cherry Hill, and Kadlec Regional Medical Center.

All of the hospitals listed above are accredited. The Providence hospitals and Kadlec Regional Medical Center are accredited by the Joint Commission. The Swedish hospitals are accredited by Det Norske Veritas (DNV). [source: Joint Commission website, DNV website, ILRS]

The department also reviewed the survey deficiency history for years 2016 through 2018 for all Providence and Providence-affiliated hospitals located in Washington State. Of the Washington State hospitals, three had deficiencies in one of the three years. All deficiencies were corrected with no outstanding compliance issues. The department did not identify any concerns specific to the operation of a PCI program comparable to the one under review.

In addition to the hospitals above, department also reviewed the compliance history for the two ambulatory surgical facilities and 13 in-home service agency licenses, including home health, hospice and a hospice care center. All of these facilities are operational. Using its own internal database, the survey data showed that more than 40 surveys have been conducted and completed by Washington State surveyors since year 2016. All surveys resulted in no significant non-compliance issues. [source: ILRS survey data and Department of Health Investigations and Inspections Office]

Other States
In addition to a review of all Washington State facilities owned and operated by Providence, the department also examined a sample of Providence/St Joseph Health facilities nationwide. According to information in the application and its website, Providence operates healthcare facilities across the western United States. The department looked up compliance with federal standards at Providence and Providence-affiliated facilities in Montana, California, Alaska, Oregon and Texas. The department identified that the majority of Providence and Providence-affiliated facilities operate in compliance with federal standards without noticeable patterns in non-compliance. The department spot-checked state survey data for California and Texas hospitals – more than half of the total hospitals operated by Providence – and did not find patterns of non-compliance of concern. No evidence on any of the state licensing websites indicated that any of the facilities have ever been closed or decertified from participation in Medicare or Medicaid as a result of compliance issues. Furthermore all were resolved through relatively minor administrative fines.

In addition to the facility review above, Swedish provided the names and credential numbers for all physicians who could perform PCIs at Swedish Issaquah. A review of each providers credential revealed no sanctions.

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14 The three hospitals were Holy Family Hospital in Spokane County, Providence Regional Medical Center-Everett in Snohomish County, and Providence St. Peter in Thurston County.
**Swedish Health Services**

In response to this standard, Swedish Health Services provided their Elective Percutaneous Coronary Intervention Performance Improvement Plan. [source: Screening 1 Response pdf10, Application Exhibit 5]

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**

Swedish Health Services provided a PCI Continuous Quality Improvement Plan to meet many of the PCI standards.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Swedish Health Services 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**

**Swedish Health Services**

In response to this standard, Swedish Health Services provided their Elective Percutaneous Coronary Intervention Performance Improvement Plan. [source: Screening 1 Response pdf11, Application Exhibit 5]

“Patient selection is performed through the use of Appropriate Use Criteria (AUC), which is the national standard. This is indicated in Exhibit 5: Swedish Health Services, Elective Percutaneous Coronary Intervention Performance Improvement Plan, page 5 (Attachment A) and page 8 (Attachment C).”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**

Swedish Health Services provided a PCI Continuous Quality Improvement Plan to meet many of the PCI standards.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Swedish Health Services demonstrated compliance with this standard. **This sub-criterion is met.**
**WAC 246-310-740(3) A process for formalized case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases**

**Swedish Health Services**
In response to this standard, Swedish Health Services provided their Elective Percutaneous Coronary Intervention Performance Improvement Plan. [source: Screening 1 Response pdf11, Application Exhibit 5]

“Swedish use a multidisciplinary Heart Team approach in attending to elective PCI cases. This includes partnership with the surgical team as Swedish Health Services dba Swedish Cherry Hill. This is indicated in Exhibit 5: Swedish Health Services, Elective Percutaneous Coronary Intervention Performance Improvement Plan, page 8 (Attachment C).”

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**
Swedish Health Services provided a PCI Continuous Quality Improvement Plan to meet many of the PCI standards.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Swedish Health Services 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.**

**Swedish Health Services**
In response to this standard, Swedish Health Services provided their Elective Percutaneous Coronary Intervention Performance Improvement Plan. [source: Screening 1 Response pdf11, Application Exhibit 5]

“Swedish has already been reporting PCI data to the department through COAP, including those from Issaquah campus. This is indicated in Exhibit 5: Swedish Health Services, Elective Percutaneous Coronary Intervention Performance Improvement Plan, page 2-3.”

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**
Swedish Health Services provided a PCI Continuous Quality Improvement Plan to meet many of the PCI standards.
Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Swedish Health Services demonstrated compliance with this standard. **This sub-criterion is met.**

Based on the above information, the department concludes that Swedish demonstrated reasonable assurance that Swedish Issaquah would continue to operate in compliance with state and federal requirements if this project is approved. **This sub-criterion – WAC 246-310-230(3) – is met.**

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

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

**Swedish Health Services**

Swedish provided their Patient Transfer Agreement to demonstrate conformance with this sub-criterion. [source: Application Exhibit 15]

**Public Comments**

None

**Rebuttal Comments**

None

**Department Evaluation**

This evaluation takes into consideration the numeric methodology and rules related to the establishment of a new adult, elective PCI program within a planning area.

However, one of the providers in the planning area is not performing at the minimum of 200 adult PCIs as required under WAC-310-720(2)(b). Therefore, a new provider in planning area #9 cannot be approved. For those reasons, the department concludes that approval of this project during this review cycle may result in unwarranted fragmentation of PCI services in the planning area. **This sub-criterion is not met.**

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

This sub-criterion is addressed in sub-section (3) above and **is met.**

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Swedish Health Services **did not meet** the applicable cost containment criteria in WAC 246-310-240.
(1) **Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.**

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

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

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

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

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

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

**Department Evaluation**

Step One:
The department concluded that Swedish Issaquah did not meet the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department need not move to step two.
Public Comment
None

Rebuttal
None

**Department Evaluation**
In earlier portions of this evaluation, the department concluded that the applicant had not demonstrated the project’s conformance with WAC 246-310-210, 2230, and 230.

HFCCP provided the following analysis of this sub-criterion:

“In the initial application Swedish stated that it had explored only one alternative to providing this service at Swedish Issaquah: no nothing. Swedish noted that establishing PCI services at Issaquah was superior to doing nothing for purposes of patient access and allowing cardiology providers who see patients at Issaquah to provide PCI services there, rather than both patients and physicians traveling to Swedish’s Cherry Hill facility for treatment.

Contingent upon a demonstration of need in the planning area, staff would typically find a project that improves patient access and system efficiency at no capital cost to meet this criterion. However, because this project would be established at a facility that is projecting to lose significant and increasing amounts of money each year, staff is not project [sic] is an appropriate option.” [source: HFCCP analysis p5]

Because of this, the department cannot conclude that approval of this facility is the superior alternative to meet the health care needs of the residents of the planning area.

This sub-criterion is **not met**.

(2) In the case of a project involving construction:
   (a) The costs, scope, and methods of construction and energy conservation are reasonable;

**Department Evaluation**
This project does not involve construction – this sub-criterion is not applicable.

   (b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

**Department Evaluation**
This project does not involve construction – this sub-criterion is not applicable.

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

**Swedish Health Services**
“The proposed elective PCI program will occupy and utilize the existing space that currently provides emergent PCIs at Swedish Issaquah. Since the same space and staff for emergent PCI service will be used for the elective PCI service, the staff’s time will be used more efficiently as they will not have to travel to Swedish Cherry Hill to provide elective PCI services. This not only reduces
unnecessary travel time but also reduces inefficiencies associated with pre-surgery preparation, testing, and care.”

“The project promotes better system efficiency by providing services and care in a single location, rather than spreading care across multiple locations. Creating an elective PCI program at Swedish Issaquah, will assist in patients receiving care in one location close to where they reside. The proposed program will help prevent unnecessary patient travel outside of the Planning Area, therefore, improving efficiency.

Given the low cost of implementation, and given available capacity in its catheterization lab for the projected incremental volumes, Swedish Issaquah will operate more efficiently as catheterization volumes grow since the fixed costs already have been incurred.

Finally, the proposed Swedish Issaquah elective program will utilize existing policies, procedures, and the experienced staff of the Swedish Heart and Vascular Institute.” [source: Application, pdf55]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
For this project, Swedish did not meet the applicable review criteria under WAC 246-310-210, 220, and 230. HFCCP provided the following statement regarding this sub-criterion:

“While this project would slightly reduce financial losses at a facility already losing money each year, staff is not convinced, given the status of the overall facility, that the proposed project is an appropriate option.” [source HFCCP analysis p5]

Therefore, the department concludes **this sub-criterion is not met.**
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<th>2017 PCIs (COAP ONLY)</th>
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### Department of Health
#### Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology

Using CHARS and DOH survey data

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Source: County Age Pop. Projections OFM August 2017
Sub county Pop Claritas 2017-2022
PCI Outpatient 2017 Data Survey
Washington + Oregon Inpatient Data for 2017
# Department of Health

## Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology

Using CHARS and DOH survey data

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Sub county Pop Claritas 2017-2022
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Washington + Oregon Inpatient Data for 2017