STATE OF WASHINGTON
DEPARTMENT OF HEALTH

May 10, 2012

CERTIFIED MAIL # 7010 2780 0003 6529 7748

Kevin Brown, CEO
Swedish Health Services
747 Broadway
Seattle, Washington 98122

RE: CN11-20

Dear Mr. Brown:

We have completed review of the Certificate of Need application submitted by Swedish Health Services (SHS) proposing to establish an adult, elective percutaneous coronary intervention (PCI) program at Swedish Issaquah Campus Hospital. 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.

Need	WAC[1] 246-310-210
PCI Need Forecasting Methodology	WAC 246-310-745
PCI Standards	WAC 246-310-720
Financial Feasibility	WAC 246-310-220
Structure and Process of Care	WAC 246-310-230
General PCI Program Requirements	WAC 246-310-715
Partnering and Transportation Agreements	WAC 246-310-735
Cost Containment	WAC 246-310-240

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

Appeal Option 1:
You or any interested or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington

[1] Washington Administrative Code.

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:	Other Than By Mail
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

Appeal Option 2:
You or any affected person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:	Other Than By Mail
Adjudicative Service Unit	Adjudicative Clerk Office
Mail Stop 47879	310 Israel Road SE, Building 6
Olympia, WA 98504-7879	Tumwater, WA 98501

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

Sincerely,

Steven M. Saxe, FACHE
Director, Health Professions and Facilities

Enclosure

cc: Linda Foss, Department of Health, Investigations and Inspections Office

EVALUATION DATED May10, 2012 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY SWEDISH HEALTH SERVICES PROPOSING TO ESTABLISH AN ADULT ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT SWEDISH MEDICAL CENTER ISSAQUAH CAMPUS HOSPITAL

APPLICANT DESCRIPTION

Swedish Health Services (SHS) is a not-for-profit corporation and a 501(c)(3) exempt organization with 100% ownership of Swedish Medical Center.[1] Swedish Medical Center is also a Washington private, not-for-profit corporation and a 501(c)(3) exempt organization. Swedish Medical Center (SMC) provides Medicare and Medicaid acute care services at the following five hospitals [Source: Application, p2 & 13 and ILRS]

Name	Address/City	County
Swedish Medical Center	747 Broadway, Seattle	King
SMC-Ballard Campus[2]	5300 Tallman Avenue Northwest, Seattle	King
SMC-Cherry Hill	500 – 17th Avenue, Seattle	King
SMC-Issaquah Campus	751 Northeast Blakely Drive, Issaquah	King
Swedish Edmonds[3]	21601 76th Avenue West, Edmonds	Snohomish

PROJECT DESCRIPTION

Currently, SMC provides both open heart surgery and adult elective percutaneous coronary interventions (PCIs) at its Cherry Hill campus. PCI means invasive, but non-surgical, mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:

(a) Bare and drug-eluting stent implantation;
(b) Percutaneous transluminal coronary angioplasty (PTCA);
(c) Cutting balloon atherectomy;
(d) Rotational atherectomy;
(e) Directional atherectomy;
(f) Excimer laser angioplasty;
(g) Extractional thrombectomy.[4]

This application proposes the establishment of elective adult PCI services at SMC Issaquah Campus. For ease of the reader, SMC Issaquah Campus will be referred to Swedish-Issaquah.

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[1] Swedish Health Services also has ownership percentages in a variety of other healthcare entities, such as home health, ambulatory surgery, and urgent care clinics. Since these entities are not pertinent to this project, they will not be discussed in this evaluation.

[2] SMC Ballard is licensed under the Swedish Medical Center license

[3] On February 26, 2010, SHS created a separate corporation known as Swedish Edmonds, where SHS is 100% sole member. On August 26, 2010, CN #1426 was issued to Swedish Edmonds approving a long-term lease agreement with Public Hospital District #3-Stevens Hospital located in Edmonds, within Snohomish County. The lease agreement became effective September 1, 2010, and is expected to continue for 30 years, with two 10-year options to renew.

[4] Source: WAC 246-310-705(4)

On July 2, 2007, the department approved SHS to construct a new hospital in the city of Issaquah. After the land use requirements were met, CN #1379 was issued on July 31, 2008.[5] CN #1379 approved establishment of the hospital in three phases. At the time this PCI application was submitted in February 2011, Swedish-Issaquah was still under construction. Swedish-Issaquah became operational with 80 licensed acute care beds in October 2011 (phase one). Phases two and three are expected to be complete by the end of year 2019. At the completion of phase three, Swedish-Issaquah will have 175 licensed acute care beds. [Source: SHS quarterly progress reports and CN historical files]

SHS proposes that elective PCIs would be offered at Swedish-Issaquah beginning in year 2012. The PCI program would be initially staffed by interventional cardiologists from SMC Cherry Hill. In its 2004 CN application to establish the hospital in Issaquah, SHS included a catheterization lab to provide emergent PCIs[6]. SHS proposes the elective PCIs would be provided in the same lab currently used to provide emergent PCIs. As a result, this application does not require additional construction or capital expenditure beyond the $210,944,529 already approved in the 2004 application to establish the hospital at Issaquah.[7]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need (CN) review because it is the establishment of a new tertiary service as defined in Revised Code of Washington (RCW) 70.38.025(14) and WAC 246-310-010(58). PCI tertiary services require prior Certificate of Need review and approval before establishment under RCW 70.38.105(4)(f) and WAC 246-310-020(1)(d)(i)(E).

CRITERIA EVALUATION

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

[5] Subsequent to the initial approval, SHS was also issued CN #1379A approving a change in the approved site to another parcel of land in Issaquah, within King County. SHS was also issued CN #1379A2 approving a change in the financing for the hospital. These two amendments to CN #1379 are not pertinent to this project; they will not be further discussed in this evaluation.

[6] An Emergent PCI is provided to a patient that needs an immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. [Source: WAC 246-310-705(3)]

[7] SHS attributes $4,549,000 for the establishment of the catheterization lab at the Issaquah hospital.

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

In the event the 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;
(ii)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."

WAC 246-310-700 through 755 contains service or facility specific criteria for elective PCI projects and must be used to make the required determinations.

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); and 246-310-240 (cost containment).[8] Where applicable, the applicant demonstrates compliance with the above criteria by meeting the Adult Elective Percutaneous Coronary Interventions (PCI) Without On-Site Cardiac Surgery Standards and Forecasting Method outlined in WAC 246-310-700 through 755.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-710 the department accepted this project under the 2011 PCI Concurrent Review Cycle. Below is a chronologic summary of the project.

Action	SHS
Letter of Intent Submitted	January 27, 2011
Application Submitted	February 28, 2011
Department's Pre-Review activities, including screening and responses	March 1, 2011, through June 16, 2011
Department Begins Review; no public hearing requested or conducted	June 17, 2011

[8] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(5) and (6); WAC 246-310-220(3); and WAC 246-310-240(2) and (3).

Action	SHS
End of Public Comment	July 21, 2011
Rebuttal Documents Received	August 4, 2011
Department's Anticipated Decision Date	September 19, 2011
Department's Anticipated Decision Date (with 30 day extension)	October 19, 2011
Department's Actual Decision Date	May 10, 2012

CONCURRENT REVIEW AND AFFECTED PERSONS

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), which includes defined zip codes located in east King County. No other application was submitted proposing to serve this planning area. In accordance with WAC 246-310-701(3) the department converted the review to a regular review process.

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."

For this project, two entities received affected person status under WAC 246-310-010(2).

- Overlake Hospital and Medical Center – located in Bellevue and currently a provider of both PCI and open heart surgery.
- Evergreen HealthCare – located in Kirkland and currently a provider of elective adult PCI services, with no onsite open heart surgery program.

SOURCE INFORMATION REVIEWED

- Swedish Health Services Certificate of Need application submitted February 28, 2011
- Swedish Health Services supplemental information dated May 5, 2011, and June 8, 2011
- Public comments submitted by community members and healthcare providers
- Rebuttal comments provided by Evergreen Health Care received August 4, 2011
- Rebuttal comments provided by Overlake Hospital Medical Center received August 4, 2011
- Rebuttal comments provided by Swedish Health System received August 4, 2011
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Hospital and Patient Data Systems
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2007, 2008, and 2009 summaries)

- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems received September 23, 2011
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Department of Health 2009 PCI utilization survey data related to outpatient PCIs obtained in year 2010

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Swedish Health Services proposing to establish an adult elective percutaneous coronary intervention program at SMC Issaquah Campus Hospital is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

A. Need (WAC 246-310-210), Need Forecasting Methodology (WAC 246-310-745), PCI Standards (WAC 246-310-720(1), (2), and WAC 246-310-715(1), (2))

Based on the source information reviewed, the department concludes the Swedish Health Services project has not met the need criteria in WAC 246-310-210 and the PCI methodology and standards in WAC 246-310-720, WAC 246-310-715(1) and (2), and WAC 246-310-745.

(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 population's 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 PCI specific numeric methodology applied is detailed under WAC 246-310-745. WAC 246-310-210(1) criteria is also identified in WAC 246-310-720(1) and (2), and 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 complete methodology is in Appendix A attached to this evaluation.

For PCI programs, Washington State is divided into 14 separate planning areas.[9] Swedish-Issaquah is located in the city of Issaquah, within King County. King County is divided into King West and King East planning areas. Swedish-Issaquah is located in Planning Area #9, King East which includes the 44 zip codes shown in Table 1.

Table 1
King East Planning Area Zip Codes

King East PCI Planning Area Zip Codes				
98001	98002	98003	98004	98005
98006	98007	98008	98010	98011
98014	98019	98022	98023	98024
98027	98028	98029	98030	98031
98032	98033	98034	98038	98039
98042	98045	98047	98051	98052
98053	98055	98056	98057	98058
98059	98065	98072	98074	98075
98077	98092	98224	98288	

[9] WAC 246-310-705.

The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation is limited to Planning Area #9.

Swedish-Issaquah is one of eight hospitals operating in Planning Area #9. The eight hospitals are identified in Table 2 below.

Table 2
Planning Area 9 Hospitals

Hospital	Elective PCI's Provided	# of all PCIs Performed in 2009[10]
Evergreen Hospital and Medical Center (CN issued 11/13/2009 and began offering elective services April 2011)	Yes	198
Overlake Hospital and Medical Center	Yes	1,064
Valley Medical Center (CN issued 11/13/2009 and began offering elective services December 2009)	Yes	148
St. Francis Hospital (CN issued 11/13/2009 and began offering elective services December 2009)	Yes	92
Auburn Regional Medical Center (CN issued 11/13/2009 and began offering elective services December 2009)	Yes	80
St. Elizabeth Hospital[11]	No	0
SMC-Issaquah Campus (Hospital was under construction during 2009, began offering hospital services in October 2011)	No	0
Snoqualmie Valley Hospital	No	0

SHS's Methodology

In order to provide a numeric need methodology, data from existing Washington State hospitals must be obtained. SHS relied on the department's utilization survey for outpatient PCIs and CHARS data for inpatient PCIs. SHS used 2009 Hospital Discharge Data from Oregon Health Policy and Research for King East residents having a PCI performed in an Oregon Hospital. [Source: Application p18] For the population data in step 1, the applicant considered the use of two sources:

- Claritas 2010; and
- Washington State Office of Financial Management (OFM) Estimates of Total Population for Zip Codes 2000-2010.

SHS states "*because OFM population estimates by age cohort, and OFM population projections, are available only at the county level (i.e., not at the zip code level which would allow calculations for all PCI Planning Areas), other CN applicants have relied upon Claritas data for PCI applications, which has been permitted by the Department.*" [Source: Application, p20-21] SHS goes on to assert that the Claritas data underestimates the population

[10] As reported on the Department of Health's 2009 PCI Utilization Survey conducted in 2010 and through CHARS.
[11] Formerly Enumclaw Regional Hospital

for the King East zip codes, so SHS used the OFM Estimates of Total Population by zip code, 2000-2010 and OFM Intercensal and Postcensal Estimates 1990-2010. SHS obtained OFM data by zip code for the base year, but not for the 2014 OFM projections. Therefore, SHS calculated an estimate of the 15 and over population by taking the 2010 age percentage of the total population and multiply this percentage times the total 2014 population. [Source: Application, p21]

Below is a summary of SHS's five step methodology.

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 fifteen years of age and over[12] by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

For PCI programs, 'base year' is defined as the most recent calendar year that December 31 data is available from the department's Comprehensive Hospital Abstract Reporting System (CHARS) reports (or successor reports) as of the first day of the application submission period. For this project, the first day of the application submission period was February 1, 2011. The base year data for this project is year 2009.[13]

SHS's Step 1 calculation is as follows:

a) The age 15+ 2009 population was calculated to be 875.229 which is 875,229/1,000.

b) The number of inpatient PCIs was 1,280 and the number of outpatient PCIs was 559 for a total of 1,839 PCIs for the planning area.
1,839/875.23 is 2.101 –the calculated PCI use rate for the planning area

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.[14]

The "forecast year" is the fifth year after the base year. Since the base year is 2009, the forecast year is 2014. SHS used the same OFM population data source for 2014 as used for the 2009 population.

The Step 2 calculation is as follows:

[12] Residents 15 years of age and older.
[13] Year 2010 CHARS data became available in early August 2011 approximately 5 months after the February data cutoff. Therefore, the 2010 data will not be used in this evaluation.
[14] Residents 15 years of age and older.

- The age 15+ population for 2014 was calculated to be 952.093 which is 952,093/1,000.
- The 2009 use rate was 2.101 from step 1(b)
- 952.093 multiplied by 2.101 is 2,000.35 which is the projected number of resident PCIs for year 2014. SHS rounded this number to 2,001.

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

(a) Identify all inpatient procedures at CON approved hospitals within the planning area using CHARS data;

(b) Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data; or

(c) Calculate the difference between total PCI procedures by CON approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.

(d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.

SHS provided the following discussion related to this step in the methodology. [Source: Application, p24-25]

"Three of the four programs in the Planning Area performed fewer than 300 PCIs in 2009. However, because these programs are less than three years old, we have measured their capacity at 300 for purposes of the need forecasting methodology, consistent with the regulation. Auburn Regional Medical Center/St. Francis Hospital program is a joint program, and therefore we have measured the capacity of the program (i.e., not the individual hospitals) at 300.

For Overlake's capacity, we have used the actual volume of procedures performed on residents of the Planning Area (i.e., we have not included procedures performed on residents of other Planning Areas at Overlake). This is consistent with the language of the regulation to 'identify ….procedures…within the planning area.' That this is the correct reading of the regulation is confirmed by considering the following:

1. *In WAC 246-310-745(5), we calculated a use rate using "the number of PCIs performed on the residents of a planning area[.]" (Emphasis added.) It only makes logical sense for us to calculate the capacity available to meet this need based on the number of procedures for Planning Area residents. Otherwise, there will be a shortage of capacity*
2. *In the Overlake Hospital v. Department of Health case (2010), the Washington Supreme Court's most recent opinion regarding CN laws, the Supreme Court ruled that when there are two possible interpretations of the CN regulations, the interpretation that most promotes access to health care services should be used. In the Overlake case, this meant the interpretation of WAC 246-310-270(9) leading to approval of more ASCs; here, this means approval of more PCI programs."*

Based on the statements above, SHS provided the following table showing the step 3 calculations.

Table 3
SHS Methodology
Hospital PCI Capacity Planning Area #9

Hospital	Inpatient	Outpatient	Total PCIs[15]
Overlake Hospital and Medical Center	614	173	787
Evergreen Hospital and Medical Center	112	3	300
Valley Medical Center	133	-	300
Auburn Regional Medical Center/St. Francis Hospital	131	-	300
King East Planning Area Total	**990**	**176**	**1,687**

As shown in Table 3, SHS determined the planning area #9 current capacity to be 1,687.

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

For this step SHS subtracted the calculated capacity of 1,687 (step 3) for year 2014 from the projected need for 2014 of 2,001 (step 2) and determined a net projected need of 313.5 PCIs.

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

SHS divided the project 313.5 by 300 to calculate a need for 1.05 programs in the planning area, which is then rounded down to 1 new program in year 2014.

Department Numeric Methodology

This portion of the evaluation will describe, in summary, the calculations made by the department at each step and the assumptions and adjustments, if any, made in that process. 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.

[15] New PCI Programs approved in 2009 have three years to reach the 300 PCI level, until then capacity is counted at the actual volume or 300 whichever is greater [WAC 246-310-745(2)].

(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.

The department used zip code and age population projections from Claritas years 2009 and 2014. The data was obtained by age group and zip code for King County. Claritas is a recognized source of reliable population data. It has been the policy of the department to use Claritas for zip code level data because at this time OFM does not produce zip code level projections by age groups.

Using the definition in WAC 246-310-745, the base year data is year 2009 data.
Calculations for Step 1 are shown below.

a) The age 15+ 2009 population is 825.456 which 825,456/1000.
b) The number of inpatient PCIs is 1,294, outpatient PCIs is 613 and inpatient from the state of Oregon is 7 resulting in a total of 1,914 PCIs. The 1,914 PCIs are divided by 825.456 to get a calculated use rate of 2.32 for the planning area.

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.[16]

For this project, the forecast year is year 2014. In this step, the department multiplied the use rate of 2.32 calculated in Step 1 by the Claritas projected planning area population of 879.619. The results are 2,040.719 which rounds to 2,041 PCIs for planning area #9 residents in 2014.

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

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

This step requires computation of the planning area's current capacity. WAC 246-310-745 (2) defines "Current capacity" to mean:

"*...the sum of all PCIs performed on people (aged fifteen years of age and older) by all CON approved adult elective PCI programs, or department grandfathered*

[16] Residents 15 years of age and older.

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."

Table 4 shows the PCI providers located in Planning Area #9 and their PCIs for 2009.

Table 4
Need Forecasting Methodology
Hospital Capacity Planning Area #9

Hospital	Inpatient Actual	Outpatient Actual	Total PCI Counted Per Method
Overlake Hospital and Medical Center	823	241	1,064
Evergreen Hospital and Medical Center	195	3	300
Valley Medical Center	144	4	300
Auburn Regional Medical Center	80	-	300
St. Francis Hospital	92	-	300
King East Planning Area Total	**1,334**	**248**	**2,264**

Table 4 above shows that only Overlake is performing more than 300 PCIs in 2009. The other hospitals were approved in November 2009 to offer elective adult PCIs. Because these programs are less than three years old, the department counts their capacity at 300 for purposes of the need forecasting methodology, as required in WAC 246-310-745(10). Additionally while the Auburn Regional Medical Center/St. Francis Hospital program is a joint program, each hospital is required to meet 300 PCIs by the end of the third year of operation. Prior to accepting the joint application from Auburn Regional and St. Francis, the department made the policy decision that to ensure the patient safety and quality outcomes the PCI rules are intended to promote, each facility had to meet the minimum volume standards at each site. As a result, the PCI capacity in planning area #9 is 2,264 as shown in Table 4 above.

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

A subtraction of the current capacity of 2,264 (step 3) from the year 2014 projected need of 2,041 (step 2), results in a surplus of 223 procedures, or -223. This means that there is a surplus of capacity in the planning area.

Step 5: If Step 4 is greater than three hundred, calculate the need for additional programs.

(a) Divide the number of projected procedures from Step 4 by three hundred.

(b) Round the results down to identify the number of needed programs. (For example: 575/300 = 1.916 or 1 program.)

This final step calculates how many new PCI programs could be approved in a planning area. Because there is a surplus in planning area #9, the net need is 0. The calculation then is 0/300 which equals 0. Therefore no new programs can be approved for PCI planning area #9.

Department Conclusion Methodology Review

The department does not agree with SHS's population projections. If there was no known, recognized source of reliable zip code level population projection data by age group available, the department would then consider the approach used by SHS. However, that is not the case here. Claritas is a recognized source of zip level data, by age group, that the department and applicants have used for several years. Therefore, use of the zip code level population projections from Claritas is appropriate rather than the method used by SHS to estimate the population for the planning area.

WAC 246-310-745(2) defines how "current capacity" is to be measured.[17] Review of SHS's application of the numeric methodology shows that SHS reduced the capacity of the Auburn Regional Medical Center/St. Francis Hospital joint program to 300 procedures to be shared between the two hospitals. Additionally SHS counted Overlake Hospital Medical Center at 787 PCIs (Table 3) rather than 1,064 PCIs (Table 4) used by the department. These are significant deviations from the methodology and not consistent with the determination of capacity made by the department on PCI applications submitted in the first concurrent review for PCI services in 2009.

Both Evergreen HealthCare and Overlake Hospital Medical Center submitted comments related to SHS's application of the numeric methodology. Specifically, both hospitals objected to the changes SHS made to the methodology and SHS's interpretation of the rules for calculating the need for PCI services. Both hospitals stated that the rules regarding the methodology have been applied consistently by the department since they became effective in December 2008. Both hospitals especially objected to SHS attempts to reduce the existing PCI capacity by ignoring the rules or making new interpretations. [Source: August 4, 2011 rebuttal comments Overlake Hospital Medical Center, p 1-5; August 4, 2011 rebuttal comments Evergreen Healthcare, p2-3]

[17] WAC 246-310-745 (2) "Current capacity" means the sum of all PCIs performed on people (aged fifteen years of age and older) by all CON 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.

SHS Rebuttal

In response to the comments provided by both Evergreen HealthCare and Overlake Hospital Medical Center, SHS state that its interpretation is correct and any other interpretation would lead to absurd results. [Source: SHS rebuttal, p2]

Department's Evaluation

The department does not agree with SHS's interpretation of "current capacity". The definition of "current capacity" is clearly stated to mean "*the sum of all PCIs performed on people (aged fifteen years of age and older) by all CON approved adult elective PCI programs, or department grandfathered programs within the planning area*." In fact during the development of the CN PCI rules in 2008 and 2009, representatives of SHS provided the following comments at the September 30, 2008, rules public hearing.

> *"In addition, despite what others have argued for, because volumes do matter,* ***the department is correct in not discounting existing volumes.*** *For other tertiary services and even a number of other CN regulated activities-from transplantation to Level II and Level III neonatal care to open heart and pediatric open heart services to bed need rules-the Department counts existing provider volumes (or number of beds) accurately. It* ***does not discount*** *existing capacity. There is no arbitrary volume figures established for existing providers for any tertiary services, as some have recommended for PCI need analysis."*
> Emphasis added. [Source: September 30, 2008 PCI public hearing]

As stated in the department's Concise Explanatory Statement at the time the rules were adopted, "*The intent is to calculate capacity regardless of the origin of the patients.*" The approach SHS now asks the department to take would be inconsistent with that stated intent.

Based on the need methodology outlined above, the department concludes there is no projected need for an additional PCI program in PCI Planning Area #9. The department concludes **this sub-criterion is not met.**

General Requirements in WAC 246-310-715 require the applicant hospital to submit a detailed analysis regarding the effect that an additional PCI program will have on the University of Washington Medical Center (UWMC) program and how the hospital intends to meet the minimum number of procedures. The criteria and 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.

To demonstrate compliance with this standard, SHS provided a table showing the number of PCIs performed at University of Washington (UWMC) on Planning Area #9 residents in year 2009 by patient zip code. A total of 55 PCIs [30 inpatient and 25 outpatient] were

performed. In that same year, UWMC performed a total of 312 PCIs. SHS then identified 5 zip codes within a 5 mile radius of the Swedish-Issaquah location. These zip codes are stated to be closer to the Swedish-Issaquah than any other hospital. The total number of PCIs performed on patients from these 5 zip codes was 227. Of these 227 PCIs only 6 were performed at UWMC, which was less than 2% of UWMC's total PCIs in year 2009. [Source: Application, pp31]

SHS also provided a copy of an email from Howard Lewis, MD, Executive Medical Director of the Swedish Heart and Vascular Institute to Larry Dean, Director of the UW Medicine Regional Heart Center stating:

> *"As you are aware, Swedish Health Services is building a new hospital in Issaquah. Included in the scope of clinical services is an elective PCI program. This program will not impact the PCI program volume at the University of Washington and you will have adequate volume to meet the needs of your training program."*
> [Source: Application, Exhibit 5]

Department's Evaluation

The application contained no direct response to this email from Dr. Lewis. It's not known if any letter was sent to UWMC's administration about the proposed PCI program's impact on UWMC training program.

SHS asserts this project will have no impact on PCI referrals to UWMC because of the small percentage of PCIs from the identified 5 zip codes that received PCI services at UWMC. At the time this application was submitted to the department, Swedish-Issaquah was still under construction. Therefore it had no established hospital service area based on actual hospital use. SHS selected 5 zip codes of the planning area's 44 to base its UWMC impact analysis on. However, it's not known if this number is correct or if the zip codes selected are the only ones. For example, the initial Swedish-Issaquah hospital application identified 24 of the 44 PCI planning area zip codes as its planning area.

UWMC performed a total of 55 PCIs on planning area #9 residents during 2009. This represents 17.63% of UWMC's total PCIs for 2009. If UWMC's PCI volumes are reduced just 4.17%, UWMC's PCI program would be under the department's minimum volume standard of 300. Because Swedish-Issaquah was still under construction when the application was submitted and when the record closed, neither SHS nor the department can reasonably determine that another new PCI program in planning area #9 would not have an unreasonable impact on UWMC's training program. Therefore, the department must conclude **this sub-criterion is not met**.

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

SHS provided a table showing the projected number of PCIs it expects to perform through the first three years of the proposed program. Table 6 below summarizes the projected PCIs for Swedish-Issaquah. [Source: Application, p16]

Table 6
2012-2016 Projected PCI Procedures for Swedish-Issaquah

Type of PCI	2012 partial (year)	2013	2014	2015
Emergent	34	57	79	91
Elective/Scheduled	76	137	170	218
Total	**110**	**194**	**249**	**309**

SHS provided its methodology and assumptions used to project the PCI procedures in Table 6. The projections are based on the following factors:

- Swedish Health Services commits to increasing its cardiology presence in King East prior to opening the Swedish-Issaquah.
- SHS is projecting a growth of 34% PCIs from 2012-2015. [Source: Application, p28]
- SHS is projecting to capture a substantial outmigration market share, especially those resident cases currently going to the SMC Cherry Hill (253 in 2009) [Source: Application, p28]
- Swedish-Issaquah does not have any historical emergent PCI volume to build from, so its emergent PCI volumes are based on capturing emergent market share and growth of Swedish-Issaquah's market share.

Department's Evaluation

The department agrees with SHS that it does not have any historical emergent PCI volume to build from because the hospital was still under construction when the application was submitted and only became operational in October 2011. In its volume projections, SHS assumes to capture a substantial outmigration market share. When this application was submitted (February 2011), PCI Planning Area #9 had four new hospital locations that were approved to perform elective PCIs. Three had just completed their first full year of operation and the fourth had not yet began providing elective services. These new PCI programs are expected to reduce the planning area's outmigration. Swedish-Issaquah began operating October 2011 and the level of market share this new hospital will achieve in the planning area as a general hospital is unknown. Therefore the department cannot conclude at this time the volume projections are reasonable.

WAC 246-310-720(2) Hospital volume standard state:

> *"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."* [Emphasis added]

To demonstrate that all existing PCI programs in the planning area are meeting or exceeding the minimum volume standard, SHS states, "*There are four existing PCI programs in the*

Planning Area: Overlake; Evergreen; Valley; and the joint Auburn Regional/Saint Francis program. Overlake's volumes are well above the minimum volume standard. The other three programs have been in existence less than three years and accordingly are measured at 300-PCI minimum volume standard. Therefore, all existing PCI programs in the Planning Area are meeting or exceeding the minimum volume standard." [Source: Application, p29]

WAC 246-310-720(2) is a two pronged measure and each must be met to approve a new program. Because the second prong of this test is not met, the department must disagree with SHS's conclusion that all existing PCI programs are meeting or exceeding the minimum volume standard. As SHS acknowledges and shown in the table below, only Overlake is at or above the minimum hospital volume standard.

Planning Area 9 Hospitals

Hospital	# of all PCIs Performed in 2009[18]
Evergreen Hospital and Medical Center (CN issued 11/13/2009. Began offering elective services April 2011)	198
Overlake Hospital and Medical Center	1,064
Valley Medical Center (CN issued 11/13/2009. Began elective offering services December 2009)	148
St. Francis Hospital (CN issued 11/13/2009. Began offering elective services December 2009)	92
Auburn Regional Medical Center (CN issued 11/13/2009. Began offering elective services December 2009)	80

The plain language of this hospital volume standard is clear when it states "*all existing PCI program in the planning area are meeting or exceeding the minimum volume standard*". Since only one program is currently meeting this standard, the department must conclude **this standard is not met**.

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

To determine whether all residents of a planning area would have access to an applicant's proposed services, the department requires the applicant to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion SHS provided a copy of a draft Patient Rights and Responsibilities that is to be used at Swedish Issaquah. SHS states it is the same

[18] As reported on the Department of Health's 2009 PCI Utilization Survey conducted in 2010 and through CHARS.

that is currently used by SHS at its other hospitals. The document states that SHS admits any patient without regard to race, color, gender, age, religious creed, ancestry, disability/ handicap, payer source, or inability to pay. The document outlines the roles and responsibilities of the patient and SHS. The document does not take the place of a patient admission policy; rather it would be used to supplement the Admission Policy. [Source: Application, Exhibit 7] SHS stated an admission policy would be developed immediately prior to the hospital's opening. [Source: Application, p34] Without at least a draft of the proposed admission policy, the department cannot conclude Swedish-Issaquah meets this portion of this sub-criterion.

To determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

SHS currently provides services to Medicare and Medicaid eligible patients at its other SMC facilities. Documents provided in the application demonstrate that it intends to provide care to Medicare and Medicaid patients at Swedish-Issaquah. A review of the draft policies and projections provided for Swedish-Issaquah identifies projected financial resources as including both Medicare and Medicaid revenues. [Source: Application, p9 & Exhibit 9]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

SHS demonstrated that it currently provides charity care to the residents of the service area and surrounding communities at its other existing hospitals. For Swedish-Issaquah, SHS also intends to provide charity care services. SHS submitted its current charity care policy used at SHS hospitals including the Swedish-Issaquah. The policy outlines the process one would use to access this service. The charity care policy was recently revised (May 2010) and approved by the department's Hospital and Patient Data Systems office. [Source: Application, Exhibit 6] SHS also included a 'charity care' line item as a deduction from revenue within the pro forma income statement documents. [Source: Application, Exhibit 9]

For charity care reporting purposes, HPDS divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Swedish-Issaquah is located in King County within the King County Region. Currently there are 21 hospitals located within the region including Swedish-Issaquah. According to 2007 - 2009 charity care data obtained from HPDS, SHS has historically provided more than the average charity care provided in the region based on SMC and excluding Swedish Cherry Hill.[19] SHS's most recent three-year (2007 - 2009) average percentages of charity care for gross and adjusted revenues are 1.64% and 2.77%, respectively.[20] The 2007 - 2009 average for the

[19] Harborview is excluded from the charity care calculations
[20] Since Swedish-Issaquah opened in October 2011, its charity care history is not included in these percentages

King County Region is 1.42% for gross revenue and 2.51% for adjusted revenue. [Source: HPDS 2007-2009 charity care summaries]

SHS submitted pro forma revenue and expense statements for proposed PCI project. [Source: Exhibit 9] The statements indicate that Swedish-Issaquah projects to provide charity care at approximately 1.71% of gross revenue and 2.24% of adjusted revenue. The projected adjusted revenue level of charity care is slightly below the King County 3-year average. RCW 70.38.115(2)(j) requires hospitals to meet or exceed the regional average level of charity care. Since Swedish-Issaquah has no history of providing charity care and because its adjusted revenue level of charity care is below the 3-year regional average, if this project were to be approved the department would include a charity care condition.

Based on the SHS's failure to provide at a minimum a draft admission policy the department concludes, **this sub-criterion is not met**.

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

Based on the source information reviewed, the department determines that the applicant has not met the financial feasibility criteria in WAC 246-310-220.

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

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

To demonstrate compliance with this sub-criterion, SHS provided its projected Statement of Operations for the catheterization cost center only and for Swedish-Issaquah as a whole with and without the project for projected years 2012 through 2015. [Source: Application, Exhibit 9] A summary of the projected Statement of Operations for the catheterization lab cost center only is shown in Table 7.

Table 7
Catheterization Lab Cost Center
Projected Statement of Operations Summary
Years 2013 through 2015

Swedish - Issaquah	PCI - No deductions provided		
Rate per Various	**CONyr1**	**CONyr2**	**CONyr3**
Cases	194	249	309
Gross Revenue	14,152,767	16,871,485	19,285,254
Deductions From Revenue	-	-	-
Net Patient Billing	14,152,767	16,871,485	19,285,254
Other Operating Revenue	-	-	-
Net Operating Revenue	14,152,767	16,871,485	19,285,254
Operating Expense	3,853,422	4,271,527	4,706,601
Operating Profit	10,299,345	12,599,958	14,578,653
Other Revenue	-	-	-
Net Profit	10,299,345	12,599,958	14,578,653
Operating Revenue per Case	$ 72,952	$ 67,757	$ 62,412
Operating Expense per Case	$ 19,863	$ 17,155	$ 15,232
Net Profit per Case	$ 53,089	$ 50,602	$ 47,180

[Source: September, 2011 Analysis, revised April 23, 2012]

Table 7 reflects the increase in both emergent and elective PCIs projected for Swedish-Issaquah. As shown in Table 7, if Swedish-Issaquah met its volume projections, the PCI cost center is projected to be profitable in years 2013 through 2015. However, deductions from revenue were not provided.

SHS also provided its projected Statement of Operations for Swedish-Issaquah as a whole with PCI services for projected years 2013 through 2015. The information is summarized in Table 8. [Source: Application, Exhibit 9]

Table 8
Swedish-Issaquah
Projected Statement of Operations Summary-With the Project
Years 2013 through 2015

	Projected Year 1 (2013)	**Projected Year 2 (2014)**	**Projected Year 3 (2015)**
Total Operating Revenue	$141,498,451	$181,376,184	$218,399,388
Total Expenses	$143,078,188	$171,478,487	$201,314 ,660
Net Profit or (Loss)	**($1,579,737)**	**$9,897,697**	**$17,084,728**

[Source: Application, p97]

The 'total operating revenue' line item in Table 8 is the result of gross revenue, and non-operating revenue minus any deductions for contractual allowances, bad debt, and charity care. The 'total expense' line item includes all hospital staff salaries/wages, other direct expenses, and all cost allocations. As shown in Table 8, Swedish-Issaquah is projected to be

operating at a loss in year 1 (2013). In years 2014 and 2015 the hospital would realize a profit, if the hospital's overall volume of services is realized.

To determine whether Swedish-Issaquah would meet its immediate and long range capital costs with an elective PCI program, HPDS reviewed 2009 balance sheet for SHS. The balance sheet in Table 9A indicates that SHS has sufficient assets to meet the immediate capital costs of the project. The balance sheet Table 9B indicates that Swedish-Issaquah will not have accumulated any equity but that is expected due to the facility being new. [Source: HPDS analysis, p2 and Application, Exhibit 9]

Table 9A
Swedish Health Services Balance Sheet for 2009

Swedish Health Services 2009			
Assets		**Liabilities**	
Current	287,879,000	Current	148,870,000
Board Designated	510,304,000	Long Term Debt	538,662,000
Property/Plant/Equipment	719,252,000	Other	260,540,000
Other	71,303,000	**Equity**	640,666,000
Total	1,588,738,000	**Total**	1,588,738,000

[Source: September 23, 2011, HPDS Analysis revised April 23, 2012 based on audited financial statements]

Table 9B
Swedish-Issaquah Hospital Balance Sheet for Projected Year 3 – 2015

Swedish -Issaquah -2015			
Assets		**Liabilities**	
Current	47,073,800	Current	27,011,035
Board Designated	-	Long Term Debt	168,755,624
Property/Plant/Equipment	107,738,360	Other	-
Other	35,774,347	**Equity**	(5,180,152)
Total	190,586,507	**Total**	190,586,507

[Source: September 23, 2011, HPDS Analysis revised April 23, 2012 based on Application data]

To assist the department in its evaluation of this sub-criterion, the department's Hospital and Patient Data Systems (HPDS) provided a summary of the short and long-term financial feasibility of the project, which includes a financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively.

For Certificate of Need applications, HPDS compared the projected ratios with the most recent year's financial ratio guidelines for hospital operations. For this project, HPDS used 2009 data for comparison. The table below shows that comparison. SHS09 is for Swedish Health Services and not Swedish-Issaquah.

				Swedish - Issaquah		
Ratio Category	**Trend**	**State2009**	**SHS09**	**ConYr1**	**ConYr2**	**ConYr3**
Long Term Debt to Equity	B	0.545	0.841	(5.684)	(7.895)	(32.577)
Current Assets/Current Liabilities	A	2.262	1.934	1.363	1.128	1.743
Assets Funded by Liabilities	B	0.430	0.433	1.187	1.124	1.027
Operating Expense/Operating Revenue	B	0.945	0.970	0.272	0.253	0.244
Debt Service Coverage	A	6.169	11.578	1.465	1.792	2.073

Long Term Debt to Equity	Long Term Debt/Equity
Current Assets/Current Liabilities	Current Assets/Current Liabilities
Assets Funded by Liabilities	Current Liabilities+Long term Debt/Assets
Operating Expense/Operating Revenue	Operating Expense/Operating Revenue
Debt Service Coverage	Net Profit+Depr and Interest Exp/Current Mat. LTD and Interest Exp

[Source: September 23, 2011, HPDS Analysis revised April 23, 2012]

As shown in the table above, Swedish-Issaquah's ratios are out of range for 4 out of the 5 ratios. HPDS staff provided the following statements related to the ratios:

> *"The Hospital PCI program is breaking even at the end of the third year and has the reserves to sustain this project. The Long Term debt to equity is negative because Equity is negative. This ratio is out of range. As noted earlier, the hospital has not had time for its operation profit to improve its Equity so it is a positive number. Current Assets/Current Liabilities, Assets Funded by Liabilities and Debt Service Coverage are also out of range for the similar reasons; the hospital as a start-up has not had enough time for their yearly profit to improve the Balance Sheet to get them in range of the statewide averages. The Balance Sheet information used in the above ratios is for the entire Swedish – Issaquah campus, not just the PCI project. Review of the financing and ratios show that the immediate and long range capital needs can be met."*

At the time this application was submitted to add the tertiary health service, adult elective PCI, Swedish-Issaquah was still under construction. In the need section of this analysis, the department concluded there was no need in the planning area for another PCI program. Therefore the department concludes SHS may not be able to meet its short and long term costs of this PCI project.

Based on the information above, the department concludes that the immediate and long-range operating costs of the project cannot 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.

As previously stated SHS submitted this application prior to opening the hospital, SHS proposes the adult elective PCIs would be provided within the new hospital's cardiac catheterization lab. There is no additional construction, equipment, or capital costs for this project.

This sub-criterion also requires the department to consider the operational costs of this project and the impact of those costs on the costs and charges for health services. The projected revenue and expense statement for the PCI project indicates that the project would be profitable in the first full year and for the following two years, provided the hospital met the PCI volume projections. Swedish-Issaquah, as a whole, is projected to operate at a loss for 2012, the first partial year of operation, and then a profit in subsequent years. Again, the projected profitability is based on the hospital meeting its utilization projections.

To assist the department in its evaluation of this sub-criterion, HPDS reviewed CHARS PCI procedure data and hospital financial data. Staff from HPDS provided the following analysis. [Source: HPDS analysis, p3]

> *"In reviewing PCI procedures in the 2010 Comprehensive Hospital Abstract Reporting System (CHARS) there is some variation among hospitals in the billed charges based on the healthcare common procedure coding system (HCPCS). I also reviewed the 0481 Cardiac Catheterization Lab cost center in 2010 CHARS and there is variation among hospitals in this category also. However in both instances the variation is not extremely large. The financial database does not have a cost center that is exclusive to cardiac catheterization."*

At the time this application was submitted to expand Swedish-Issaquah's services, the hospital was still under construction. It's unknown if the hospital will meet these volume projections for either the PCI program or the hospital as a whole.

In the need section of this analysis, the department concluded there was no need in the planning area for another PCI program. Therefore, the department concludes that this project might result in an unreasonable impact on the costs and charges for health services.

Based on the information above, the department concludes **this sub-criterion is not met.**

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

Based on the source information reviewed, the department determines that the applicant has not met the criteria and standards in WAC 246-310-230, WAC 246-310-715, WAC 246-310-735, and WAC 246-310-740.

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

For 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.

To demonstrate compliance with this sub-criterion SHS stated that the catheterization lab would initially start with a total of 6 FTEs. The table below was submitted by SHS to show the staffing of the proposed project.

Staff Position	Current FTEs	Cath. Lab FTEs				Total FTEs
		Partial Yr. 2012	Yr. 1 2113	Yr. 2 2014	Yr. 3 2014	
Cath. Lab	N/A	6	6	6	6	

[Source: Application, p40]

The table shows that SHS does not intend to add staff during the first 3 years of operation. Since the catheterization lab was not operational when this application was submitted the application, SHS did not provide the staffing information requested in the PCI application.

SHS states it *"has not selected a medical director for the cardiac catheterization lab. Once identified, the Medical Director will enter into a Medical Director Agreement substantially similar to Exhibit 18 (new), attached."* [Source: June 8, 2011 Screening Responses, p1] Additionally, SHS states *"The hospital is not yet open, thus staff have not been hired."* [Source: Application, p41] SHS states is does not anticipate that this program will affect staffing at other Planning Area PCI programs. [Source: Application, p41]. SHS further states it is expecting to staff the catheterization lab with appropriately trained RNs and technicians. The staff initially will be rotated from the Swedish Heart and Vascular Institute at the Cherry Hill campus, if needed, to either staff the lab or train new hospital employees. SHS did not provide a specific plan for initially staffing this unit, identify the specific staff positions to hired at the proposed catheterization lab, or provide commitments from non-physician Swedish Heart and Vascular Institute staff to work at Swedish-Issaquah.

Based on the source information reviewed, the department concludes **this sub-criterion is not 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.
To demonstrate compliance with this sub-criterion, SHS provided a listing of "ancillary procedure" equipment to be installed in the catheterization lab at Swedish-Issaquah when complete. [Source: May 5, 2011 Screening Responses, Exhibit 17]. SHS provided documentation to demonstrate that catheterization laboratory and equipment meets the standards outlined in WAC 246-310-730(2).

To demonstrate that catheterization laboratory staff will be qualified as required under this standard, SHS, provided job descriptions and skills review documents for the PCI program nurses, imaging technologists, and respiratory care practitioner staff. [Source: Application, Exhibit 10] A review of these documents shows that they do not contain signatures for the Director, Administration, or Human Resources. Therefore, the documents are considered drafts. Since Swedish-Issaquah was still under construction when this application was submitted and SHS did not identify the specific positions to be hired for the operation of the catheterization lab, the department cannot verify that these are the only nursing and technical staff needed to comply with this standard. Therefore, the department concludes **this sub-criterion is not 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.*
To demonstrate compliance with this sub-criterion, SHS states it will have teams composed of one trained cardiac catheterization lab Registered Nurse, plus two catheterization lab technicians available 24 hours per day 7 days per week. The team will be available on site Monday through Friday 7 am to 5 pm. The team will be on-call weekdays after 5pm and on weekends. The on-call team will always be available by pager and/or cell and is expected to arrive at the hospital within 30 minutes of being contacted. Specific algorithms for triage and management of an emergently ill cardiac patient while another case is in progress are currently in use at all SHS campuses and these algorithms will also be used at the Swedish-Issaquah Hospital.

On-site staffing requirements include 1.4 FTE for Registered Nurse staff and 2.8 FTE for lab technicians. This model also assumes an additional 0.5 FTE for each of these 3 FTEs for on-call requirements, resulting in approximately 6.0 FTEs total. [Source: Application, p41]. The above information would suggest that the standard is met. However, because SHS did not identify the specific positions to be hired for the operation of the catheterization lab, the department is unable to verify this standard is met.

Based on the documentation provided, the department concludes **this sub-criterion is not met**.

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

SHS expects cardiologists from the Swedish Medical Group to provide the physician staffing for the catheterization. SHS provided commitment letters from Dr. Casterella, Dr. Demopulos, and Dr. Westcott in the application. [Source: Application, Exhibit 11]

SHS provided a letter from Dr. Howard Lewis, Director of Swedish Heart and Vascular Institute attesting that each physician had performed at least 75 procedures per year for years 2008, 2009, and 2010. [Source: May 5, 2011 Screening Responses, Exhibit 16] The numbers are substantiated and consistent with the numbers reported to the HPDS data system. As a result, all three physicians have met the volume standards prescribed. [Source: Application, p12 &13; May 5, 2011 Screening Responses, Exhibit 16] Based on the information above, the department concludes **this sub-criterion is met**.

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

SHS identified three cardiologists and provided letters of commitment from all three stating they intend to provide PCIs on an emergent basis and if CN approval is granted, would expect to also provide elective PCIs based on their clinical judgment of the most appropriate location for these procedures. [Source: Application, p147-153; May 5, 2011 Screening Responses, Exhibit 16] Based on the information above, the department concludes, **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*

SHS states *"The hospital is not yet open, thus staff have not been hired."* [Source: Application, p41] SHS did not identify the specific positions to be hired for the operation of the catheterization lab. [Source: Application, p40] SHS did provide job descriptions and skills review documents for the PCI program nurses and technical staff. [Source: Application, Exhibit 10] A review of these documents shows that they do not contain signatures for the Director, Administration or Human Resources. Therefore these are considered drafts. If this project were to be approved, a condition would be necessary requiring the submission for review and approval of the adopted job descriptions and skill level documents that is consistent with the draft submitted in the application. SHS would need to provide the names and professional license numbers of all nursing and technical staff associated with proposed elective PCI program.

Documentation provided demonstrated that catheterization laboratory staff will be required to meet the standards outlined in WAC 246-310-730(2). The department concludes **this sub-criterion is met.**

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

At the time this application was submitted, SHS did not have all of its general ancillary agreements in place, since the hospitals was still under construction. The hospitals became operational October 2011, which is well after the record closed for this application. The department would expect the appropriate general ancillary and support services to have been in place upon opening in October. Specific to PCI projects, 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.

To demonstrate compliance with this standard, SHS provided a copy of its Partner agreement between SMC Cherry Hill and Swedish-Issaquah dated February 2011. Since this Partner agreement was signed before the construction of the Swedish-Issaquah hospital was complete, the department considers this a signed "Letter of Agreement to finalize." The agreement identifies SMC Cherry Hill as the primary hospital for PCI patients requiring a transfer from Swedish-Issaquah. The agreement acknowledges SMC Cherry Hill is not required to maintain an available surgical suite 24/7. Section 1.6 of the agreement states: *"The Transferring Hospital shall keep the Receiving Hospital informed of its hours of operation of elective PCI services."* Section 2.2 states: "*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.*" [Source: Application, Exhibit 12]

If this project were to be approved, the department would require SHS to provide a copy of the executed Partner agreement. Provided SHS agreed to the condition, the department concludes **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.

Section 2 of the draft Partner agreement addresses this standard. Section 2.2 states: "*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.*" [Source: Application, Exhibit 12]. If this project were to be approved, the department would require SHS to provide a copy of the executed Partner agreement. Provided SHS agreed to the condition, the department concludes **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.

The draft Partner agreement addresses this standard. Section 1.3 of the agreement identifies all documents to be transferred with the patient. [Source: Application, Exhibit 12] If this project were to be approved, the department would require SHS to provide a copy of the executed Partner agreement. Provided SHS agreed to the condition, the department concludes **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.

The draft Partner agreement addresses this standard. Section 1.5 of the agreement states: *"The Transferring Hospital shall coordinate communications between the physicians performing the elective PCI and the cardiac surgeons at the Receiving Hospital regarding the reasons for the patient's transfer and clinical condition*." [Source: Application, Exhibit 12] If this project were to be approved, the department would require SHS to provide a copy of the executed Partner agreement. Provided SHS agreed to the condition, the department concludes **this sub-criterion is met.**

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

The draft Partner agreement addresses this standard. Section 2.1 of the agreement ensures that SMC Cherry Hill will accept all referred patients from Swedish-Issaquah. [Source: Application, Exhibit 12] If this project were to be approved, the department would require SHS to provide a copy of the executed Partner agreement. Provided SHS agreed to the condition, the department concludes **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.

To demonstrate compliance with this standard, SHS provided a copy of its executed Hospital Medical Transportation Agreement with American Medical Response (AMR) Ambulance Service, Inc. This agreement dated December 2010 is between SHS and AMR for all of SHS's hospitals and freestanding emergency departments (EDs). The agreement outlines roles and responsibilities for both entities in providing transports, including maintaining qualified staff to conduct the safe and effective transport of patients. The Agreement includes an automatic renewal clause. [Source: Application, Exhibit 13] This agreement was signed while the Swedish-Issaquah hospital was still under construction. Although the agreement anticipated Swedish-Issaquah's inclusion in this agreement it appears to be a general transportation agreement and does not contain specifics for this proposed PCI program.

Based on the review of the Transportation Agreement with American Medical Response Ambulance Service, Inc., the department concludes **this sub-criterion is not met.**

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

The draft Partner agreement addresses this standard. Section 1.2 of the agreement states: *"…The Emergency transport shall commence within twenty (20) minutes of the initial identification of a complication."* [Source: Application, Exhibit 12] The department also reviewed the Transportation Agreement with American Medical Response Ambulance Service, Inc. Exhibit A of the transportation agreement states: *"As defined below, response*

times will not exceed thirty (30) minutes for CCT[21]-STAT 0-30 transfer patient services, and response times will not exceed sixty (60) for CCT 0-60 and BLS 60 transfer patient services." [Source: Hospital Medical Transportation Services Agreement, dated December 2010, Exhibit A, p168] The Transportation Agreement with American Medical Response does not include language specific to the transport of PCI patients or transportation of these patients and the time limits associated with them. [Source: Application, Exhibit 13]

Based on the review of the draft Partner agreement and the Transportation Agreement with American Medical Response Ambulance Service, Inc., the department concludes **this sub-criterion is not 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).*
The draft Partner agreement, addresses this standard. Section 1.2 of the agreement addresses the qualifications of the emergency transport staff. [Source: Application, Exhibit 12] Additionally, SHS states: *"If necessary, Swedish will provide an ACLS-trained and intra-aortic balloon pump-trained RN to accompany the patient."* [Source: Application, p45] The Transportation Agreement's Exhibit A assures the patient will be transported with appropriately qualified personnel. This agreement also states: *"…Other specialized critical patient care equipment or procedures as ordered by the patient's physician (such as cardiac STEMI patients).* [Source: Application, Exhibit 13]

If this project were to be approved, the department would require SHS to provide a copy of the executed Partner agreement. Provided SHS agreed to the condition, the department concludes **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.*
The draft Partner agreement addresses this standard. Section 1.4 of the agreement ensures that the transport time will be less than 120 minutes. [Source: Application, Exhibit 12]

The department also reviewed the Transportation Agreement with American Medical Response Ambulance Service, Inc. Section 1(g) states: "*Provider will provide other, non-dedicated units when necessary to meet response time requirements."* Exhibit A of this same agreement states: *"As defined below, response times will not exceed thirty (30) minutes for CCT-STAT 0-30 transfer patient services, and response times will not exceed sixty (60) for CCT 0-60 and BLS 60 transfer patient services."* [Source: Hospital Medical Transportation Services Agreement, dated December 2010, Exhibit A, p168] The Transportation Agreement with American Medical Response does not include language specific to the transport of PCI patients, transportation of these patients or specific PCI transportation time limits. [Source: Application, Exhibit 13]

[21] Critical Care Transport

Based on the review of the draft Partner agreement and the Transportation Agreement with American Medical Response Ambulance Service, Inc, the department concludes **this sub-criterion is not met.**

WAC 246-310-735(10) *At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.*
The draft Partner agreement, addresses this standard, in part. Section 1.7 of the agreement states: "*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*." However this agreement is silent under the section on the Receiving Hospital's responsibility to participate in these drills. [Source: Application, Exhibit 12]

The Transportation Agreement with American Medical Response Ambulance Service, Inc. (AMRAS) was executed in December 2010, should also address this standard. This agreement was signed while the Swedish-Issaquah hospital was still under construction. While the agreement anticipated Swedish-Issaquah's inclusion in this agreement, it appears to be a general transportation agreement and does not contain specifics for this proposed PCI project. Additionally, this standard implies that the transport company, in this case, AMRAS, would also participate in these required drills. The transportation agreement does not contain any language that AMRAS and its personnel will participate in these required drills. [Source: Application, Exhibit 13]

Based on the review of the draft Partner agreement and the Transportation Agreement with American Medical Response Ambulance Service, Inc., the department concludes **this sub-criterion is not 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
To demonstrate compliance with this standard, SHS provided a copy of the draft Swedish-Issaquah Consent for Percutaneous Cardiac Interventional Procedure form proposed to be used. The form is specific to PCI procedures and explains the procedure in plain talk. The document further discusses potential risks and complications related to the procedure. The document provides the following language related to this sub-criterion:

> "***Potential Need to Transfer to a Hospital with Open Heart Surgery***
> *This procedure is being performed without on-site surgical back up. I understand that my doctor has determined that my risk of complications during this procedure(s) is low. In the event of an unexpected complication, and if cardiac surgery is required, I will be stabilized and immediately transferred to another hospital that can perform an emergency cardiac surgical procedure on my heart. If such a situation occurs I will be transferred to Swedish Cherry Hill Campus or _____.*

If transfer to the other hospital is necessary, an ambulance will be called for transport. There is risk associated with the time it takes to transfer a patient from one facility to another. The general risks associated with an emergent transfer to another facility include: automobile accident, delayed treatment, heart rhythm irregularities and death." [Source: Application, Exhibit 14]

If this project were to be approved, a condition would be necessary requiring the submission for review and approval of the adopted Consent for Percutaneous Cardiac Interventional Procedure form that is consistent with the draft submitted in the application. Based on the review of the draft "Issaquah Consent for Percutaneous Cardiac Interventional Procedure Form" the department concludes **this sub-criterion is met.**

WAC 246-310-735(12) *Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases.*
The draft Partner agreement, addresses this standard. Section 3.2 and Exhibit A of this agreement ensures that both hospitals will participate in cardiac patient care conferences at least quarterly with review of preoperative and post-operative cases including all transport cases.

Additionally, SHS provided a draft copy of its Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011. The plan states: *"Although the Issaquah facility has not opened yet, this document will function as the structure of our PCI performance plan. Details may change as the facility becomes operational."* [Source: Application, Exhibit 4, p65] The Plan identifies that SHS will participate in the Washington State Clinical Outcomes Assessment Program (COAP) to ensure quality and quality improvement. For accountability, SHS's Issaquah Hospital will report the results of its performance to the Medical Executive Committee, Board Quality Committee, and Board of Swedish. [Source: Application, Exhibit 4]

If this project were approved, a condition would be necessary requiring the submission for review and approval of the adopted Elective Percutaneous Coronary Intervention Performance Improvement Plan. Based on the review of the draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan and the executed Partner agreement, the department concludes **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.).
The draft partner agreement with SMC Cherry Hill, addresses this standard. Section 3.3 states: *"The parties shall address peak volume periods, as necessary, if capacity issues arise."* [Source: Application, Exhibit 12] The information contained in the draft Partner agreement is insufficient for department to conclude this sub-criterion is met. Therefore the department must conclude **this sub-criterion is not 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.*
SHS provides healthcare services to the residents of east King County, and Washington State as a whole, through its various healthcare facilities. SHS does not operate any healthcare facilities outside of Washington State. Since January 2008, the Department of Health's Investigations and Inspections Office has completed at least seven compliance surveys for SHS or its related healthcare providers including the initial compliance surveys for the Swedish-Issaquah.[22] Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the SHS healthcare facilities. These non-compliance issues were typical of the specific type of facility and SHS submitted and implemented acceptable plans of correction. [Source: facility survey data provided by the Investigations and Inspections Office] However, the department must conclude that the proposed PCI services would be provided in a manner that ensures safe and adequate care to the public. At the time this application was submitted to add elective PCI services to Swedish-Issaquah, the hospital was still under construction. Therefore, this hospital (Swedish-Issaquah) has no quality of care history that would allow the department to evaluate whether adding a tertiary health service was appropriate.

For PCI projects, WAC 246-310-230(3) criteria is also identified in WAC 246-310-740.
WAC 246-310-740(1) A process for ongoing review of the outcomes of adult elective PCI's. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.
SHS provided a copy of its draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011. The plan states: *"Although the Issaquah facility has not opened yet, this document will function as the structure of our PCI performance plan. Details may change as the facility becomes operational."* [Source: Application, Exhibit 4, p65] This plan identifies the Washington State Clinical Outcomes Assessment Program (COAP) as the benchmark for PCI outcomes. [Source: Application, Exhibit 4, Attachment A] If this project were to be approved, a condition would be necessary requiring the submission for review and approval of the adopted plan that is consistent with the draft submitted in the application.

Based on the review of the draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011, the department concludes **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
The draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011 addresses this standard. Attachment A to this plan states that the patient selection benchmark will be ACC guidelines. [Source: Application, Exhibit 4, Attachment A] If this project were to be approved, a condition would be necessary

[22] Compliance surveys completed August 2008, January 2010, September 2010, November 2010, June 2011, and July 2011, and October 2011.

requiring the submission for review and approval of the adopted plan that is consistent with the draft submitted in the application.

Based on the review of the draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011, the department concludes **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

The draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011, addresses this standard. [Source: Application, Exhibit 4] If this project were to be approved, a condition would be necessary requiring the submission for review and approval of the adopted plan that is consistent with the draft submitted in the application.

Based on the review of the draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011, the department concludes **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.

SHS provided a copy of its draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011 specific to elective and emergent PCI services. The Plan describes the reporting processes to be used. [Source: Application, Exhibit 4] If this project were to be approved, a condition would be necessary requiring the submission for review and approval of the adopted plan that is consistent with the draft submitted in the application.

Based on the review of the draft Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2011, the department concludes **this sub-criterion is met.**

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

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

The department recognizes that SHS is a long-time provider of health care services in Washington State, and as such, has established long term relationships within the healthcare system for its other hospitals and health care facilities. [Source: CN historical files] However, at the time this application was submitted to add a tertiary health service to Swedish-Issaquah the hospital was still under construction. Therefore, this hospital (Swedish-Issaquah) had no established relationships with the service area's existing health system. Additionally, the department previously concluded there was no demonstrated need for an additional PCI program in the planning area.

Therefore, the department concludes **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 not met**.

D. Cost Containment (WAC 246-310-240)
Based on the source information reviewed, the department determines that the applicant has not met the cost containment criteria in WAC 246-310-240.

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

If the project met WAC 246-310-210 through 230 criteria, the department would move to step two in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific criteria (tie-breaker) contained in WAC 246-310. The tiebreaker 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 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.

Step One

For this project, SHS does not meet the review criteria under WAC 246-310-210, WAC 246-310-220, WAC 246-310-230 and the PCI specific standards of WAC 246-310-715, WAC 246-310-720, WAC 246-310-735, and WAC 246-310-740. Therefore, the department concludes this project is not the best available alternative. **This sub-criterion is not met**, and the department does not review steps two or three for this project.