STATE OF WASHINGTON
DEPARTMENT OF HEALTH

April 4, 2013

CERTIFIED MAIL # 7011 1570 0002 7809 5575

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

RE: CN12-23

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 First Hill 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 PCI Need Forecasting Methodology PCI Standards	WAC[1] 246-310-210 WAC 246-310-745 WAC 246-310-720
Financial Feasibility	WAC 246-310-220
Structure and Process of Care General PCI Program Requirements	WAC 246-310-230 WAC 246-310-715
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:

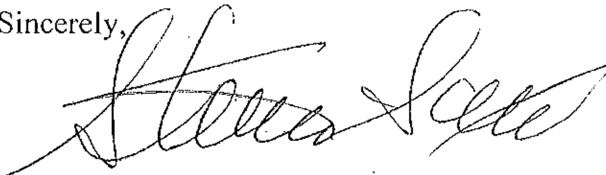
Mailing Address:	Other Than By Mail
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

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 APRIL 4, 2013 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 IN PCI PLANNING AREA #10

APPLICANT DESCRIPTION

Swedish Health Services (SHS) is a not-for-profit corporation with 100% ownership of Swedish Medical Center.[1] Swedish Medical Center is also a Washington private, not-for-profit corporation. 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
SMC-First Hill	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, SHS provides both open heart surgery and adult elective percutaneous coronary interventions (PCIs) at its Cherry Hill campus (0.53 miles from SMC-First Hill). 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]

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[1] Swedish Health Services also has ownership percentages in a variety of other healthcare entities, such as 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)

This application proposes the establishment of elective adult PCI services at Swedish Medical Center First Hill. For ease of the reader, Swedish Medical Center First Hill will be referred to as SMC-First Hill.

The applicant reports that the current catheterization lab at SMC-First Hill is out-of-date and thus is rarely used. The current lab at this facility would not support the provision of either emergent or elective PCIs without significant renovation and new equipment.

The proposed project will include the construction and operation of a hybrid cardiac catheterization laboratory/operating suite. Hybrid cardiac catheterization laboratory operating rooms ("ORs") allow surgeons to perform open, minimally invasive, image guided and/or catheter-based procedures in the same OR and in the same operative setting. These interdisciplinary, multifunctional rooms bring technology to the patient with the goals of maximizing patient care, improving overall outcomes and decreasing time in the hospital. The hybrid OR suite integrates digital imaging diagnostics, and radiological, catheterization and surgical capabilities. Construction of a hybrid OR is an important part of SMC-First Hill's larger improvement of cardiac services of which the provision of emergent and elective PCIs is central. SHS proposes that elective PCIs would be offered beginning in January 2014. The PCI program would be initially staffed by interventional cardiologists from SMC-Cherry Hill. The estimated capital cost of this project is $4,876,253. Of the total cost 30% is related to construction, 52% is related to equipment, and 17% is related to taxes and fees. If this project is approved SHS anticipates that the hybrid OR would be operating by January 2014. Under this timeline, year 2014 would be the facilities first full calendar of operation and 2016 would be the third full year of operation. [Source: Application: p16 & 18]

APPLICABILITY OF CERTIFICATE OF NEED LAW

In a desire to promote the stability of Washington's cardiac care delivery system, the legislature in 2007 directed the department to establish review criteria that would allow the approval of hospitals to perform elective percutaneous coronary interventions (PCI) where the hospital did not provide on-site cardiac surgery. Prior to developing the current review criteria, the department contracted for an independent, evidence-based, review of the circumstances under which adult elective PCI should be allowed. That review addressed factors related to access to care, patient safety, quality outcomes, costs, and the stability of Washington's cardiac care delivery system and of cardiac care providers. It also addressed the elective PCI volumes necessary for the University of Washington academic medical center to maintain its accreditation for training of cardiologists.

The report recognized the public policy implications of expanding elective PCI availability may in certain settings provide needed access, but it may have the untoward effect of splitting the need between competing institutions. This expansion of services could cause a situation where the minimum procedure volume necessary to maintain quality and financial viability is lost to all programs in the planning area. The recommendations for volume minimums for each program in the independent report and the work during the rule development process acknowledged the public policy of balancing patient access with maintaining adequate number of procedures at existing programs to maintain the quality of care for patients.

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). Elective Adult 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).

EVALUATION CRITERIA

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

> *"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.*
> *(a) In the use of criteria for making the required determinations, the department shall consider:*
> *(i) The consistency of the proposed project with service or facility standards contained in this chapter;*
> *(ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
> *(iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."*

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

> *"The department may consider any of the following in its use of criteria for making the required determinations:*
> *(i)Nationally recognized standards from professional organizations;*
> *(ii)Standards developed by professional organizations in Washington State;*
> *(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).[5] 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.

[5] 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); and WAC 246-310-240(3).

APPLICATION CHRONOLOGY

Action	Swedish Medical Center
Letter of Intent Submitted	January 31, 2012
Application Submitted	February 29, 2012
Department's Pre-Review activities, including screening and responses	March 1, 2012, through August 27, 2012
Department Begins Review; no public hearing requested or conducted	August 28, 2012
End of Public Comment	October 3, 2012
Rebuttal Documents Received	October 17, 2012
Department's Anticipated Decision Date	December 3, 2012
Department's Actual Decision Date	April 4, 2013

TYPE OF REVIEW

As directed under WAC 246-310-710 the department accepted this project under the 2011 PCI Concurrent Review Cycle. This application is reviewed under the concurrent review process. 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 to 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. SMC-First Hill is located in planning area #10 as defined in WAC 246-310-705(5), which includes defined zip codes located in west 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. Below is the discussion regarding persons requesting affected person status for this application.

AFFECTED PERSONS

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

"…an "interested person" who:

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

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

- University of Washington Medical Center – located in the city of Seattle and currently a provider of both PCI and open heart surgery and provides cardiac fellowship training programs.

SOURCE INFORMATION REVIEWED

- Swedish Health Services Certificate of Need application submitted February 29, 2012
- Swedish Health Services supplemental information dated May 24, 2012, and July 31, 2012
- Public comments submitted by community members and healthcare providers
- Public comments provided by University of Washington Medical Center received October 1, 2012
- Rebuttal comments provided by Swedish Health System received October 17, 2012
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Hospital and Patient Data Systems (HPDS)
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2008, 2009, and 2010 summaries)
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems (HPDS) received October 29, 2012
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office (IIO)
- Department of Health 2011 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 the Swedish First Hill Campus 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) <u>The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need</u>

WAC 246-310-700 requires the department to evaluate all adult elective PCI applications based on the 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).

<u>PCI Methodology WAC 246-310-745</u>

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.[6] SMC-First Hill is located in the city of Seattle, within King County. King County is divided into King West and King East planning areas. SMC-First Hill is located in Planning Area #10, King West which includes the 37 zip codes shown in the table below.

Table 1
King West Planning Area #10 Zip Codes

King West PCI Planning Area Zip Codes				
98040	98070	98101	98102	98103
98104	98105	98106	98107	98108
98109	98112	98115	98116	98117
98118	98119	98121	98122	98125
98126	98133	98134	98136	98144
98146	98148	98155	98158	98166
98168	98177	98178	98188	98195
98198	98199			

[6] 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 #10.

SMC-First Hill is one of ten hospitals operating in Planning Area #10. The ten hospitals are identified in the table below.

Table 2
Planning Area 10 Hospitals

Hospital	Elective PCI's Provided	# of all PCIs Performed in 2010[7]
Seattle Children's Hospital	No	0
Group Health Seattle Hospital	No	0
Harborview Medical Center	No	87
Northwest Hospital	Yes	203
Swedish Medical Center Ballard Campus	No	0
Swedish Medical Center Cherry Hill	Yes	1,172
University of Washington Medical Center	Yes	225
Virginia Mason Medical Center	Yes	568
Highline Medical Center	No	111
Swedish Medical Center First Hill	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 2010 Hospital Discharge Data from Oregon Health Policy and Research for King West residents having a PCI performed in an Oregon Hospital. [Source: Application pp23-28] For the population data in step 1, the applicant considered the use of two sources:

- Claritas 2011; and
- Washington State Office of Financial Management (OFM) Estimates of Total Population for Zip Codes 2000-2010.

SHS used 2011 Claritas population data for this application. SHS did not use 2010 base year population data as identified in the methodology. [Source: Application, pp 24-25]

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.

[7] As reported on the Department of Health's 2010 PCI Utilization Survey conducted in 2011 and through CHARS.

(b) *Divide the total number of PCIs performed on the planning area residents fifteen years of age and over*[8] *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 for which December 31 data is available as of the first day of the application submission period from the department's Comprehensive Hospital Abstract Reporting System (CHARS) reports (or successor reports). For this project, the first day of the application submission period was February 1, 2012. The base year data for this project is year 2010.

SHS's Step 1 calculation is as follows:

a) The age 15+ 2011 population was calculated to be 743.353 which is 743,353/1,000.

b) The number of inpatient and outpatient PCIs was 1,342 for the planning area. 1,342/743.35 is 1.805 –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.*[9]

The "forecast year" is the fifth year after the base year. Since the base year is 2010, the forecast year is 2015. SHS used 2015 Claritas population data which is the correct data as identified in the methodology.

The Step 2 calculation is as follows:

- The age 15+ population for 2015 was calculated to be 768.889 which is 768,889/1,000.
- The 2010 use rate was 1.805 from step 1(b)
- 768.889 multiplied by 1.805 is 1,387.8 which is the projected number of resident PCIs for year 2015. SHS rounded this number to 1,388.

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.*

[8] Residents 15 years of age and older.

[9] Residents 15 years of age and older.

SHS provided the following discussion related to this step in the methodology. [Source: Application, p26]

"For 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). This is the approach we believe the Department's methodology directs the Department to follow.[10]

Under Model One, since the PCI methodology is based on planning area resident need, supply is also evaluated for PCI's provided to Planning Area residents only—it does not include in-migration in provider supply volumes.

The Step 3 calculation is shown in the following table.

Table 3
SHS Methodology
Hospital PCI Capacity Planning Area #10

Hospital	Inpatient	Outpatient	Total PCIs[11]
Swedish Medical Center	322	287	609
Virginia Mason Medical Center	116	98	214
University of Washington Medical Center	112	3	300
Northwest Hospital	64		
Seattle Children's	1		
King West Planning Area Total	**652**	**414**	**1,066**

As shown in Table 3, SHS determined the planning area #10 current capacity to be 1,066.

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 1,066 (step 3) for year 2015 from the projected need for 2015 of 1,388 (step 2) and determined a net projected need of 322.1 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.)

[10] Please see Exhibit 24(of the application) for a detailed analysis of this issue.
[11] 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)].

SHS divided the projected 322.1 by 300 to calculate a need for 1.07 programs in the planning area, which is then rounded down to 1 new program in year 2015.

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.*
- *(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 2010 and 2015. 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 2010 data.

Calculations for Step 1 are shown below.

- a) The age 15+ 2010 population is 735.45 which 735,452/1000.
- b) The number of inpatient PCIs is 910, outpatient PCIs is 461 and inpatient from the state of Oregon is 2 resulting in a total of 1,373 PCIs. The 1,373 PCIs are divided by 735.45 to get a calculated use rate of 1.87 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.*[12]

For this project, the forecast year is 2015. In this step, the department multiplied the use rate of 1.87 calculated in Step 1 by the Claritas projected planning area population of 757,177. The results are 1,415.59 which rounds to 1,416 PCIs for planning area #10 residents in 2015.

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;*

[12] Residents 15 years of age and older.

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

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

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

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 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 #10 and their PCI procedures for 2010.

Table 4
Need Forecasting Methodology
Hospital Capacity Planning Area #10

Hospital	Inpatient Actual	Outpatient Actual	Total PCI Counted Per Method
SMC- Cherry Hill	591	579	1,170
Virginia Mason Medical Center	260	308	568
University of Washington Medical Center	225	47	272
Northwest Hospital	203	41	244
Seattle Children's[13]	0	0	0
King West Planning Area Total	**1,279**	**975**	**2254**

Table 4 above shows that Swedish Medical Center and Virginia Mason Medical Center provided more than 300 PCI procedures in 2010. Northwest Hospital and the University of Washington Medical Center provided less than 300 PCI procedures in 2010.

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.

[13]For capacity the department only counts PCIs performed at hospitals with CN approved adult elective PCI programs.

A subtraction of the current capacity of 2,254 (step 3) from the year 2015 projected need of 1,416 (step 2), results in a surplus of 838 procedures, or negative 838. 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 #10, 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 #10.

Department Conclusion Methodology Review

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 data from Claritas is appropriate. The department does not agree with SHS's use of 2011 population data. The methodology identifies the base year as being 2010. Therefore, use of the zip code level population projections from Claritas is appropriate as long as 2010 and 2015 data is used.

WAC 246-310-745(2) defines how "current capacity" is to be measured.[14] Review of SHS's application of the numeric methodology shows that SHS included only the PCIs performed on King West residents thus reducing the capacity of the existing providers. This is a significant deviation from the methodology and is 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.

Department's Evaluation

The department does not agree with SHS's interpretation of "current capacity". The definition of "current capacity" states "*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.

[14] 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.

"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 PCI 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 #10. 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 #10 residents in year 2010 by patient zip code. The applicant contends that since all the patients would come from Swedish Cherry Hill there would be no impact on the UWMC program. A total of 64 inpatient PCIs were performed on the planning area residents by UWMC. Also for 2010, UWMC performed a total of 272 PCIs. UWMC had 23.5% of their inpatient PCIs generated by residents of planning area #10. The UWMC market share of planning area #10 is 7.2%. It would appear that any loss of patients from planning area #10 by UWMC would be significant. [Source: Application, pp31 & 32]

SHS also provided a copy of an email from Todd Strumwasser, MD, Director of Case Management SHS to Larry Dean, Director of the UW Medicine Regional Heart Center stating:

"As you are aware, Swedish Health Services is applying certificate of need approval to operate an elective PCI program at its First Hill Campus. This program will not impact the PCI volume at the University of Washington Medical Center, since it is intended to transfer PCI cases from Swedish Cherry Hill. Thus, it will have no effect

on PCI volumes that the UWMC uses for its training program. [Application, Exhibit 10]

Public Comment

In its public comment, the University of Washington Medical Center provided the following discussion.

> "The intent of this provision was to safeguard the cardiac fellowship training programs at the University of Washington School of Medicine (UW); the only such program in the five state Washington, Wyoming, Alaska, Montana, and Idaho (WAMI) region. The fellowship training requirements referenced in rule are published by the Accreditation Council for Graduate Medical Education (ACGME). A cardiovascular disease fellowship at UW is a three year program, and an interventional cardiology fellowship is a twelve month fellowship available only after successful completion of a cardiovascular disease fellowship. UW currently accepts seven fellows per year into its cardiovascular disease fellowship program and is approved by ACGME for two interventional cardiology fellowships. To maintain ACGME accreditation of the interventional program UWMC must perform a minimum of 400 interventional procedures of the heart per year. In addition, each interventional fellow needs to individually perform a minimum of 250 cases. Given the number of fellows and the current PCI annual volumes at UWMC, any reduction in volume could compromise training.
>
> In past Certificate of Need reviews for new PCI programs, the applicants and UW collaborated on a response to this requirement, which has led, in several instances, to enhanced referral relationships that benefit the patient, the UW's fellowship program, and the referring hospital. To date, we have not had any conversation with Swedish in regard to this requirement."

The data indicates that a substantial number of patients receiving PCIs from UWMC reside in the West King Planning Area. UWMC contends that any additional programs could reduce the number of PCIs performed by their program to the extent that it could jeopardize the Interventional Cardiology Fellowship training program provided at the University of Washington. As of the date of the public comment letter, Swedish and the University of Washington had not had these discussions. Therefore the department concludes **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. The table below summarizes the projected number of PCIs for SMC-First Hill. [Source: Application, p17]

Table 5
2014-2016 Projected PCI Procedures
For SMC-First Hill

Type of PCI	2014	2015	2016
Emergent	59	75	95
Elective/Scheduled	137	175	221
Total	**196**	**250**	**316**

SHS provided its methodology and assumptions used to project the number of PCI procedures in the table above. The projections are based on the following factors:

- PCI cases that now transfer to SMC-Cherry Hill will remain at SMC-First Hill based on patient need and physician clinical judgment.
- Approximately 10% of the current SMC-Cherry Hill PCI volumes (1172 for 2010) will, be performed at SMC-First Hill in year one.
- The case volumes will increase over years two and three such that SMC-First Hill will perform about 1/3 of the current SMC-Cherry Hill volumes at the end of year three. [Source: Application: p17]

<u>Department's Evaluation</u>

SMC-First Hill was providing elective PCIs until 2008, at that time the decision was made to discontinue performing PCIs at SMC-First Hill. The PCIs are now performed at the Swedish Heart and Vascular Institute located at SMC-Cherry Hill Campus. SHS states that since SHS is a closed system, all elective PCIs performed at SMC-First Hill will be from not transferring patients to SMC-Cherry Hill or other patients already in the SHS system. Although SMC-Cherry Hill performed 1,172 PCIs in 2010; the applicant reported that over half (51%) of the patients came from outside of the PCI Planning area 10. Since three new programs had just been approved in the adjacent PCI planning area 9, the department is not able to determine the impact of these programs on the in-flow of PCI patients to the Swedish system. There volumes are still growing and thus the full impact of these new programs on the outflow of patients from PCI planning area #9 has not been felt.

Therefore the department cannot conclude at this time the volume projections are reasonable, since as the three new programs grow the number of patients coming from PCI planning area 9 to planning area 10 is likely to decline.

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;* ***<u>and</u>***
> *(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: SMC-Cherry Hill Medical Center, Virginia Mason Hospital and Medical*

Center, University of Washington Medical Center, and UW Medicine/Northwest Hospital and Medical Center " [Source: July 31, 2012 Supplemental Information, p3]

WAC 246-310-720(2) is a two pronged measure and each must be met to approve a new program. The data in the table below indicates 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 SMC-Cherry Hill and Virginia Hospital and Medical Center are at or above the minimum hospital volume standard.

Table 6
Planning Area 10 Hospitals
2010 PCIs

Hospital	PCIs
SMC-Cherry Hill Medical Center	1,172
Virginia Mason Hospital & Medical Center	568
University of Washington Medical Center	272
Northwest Hospital & Medical Center	244

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 two of the four programs are 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 the Patient Rights and Responsibilities that is to be used at SMC-First Hill. SHS states it is the same document 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, p 34 &Exhibit 13] Without at least a draft of an admission policy, the department cannot conclude SMC-First Hill meets this portion of this sub-criterion.

Medicare and Medicaid Programs
The department uses Medicare certification to determine whether the elderly would have access, or continue to have access, to the proposed services

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services.

SHS currently provides services to Medicare and Medicaid eligible patients at SMC-First Hill. Documents provided in the application demonstrate that it intends to continue to provide care to Medicare and Medicaid patients at SMC-First Hill. A review of the draft policies and projections provided for SMC-first Hill identifies projected financial resources as including both Medicare and Medicaid revenues. [Source: Application, p11 & May 22 Supplemental Information, Exhibit 16]

Charity Care Policy

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 SMC-First Hill and its other existing hospitals. SHS submitted its current charity care policy used at SMC-First Hill. 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 11] SHS also included a 'charity care' line item as a deduction from revenue within the pro forma income statement documents. [Source: Supplemental Information, Exhibit 16]

For charity care reporting purposes, HPDS divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. SMC-First Hill is located in King County within the King County Region. Currently there are 21 hospitals located within the region including SMC-First Hill. According to 2008 - 2010 charity care data obtained from HPDS, SMC-First Hill has historically provided more than the average charity care provided in the region excluding Harborview Medical Center.[15] SHS's most recent three-year (2008 - 2010) average percentages of charity care for gross and adjusted revenues are 1.70% and 3.01%, respectively.[16] The 2008 - 2010 average for the King County Region is 1.64% for gross revenue and 3.00% for adjusted revenue. [Source: HPDS 2008-2010 charity care summaries]

SHS submitted a pro forma revenue and expense statements for the proposed PCI project. [Source: May 22, 2012 Supplemental Information Revised Exhibit 16] The statements indicate that SMC-First Hill projects to provide charity care at approximately 1.7% of gross revenue and 3.01% of adjusted revenue. The projected adjusted revenue level of charity care is slightly above 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 SMC-First Hill is currently

[15] Harborview is excluded from the charity care calculations

[16] Since Swedish-Issaquah opened in October 2011, its charity care history is not included in these percentages

providing charity care and because its adjusted revenue level of charity care is above the 3-year regional average the department concludes this part of the sub-criterion is met.

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

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that 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, SMC-First Hill provided its projected Statement of Operations for the catheterization cost center only and for SMC-First Hill as a whole with and without the project for projected years 2014 through 2016. [Source: May 22, 2012 Supplemental Material, Revised Exhibit 16] A summary of the projected Statement of Operations for the catheterization lab cost center only is shown in table below.

Table 7
SMC-First Hill Catheterization Lab Cost Center
Projected Statement of Operations Summary
Years 2014 through 2016

	CON yr1	CONyr2	CONyr3
Cases	195	250	315
Gross Revenue	$16,265,415	$20,853,096	$26,274,901
Deductions from Revenue	$12,169,84	$15,601,389	$19,657,751
Net Patient Billing	$4,096,331	$5,251,707	$6,617,150
Other Operating Revenue	$0	$0	$0
Net Operating Revenue	$4,096,331	$5,251,707	$6,617,150
Operating Expense	$3,724,106	$4,774,494	$6,015,863
Operating Profit	$372,225	$477,213	$601,287
Net Profit	$372,225	$477,213	$601,287
Operating Revenue per Case	$21,007	$21,007	$21,007
Operating Expense per Case	$19,098	$19,098	$19,098
Net Profit per Case	$1,909	$1,909	$1,909

Source: October 29, 2012 HPDS Analysis, Includes overhead allocations

The table above shows that SMC-First Hill is projecting that the number of PCIs to increase from 195 in year one to 315 in year three. As shown in the table above, if SMC-First Hill met its volume projections, the PCI cost center is projected to be profitable in years 2014 through 2016.

The applicant also provided its projected Statement of Operations for SMC-First Hill as a whole with PCI services for projected years 2014 through 2016. The information is summarized in Table 8. [Source: May 22, 2012 Supplemental Material, Revised Exhibit 16]

Table 8
SMC-First Hill
Projected Statement of Operations Summary-With the Project
Years 2014 through 2016

	Projected Year 1 (2014)	Projected Year 2 (2015)	Projected Year 3 (2016)
Total Operating Revenue	$854,919,360	$871,835,939	$889,066,961
Total Expenses	$773,662,483	$785,962,487	$800,430,922
Net Profit or (Loss)	**$81,256,877**	**$85,873,170**	**$88,636,039**

Source: May 22, 2012 Supplemental Materials, Exhibit 16

The 'total operating revenue' line item in the table above 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. As shown in the table above, SMC-First Hill is projected to be operating at a profit for all three years.

To determine whether SMC-First Hill would meet its immediate and long range capital costs with an elective PCI program, HPDS reviewed the applicant's 2011 balance sheet. The balance sheet summarized in Table 9A indicates that SMC-First Hill has sufficient assets to meet the immediate capital costs of the project. The balance sheet summarized in the tables below indicates that SMC-First Hill has sufficient resources to meet the immediate and long range capital costs of this project.. [Source: HPDS analysis, p2 and Application, Exhibit 16]

Table 9A
SMC-First Hill Balance Sheet for 2011

Assets		**Liabilities**	
Current	$275,017,896	Current	$217,116,101
Board Designated	$12,201,046	Long Term Debt	$801,294,741
Property/Plant/Equipment	$967,908,240	Other	$0
Other	$571,420,154	**Equity**	**$808,136,494**
Total	**$1,826,547,336**	**Total**	**1,826,547,336**

Source: October 29, 2012 HPDS Analysis

Table 9B
SMC-First Hill Balance Sheet for Projected Year 3 – 2016

Assets		**Liabilities**	
Current	$887,806,044	Current	$378,464,229
Board Designated	594,580,251	Long Term Debt	$842,527,482
Property/Plant/Equipment	$1,135,652,607	Other	$533,230,218
Other	$28,929,102	**Equity**	**$892,746,075**
Total	**2,646,968,004**	**Total**	**$2,646,968,004**

Source: Application, Exhibit 16

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 2010 state data for comparison. The table below shows that comparison. SHS 2011 is for Swedish Health Services and not for SMC-First Hill.

Table 10
Current and Projected HPDS Debt Ratios for SHS

Category	Trend[17]	State 2010	SHS 2011	SHS2014	SHS2015	SHS2016
Long Term Debt to Equity	B	0.554	0.992	N/A	N/A	N/A
Current Assets/Current Liabilities	A	2.283	1.267	N/A	N/A	N/A
Assets Funded by Liabilities	B	0.434	0.558	N/A	N/A	N/A
Operating Exp./Operating Rev.	B	0.947	0.978	0.909	0.909	0.909
Debt Service Coverage	A	5.876	4.801	N/A	N/A	N/A

Definitions:	Formula
Long Term Debt to Equity	Long Term Debt/Equity
Current Assets/Current Liabilities	Current Assets/Current Liabilities
Assets Funded by Liabilities	Current Liabilities + Long term Debt/Assets
Operating Exp./Operating Rev.	Operating expenses / operating revenue
Debt Service Coverage	Net Profit+Depr and Interest Exp/Current Mat. LTD and Interest Exp

Source: October 29, 2012 HPDS Analysis

[17] A is better if above the ratio, and B is better if below the ratio.

As shown above, while all the ratios for SHS are out of range, SHS was in the middle of a large capital project in 2011 which could cause these issues. The hospital is average in overall financial health.

Based on the information above, the department concludes that the immediate and long-range operating costs of the project can be met. **This sub-criterion is met.**

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

SMC-First Hill proposes to begin providing elective PCI services in January 2014. The estimated capital expenditure for this portion of the project is $4,876,253. A breakdown of the total capital costs is shown in the table below. [Source: July 31, 2012 Supplemental Information, p111]

Table 11
SMC-First Hill Capital Expenditure
Elective PCI Program

Item	Cost	% of Total
Building Construction	$1,482,430	30.40%
Fixed Equipment	$1,249,753	25.63%
Moveable Equipment	$1,299,481	26.65%
Architect/Engineer Fees	$282,170	5.79%
Supervision and Inspection	$168,400	3.45%
Consulting Fees	$5,000	0.10%
Sales Tax	$389,019	7.98%
Total	**$4,876,253**	**100.00%**

SHS also provided a copy of the project manager's estimate of the construction costs. The letter confirms that the construction cost estimate for the C-Level Hybrid OR is within the expected range of construction costs. [Source: Application, Exhibit 17]

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 three years of operation, provided the hospital met the PCI volume projections. SMC-First Hill as a whole is projected to operate at a profit for all three years.

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."*

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 may 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.**

(3) <u>*The project can be appropriately financed.*</u>
WAC 246310 does not contain specific source of financing criteria as identified in WAC 246-310-200(3)(a)(i). There are also no known recognized standards as identified in WAC 246-31-200(3)(a)(ii) and (b) that direct how a project of this type and size should be financed. Therefore, using it experience and expertise the department compared the proposed project, source of financing to those previously considered by the department.

The capital expenditure associated with the construction of the hybrid OR is $4,876,253. The applicant states the project will be funded using reserves from SHS. To demonstrate compliance with this sub-criterion, the applicant provided a letter from the Chief Financial Officer demonstrating the financial commitment to this project. [Source: Application, Exhibit 18] Based on the information above, the department concludes **this sub-criterion is 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 (10) 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 (4), WAC 246-310-715, and WAC 246-310-735(13).

(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 staff would initially rotate from SMC-Cherry Hill and they anticipate recruitment of additional staff would not affect other programs in the area. The applicant provided job descriptions for the personnel that would staff the proposed PCI program. [Source: Application, p41] Based on the source information reviewed, the department concludes **this sub-criterion is met.**

WAC 246-310-715(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, life sustaining apparati, intra-aortic balloon pump assist device (IABP). The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.
To demonstrate compliance with this sub-criterion, the applicant provided a listing of "ancillary procedure" equipment to be installed in the catheterization lab at SMC-First Hill when complete. [Source: Application, Exhibit 3]. SHS provided documentation to demonstrate that catheterization laboratory and equipment meets the standards outlined in WAC 246-310-730(2). The proposed catheterization lab would be a combination catheterization lab/operating room.

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: July 31, 2012 Supplemental Materials, Revised Exhibit 19] A review of these documents shows that they contain signatures for the Director, Administration, or Human Resources. Therefore, the documents are considered to be the officially adopted job descriptions and skills review documents for this service. Therefore, the department concludes, **this sub-criterion is met.**

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

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 SMC-First Hill.

The staffing matrix for this service is shown in the table below.

Table 13
SMC First Hill Catheterization Lab
Staffing Pattern

Staff	Schedule*	Monday	Tuesday	Wed.	Thursday	Friday	Total Hours per week	FTEs
RN	8	8	8	8	8	8	40	1.0
RN	6	6	6	6	6	6	30	0.8
CIRT[18]	10	10	10	10	10	10	50	1.3
Cardio.Tech.	10	10	10	10	10	10	50	1.3
Totals							**170**	**4.3**

*Routine hours of operation Monday through Friday 7am to 5pm

On Call Staff	Standby Hours per week	Est. Overtime & Callback Hours per Week	Est. Overtime & Callback FTEs
RN	115.5	20	0.5
CIRT	115.5	20	0.5
Cardio. Tech.	115.5	20	0.5
Total	**346.5**		**1.5**
Total FTE			**5.8**

On-site staffing requirements include 1.4 FTE for RN 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 5.7 FTEs total. [Source: Application, p41]. The above information indicates that SMC-First Hill would be able to staff this service 24/7.

Based on the documentation provided, the department concludes **this sub-criterion is met**.

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

[18] CIRT- Cardiovascular Interventional Radiology Technologist

SHS expects cardiologists from the Swedish Medical Group to provide the physician staffing for the catheterization. SHS provided commitment letters from Dr. Desai, Dr. Demopulos, and Dr. Albro in the application. [Source: Application, Exhibit 20]

SHS provided a letter from Dr. Jeffrey Westcott, Medical Director of Swedish Heart and Vascular Institute attesting that each physician had performed at least 75 procedures per year for years 2009, 2010, and 2011. [Source: May 22, 2012 Screening Responses and Application p43 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. 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, 2012 Supplemental Information, 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 provided the names and professional license numbers of all nursing and technical staff associated with the proposed elective PCI program. SHS also provided a list of RNs and technical staff that currently provide the services at SMC-Cherry Hill. SHS provided job descriptions and skills review documents for the PCI program nurses and technical staff. [Source: July 31, 2012 Supplemental Information, Exhibit 25] Based on the information above, 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.*
The applicant reports that Swedish-First Hill has the necessary ancillary and support services to support the proposed project. The applicant provided a listing of other cardiac services currently being provided at Swedish-First Hill. [Source: Application, p44 and July 31, 2012 Supplemental Materials, pp 1& 2]

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 Patient Transfer agreement between SMC-Cherry Hill and SMC-First Hill dated February 16, 2012. Since WAC 246-310-745 refers to these agreements as partnering agreements, the department will refer to this agreement as the Partner agreement rather than the Patient Transfer Agreement used by the applicant. The agreement identifies SMC-Cherry Hill as the primary hospital for PCI patients requiring a transfer from SMC-First Hill. 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 21] 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 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 21]. 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 Partner agreement addresses this standard. Section 1.3 of the agreement identifies all documents to be transferred with the patient. [Source: Application, Exhibit 12] 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 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 21] The department concludes **this sub-criterion is met.**

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

The Partner agreement addresses this standard. Section 2.1 of the agreement ensures that SMC Cherry Hill will accept all referred patients from SMC-First Hill. [Source: Application, Exhibit 21] 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 22] Although the agreement appears to be a general transportation agreement amendments have been added to address 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 met.**

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

The 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 21] The department also reviewed the revised Transportation Agreement with American Medical Response Ambulance Service, Inc. provided in the supplemental materials provided by the applicant. The amendment effective May 1, 2012 of the transportation agreement states: *"In conformance with WAC 246-310-735 (7), Provider will ensure transport for emergent percutaneous coronary intervention (PCI") cases will begin within twenty (20) minutes of the initial identification of a complication as determined by SHS's treating physician."* [Source: July 31, 2012 Supplemental Materials, p7 & Revised Exhibit 22]

Based on the review of the Partner agreement and the Transportation Agreement with American Medical Response Ambulance Service, Inc., the department concludes **this sub-criterion is met.**

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

The Partner agreement, addresses this standard. Section 1.2 of the agreement addresses the qualifications of the emergency transport staff. [Source: Application, Exhibit 21] 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 Revised 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, Revised Exhibit 22 Amendment A]

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 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 21]

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."Revised* Exhibit 22 Amendment of this same agreement states: *"In conformance with WAC 246-310-735 (9) and specifically regarding transport of PCI Patients, transportation time will be less than one hundred and twenty (120) minutes."* [Source: July 31, 2012 Supplemental Materials, Revised Exhibit A]

Based on the review of the Partner agreement and the Revised Amendment to the Transportation Agreement with American Medical Response Ambulance Service, Inc, the department concludes **this sub-criterion is met.**

WAC 246-310-735(10) *At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.*
The 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 21]

The Transportation Agreement with American Medical Response Ambulance Service, Inc. (AMRAS) executed in December 2010, addresses this standard in the Revised Exhibit 22, Amendment. The revised exhibit 22 amendment now includes the following language: "*In conformance with WAC 246-310-735 (10), SHS and provider will participate in a minimum of two annual time emergency transportation drills pursuant to the provision of PCI services at SHS, with outcomes reported to SHS's quality assurance program."*

Based on the review of the Partner agreement and the Transportation Agreement with American Medical Response Ambulance Service, Inc., the department concludes **this sub-criterion is met.**

WAC 246-310-735(11) Patient signed informed consent for adult elective (and emergent) PCIs. Consent forms must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements
To demonstrate compliance with this standard, the applicant provided a copy of the SMC-first Hill 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 23]

Based on the review of the "First Hill 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 Partner agreement, addresses this standard. Section 3.2 and Exhibit 22 Amendment 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, the applicant provided a copy of its SMC-First Hill, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012. [Source: Application, Exhibit 9] The Plan identifies that SMC-First Hill; will participate in the Washington State Clinical Outcomes Assessment Program (COAP) to ensure quality and quality improvement. For accountability, SMC-First Hill will report the results of its performance to the Medical Executive Committee, Board Quality Committee, and Board of Swedish. [Source: Application, Exhibit 9]

Based on the review of the SMC-First Hill, 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 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] In the July 31, 2012 supplemental material, the applicant states that, the proposal is for patients to be retained at SMC-First Hill and addition of a new service for this hospital. They are not anticipating an increase in the number of PCI patients.

The department agrees with this conclusion since the number of PCIs performed at Swedish-Cherry Hill has been declining, in recent years. The information contained in the Partner agreement is insufficient for department to conclude this sub-criterion is met. However, supporting information in the application confirms the conclusion by the applicant that peak volumes are not likely to occur. Therefore the department must conclude **this sub-criterion is met.**

(3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*
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 2010, the Department of Health's Investigations and Inspections Office has completed at least six compliance surveys for SHS or its related healthcare providers including the initial compliance surveys for the Swedish-Issaquah.[19] 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] Based on the information above, the department concludes, **this sub-criterion is met**.

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 SMC-First Hill, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012. [Source: Application, Exhibit 9] This plan identifies the Washington State Clinical Outcomes Assessment Program (COAP) as the benchmark for PCI outcomes. [Source: Application, Exhibit 9, Attachment A]

Based on the review of the SMC-First Hill, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012, 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 SMC-First Hill, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012 addresses this standard. Attachment A to this plan states that the patient selection benchmark will be ACC guidelines. [Source: Application, Exhibit 9, Attachment A]

Based on the review of the SMC-First Hill Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012, the department concludes **this sub-criterion is met.**

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

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 SMC-First Hill Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012, addresses this standard. [Source: Application, Exhibit 9]

Based on the review of the SMC-First Hill Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012, 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 SMC-First Hill, 2012 Elective Percutaneous Coronary Intervention Performance Improvement Plan specific to elective and emergent PCI services. The Plan describes the reporting processes to be used. [Source: Application, Exhibit 9]

Based on the review of the Swedish Medical Center, Elective Percutaneous Coronary Intervention Performance Improvement Plan, 2012, 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.

Heart disease is a major concern in the state of Washington. DOH has been working on a system to improved outcomes for patients experiencing suspected heart attacks or strokes. The Washington State Emergency Cardiac and Stroke System began to phase-in starting in July 2011. The system has designated regions for identifying resources available to provide treatment for these patients. Swedish-First Hill is located in the Central Region which is all of King County. There are 16 hospitals in King County participating in the Emergency Cardiac and Stroke System. In the city of Seattle where Swedish First Hill is located there are 6 hospitals participating in the Emergency Cardiac and Stroke System. These hospitals and their Categorization are shown in the Table below,

Table 14
Emergency Cardiac and Stroke System
Participating Hospitals City of Seattle

	Categorization [20]	
Hospital	**Cardiac**	**Stroke**
Harborview Medical Center	I	I
Northwest Hospital and Medical Center	I	I
Swedish Ballard	II	III
Swedish-Cherry Hill	I	I
Swedish-First Hill	II	II
University of Washington Medical Center	I	III
Virginia Mason Medical Center	I	I

Source: DOH Website

SMC Cherry Hill- is the level I cardiac center for the SHS and SMC-First Hill is the level II cardiac center for the SHS. As discussed previously in this analysis, SMC-First Hill performed both emergent and elective adult PCIs until 2008. With the closure of the catheterization lab at SMC-First Hill, the PCIs were provided at the Cherry Hill campus.

In support of the application, SHS states patients seen at the SMC-First Hill emergency room or inpatients at SMC-First Hill needing catheterization lab services must be transferred by ambulance to SMC-Cherry Hill. This results in additional costs to some patients and some delay in treatment. However the system implemented in 2011 was designed to ensure that patients are transported to the closest hospital providing the services needed by the patient. In the case of patients requiring a PCI procedure, the appropriate hospital is SMC-Cherry Hill. This project would result in cardiac facilities and services being duplicated at SMC-First Hill with level I cardiac services being available within minutes at other hospitals.

The department concludes that this project is contrary to the SHS 2008 attempt to consolidate cardiac services, including PCIs, at the Cherry Hill campus. 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.*

The sub-criterion is also addressed in WAC 246-310-230 sub-section (3). The department reviewed historical survey data from the Department of Health's Investigations and Inspections office and concluded that the facilities operated by SHS were operated in accordance with the appropriate rules and regulations. The department has no reason to believe this project would not be operated in accordance with the appropriate rules and regulations. **This sub-criterion is met**.

[20] A level 1 is the highest level of service and a level II is the next level of service

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 246-310-230 and the PCI specific standards of WAC 246-310-735, and WAC 246-310-740. Therefore, the department concludes this project is not the best available alternative. As discussed previously in the need section of this evaluation, the PCI methodology does not show a need for an additional PCI program in the King West PCI planning area #10. This proposed project would be the establishment of a new program, since SMC-First Hill discontinued their catheterization lab services and consolidated these services at the SMC Cherry Hill campus. **This sub-criterion is not met.** The department does not review steps two or three for this project.

(2) *In the case of a project involving construction:*
(a) *The costs, scope, and methods of construction and energy conservation are reasonable; and*
Based on the source information provided, the department concludes that the cost, scope, and methods of construction are reasonable and approval of this project is not expected to have an unreasonable impact on the costs and charges to the public. **This sub-criterion is met**.

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

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2).

Certificate of Need
2012-2013 PCI Need Methodology

Updated 4/30/12

Planning Area	County	2011 15+ Pop.	2011 PCI Pop./1000 (1a)	2011 In-Patient PCIs	2011 Out-Patient PCIs	WA pts from Oregon	2011 Use Rate (1b)	2016 15+ Pop.	2016 PCI Pop./1000	2011 Use Rate	2016 Projected Demand (2a)	Current PCI Capacity (3d)	2016 Projected Net Need (4)	Projected Need/300 (5a)	# of New Programs (5b)
PSA 1	Adams	13,417		25	45	0		14,220							
	Asotin	17,816		34	19	0		18,157							
	Ferry	6,387		12	18	0		6,531							
	Grant	67,299		93	61	0		72,681							
	Lincoln	8,677		18	9	0		8,716							
	Pend Oreille	10,827		23	12	0		11,168							
	Spokane	383,928		585	417	0		400,438							
	Stevens	35,505		65	58	1		36,896							
	Whitman	39,382		41	42	0		40,283							
	Total	**583,238**	583.24	896	681	1	**2.71**	609,090	609.09	2.71	1,648	2,029	(381)	-1.27	**0**
PSA 2	Benton	137,461		153	105	0		146,774							
	Columbia	3,418		3	4	0		3,408							
	Franklin	56,612		53	44	1		64,034							
	Garfield	1,910		5	0	0		1,928							
	Walla Walla	48,143		57	48	1		49,424							
	Total	**247,544**	247.54	271	201	2	**1.91**	265,568	265.57	1.91	509	521	(12)	-0.04	**0**
PSA 3	Chelan	58,069		77	45	0		60,449							
	Douglas	30,252		38	11	0		30,229							
	Okanogan	33,329		61	38	1		34,060							
	Total	**121,650**	121.65	176	94	1	**2.23**	124,738	124.74	2.23	278	306	(28)	-0.09	**0**
PSA 4	Kittitas	35,009		45	18	0		36,663							
	Klickitat (E)	6,613		10	0	16		6,738							
	Yakima	183,314		365	94	5		192,603							
	Total	**224,936**	224.94	420	112	21	**2.46**	236,004	236.00	2.46	580	353	227	0.76	**0**
PSA 5	Clark	336,548		438	23	105		360,409							
	Cowlitz	82,672		87	42	131		85,608							
	Klickitat (W)	9,903		2	0	22		10,274							
	Skamania	9,161		4	1	13		9,533							
	Wahkiakum	3,398		5	1	4		3,413							
	Total	**441,682**	441.68	536	67	275	**1.99**	469,237	469.24	1.99	933	817	116	0.39	**0**
PSA 6	Grays Harbor	60,094		152	51	1		61,017							
	Lewis	61,650		165	27	3		63,668							
	Mason	51,048		141	29	0		53,778							
	Pacific	17,931		24	13	12		17,943							
	Thurston	207,247		421	62	1		221,171							
	Total	**397,970**	397.97	903	182	17	**2.77**	417,577	417.58	2.77	1,156	1,151	5	0.02	**0**

Certificate of Need
2012-2013 PCI Need Methodology

PSA 7	Pierce East														
	Total	**284,470**	284.47	522	158	0	**2.39**	309,069	309.07	2.39	739	300	439	1.46	**1**
PSA 8	Pierce West														
	Total	**350,052**	350.05	604	186	0	**2.26**	363,673	363.67	2.26	821	1,303	(482)	-1.61	**0**
PSA 9	King East														
	Total	**871,693**	871.69	1100	742	3	**2.12**	913,568	913.57	2.12	1,934	1,971	(37)	-0.12	**0**
PSA 10	King West														
	Total	**748,910**	748.91	910	461	2	**1.83**	774,097	774.10	1.83	1,419	1,994	(575)	-1.92	**0**
PSA 11	Snohomish														
	Total	**576,855**	576.86	876	428	3	**2.27**	612,454	612.45	2.27	1,388	1,049	339	1.13	**1**
PSA 12	Skagit	95,070		208	69	1		99,649							
	San Juan	13,881		24	3	1		14,092							
	Island	65,487		168	0	0		67,354							
	Total	**174,438**	174.44	400	72	2	**2.72**	181,095	181.10	2.72	492	293	199	0.66	**0**
PSA 13	Clallam	61,001		118	85	0		62,013							
	Jefferson	26,479		63	37	0		26,529							
	Kitsap	207,204		321	195	0		217,558							
	Total	**294,684**	294.68	502	317	-	**2.78**	306,100	306.10	2.78	851	586	265	0.88	**0**
PSA 14	Whatcom														
	Total	**168,128**	168.13	371	111	0	**2.87**	177,122	177.12	2.87	508	771	(263)	-0.88	**0**

County_Age Pop. Projections OFM May 2012 update
Sub county Pop Projections Claritas 2011 to 2016
PCI Outpatient 2011 Data Survey by DOH
PCI Inpatient CHARS Data for 2011
WA resident PCIs performed in Oregon 2011 data
Column H data as Feb. 20, 2013 inpatient and outpatient