STATE OF WASHINGTON
DEPARTMENT OF HEALTH

November 25, 2013

CERTIFIED MAIL # 7011 2000 0000 5081 8685

Mara Burke
Assistant Administrator
Strategic Planning & Communications
Highline Medical Center
16251 Sylvester Road SW
Burien, Washington 98166

RE: CN13-30

Dear Ms. Burke:

We have completed review of the Certificate of Need application submitted by Highline Medical Center proposing to establish an adult, elective percutaneous coronary intervention (PCI) program in Burien. Enclosed is a written evaluation of the application.

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

Need	WAC[1] 246-310-210
PCI Need Forecasting Methodology	WAC 246-310-745
General Requirements	WAC 246-310-715
Hospital Volume Standards	WAC 246-310-720
Financial Feasibility	WAC 246-310-220
Structure and Process of Care	WAC 246-310-230
Partnering Agreements	WAC 236-310-735
Cost Containment	WAC 246-310-240

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

[1] Washington Administrative Code.

Appeal Option 1:
You, any interested person, 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 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
Janis Sigman, Manager	Department of Health
Certificate of Need Program	Certificate of Need Program
Department of Health	111 Israel Road SE
Mail Stop 47852	Tumwater, WA 98501
Olympia, WA 98504-7852	

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

Mailing Address:	Other Than By Mail
Adjudicative Service Unit	Adjudicative Clerk Office
Mail Stop 47879	311 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, Community Health Systems

Enclosure

EVALUATION DATED NOVEMBER 25, 2013 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY HIGHLINE MEDICAL CENTER PROPOSING TO ESTABLISH AN ADULT ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM IN KING WEST PCI PLANNING AREA #10

APPLICANT DESCRIPTION

Highline Medical Center (Highline) is a not-for-profit hospital corporation located in the city of Burien within King County. Highline provides Medicare and Medicaid acute care hospital services to residents of the cities of Burien, Normandy Park, Des Moines, SeaTac, Tukwila, Georgetown, and White Center. This area defined by Highline as its service area is also known as Southwest King Planning Area.[1] The Southwest King planning area is a smaller area within the King West Percutaneous Coronary Intervention (PCI) planning area #10. [Source: Application, p1-9]

PROJECT DESCRIPTION

Currently, Highline provides heart and vascular services at its main campus. Highline provides emergency PCIs but not elective PCIs at their hospital. 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.[2]

Highline proposes the establishment of adult elective PCI services at its Burien campus. The applicant reports that it is increasingly difficult to operate a program on emergency PCIs only and difficult to recruit and or retain interventional cardiologists, trained technical staff, and registered nurses with the limitations of the existing program. Highline proposes that elective PCIs would be provided in 2013 upon approval and issuing a certificate of need. Under this timeline, year 2014 would be Highline's first full calendar year of operation and 2016 would be the third full year of operation. The estimated capital cost of this project is zero dollars. [Source: Application: Face page, p10]

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

[1] This is a hospital planning area, previously defined in the 1987 Washington State Health Plan, for providing primary health care services.
[2] Source: WAC 246-310-705(4)

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 (C of N) 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).[3] Where applicable, the applicant demonstrates compliance with the above criteria by meeting the Adult Elective Percutaneous Coronary Interventions (PCI) Without On-Site Cardiac Surgery Standards and Forecasting Method outlined in WAC 246-310-700 through 755.

APPLICATION CHRONOLOGY

Action	Highline Medical Center
Letter of Intent Submitted	January 31, 2013
Application Submitted	February 28, 2013
Department's Pre-Review Activities •Department 1st Screening Letter Sent •Highline 1st screening Responses Received •Department 2nd Screening Letter Sent •Highline 2nd Screening Responses Received	 March 29, 2013 May 13, 2013 June 3, 2013 July 18, 2013
Department Begins Review; no public hearing requested or conducted	July 24, 2013
Highline requests extension of public comment period	August 19, 2013
End of Public Comment[4]	September 26, 2013
Rebuttal Documents Received	October 11, 2013
Department's Anticipated Decision Date	November 25, 2013
Department's Actual Decision Date	November 25, 2013

[3] 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).
[4] Applicant requested extension of public comment from August 28, 2013 to September 26, 2013

TYPE OF REVIEW

As directed under WAC 246-310-710 the department accepted this project under the 2013 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. Highline Medical Center 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).

- MultiCare Health Services – located in Pierce and King counties with hospitals that provide both PCI and open heart surgery.

SOURCE INFORMATION REVIEWED

- Highline Medical Center Certificate of Need application submitted February 28, 2013
- Highline Medical Center supplemental information dated May 8, 2013 and July 18, 2013
- Public comments submitted by community members and healthcare providers
- Public comments provided by MultiCare Health Systems received July 3, 2013
- Highline Medical Center Rebuttal comments received October 11, 2013
- 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 (2009, 2010, and 2011 summaries)
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems (HPDS) received November 18, 2013
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office (IIO)
- Department of Health 2012 PCI utilization survey data related to outpatient PCIs obtained in year 2011

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Highline Medical Center proposing to establish an adult elective percutaneous coronary intervention program at the Burien 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), and WAC 246-310-715(1), (2))

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

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

WAC 246-310-700 requires the department to evaluate all adult elective PCI applications based on the population's need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The PCI specific numeric methodology applied is detailed under WAC 246-310-745. WAC 246-310-210(1) criteria is also identified in WAC 246-310-720(1) and (2), and WAC 246-310-715(1) and (2).

PCI Methodology WAC 246-310-745

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

For PCI programs, Washington State is divided into 14 separate planning areas.[5] Highline Medical Center is located in the city of Burien, within King County. King County is divided into King West and King East planning areas. Highline 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			

[5] 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.

Highline Medical Center 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 2011[6]
Seattle Children's Hospital	No	0
Group Health Seattle Hospital	No	0
Harborview Medical Center	No	61
Northwest Hospital	Yes	214
Swedish Medical Center Ballard Campus	No	0
Swedish Medical Center Cherry Hill	Yes	1,019
University of Washington Medical Center	Yes	216
Virginia Mason Medical Center	Yes	545
Highline Medical Center	No	103
Swedish Medical Center First Hill	No	0

Swedish Medical Center and Virginia Mason Medical Center are located 10.5 miles from Highline. Valley Medical Center, Renton located in King East PCI planning area #9 is 5.96 miles from Highline Medical Center. UWMC is located 15.4 miles from Highline and Northwest Hospital is located 16.4 miles from Highline.

Public Comment

MultiCare Health System (MHS) provided public comment regarding Highline's request that the department use the Southeast King Hospital Planning area to review this application rather than the King West PCI Planning area identified in rule. MHS did not support this recommendation since the hospital planning areas are for primary care services not tertiary care services. Also development of the rules regarding the PCI services had extensive public involvement and agreement as to the number and location of PCI planning areas. MHS also provided comment on the projected volumes which will be discussed later in this evaluation.

Department's Evaluation

The PCI planning areas are defined in rule and to be changed would require a change in the rules. Since the planning areas were developed for totally different reasons, the department will continue to use the PCI planning areas in rule.

Highline's Methodology

In order to provide a numeric need methodology, data from existing Washington State hospitals must be obtained. Highline relied on the department's utilization survey for

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

outpatient PCIs and CHARS data for inpatient PCIs. Highline also added PCIs from the CHARS observation data base and included PCIs not included in the DRGs in the rule. Highline used 2011 Claritas population data for this application. [Source: Application, p20]

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

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

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

(b) Divide the total number of PCIs performed on the planning area residents fifteen years of age and over[7] 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, 2013. The base year data for this project is year 2011 and the base year population provided by the applicant is 750,443.

Highline's Step 1 calculation is as follows:

a) The age 15+ 2011 per 1,000 population was calculated to be 750.443 which is 750,443/1,000.

b) The number of inpatient and outpatient PCIs was 1,225 for the planning area. 1,225/750.443 is 1.6 –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.[8]

The "forecast year" is the fifth year after the base year. Since the base year is 2011, the forecast year is 2016. Highline used 2016 Claritas population data which is the correct data as identified in the methodology and the population for 2016 provided by the applicant was 750,443.

The Step 2 calculation is as follows:

- The age 15+ per 1,000 population for 2016 was calculated to be 750.4 which is 750,443/1,000.
- The 2011 use rate was 1.6 from step 1(b)
- 750.4 multiplied by 1.6 is 1,288 which is the projected number of resident PCIs for year 2016.

[7] Residents 15 years of age and older.
[8] Residents 15 years of age and older.

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.

The table below shows the capacity of the PCI planning area hospitals as identified by the applicant.

Table 3
Applicant's Hospital Capacity Planning Area #10

Hospital	Inpatient Actual	Outpatient Actual	Total PCI Counted Per Method
SMC- Cherry Hill	488	535	1,023
Virginia Mason Medical Center	287	257	544
University of Washington Medical Center	185	33	218
Northwest Hospital	140	74	214
TOTAL	**1100**	**899**	**1999**

Highline determined the PCI capacity for all providers in Planning Area #10 is 2,017 by including additional PCIs not counted by the department.

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 Highline subtracted the calculated capacity of 2,017 (step 3) for year 2016 from the projected need for 2016 of 1,288 (step 2) and determined a net projected surplus of 729 PCIs.

Highline used some PCIs in the capacity that are not counted by the department; therefore Highline's capacity is slightly higher than that calculated by the department. This higher capacity still results in a surplus of programs calculated in the methodology.

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.)

Highline divided the projected surplus of -729 by 300 to calculate a surplus of 2.4 programs in the planning area, which is then rounded down to a surplus of two programs in year 2016.

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 for the years 2011 and 2016. 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 2011 data and the population provided by the department is 748,910.

Calculations for Step 1 are shown below.

a) The age 15+ 2011 per 1,000 population is 748.91 which 748,910/1000.

b) The number of inpatient PCIs is 791, outpatient PCIs is 396 and inpatient from the state of Oregon is 2 resulting in a total of 1,187 PCIs. The 1,187 PCIs are divided by 748.91 to get a calculated use rate of 1.59 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]

For this project, the forecast year is 2016. In this step, the department multiplied the use rate of 1.59 calculated in Step 1 by the Claritas projected planning area population of 774,097. The results are 1,230 PCIs for planning area #10 residents in 2016.

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

[9] Residents 15 years of age and older.

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

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

> "*...the sum of all PCIs performed on people (aged fifteen years of age and older) by all CON approved adult elective PCI programs, or department grandfathered 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 2011.

Table 4
Need Forecasting Methodology
Hospital Capacity Planning Area #10

Hospital	Inpatient Actual	Outpatient Actual	Total PCI Counted Per Method
SMC- Cherry Hill	484	535	1,019
Virginia Mason Medical Center	288	257	545
University of Washington Medical Center	183	33	216
Northwest Hospital	140	74	214
Seattle Children's[10]	0	0	0
King West Planning Area Total	**1,095**	**899**	**1,994**

Table 4 above shows that Swedish Medical Center and Virginia Mason Medical Center provided more than 300 PCI procedures in 2011. Northwest Hospital and the University of Washington Medical Center provided less than 300 PCI procedures in 2011.

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

[10]For capacity the department only counts PCIs performed at hospitals with C of N approved adult elective PCI programs.

need for procedures is less than three hundred, the department will not approve a new program.

A subtraction of the current capacity of 1,994 (step 3) from the year 2016 projected need of 1,230 (step 2), results in a surplus of procedures, or negative 766. 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 code 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. Highline and the department used population data for the years 2011 and 2016 from Claritas.

Highline deviated slightly from the PCI methodology by including some PCIs that do not get included in the DRGs defined in the PCI rules included in WAC 248-310-745. These PCIs were also included in the capacity identified for the King West PCI planning area #10. The changes made to the methodology did not change the outcome of the calculations. The applicant and the department found no need for additional programs in the King West Planning area.

WAC 246-310-745(2) defines how "current capacity" is to be measured.[11] Review of Highline's application of the numeric methodology shows that Highline counted a similar amount of procedures. Highline appeared to include some PCI procedures not counted by the department.

Rather than using the PCI planning area defined in rule, Highline proposed the department use the Southwest King Hospital planning area as defined in the 1987 Washington State Health Plan. Using this approach, Highline would be the only hospital provider in the

[11] 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.

planning area. This would make the capacity for the planning area zero and the Highline states this would result in need for a program.

Department's Conclusion
The department and Highline both determined there is not a need for any new PCI programs in the King West PCI planning area #10.

The department rejected the proposal that Highline have a PCI planning area different than the planning area identified in WAC 246-310-705.

Based on the need methodology outlined above, the department concludes there is no projected need for an additional PCI program in King West 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, Highline provided a table showing the number of PCIs performed at University of Washington (UWMC) on residents of Southwest King Hospital planning area in year 2011 by patient zip code. A total of 12 inpatient PCIs were performed on the Southwest King planning area residents by UWMC out of 608 resident PCIs. The applicant reports that this is a market share of 3% of all the PCIs from the King West PCI Planning area #10.

Highline also provided a copy of a letter from Dr. Arun Kalyanasundaram Medical Director for the Highline Cardiac Catheterization Lab, The letter addressed to Dr. Larry Dean, Director of UWMC's Regional Heart Center describes the program operated by Highline and indicated that 3% of the West King residents receiving PCIs came from the Southwest King Service area. Highline did not receive any response from UMMC or its representatives to this letter.

Public Comment
UWMC did not provide public comment specific to this application, however the following comments were provided in response to previous applications submitted in 2009 for PCI services in King County and the program has no reason to believe the comments do not still hold true.

"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.

The data provided by the applicant indicates that 12 patients receiving PCIs in 2011 from UWMC reside in the Southwest King planning area. The analysis provided by the applicant on the 12 patients only addressed a portion of the planning area residents. While this data would suggest a small impact Highline did not address any mitigation plans eliminating any impact to UWMC.

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. 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.

Highline 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 Highline. [Source: Application, p22]

Table 5
2014-2016 Projected PCI Procedures
For Highline

Type of PCI	2014	2015	2016
Total	**180**	**252**	**305**

Highline 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:

- Using the current and future total service area PCI volumes performed on Southwest King Planning area residents.

- Using actual data regarding the number of cases the cardiologists currently perform directly or refer to Seattle hospital (non-University of Washington) providers. [Source: Application: p22]

Public Comment

MHS commented that PCI volumes projected by Highline cannot be supported as reasonable based on the historical decline of emergent PCIs performed at Highline. Their analysis indicates that Highline is projecting an 18.6% annual growth from 2011 to 2014 and a 26.4% growth from 2014 to 2016.

Rebuttal

Highline disputes the MHS analysis stating that the number of emergent PCIs performed at Highline is increasing in 2012 and 2013. The applicant stated that one of the physicians performing PCIs at Highline also performs PCIs at Swedish Cherry Hill. The applicant also stated this physician would be available to perform the elective PCIs at Highline if this application were approved.

Department's Evaluation

Highline provided data indicating that 397 patients receiving PCIs in 2011 resided in the SW King Hospital planning area. Highline projected that there would be 415 patients receiving PCIs in 2016.

Therefore the department concludes that Highline's volume projections for this project are reasonable but that if Highline achieves their projected volumes existing programs may be impacted. **This sub-criterion is met.**

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

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

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

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

There are four existing PCI programs in the King West Planning Area #10. These four programs are SMC-Cherry Hill Medical Center, Virginia Mason Hospital and Medical Center, University of Washington Medical Center, and UW Medicine/Northwest Hospital and Medical Center

WAC 246-310-720(2) is a two pronged measure and each must be met to approve a new program. The data in table 6 below indicates the second prong of this test is not met. As shown in the table 6 below, only SMC-Cherry Hill and Virginia Hospital and Medical Center are at or above the minimum hospital volume standard.

Table 6
King West PCI Planning Area 10 Hospitals
2011 PCIs

Hospital	PCIs
SMC-Cherry Hill Medical Center	1,019
Virginia Mason Hospital & Medical Center	545
University of Washington Medical Center	216
Northwest Hospital & Medical Center	214

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.*

Highline is currently a provider of health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. As an acute care hospital, Highline participates in the Medicare and Medicaid programs. To determine whether all residents of the service area would have access to an applicant's proposed services, the department requires applicants 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, Highline provided a copy of its current Admission Policy used for the hospital. The policy outlines the process/criteria that Highline uses to admit patients for treatment or care and states that any patient requiring care will be accepted for treatment regardless of race, creed, gender, national origin or religious preference. [Source: Application, Exhibit 2]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. Highline currently provides services to Medicare eligible patients in their medical facilities. Details provided in the application demonstrate that Highline intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [Source: Application P4 & Exhibit 3]

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. Highline currently provides services to Medicaid eligible patients in their medical facilities. Details provided in the application demonstrate that Highline intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Application P4 & Exhibit 3]

Public Comment

Highline received nine letters for support for this project. The letters emphasized the economic status, ethnic population concerns, and other barriers to healthcare services faced by the population in the Southwest King planning area.

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.

Highline demonstrated its intent to provide charity care to Washington residents by, submitting its current charity care policy, reviewed and approved by the Department of Health's Hospital and Patient Data Systems (HPDS) program. It outlines the process one would use to access services when they do not have the financial resources to pay for the required treatments. Highline also included a 'charity care' line item as a deduction from revenue within the pro forma income statements for their facility. [Source: Application, p, Exhibit 2 & Exhibit 3]

For charity care reporting purposes, HPDS divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Highline is located in King County within the King County Region. Currently there are 21 hospitals located within the region including Highline. According to 2009 - 2011 charity care data obtained from HPDS, Highline has historically provided more than the average charity care provided in the region excluding Harborview Medical Center.[12] Highline's most recent three-year (2009 - 2011) average percentages of charity care for gross and adjusted revenues are 1.99 and 4.72%, respectively.[13] The 2009 - 2011 average for the King County Region is 1.67% for gross revenue and 3.06% for adjusted revenue. [Source: HPDS 2009-2011 charity care summaries]

Highline submitted a pro forma revenue and expense statements for the proposed PCI project. [Source: Application, p68] The statements indicate that Highline projects to provide charity care at approximately 1.55% of gross revenue and 3.60% 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 Highline is currently providing charity care and because its adjusted revenue level of charity care is above the 3-year regional average the department concludes **this sub-criterion is 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.

[12] Harborview is excluded from the charity care calculations

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

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

To demonstrate compliance with this sub-criterion, Highline provided its projected Statement of Operations for the catheterization cost center only and for Highline as a whole with and without the project for projected years 2014 through 2016. A summary of the projected Statement of Operations for the catheterization lab cost center only is shown in table 7 below.

Table 7
Highline Catheterization Lab Cost Center
Projected Statement of Operations Summary
Years 2014 through 2016

	CON yr1	CONyr2	CONyr3
Cases	180	252	304
Gross Revenue	$14,251,216	$19,951,701	$24,147,893
Deductions from Revenue	$10,903,605	$15,265,046	$18,475,553
Net Patient Billing	$3,347,611	$4,686,655	$5,672,340
Other Operating Revenue	$0	$0	$0
Net Operating Revenue	$3,347,611	$4,686,655	$5,672,340
Operating Expense	$2,384,366	$3,378,483	$5,672,340
Operating Profit	$963,245	$1,308,172	$1,533,344
Net Profit	$963,245	$1,308,172	$1,533,344
Operating Revenue per Case	$18,598	$18,598	$18,598
Operating Expense per Case	$13,246	$13,407	$13,570
Net Profit per Case	$5,351	$5,191	$5,027

Source: November 18, 2013 HPDS Analysis, Does not Include overhead allocations

The table above shows that Highline is projecting that the number of PCIs would increase from 180 in year one to 304 in year three. As shown in the table above, if Highline 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 Highline as a whole with PCI services for projected years 2014 through 2016. The information is summarized in Table 8 below. [Source: Application, p68]

Table 8
Highline
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	$207,193,974	$229,823,018	$255,332,622
Total Expenses	$214,801,929	$227,322,286	$245,412,227
Net Profit or (Loss)	**($7,607,955)**	**$2,500,732**	**$9,920,395**

Source: Application, p68

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, Highline is projected to be operating at a loss in year 2014 and a profit for years 2015 and 2016.

To determine whether Highline 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 9 indicates that Highline has sufficient assets to meet the immediate capital costs of the project. The balance sheet summarized in the tables below indicates that Highline has sufficient resources to meet the immediate and long range capital costs of this project.. [Source: HPDS analysis, p2]

Table 9
Highline Balance Sheet for 2011

Assets		**Liabilities**	
Current	$67,341,133	Current	$40,555,290
Board Designated	$12,965,067	Long Term Debt	$142,565,105
Property/Plant/Equipment	$119,675,422	Other	
Other	$43,348,033	**Equity**	**$60,209,260**
Total	**$243,329,655**	**Total**	**$243,329,655**

Source: November 18, 2013 HPDS Analysis

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 2011 state data for comparison. The table below shows that comparison.

Table 10
Current and Projected HPDS Debt Ratios for Highline

Category	Trend [14]	State 2011	H 2011	H2014	H2015	H2016
Long Term Debt to Equity	B	0.565	2.368	2.695	3.046	2.775
Current Assets/Current Liabilities	A	2.029	1.660	1.006	0.954	0.896
Assets Funded by Liabilities	B	0.442	0.753	0.732	0.757	0.754
Operating Exp./Operating Rev.	B	0.965	0.811	0.712	0.721	0.730
Debt Service Coverage	A	4.340	0.209	0.073	0.068	0.059

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: November 18, 2013 HPDS Analysis

As shown above, all the ratios for Highline are out of range, the data provided by Highline shows that this project will improve the financial picture. The hospital is below 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) *The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.*

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

Highline proposes to begin providing elective PCI services upon approval of the C of N. The estimated capital expenditure for this project is zero dollars.

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. Highline as a whole is projected to operate at a loss for year 2014 and at a profit for years 2015 and 2016.

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

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 2012 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) *The project can be appropriately financed.*
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 this project is zero dollars. There is no financing required. [Source: Application, Face sheet] 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, and WAC 246-310-735(11).

(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 Highline stated that the catheterization lab would initially start with a total of 8.6 FTEs. No additional staff would be added for the first three years of operation. [Source: Application, p32] 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.
Highline is currently operating a catheterization laboratory that currently provides emergent PCI services.

To demonstrate that catheterization laboratory staff will be qualified as required under this standard, Highline provided job descriptions and skills review documents for the PCI program nurses, imaging technologists, and respiratory care practitioner staff. Highline also provided a listing of the current licensed staff.

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, Highline states it will have three trained cardiac catheterization lab Registered Nurses, plus three catheterization lab technicians available on site Monday through Friday from 7:00 am to 5:30 pm. The on-call staff of one RN and two catheterization lab technicians 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.

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.*
Highline currently has four interventional cardiologists on its active medical staff, all of whom are board certified or otherwise qualified to perform PCIs. Highline provided the names and medical license numbers of its existing providers. [Source: Application, p 36]

Highline provided documentation attesting that Dr Arun Kalyanasundaram had performed at least 75 procedures per year for years 2010, 2011, and 2012. [Source: Applicationon p37] Dr Kalyanasundaram will perform all the elective PCIs if this application is approved. 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

Highline identified four cardiologists who currently provide PCIs on an emergent basis and if C of N approval is granted, one would provide elective PCIs based on their clinical judgment of the most appropriate location for these procedures. [Source: Application, p37] 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*

Highline provided the names and professional license numbers of all nursing and technical staff associated with the proposed elective PCI program. The applicant also provided a list of RNs and technical staff that currently provide the services at Highline. The applicant provided job descriptions and skills review documents for the PCI program nurses and technical staff. [Source: Application, p32-35Exhibit 4] 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 Highline has the necessary ancillary and support services to support the proposed project. [Source: Application, p37]

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, Highline provided a copy of its elective PCI Partnering Agreement Swedish Medical Center dated April 1, 2013. The agreement identifies Swedish Medical Center as the primary tertiary hospital for PCI patients requiring a transfer from Highline. The agreement acknowledges Swedish Medical Center 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 3 of the Partner agreement addresses this standard. Section 3 states: "Both t*he Transferring Hospital and Tertiary Hospital agree to coordinate, when possible, the availability of surgical teams and operating rooms so that for all hours that elective PCIs are being performed at the Transferring Hospital the Tertiary Hospital is available to accept a referral.*" [Source: Supplemental Material, p65-68]. 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 6 of the agreement identifies that appropriate clinic or other data will be transferred with the patient. [Source: Supplemental Material, p65-68] 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 7 of the agreement states: "*The Transferring Hospital will monitor to ensure the physician performing the elective PCI and communicates immediately and directly with the cardiac surgeons at the Tertiary Hospital regarding the reasons for the patient's transfer and clinical condition.*" [Source: Supplemental Material, p65-68] 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 4 of the agreement requires patients to be rescheduled if high census is a problem at the Tertiary Hospital. [Source: Supplemental Material, p65-68] 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, Highline provided a copy of its draft Hospital Medical Transportation Agreement with American Medical Response (AMR) Ambulance Service, Inc. 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 7] Although the agreement appears to be a general transportation agreement amendments have been added to address specifics for this proposed PCI program. If this project is approved, the department would require Highline to provide a signed copy of the transportation agreement with AMR consistent with the draft agreement provided in the application.

With agreement to the condition on the transportation agreement and based on the information provided above, 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 5b *"The Transferring hospital will document and confirm that emergency transportation begins for each patient within (20) minutes of the initial identification of a complication."* [Source: Application, Exhibit7] 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 5a of the agreement addresses the qualifications of the emergency transport staff. [Source: Supplemental Material, p65-69] The Transportation Agreement's Exhibit A assures the patient will be transported with appropriately qualified personnel. 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 5c of the agreement ensures that the transport time will be less than 120 minutes. [Source: Supplemental Material, p65-69]

The department also reviewed the Transportation Agreement with AMR and AMR agrees to meet the standards for transporting PCI patients. [Source: Application, Exhibit7]

Based on the review of the Partner agreement and the Exhibit A to the Transportation Agreement with AMR, 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, Section 5d 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: Supplemental Material, p65-69]

The draft Transportation Agreement with AMR, addresses this standard in Schedule A. Section 6 identifies the requirement for two timed drills.

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 referenced the Partner Agreement which lists the requirements for the consent form in Section 1. The department did not find a copy of the consent form in the partnership agreement. The applicant also provided a copy of the Highline PCI quality assurance plan. The quality assurance also did not have a copy of the consent form. Based on the review of the documentation submitted by Highline the department concludes **this sub-criterion is not 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 9 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.

Based on the review of 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, addresses this standard. Section 4 states: *"During times of high census wherein the Tertiary Hospital's ability to accept a patient referral is impacted by a lack of bed availability or a closed emergency department (ED). The Tertiary Hospital will notify the Transferring Hospital and elective procedures will be rescheduled as long as in the attending physician's assessment such delay does not compromise the patient's care and condition."* The department concludes **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.

Highline provides healthcare services to the residents of Southwest King County. Highline does not operate any healthcare facilities outside of Washington State. The Department of Health's Investigations and Inspections Office completed a survey for Highline in December 2012. The compliance survey revealed minor non-compliance issues related to the care and management at Highline. These non-compliance issues were typical of the specific type of facility and Highline submitted and implemented an acceptable plan 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.

Highline provided a copy of its Percutaneous Coronary Intervention Performance Improvement Plan. This plan identifies the Washington State Clinical Outcomes Assessment Program (COAP) as the benchmark for PCI outcomes. [Source: Application, Exhibit 8]

Based on the review of the Highline Percutaneous Coronary Intervention Performance Improvement Plan, 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
Highline provided a copy of their quality improvement plan which states that the patient selection benchmark will be SCAI guidelines. [Source: Application, Exhibit 8]

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

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

The Highline Percutaneous Coronary Intervention Performance Improvement Plan addresses this standard. [Source: Application, Exhibit 8]

Based on the review of the Highline Percutaneous Coronary Intervention Performance Improvement Plan, 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.
Highline provided a copy of its 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 8]

Based on the review of the Highline Percutaneous Coronary Intervention Performance Improvement Plan, 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.

Given the surplus of PCI services in the King West PCI Planning Area #10, approval of this project would cause additional fragmentation of these services in the planning area. The additional fragmentation of services would create a barrier to existing providers meeting the 300 minimum volume standard. 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 Highline 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**.

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, Highline 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. **This sub-criterion is not met.** The department does not review steps two or three for this project.

APPENDIX A

Washington State Department of Health

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**

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	1093	682	3	**2.04**	913,568	913.57	2.04	1,863	1,971	(108)	-0.36	**0**
PSA 10	King West														
	Total	**748,910**	748.91	791	396	2	**1.59**	774,097	774.10	1.59	1,229	1,994	(765)	-2.55	**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 7,916 3,259
PCI Inpatient CHARS Data for 2011
WA resident PCIs performed in Oregon 2011 data