



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

October 23, 2009

CERTIFIED MAIL # 7007 3020 0000 3056 2681

Michael Carter, CEO
Stevens Hospital
21601 76th Avenue West
Edmonds, Washington 98026-7507

Dear Mr. Carter:

We have completed review of the Certificate of Need application submitted on behalf of Snohomish Hospital District #2 dba Stevens Hospital proposing to establish an elective, adult percutaneous coronary intervention (PCI) program within space at the hospital. Enclosed is a written evaluation of the application. For the reasons stated in this evaluation, the department has concluded that the project is consistent with the Certificate of Need review criteria, provided Stevens Hospital agrees to the following term and conditions.

Terms

1. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a final Admission Policy. The final Policy will be consistent with the draft plan provided in Exhibit 11 of the application.
2. Prior to commencement of the project, Stevens Hospital will submit to the Certificate of Need Program an executed copy of a Department of Health's Hospital and Patient Data Systems program approved Charity Care Policy. The approved policy will include the Charity Care Exclusion document referenced within the policy submitted with this application.
3. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a copy of Exhibit A from the transfer agreement with Rural/Metro Ambulance.
4. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a final Performance Improvement Plan. The final Plan will be consistent with the draft plan provided in Exhibit 21 of the application.



5. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a final Informed Consent. The final policy will be consistent with the draft plan provided in Exhibit 20 of the application.

Conditions

1. Stevens Hospital will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Stevens Hospital will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Puget Sound Region. Currently, this amount is 1.93% of gross revenue and 4.20% of adjusted revenue. Stevens Hospital will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.
2. Stevens Hospital must make all reasonable efforts to refer patients as likely Percutaneous Coronary Intervention candidates to the University of Washington Medical Center for the procedure if:
 1. The University of Washington Medical Center, at the end of any calendar quarter, demonstrates that its interventional program volumes are not on track for the calendar year to maintain the annual minimum volume that is required by a certification organization to maintain the University of Washington Medical Center's training program.
 2. The maximum number of patient referrals that may be expected of Stevens Hospital in any one calendar year is 50.
 3. The University of Washington Medical Center makes a written request to Stevens Hospital for patient referrals. The request must:
 - include the number of patients residing in Stevens Hospital's PCI planning area that already have had the procedure done at the University during that calendar year; and
 - The University's request for referrals may not exceed the difference between the maximum patient referral number (50) and the number of patients from the planning area that has already received a PCI procedure at the University of Washington.

There is no capital expenditure associated with the establishment of PCI services at Stevens Hospital.

With the terms and conditions stated above, the Department of Health concludes that the project satisfies the application criteria. Without the term and condition, the project would not be consistent with applicable Certificate of Need criteria, and a Certificate of Need would be denied.

Please notify the Department of Health within 20 days of the date of this letter whether you agree to the term and condition attached to the department's approval.

Michael Carter, CEO
Stevens Hospital
Certificate of Need App #09-20
October 23, 2009
Page 3 of 3

Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:

Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

FedEx and UPS:

Department of Health
Certificate of Need Program
310 Israel Road SE
Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact 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 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON
BEHALF OF HOSPITAL DISTRICT #2 OF SNOHOMISH COUNTY dba STEVENS
HOSPITAL PROPOSING TO ESTABLISH AN ADULT ELECTIVE PERCUTANEOUS
CORONARY INTERVENTION PROGRAM AT THE HOSPITAL**

PROJECT DESCRIPTION

Hospital District #2 of Snohomish County-Stevens Hospital (Stevens) is located at 21601 76th Avenue West in the city of Edmonds within Snohomish County. Stevens is currently a provider of Medicare and Medicaid acute care services to the residents of Snohomish County and the surrounding area and holds a three-year accreditation from the Joint Commission. [Application, p1; CN historical files; and DOH Investigations and Inspections Office]

Stevens is currently licensed for 217 acute care beds, and of those, 25 beds are used for inpatient psychiatric services. Stevens has been providing emergent percutaneous coronary intervention (PCI) services; totaling 113 in 2007.¹ 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: [Stevens Hospital facility file; Application, p10]

- (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.

[WAC 246-310-705(4)]

This application proposes to establish an adult, elective PCI program within space at the hospital.² [Application, p10]

Stevens anticipates the elective PCI services would be available in January, 2010. The capital expenditure is associated with this project is equal to \$144,837. The costs are broken down in Table 1. [Application, p13]

¹ Emergency means a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. [source: WAC 246-310-705(3)]

² For PCI programs, 'adult' is defined as 15 years of age and older. 'Elective' means a PCI performed on a patient with cardiac function that has been stable in the days or weeks prior to the operation. Elective cases are usually scheduled at least one day prior to the surgical procedure. [source: WAC 246-310-705(2)]

Table 1
Estimated Capital Costs - Stevens Hospital PCI

Item	Amount	% of Total
Construction	\$0	0%
Equipment (Fixed/Moveable)	\$133,000	92%
Taxes	\$11,837	8%
Fees	\$0	0%
	\$144,837	100%

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

CRITERIA EVALUATION

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

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

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

- (i) The consistency of the proposed project with service or facility standards contained in this chapter;*
- (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
- (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.”*

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

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

- (i) Nationally recognized standards from professional organizations;*
- (ii) Standards developed by professional organizations in Washington State;*
- (iii) Federal Medicare and Medicaid certification requirements;*
- (iv) State licensing requirements;*
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*

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

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 general criteria by meeting the Adult Elective Percutaneous Coronary Interventions (PCI) Without On-Site Cardiac Surgery Standards and Forecasting Method outlined in WAC 246-310-700 through 755.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-710 the department accepted this project under the year 2009 PCI Concurrent Review Cycle. Below is a chronologic summary of the project.

January 27, 2009	Letter of Intent Submitted
February 27, 2009	Application Submitted
February 28, 2009 through May 17, 2009	Department’s Pre-Review activities, including screening responses received from applicant
May 18, 2009	Department Begins Review; no Public Hearing Requested or Conducted
July 17, 2009	End of Public Comment
August 17, 2009	Rebuttal Documents Received
October 1, 2009	Department's Anticipated Decision Date
November 2, 2009	Department's Updated Decision Date
October 23, 2009	Department's Decision Date

CONCURRENT REVIEW AND AFFECTED PERSONS

The purpose of the concurrent review process is to comparatively analyze and evaluate competing or similar projects to determine which of the projects may best meet the identified need. For PCI projects, concurrent review allows the department to review PCI applications proposing 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. Stevens is located in planning area #11 as defined in WAC 246-310-705(5), as all of Snohomish County. No other application was submitted proposing to serve this planning area.

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(2).

For this project, one entity sought and received affected person status under WAC 246-310-010.

- University of Washington Medical Center – located in Seattle and currently a provider of both PCI and heart surgery. Additionally, University of Washington Medical Center is the only hospital in Washington State with a Cardiovascular Disease and Interventional Cardiology Fellowship Training program.

SOURCE INFORMATION REVIEWED

- Stevens Hospital Certificate of Need Application submitted February 27, 2009
- Stevens Hospital supplemental information dated April 29, 2009
- Public comments submitted by community members and healthcare providers
- Rebuttal comments provided by Stevens Hospital received August 17, 2009
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Hospital and Patient Data Systems
- Data obtained through the Clinical Outcomes Assessment Program (COAP)
- Department of Health 2007 PCI Utilization Survey
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2005, 2006, and 2007 summaries)
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems received September 11, 2009
- Department of Health's Investigation and Inspection's Office (IIO) files

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Hospital District #2 of Snohomish County-Stevens Hospital is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need should be issued provided the applicant agrees to the five terms and two conditions stated below.

The approved capital expenditure for this project is \$144,837.

Terms

1. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a final Admission Policy. The final Policy will be consistent with the draft plan provided in Exhibit 11 of the application.
2. Prior to commencement of the project, Stevens Hospital must submit its Charity Policy, including the referenced exclusion document, for review and approval by the Certificate of Need program and the Department's Hospital and Patient Data Systems program. The exclusion document must not exclude elective scheduled PCI procedures from charity care eligibility.
3. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a copy of Exhibit A from the transfer agreement with Rural/Metro Ambulance.

4. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a final Performance Improvement Plan. The final Plan will be consistent with the draft plan provided in Exhibit 21 of the application.
5. Prior to commencement of the project, Stevens Hospital must provide to the Certificate of Need Program for review and approval a final Informed Consent. The final policy will be consistent with the draft plan provided in Exhibit 20 of the application.

Conditions

1. Stevens Hospital will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Stevens Hospital will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Puget Sound Region. Currently, this amount is 1.93% of gross revenue and 4.20% of adjusted revenue. Stevens Hospital will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.
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 1. The University of Washington Medical Center, at the end of any calendar quarter, demonstrates that its interventional program volumes are not on track for the calendar year to maintain the annual minimum volume that is required by a certification organization to maintain the University of Washington Medical Center's training program.
 2. The maximum number of patient referrals that may be expected of Stevens Hospital in any one calendar year is 50.
 3. The University of Washington Medical Center makes a written request to Stevens Hospital for patient referrals. The request must:
 - include the number of patients residing in Stevens Hospital's PCI planning area that already have had the procedure done at the University during that calendar year; and
 - The University's request for referrals may not exceed the difference between the maximum patient referral number (50) and the number of patients from the planning area that has already received a PCI procedure at the University of Washington.

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

Based on the source information reviewed and the applicant's agreement to the terms and conditions identified in the "Conclusion" section of this evaluation, the department determines that Stevens Hospital's project has met the methodology criteria in WAC 246-310-210 and the PCI methodology and standards cited in WAC 246-310-745, and WAC 246-310-715(1) & (2).

(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 246-310-715(1), and (2).

PCI Methodology WAC 246-310-745

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

For PCI programs, Washington State is divided into 14 separate planning areas⁴. Stevens Hospital is located in Snohomish County. Snohomish County is included in Planning Area #11. The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation will be limited to Planning Area #11.

Snohomish County is served, in part, by three public hospital districts (PHD). Stevens Hospital is part of Hospital District #2. Providence Everett Medical Center (PEMC) also operates in the planning area and is the only location which currently maintains an open-heart surgery program allowing elective PCI's to be scheduled. The four hospitals are identified in Table 2 on the following page. [Application, p15]

⁴ WAC 246-310-705

**Table 2
PCI Planning Area 11 Hospitals**

Hospital	Elective PCI's provided	# Elective PCI's performed⁵
Cascade Valley Hospital – PHD #3	No	-
Providence Everett Medical Center	Yes	935
Stevens Hospital – PHD #2	No	-
Valley General Hospital – PHD #1	No	-

Stevens Hospital

Stevens followed the methodology as prescribed while relying upon use rates and population values calculated independent from the department's methodology which will be detailed below.

To establish the planning area use rate, Stevens provided a zip code analysis of the reported PCI cases for the residents of Snohomish County in 2007. The data identified the degree of out-migration and the volume at the county hospitals. Of the 1,510 PCI cases reported for Snohomish residents, 935 procedures are performed at PEMC. This equals approximately 48% of the residents receiving PCI procedures. [Application, p16]

The applicant's population projections were derived through calculating a population growth rate for residents 0-64 and 65+ separately. After combining the applicable population totals for the planning area, the final 15 and over population for 2007 was projected to be 539,517. The use rate derived by the applicant from these values was 2.80. [Application, p17-19]

When Stevens applied this use rate to the projected population for 2012, it produced a projected demand of 740 additional PCI procedures for Planning Area #11. When divided by 300, the Applicant's results showed a need of 2.47, or up to two additional elective PCI programs is projected.

Department Numeric Methodology

This portion of the evaluation will describe, in summary, the calculations made 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.*

⁵ As reported on the Department of Health 2007 PCI Utilization Survey conducted in 2008

- (b) *Divide the total number of PCIs performed on the planning area residents over fifteen years of age⁶ by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.*

For PCI programs, 'base year' is defined as the most recent calendar year that December 31 data is available from the department's Comprehensive Hospital Abstract Reporting System (CHARS) reports (or successor reports) as of the first day of the application submission period. For this project, the first day of the application submission period was February 1, 2009. The base year data is year 2007.⁷

The department used year 2007 PCI survey data and planning area population data obtained from population forecasts published by the Washington State Office of Financial Management (OFM) based on the 2000 census, updated November 2007⁸. The results produced a Planning Area #11 PCI use rate of 2.78 per 1,000 residents [2.78/1,000]; nearly equal to the applicant's use rate of 2.80

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 PCI programs, the 'forecast year' is defined as the fifth year after the base year. For this project, the forecast year is year 2012. In this step, the department multiplied the use rate of 2.78 calculated in Step 1 with the OFM projected planning area population of 600,476. The results are 1,669,323. This number is then divided by 1,000, which produced a need for 1,669 procedures for planning area #11 residents in 2012.

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.*

⁶ Residents 15 years of age and older.

⁷ Although, Year 2008 CHARS data became available in early August 2009. WAC 246-310-745 directs to specific CHARS data to use. Therefore, the 2008 data will not be discussed in this evaluation.

⁸ County & Age Pop. Projections OFM Sept 2007 update, Released Nov. 2007

⁹ Residents 15 years of age and older.

This step requires computation of the planning area's current capacity. PEMC in Everett is the only provider of elective PCI services in the planning area. According to 2007 PCI survey data, PEMC performed 935 PCI procedures in 2007. This was applied as the current capacity.

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

A subtraction of 935 (current capacity from step 3) from 1,669 (projected need from step 2), results in a net need of 734 procedures.

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. This is done by dividing the planning area's net need by the minimum hospital volume standard identified in WAC 246-310-720. For Planning Area #11, this calculation is $734 / 300$ resulting in a value of 2.45. This number is rounded down as directed in WAC 246-310-745(2) to two. Up to 2 additional programs could be approved.

The methodology outlined above also addresses the availability and accessibility of existing providers in the planning area by applying 100% of the procedures reported by the elective PCI programs currently in the planning area. Based on the results of the methodology, the PEMC program is determined not to be available or accessible to meet the projected planning area need.

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

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

Information provided by Stevens detailed the PCI procedures performed on planning area #11 residents at the UWMC program. The zip code breakout identified a total of 50 PCI procedures; or 12% of the total procedures reported for the UWMC, residing in planning area #11. With the exception of a single outlier¹⁰, the trend was 7.1% of residents or less going

¹⁰ The single zip code of 98043 exceeded the trend of the other county zip codes with a out-migration rate of 10.9%

outside of the planning area to receive services from the UWMC program. Stevens concluded that UWMC relies upon planning area #11 to provide a modest number of procedures as part of the UWMC's PCI totals.

The application also supplied a memorandum from a Stevens Hospital administrator regarding a verbal conversation with a representative from UWMC. The applicant reported that the discussion addressed, "the medical center's physician training program and Stevens' proposed elective program. Both agreed Stevens would work to assure UWMC's training program volumes would not be reduced as a result of Stevens' new program". [Application, p24-25, Exhibit 9]

Department's Evaluation

Documentation provided by Stevens demonstrates that UWMC performed a total of 50 PCI's on patients from Planning Area #11 zip codes. In 2007, UWMC performed a total of 402 PCIs. Stevens does not assert that 100% of its referrals would be recaptured if this project is approved, rather, Stevens asserts that the referral patterns related to UWMC would not change, and UWMC would continue to receive patients from the planning area. In its public comment, UWMC voiced concerns related to the collective applicants¹¹, including Stevens, affecting patient volumes at UWMC and this standard. Specifically, UWMC asserts that its patient volumes are decreasing and considering the training program volume threshold is 400, UWMC's loss margin is zero. UWMC asserts a decrease of PCIs at its hospital endangers the UWMC's ability to train and place interventional cardiologists at, not only applicant hospitals, but hospitals in the entire WWAMI region.¹² To ensure any new PCI programs, including Stevens, would not negatively affect its PCI volumes, UWMC suggests the department condition any approvals to ensure that the PCI volumes at the UW fellowship training program are not reduced below current volumes. [July 15, 2009, UWMC public comment]

To ensure that approval of this elective PCI application, as well as the collective elective PCI applications, will not result in an adverse impact to the University of Washington fellowship training program, the following condition is necessary.

Stevens Hospital must make all reasonable efforts to refer patients as likely Percutaneous Coronary Intervention candidates to the University of Washington Medical Center for the procedure if:

1. The University of Washington Medical Center, at the end of any calendar quarter, demonstrates that its interventional program volumes are not on track for the calendar year to maintain the annual minimum volume that is required by a certification organization to maintain the University of Washington Medical Center's training program.
2. The maximum number of patient referrals that may be expected of Stevens Hospital in any one calendar year is 50.

¹¹ During the year 2009 PCI concurrent review cycle, the department received and reviewed a total of eight PCI applications, including this application from Stevens. For public comment, UWMC submitted one letter to address all eight applications.

¹² WWAMI region includes the states of Washington, Wyoming, Alaska, Montana, and Idaho.

3. The University of Washington Medical Center makes a written request to Stevens Hospital for patient referrals. The request must:
 - include the number of patients residing in Stevens Hospital’s PCI planning area that already have had the procedure done at the University during that calendar year; and
 - The University’s request for referrals may not exceed the difference between the maximum patient referral number (50) and the number of patients from the planning area that has already received a PCI procedure at the University of Washington.

With the applicant’s agreement to the above condition, this sub-criterion is met.

WAC 246-310-715(2). Submit a detailed analysis of the projected volume of adult elective PCIs that it anticipates it will perform in years one, two and three after it begins operations. All new elective PCI programs must comply with the state of Washington annual PCI volume standards (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.

Stevens provided a projection of the number of PCI they expect to perform through the first three years of the proposed program. Table 3 below details the type of procedures and the corresponding yearly totals submitted by Stevens.

Table 3
Projected PCI Procedures for Stevens Hospital by Year

Type of PCI	2010	2011	2012
Emergent	120	123	126
Elective/Scheduled	60	120	174
Total	180	243	300

Stevens discussed the assumptions used to project the PCI procedures in Table 3. The projections are based on the following factors: [Application, p15 & 21]

- Current and future total planning area PCI volumes derived directly from the department’s numeric methodology;
- Elective/scheduled PCI volumes are based on Stevens’ current in-patient market share applied to the reported out-migration for PCI services;
- Emergent PCI volumes are based on actual historical emergent market share and 2.5% annual growth.

The projections show the number of emergent cases experiencing marginal growth. The primary source of the 300 minimum is derived from the expansion into elective procedures. Specifically, Stevens assumed a high degree of initial growth due to two primary factors.

First, referring to the zip code analysis that showed that nearly 45%, or 691 PCI procedures were performed on Snohomish County residents outside of the planning area. Secondly,

based upon the commitments and statistics of the cardiologists who will be performing elective procedures at Stevens, the applicant considered the volumes to be achievable. The Applicant reasons, “Admittedly, complex cases will still be performed at Swedish, but it is reasonable to assume many elective cases can ‘migrate’ to Stevens”. [Application, p16 & 21, Exhibit 7]

If Stevens’ were approved to provide elective PCI services, the potential for Snohomish County residents to begin receiving the necessary care within the planning area appear reasonable. Based upon the information provided, and the underlying assumptions of the Applicant, the department concludes the projections appear achievable. The Applicant has sufficiently met the requirements of this sub-criterion.

Department’s Evaluation

The projections in Table 3 show the number of emergent cases experiencing minimal annual growth. The primary source of the 300 minimum was derived from Stevens’ expansion into elective/scheduled procedures. The elective/scheduled PCI projections are also reasonable because Stevens used the department’s numeric methodology as a baseline for projected PCIs and then considered current migration trends and market share.

Based on the projections provided and the underlying assumptions used by Stevens to project PCI volumes, the department concludes that both emergent and elective/scheduled PCI projections are reasonable and Stevens would meet this standard. This sub-criterion is met.

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

Stevens Hospital 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, Stevens Hospital also currently participates in the Medicare and Medicaid programs. To determine whether all residents of the service area would continue to have access to a hospital’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, Stevens Hospital provided a copy of its draft Admission Policy that would be implemented upon approval of the project. The policy outlines the process/criteria that Stevens Hospital uses to admit patients for treatment or care at the hospital. The policy also states that any patient requiring care is accepted for treatment at Stevens Hospital without regard to “race, color, national origin, sex, marital status, or on the basis of age”. [Application, Exhibit 11]

Based on the review of the draft Admission policy, the department concludes the draft policy satisfies the necessary standards and requirements. To ensure this policy would continue to meet the standards and requirement as identified, the Applicant must agree to provide a copy

of the final Admission policy to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be met.

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

Stevens Hospital currently provides services to Medicare and Medicaid eligible patients. Documents provided in the application demonstrate that it intends to maintain this status. For this project, a review of the policies and data provided for Stevens Hospital identifies the facility's financial resources as including both Medicare and Medicaid revenues. [Application, p6 & 13; Exhibit 15]

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.

Stevens Hospital's charity care policy provided in the application outlines the process a patient would use to access this service. Further, the applicant included a 'charity care' line item as a deduction from revenue within the pro forma financial documents for the hospital. Though the policy submitted with the application clearly outlines the policy, it does not include the exclusion document referenced on page 5 of the policy statement. Additionally, the charity care policy provided is not the same as the approved version the department has on file¹³. Therefore, if approved, a term will be added requiring Stevens to supply the Charity Policy, including the referenced exclusion document, for review and approval. The exclusion document must not exclude elective scheduled PCI procedures from charity care eligibility. Further, the complete Charity Care policy must receive approval from the Department of Health's Hospital and Patient Data Systems. [Application, Exhibits 10 & 15]

For charity care reporting purposes, the Department of Health's Hospital and Patient Data Systems (HPDS), divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Located in Snohomish County, Stevens Hospital is one of 18 hospitals in the Puget Sound Region. According to 2005-2007 charity care data obtained from HPDS, Stevens Hospital has historically provided significantly less than the average charity care provided in the region. Stevens Hospital's most recent three years (2005-2007) percentages of charity care for gross and adjusted revenues are 1.49% and 3.03%, respectively. The 2005-2007 average for the Puget Sound Region is 1.93% for gross revenue and 4.20% for adjusted revenue. [HPDS 2005-2007 charity care summaries]

Stevens Hospital's pro forma revenue and expense statements indicate that the hospital will provide charity care at approximately 2.00% of gross revenue and 4.65% of adjusted revenue. RCW 70.38.115(2)(j) requires hospitals to meet or exceed the regional average

¹³ Source: <http://www.doh.wa.gov/EHSPHL/hospdata/CharityCare/CharityPolicies/Default.htm>

level of charity care. The amount of charity care calculated from the forecasted financials provided in the application exceeds the three-year historical gross and adjusted revenue averages reported by the hospital. Given that the three-year historical average is below that for the region, the department concludes that a condition related to the percentage of charity care to be provided at Stevens Hospital is necessary if this project is approved. [Application, p29 & Exhibit 15]

With agreement to the terms regarding the hospital’s admission policy, charity policy, and the condition regarding the amount of charity care provided, the department concludes that all residents, including low income, racial and ethnic minorities, handicapped, and other under-served groups would have access to the services provided by the hospital. 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 met the financial feasibility criteria in WAC 246-310-220(1), (2), and (3).

(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, Stevens provided its income statement for the incremental PCI revenue and expenses projected in years 2010 through 2012. A summary of the income statement for the PCI program only is shown in Table 3 below. [Application, Exhibit 15]

**Table 4
Incremental PCI Income Statement Summary**

	Projected Year 1 (2010)	Projected Year 2 (2011)	Projected Year 3 (2012)
Total Operating Revenue	\$ 754,000	\$ 1,507,000	\$ 2,185,000
Total Operating Expense	\$ 473,000	\$ 918,000	\$ 1,318,000
Net Revenue (Expense)	\$ 281,000	\$ 589,000	\$ 867,000

Since Stevens provides emergent PCI services only, current year 2009 reports reflected the cost with emergent services only. Years 2010 through 2012 include emergent and elective PCI services. The ‘total operating revenue’ line item in Table 4 is the result of gross revenue minus any deductions for contractual allowances, bad debt, and charity care directly related to the PCI services. The ‘total operating expense’ line item includes staff salaries/wages and all hospital cost allocations related to the PCI cost center. Table 4 reflects the gradual

increase in PCIs projected by Stevens and summarized in Table 3 of this evaluation. As shown in Table 4, the PCI cost center is projected to be profitable in years 2010 through 2012.

Stevens also provided its Statement of Operations for the hospital as a whole with PCI services for projected years 2010 through 2012. A Statement of Operations summary is shown in Table 5 below. [Application, Exhibit 15]

**Table 5
Stevens Hospital Projected Statement of Operations Summary**

	Projected Year 1 (2010)	Projected Year 2 (2011)	Projected Year 3 (2012)
Total Operating Revenue	\$ 161,030,000	\$ 165,490,000	\$ 169,777,000
Total Operating Expense	\$ 158,861,000	\$ 161,510,000	\$ 164,926,000
Net Revenue (Expense)	\$ 2,170,000	\$ 3,980,000	\$ 4,850,000

The ‘total operating revenue’ line item in Table 5 is the result of gross revenue and hospital district tax revenue minus any deductions for contractual allowances, bad debt, and charity care. The ‘total operating expense’ line item includes all hospital staff salaries/wages. As shown in Table 5, the hospital as a whole is projected to be profitable in years 2010 through 2012 with the elective PCI program.

The reported capital expenditure for the proposed project is \$144,837. To determine whether Stevens would meet its immediate and long range capital costs with an elective PCI program, HPDS reviewed current and projected balance sheets. Historical year [2008] and year 3 [2012] are shown in Tables 6A below and 6B on the following page. [HPDS analysis, p2; Application, Exhibit 15]

**Table 6A
Stevens Hospital Balance Sheet for Year 2008**

Assets		Liabilities	
Current	\$ 41,851,585	Current	\$ 34,115,381
Board Designated	\$ 10,636,217	Long Term Debt	\$ 29,239,756
Property/Plant/Equipment	\$ 36,109,165	Other	\$ 1,802,588
Other	\$ 2,520,370	Equity	\$ 25,959,612
Total	\$ 91,117,337	Total	\$ 91,117,337

**Table 6B
Stevens Hospital Balance Sheet for Year 2012**

Assets		Liabilities	
Current	\$ 29,555,000	Current	\$ 23,743,000
Board Designated	\$ 28,746,000	Long Term Debt	\$ 19,900,000
Property/Plant/Equipment	\$ 38,449,000	Other	\$ 4,907,000
Other	\$ 1,392,000	Equity	\$ 49,292,000
Total	\$ 97,842,000	Total	\$ 97,842,000

As HPDS concludes, “Stevens is part of Public Hospital District #2 of Snohomish County. The capital expenditure is projected to be \$144,837 which will be paid out of cash reserves. The hospital has adequate resources to initiate this project”. [HPDS analysis, p2]

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. The financial ratios typically analyzed are 1) long-term debt to equity; 2) current assets to current liabilities; 3) assets financed by liabilities; 4) total operating expense to total operating revenue; and 5) debt service coverage. If a project’s ratios are within the expected value range, the project can be expected to be financially feasible. Additionally, HPDS reviews a project’s three-year projected statement of operations to evaluate the applicant’s immediate ability to finance the service and long term ability to sustain the service.

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 2007 data for comparison. The ratio comparisons are shown in Table 7 below. [HPDS analysis, p2]

**Table 7
Current and Projected HPDS Debt Ratios for Stevens Hospital PCI Program**

Ratio Category	Trend	State07	SH08	Projected 2010	Projected 2011	Projected 2012
Long Term Debt to Equity	B	0.523	1.126	0.639	0.490	0.404
Current Assets/Current Liabilities	A	2.135	1.227	1.109	1.177	1.232
Assets Funded by Liabilities	B	0.419	0.695	0.531	0.486	0.446
Debt Service Coverage	A	6.041	0.833	0.089	0.289	0.815
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					
Debt Service Coverage	Net Profit+Depr and Interest Exp/Current Mat. LTD and Interest Exp					

Comparing Stevens’ most current (2008) ratios with the statewide ratios (2007) revealed that Stevens is outside the normal range in each of the four categories. The ratios outside the

normal range reflect any construction, remodel, or upgrade projects that have occurred at the hospital. After evaluating the hospital’s projected ratios and statement of operations for years 2010-2012, HPDS states, “[Stevens] did however generate a positive net income in 2008 and is improving its financial status. The applicant has the reserves to sustain this project. The project, when fully implemented will improve the financial standing of [Stevens]”. [HPDS analysis, p2]

HPDS also compared Stevens’ operating expense to operating revenue ratio for the PCI project only. Stevens projects its operating revenues to exceed its operating expenses for its PCI project. This is demonstrated by the revenue to expense ratios of 0.627, 0.609, and 0.603 for years 2010, 2011, and 2012, respectively. [HPDS analysis, p2]

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.

Stevens proposes to begin providing elective PCI services in January 2010. The estimated capital expenditure for this portion of the project is \$144,837. A breakdown of the total capital costs by for each phase is reprinted in Table 8. [Application, p13]

**Table 8
Estimated Capital Costs - Stevens Hospital PCI**

Item	Amount	% of Total
Construction	\$0	0%
Equipment (Fixed/Moveable)	\$133,000	92%
Taxes	\$11,837	8%
Fees	\$0	0%
Total	\$144,837	100%

To assist the department in its evaluation of this sub-criterion, HPDS reviewed CHARS PCI procedure data and hospital financial data. HPDS concluded, “In reviewing PCI procedures in the 2008 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 2008 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.” [HPDS analysis, p3]

Based on the information provided above, the department concludes that the cost of the project will probably not result in an unreasonable impact on the costs and charges for health services within the service area. This sub-criterion is met.

(3) The project can be appropriately financed.

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

The hospital capital expenditure for this project is \$144,837 and is to be funded out of cash reserves. The hospital has adequate resources for this project. 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) and Quality Assurance (WAC 246-310-740)

Based on the source information reviewed and the applicant's agreement to the terms and conditions identified in the "Conclusion" section of this evaluation, the department determines that the applicant has met the criteria and standards in WAC 246-310-230; WAC 246-310-715(3), (4), and (5); WAC 246-310-725; and WAC 246-310-730(1) and (2); WAC 246-310-735; and WAC 246-310-740.

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

For PCI projects, specific WAC 246-310-230(1) criteria is identified in WAC 246-310-715(3), (4) and (5); WAC 246-310-725; and WAC 246-310-730 (1) and (2).

WAC 246-310-715(3). Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists without negatively affecting existing staffing at PCI programs in the same planning area.

To demonstrate compliance with this sub-criterion, Stevens stated that since it already provides both diagnostic and emergent PCIs, the majority of the nursing and technical staff required for elective procedures are already in place. The same individuals will be used to staff the elective program with incremental additions. Stevens anticipates adding the FTEs (full time equivalents) to specific staffing areas within the cardiac catheterization labs. Stevens also provided a projection of FTEs required in support services that the elective PCI program may affect. Table 8 shows the breakdown of Stevens' expected incremental increases for the three years following implementation of the program. [Application, p33]

**Table 8
Projected Incremental Increases in FTE Totals**

FTEs	Current Year 2009	Year 1 Increase	Year 2 Increase	Year 3 Increase	Total in 2012
Cath LabRN	3.65	0.32	0.32	0.28	4.57
Cardio Tech	6.42	0.00	0.00	0.00	6.42
Hospital Support Svc's	375.11	0.69	0.69	0.62	377.11
FTE Total	385.18	1.01	1.01	0.90	388.10

As shown, Stevens anticipates adding nearly one full RN FTE by the end of 2012 in support of this program. When considering the projects affect upon the entirety of the hospital's resources and services, the total FTE increases average one additional FTE equivalent in each forecast year. The applicant does not anticipate this nominal increase to affect the program currently at PEMC. [Application, p34]

To recruit this additional support, Stevens identifies a series of actions targeted towards traditional recruiting methods for health care workers. The applicant also reports interest expressed from qualified staff currently employed by the hospital and encourages internal promotion when such staff is available. [Application, p34]

Based on the documentation provided, the department concludes that all staff necessary to operate the program is available, or can be recruited. 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 apparatus, 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.

In response to this criterion, Stevens provided a list of the primary equipment utilized in their existing cardiac catheterization lab. This is in addition to a second catheterization lab used primarily for interventional procedures. The capital costs identified in this application also account for the purchase of additional equipment to be available for the staff of the PCI program. Stevens states, “[the] catheterization lab is equipped with all necessary life sustaining equipment. This includes intra-aortic balloon pumps, a fully stocked code cart with ACLS cardiac drugs, intubation equipment and a Lifepac 20 cardiac defibrillator with bi-phasic technology”. [Application, p10; April 29, 2009 Supplemental Information, p3]

Documentation provided demonstrates that catheterization laboratory staff and equipment meet the standards outlined in WAC 246-310-730(2). This sub-criterion is met.

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

With the current staffing, Stevens is able to provide emergent PCI care 24 hours a day, seven days a week. The hospital actively staffs the facility to accommodate emergent care during

traditional business hours, and during times when staff are not on site, on-call teams are available within 30 minutes. [Application, p33]

Based on the information above, the department concludes that 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.

The applicant identifies four cardiologists who will be performing elective PCI's at the facility. Each of the cardiologists currently performs emergent PCI procedures at Stevens and is available through a relationship with the Swedish Heart and Vascular Institute. Each has provided letters of commitment to continue to provide PCI services at Stevens These doctors include:

- Ralph Althouse, MD
- Eric Grassman, MD
- David Warth, MD
- Gary Weeks, MD

Volume statistics from 2005 through 2007 for these physicians are reported through data available with the Swedish Health Services Physician division. Records indicate that each of the physicians identified have meet the volume standards prescribed. [Application, p36 & Exhibit 8; April 29, 2009 Supplemental Information, p3 & Exhibit 7]

Based on the information above, the department concludes that 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.

Stevens does not currently employ any cardiologists. The applicant plans to retain the relationship with Swedish Hospital, and their related cardiologists named above, to maintain the ability to perform both elective and emergent PCI's at the hospital. [Application, p35]

Based on the information above, the department concludes that 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

The cauterization lab is currently fully staffed with qualified nurses and has detailed the requirements for those assigned to these positions in the job descriptions submitted in the application. The need for intubation or ventilator procedures may be performed by physicians available 24/7 from the hospital's emergency room department. For instances requiring transport, the applicant states, "Stevens will provide RN's who are trained in endotracheal intubation and ventilator management to ride with patients during transport, if

necessary. Further, at the discretion of the treating cardiologist, there will be a cardiologist who also accompanies critically-ill patients”. Based on the information provided, the department concludes that this sub-criterion is met. [Application, p35, Exhibit 16]

Based on the information provided to address the requirements under this section, the department concludes that 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

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

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

In response to this sub-criterion, the applicant provided a copy of an executed Patient Transfer Agreement with Swedish Health Services. The agreement identifies Swedish as the primary hospital for PCI patients requiring a transfer from Stevens Hospital. Section 1 of the agreement outlines the responsibilities of Stevens when acting as the transferring Hospital and the expectations of Swedish acting as the receiving hospital. [Application, p36 & Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services, the department concludes that 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.

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with Swedish Health Services. Section 2 of the agreement outlines the responsibilities of Swedish, acting as the receiving hospital, and ensures access to cardiac surgery services for elective PCI patients transferred from Stevens Hospital. [Application, p36 & Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services, the department concludes that 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.

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with Swedish Health Services. Section 1 of the agreement outlines the responsibilities of Stevens, acting as the transferring hospital, to assure the complete and legal transfer of a patient’s medical and other confidential records to the receiving hospital and cardiac surgeon. [Application, p36 & Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services, the department concludes that 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.

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with Swedish Health Services. Section 1 of the agreement outlines the responsibilities of Stevens, acting as the transferring hospital, and ensures communication of medical and clinical data between the physician performing the elective PCI and the cardiac surgeon. [Application, p36 & Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services, the department concludes that this sub-criterion is met.

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

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with Swedish Health Services. Section 2 of the agreement outlines the responsibilities of Swedish, acting as the receiving hospital, and ensures acceptance of all transfers under the agreement. [Application, p36 & Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services, the department concludes that 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.

In response to this sub-criterion, the applicant provided a copy of an executed Transfer Agreement with Rural/Metro Ambulance. Section 1 of the agreement references Exhibit A that reportedly outlines the responsibilities of Stevens and of Rural/Metro in providing transport of patients from the hospital. Though, a copy of Exhibit A was not included with the application. If this project is approved, a term will be added to require Stevens to submit a complete copy of the transfer agreement, inclusive of Exhibit A. [Application, p37 & Exhibit 18 & 19]

Based on the review of the transfer agreement with Rural/Metro Ambulance, and acceptance of the term regarding Exhibit A, the department concludes that this sub-criterion is met.

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

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with Swedish Health Services. The agreement outlines the responsibilities of

Stevens, acting as the transferring hospital, and ensures that emergency transport shall commence within 20 minutes of the initial identification of a complication.

To demonstrate the efforts to adhere to this standard, the applicant provided a copy of a executed Transfer Agreement with Rural/Metro Ambulance. Section 7 of the agreement outlines the obligation for full ambulance transport service. As a back-up, Stevens has also included a executed Emergency Transfer policy for those patients in a life threatening situation. This identifies the use of the Edmonds Fire department in an instance where Rural/Metro is unavailable or unable to make a self-imposed 15 minute pick-up window for these life-threatening instances. [Application, p37 & Exhibit 18 & 19]

Based on the review of the agreements addressed above, the department concludes that 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).

Information included in the Partner Agreement with Swedish Health Services, the Transfer Agreement with Rural/Metro Ambulance, and the Emergency Transfer policy address the use of qualified staff to be available as the situation require. Section 4 of the Emergency Transfer policy obligates Stevens to provide “critical care” personnel during transport as necessary. [Application, p37 & Exhibit 17, 18 &19]

Based on the review of these agreements and policy statement’s provisions, the department concludes that 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.

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with Swedish Health Services. Section 1 of the agreement outlines the responsibilities of Stevens, acting as the transferring hospital, and obligates the hospital to track and record the time taken to transfer a patient from the time a decision is made to transfer to arrival to the operating room of the receiving hospital. The agreement establishes that, “under no circumstances shall [the transfer] be longer than two (2) hours”. [Application, p37 & Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services, the department concludes that 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.

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with Swedish Health Services. Section 5 of the agreement outlines the responsibilities of Stevens, acting as the transferring hospital, and obligates the hospital to

perform two emergency transport drills each year. The agreement states, “The outcomes of these drills shall be reported to the transferring Hospital’s quality assurance program for review”. [Application, p37 & Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services e, the department concludes that 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

In response to this sub-criterion, the applicant provided two separate documents. Section 1 of the executed copy of a Partner Agreement with Swedish Health Services outlines the responsibilities of Stevens, acting as the transferring hospital, and obligates the hospital secure the patient’s signed informed consent.

To demonstrate the efforts to adhere to this standard, the applicant provided a draft Patient Consent Form. The draft outlines the catheterization procedure and the relative risks of the procedure. The draft also includes information regarding the transfer policy and the additional risks associated with such actions. [Application, p37 & Exhibit 17 & 20]

Based on the review of the draft Patient Consent Form, the department concludes the draft form satisfies the cited standards and requirements. To ensure this form would continue to meet the standards and requirement as identified, the applicant must agree to provide a copy of the final Patient Consent Form to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be 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.

In response to this sub-criterion, the applicant provided two separate documents. Section 1 of the executed copy of a Partner Agreement with Swedish Health Services outlines the responsibilities of Stevens, acting as the transferring hospital, and ensures communication of medical and clinical data between the physician performing the elective PCI and the cardiac surgeon.

In conjunction with meeting these obligations, Stevens indicates that it will implement the Performance Improvement Plan that has been drafted and included with the application. The plan identifies a PCI Performance Improvement Committee. The committee is expected to meet quarterly and shall include particular representatives from the both Stevens and Swedish hospitals. Those identified include the Medical Director of the Catheterization lab at Stevens and at least one member if the Swedish Heart institute. [Application, p36-38, Exhibit 17 & 21]

Based on the review of the draft Performance Improvement Plan, the department concludes the draft plan satisfies the cited standards and requirements. To ensure this plan would continue to meet the standards and requirement as identified, the applicant must agree to provide a copy of the final Performance Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be met.

WAC 246-310-735(13). Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).

In response to this sub-criterion, the applicant provided a copy of a executed Partner Agreement with Swedish Health Services. Section 2 of the agreement includes a recital which allows for the potential of the receiving hospital to need to transfer or divert patients to another hospital with on-site open heart surgical services. All other components regarding safety, qualified staff, and travel times remain in effect. [Application, p38, Exhibit 17]

Based on the review of the Patient Transfer Agreement with Swedish Health Services, the department concludes that 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
Stevens will continue to provide Medicare and Medicaid services at the hospital to the residents of Snohomish County and the surrounding communities. The hospital contracts with the Joint Commission to survey and accredit the quality of service provided. The Joint Commission lists Stevens Hospital in full compliance with all applicable standards following the most recent on-site survey in July 2008.¹⁴ The Joint Commission also lists certification of the hospitals home care service.

Complementing reviews performed by the Joint Commission, are the surveys conducted by the Department's Investigation and Inspection's Office. Records indicate that the department has completed a compliance survey for Stevens Hospital in 2006. The survey revealed deficiencies which are typical for the size and type of facility and Stevens submitted a plan of corrections and implemented the required corrections. [Compliance survey data provided by Investigation and Inspection's Office]

Stevens currently credentials five physicians to provide emergent PCIs at the hospital. Each is employed as an interventional cardiologist with the Swedish Heart and Vascular Institute. Four of the physicians, identified above, are qualified to perform PCIs under the Department's standards and guidelines. Stevens provided letters from each of the qualified doctors expressing their commitment to continue providing PCI services at Stevens Hospital. [Application, Exhibit 8; April 29, 2009 Supplemental Information, p3]

Quality of care for Stevens' staff is verified through the Department of Health's Medical Quality Assurance Commission. The commission credentials medical staff in Washington State and is used to review the compliance history for all medical staff, including physicians, RNs, and licensed technicians. A compliance history review of the physicians associated

¹⁴ <http://www.qualitycheck.org>

with Stevens emergent PCI and proposed elective PCI program reveals no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

In addition to the general acute care sub-criterion above, WAC 246-310-740(1)-(4) identify specific quality assurance/quality improvements requirements.

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.*

The Applicant indicates that it will implement the drafted Performance Improvement Plan included with the application. The plan is designed to facilitate, “an ongoing, organization wide effort dedicated to patient safety, continuous improvement of patient outcomes, and of performance of services through appropriate, timely and effective care”. Of the sources used to evaluate the information collected, Stevens includes COAP data, American Heart Association guidelines and AMI Core Measures produced by the Joint Commission and CMS. [Application, p38, Exhibit 21]

Based on the review of the draft Performance Improvement Plan, the department concludes the draft plan satisfies the cited standards and requirements. To ensure this plan would continue to meet the standards and requirement as identified, the applicant must agree to provide a copy of the final Performance Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be 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*

Stevens provided an outline of the data elements for patient selection in the draft Performance Improvement Plan. This includes elements addressing elective PCI criteria and the appropriate informed consent on a quarterly basis. The elements intend to be based upon benchmarks and standards published in American College of Cardiology guidelines and Washington State rule.

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*

Stevens provided an outline of the data elements for case reviews in the draft Performance Improvement Plan. On a quarterly basis, Stevens intends to review procedures, processes and outcomes of the selected procedures. Indications are that they will be measured against other available case reviews and COAP standards. Supplementing the Performance Improvement Plan is the partnering agreement with Swedish Health Services. This agreement addresses the communication between physicians and the handling of confidential information that may be necessary to complete the case review. [Application, p38, Exhibit 17 & 19]

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.

The draft Performance Improvement Plan addresses this standard by identifying the entities that Stevens will report to ensure accountability. The plan identifies a PCI Performance Improvement Committee. The committee is expected to meet quarterly and shall include particular representatives from the both Stevens and Swedish hospitals. The necessary members are identified and include the Medical Director of the Catheterization lab at Stevens and at least one member if the Swedish Heart institute. [Application, p36-38, Exhibit 17 & 21]

Based on the review of the draft Performance Improvement Plan, the department concludes the draft plan satisfies the cited standards and requirements. To ensure this plan would continue to meet the standards and requirement as identified, the applicant must agree to provide a copy of the final Performance Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be 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.

Stevens states that the additional service in the planning area will directly benefit the planning area residents. Identified rates of out-migration for cardiac services are identified by the Applicant as evidence that the existing provider is not able to account for the degree that services are used by the planning area residents. Stevens notes, "The proposed project will allow Snohomish County Planning Area residents a 2nd elective PCI provider, and will serve to increase access". In addition, "Providing elective PCI procedures is an important next step in Stevens' commitment to improving care for cardiac patients. Stevens has a proven track-record of providing cardiac care at a high standard through prevention and risk reduction programs, efforts recognized by the American Heart Association". [Application, p10 & 20]

Stevens' reasoning for adding elective PCI services at the hospital are reasonable. Stevens has been providing health care to the residents of Snohomish County and surrounding communities for many years and participates in relationships with community facilities to provide a variety of services. Approval of this project will not change the relationships in place with the existing health care providers in the service area.

The department concludes that there is reasonable assurance that approval of this project would allow residents to more readily receive the necessary care without leaving their planning area. Further, Stevens' relationships within the existing health care system would continue and is not likely to not result in an unwarranted fragmentation of services. This sub-criterion is met.

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

This sub-criterion is addressed in sub-section (3) above and is determined to be met.

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

Based on the source information reviewed, the department determines that the applicant has 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 thru 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, Stevens has met the review criteria under WAC 24-6310-210 through 230. Additionally, Stevens has met the services specific review criteria identified in WAC 246-310-715, 720, 725, 730, 735, and 740. Therefore, the department moves to step two as stated above.

Step Two

For this project, Stevens established a set of decision making criteria. The items considered included: [Application, p38]

- Maximizing quality of patient care with the improvement of local access to an elective procedure
- Providing a more fully integrated cardiac services program by including both elective and emergent PCI services
- Improving the catheterization lab operating efficiencies by increasing volumes

The options that the applicant weighed against these criteria include doing nothing or making the proposal outlined in this application. Stevens reported no obvious advantages to doing nothing. When the criteria outlined above are considered, the Applicant states, “Currently there is just a single provider for elective PCIs in the Snohomish County Planning Area, and [PEMC] is simply too far north for many Planning Area residents, as evidenced by the large out-migration to Seattle hospitals”. When combined with the minimal capital costs and staffing impact, Stevens believes that the proposed project provides many advantages and is a sensible approach. [Application, p39]

PCI is a tertiary service as defined in WAC 246-310-010, which states (*in summary*) that tertiary services mean a specialized service meeting complicated medical needs of people. Tertiary services require sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care. For these reasons, PCI is not, and should not be, offered in every hospital within the state. With a tertiary service, it is expected that a patient will be transported some distance to receive quality care from a quality provider.

The numeric need portion of this evaluation resulted in need for a PCI provider in Planning Area #11. Even though Providence Regional Medical Center-Everett receives the majority of Snohomish County’s elective PCIs and may lose PCI volumes if this project is approved.

Given the only other option to this project is do nothing, taking into account the planning area’s out-migration, and the results of the numeric need methodology, the department concludes that the project described is the best available alternative for the community. This sub-criterion is met.

Step Three

This step is used to determine between two or more approvable projects which is the best alternative. There was no other project submitted under the year 2009 Adult Elective PCI Concurrent Review timeline. As a result, this step is not applicable to this project.

After reviewing the process undertaken by Stevens to review the cost, efficiency, and effectiveness of the proposed project, the department concludes that the project described is the best available alternative for the community. This sub-criterion is met.

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

This project has the potential to improve delivery of PCI services to the residents within the Snohomish County planning area that, according to the need methodology, has unmet need. The department is satisfied the project is appropriate and needed. This sub-criterion is met. [HPDS analysis, p3]

Appendix A