



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH

October 23, 2009

CERTIFIED MAIL # 7007 3020 0000 3056 2698

Josiah "Sy" Johnson, CEO  
St. John Medical Center, PeaceHealth  
1615 Delaware Street / PO Box 3002  
Longview, Washington 98632-0302

Dear Mr. Johnson:

We have completed review of the Certificate of Need application submitted on behalf of PeaceHealth dba St. John Medical Center 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 SJMC agrees to the following term and conditions.

**Terms**

1. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a revised Admission Policy. The final Policy will be consistent with the draft plan provided in Exhibit 7 of the application and specifically address access to services for low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly .
2. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a final Quality Assurance Plan. The final Plan will be consistent with the draft plan provided in Exhibit 17 of the application.
3. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a final PCI Consent form. The final policy will be consistent with the draft form provided in Exhibit 18 of the application.
4. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a final Catheterization Conference program description. The final program will detail who will be included on the conferences and the projected meeting schedule.



## **Conditions**

1. Upon selection of additional cardiologists, SJMC must provide the physician name, credential information, and verifiable three year tally of PCI procedures to the Certificate of Need Program for review and approval prior to the physician performing any PCI services within the hospital.
2. PeaceHealth/SJMC 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 PeaceHealth/SJMC in any one calendar year is three (3).
  3. The University of Washington Medical Center makes a written request to PeaceHealth/SJMC for patient referrals. The request must:
    - include the number of patients residing in PeaceHealth/SJMC'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 three (3) 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 SJMC.

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.

Josiah "Sy" Johnson, CEO  
St. John Medical Center  
Certificate of Need App #09-19  
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 PEACEHEALTH dba ST. JOHN MEDICAL CENTER PROPOSING TO  
ESTABLISH AN ADULT ELECTIVE PERCUTANEOUS CORONARY  
INTERVENTION PROGRAM AT THE HOSPITAL**

**PROJECT DESCRIPTION**

PeaceHealth operates a hospital under the name of St. John Medical Center (SJMC) and is located at 1615 Delaware Street in Longview, Washington within Cowlitz County. SJMC is currently a provider of Medicare and Medicaid acute care services to the residents of Cowlitz County and surrounding areas. SJMC is currently licensed for 253 acute care beds. The hospital is currently a provider of Medicare and Medicaid acute care services primarily to the residents of Cowlitz and Wahkiakum counties and recently held a three-year accreditation from the Joint Commission. [Application, p6; CN historical files; and DOH Investigations and Inspections Office]

PeaceHealth owns and operates a variety of health care facilities in Alaska, Oregon, and Washington. The health care facilities are listed below.

**Alaska Hospitals**

Ketchikan General Hospital

**Washington Hospitals**

St. Joseph Hospital - Bellingham

**Oregon Medical Centers**

Sacred Heart Medical Center - Riverbend

Sacred Heart Medical Center - Eugene

**Oregon Hospitals**

Cottage Grove Community Hospital

Peace Harbor Hospital - Florence

SJMC currently provides diagnostic cardiology procedures and other cardiac procedures, but does not perform either emergency (emergent) or elective PCI procedures at the hospital.<sup>1</sup> 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: [St. John Medical Center facility file; Application, p8]

- (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.<sup>2</sup> [Application, p8]

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<sup>1</sup> 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)]

<sup>2</sup> For PCI a program, '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)]

SJMC anticipates the elective PCI services would be available upon Certificate of Need approval. No additional construction or new equipment is required for this project. As a result, no capital expenditure is associated with this project. [Application, p10 & 11]

### **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).<sup>3</sup> Additionally, the applicant must demonstrate compliance with applicable 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 26, 2009	Letter of Intent Submitted
February 27, 2009	Application Submitted
February 28, 2009 through May 17, 2009	Department's Pre-Review Activities • 1 <sup>st</sup> screening activities and responses
May 18, 2009	Department Begins Review
July 24, 2009	Public Hearing Conducted/End of Public Comment
August 18, 2009	Rebuttal Documents Received
October 8, 2009	Department's Anticipated 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. SJMC is located in planning area #5 as defined in WAC 246-310-705(5), which includes Clark, Cowlitz, Skamania, Wahkiakum, and west Klickitat counties. No other application was submitted proposing to serve this planning area.

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.

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<sup>3</sup> 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) and (3).

## **SOURCE INFORMATION REVIEWED**

- St. John Medical Center Certificate of Need Application submitted February 27, 2009
- St. John Medical Center supplemental information dated April 28, 2009
- Public comments submitted by community members and healthcare providers
- Rebuttal comments provided by St. John Medical Center received August 18, 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 17, 2009
- Department of Health's Investigation and Inspection's Office (IIO) files

## **CONCLUSION**

For the reasons stated in this evaluation, the application submitted by PeaceHealth/SJMC 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 four terms and two conditions stated below.

There are no capital expenditures identified for this project.

## **Terms**

1. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a revised Admission Policy. The final Policy will be consistent with the draft plan provided in Exhibit 7 of the application and specifically address access to services for low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly .
2. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a final QA Plan. The final Plan will be consistent with the draft plan provided in Exhibit 17 of the application.
3. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a final PCI Consent form. The final policy will be consistent with the draft form provided in Exhibit 18 of the application.
4. Prior to commencement of the project, SJMC must provide to the Certificate of Need Program for review and approval a final Catheterization Conference program description. The final program will detail who will be included on the conferences and the projected meeting schedule.

## **Conditions**

1. Upon selection of additional cardiologists, SJMC must provide the physician name, credential information, and verifiable three year tally of PCI procedures to the Certificate of Need Program for review and approval prior to the physician performing any PCI services within the hospital.

2. PeaceHealth/SJMC 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 PeaceHealth/SJMC in any one calendar year is 3.
  3. The University of Washington Medical Center makes a written request to PeaceHealth/SJMC for patient referrals. The request must:
    - include the number of patients residing in PeaceHealth/SJMC'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 (3) 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 SJMC 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 areas<sup>4</sup>. SJMC is located in Cowlitz County. Cowlitz County is included in Planning Area #5, which also includes Clark, Skamania, Wahkiakum and west Klickitat counties. The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation will be limited to Planning Area #5.

SJMC is one of three hospitals operating in PCI Planning Area #5. Southwest Washington Medical Center (SWMC) is located in Vancouver and is the only location which currently maintains an open-heart surgery program allowing elective PCI's to be scheduled. Each hospital is identified in Table 1 on the following page. [Application, p7]

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<sup>4</sup> WAC 246-310-705

**Table 1  
PCI Planning Area #5 Hospitals**

<b>Hospital</b>	<b>Elective PCI's provided</b>	<b># Elective PCI's performed<sup>5</sup></b>
Legacy Salmon Creek	No	-
Southwest Washington Medical Center	Yes	656
St. John Medical Center	No	-

**St. John Medical Center**

SJMC followed the methodology as prescribed while relying upon use rates and population values calculated independent from the department's methodology. The results are detailed below.

To establish the planning area use rate, SJMC tallied the PCI cases for the residents of Cowlitz County in 2007, including resident cases reported as receiving care in Oregon. Of the 954 PCI cases the applicant identified for Cowlitz residents, 314 procedures were performed out-of-state. This equates to approximately 33% of the residents receiving PCI procedures outside of the planning area. [Application, p1]

SJMC estimated a population total for the planning area based upon county-wide OFM reports and Claritas<sup>6</sup> data for the sub-county area totals. After combining the applicable population totals for the planning area, the final 15 and over population for 2007 was projected to be 424,275. The use rate derived by the applicant from these values was 2.25. [Application, p11-13]

When SJMC applied this use rate to the projected population for 2012, it produced a projected demand of 396 additional PCI procedures for Planning Area #5. When divided by 300, the Applicant's results show a need of 1.32, or up to one additional elective PCI program is projected.

**Department 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.*

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<sup>5</sup> As reported on the Department of Health 2007 PCI Utilization Survey conducted in 2008

<sup>6</sup> Claritas, Inc. is a recognized source of demographic information and is used for sub-county population totals

- (b) *Divide the total number of PCIs performed on the planning area residents over fifteen years of age<sup>7</sup> 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.<sup>8</sup>

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 2007<sup>9</sup>. The results produced a Planning Area #5 PCI use rate of 2.38 per 1,000 residents; slightly higher than the Applicant's use rate of 2.25

*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.<sup>10</sup>*

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 2.38 calculated in Step 1 with the OFM projected planning area population of 465,174. The results are 1,107,114. This number is then divided by 1,000, which produced a need for 1,107 procedures for Cowlitz County 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.*

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<sup>7</sup> Residents 15 years of age and older.

<sup>8</sup> 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.

<sup>9</sup> County & Age Pop. Projections OFM Sept 2007 update, Released Nov. 2007

<sup>10</sup> Residents 15 years of age and older.

This step requires computation of the planning area's available capacity. SWMC, located in Vancouver, is the only provider of elective PCI services in the planning area. According to 2007 PCI survey data, SWMC performed 656 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 656 (current capacity from step 3) from 1,107 (projected need from step 2), results in a net need of 451 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 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 #5, this calculation is  $451 / 300$  resulting in a value of 1.50. This number is rounded down as directed in WAC 246-310-745(2) to one. Up to one additional program 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 SWMC 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 SJMC, and supported by CHARS reporting, identified a total of three (3) Cowlitz County residents receiving PCI care from the UWMC program. The low number would confirm the Applicant's assumption that the trend is for Planning Area #5 residents is to travel south to Oregon rather than north to Seattle for PCI services. SJMC

concluded that it is unlikely that the proposed program would have an adverse affect on UWMC. [Application, p11 & 22]

The application also supplied details of a conversation between SJMC and UWMC representatives. The Applicant reported that the discussion addressed a collaborative relationship with the UWMC program and concluded, “At the end of this call, both parties agreed to continued dialogue in the future”. Similar discussions are reported to have taken place between the UWMC administrators and the director of the catheterization labs from the Oregon Health & Science University (OHSU); SJMC’s partnering hospital in this application. [August 20 Rebuttal Comments, p2]

#### Department’s Evaluation

Documentation of PCIs performed confirms that UWMC performed a total of 3 PCI’s on patients from Planning Area #5 zip codes. This amount equals a 0.01% portion of the total of 402 PCIs performed at UWMC. In its public comment, UWMC voiced concerns related to the collective applicants<sup>11</sup>, including SJMC, 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.<sup>12</sup> To ensure any new PCI programs, including SJMC, 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.

PeaceHealth/SJMC 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 PeaceHealth/SJMC in any one calendar year is 3.
3. The University of Washington Medical Center makes a written request to PeaceHealth/SJMC for patient referrals. The request must:

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

<sup>12</sup> WWAMI region includes the states of Washington, Wyoming, Alaska, Montana, and Idaho.

- include the number of patients residing in PeaceHealth/SJMC’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 (3) and the number of patients from the planning area that has already received a PCI procedure at the University of Washington.

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.

SJMC provided a projection of the number of PCI they expect to perform through the first three years of the proposed program. The Applicant provided a detailed description of the breakout for the projected procedures. Table 2 below summarizes the type of procedures and the corresponding yearly totals submitted by the Applicant. [Application, p9 & 21]

**Table 2**  
**Projected PCI Procedures for SJMC by Year**

<b>Type of PCI</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Emergent	18	36	100
Elective/Scheduled	55	191	229
<b>Total</b>	<b>73</b>	<b>227</b>	<b>329</b>

The forecasts show a minimum number of procedures in 2010, expanding to meet the hospitals necessary volumes as additional cardiologists are hired in the subsequent years. SJMC established the projections based upon market share data within specific zip codes.

The assumptions used to forecast the number of procedures is based upon a review of the service area. SJMC concluded that forecasts should be based upon capture rates from defined areas. Looking at specific zip codes, SJMC assumed an 80% rate from their primary service area, 30% of the residents in hospital’s secondary market, and 15% from the tertiary market on the outside of the planning area. SJMC also reduced their total projections by 20% to account for Kaiser Permanente patients who regularly migrate to Kaiser Facilities. [Application, p20, Exhibit 5]

Department’s Evaluation

The projections in Table 2 show the number of emergent and elective/scheduled cases experiencing substantial annual growth. The projections are proportional to the planned addition of new cardiac services and the population’s projected need. If SJMC were approved to provide elective PCI services, the potential for local residents to begin receiving both elective and emergent care within the planning area appear reasonable. Further, because SJMC used the department’s numeric methodology as a baseline for projecting PCIs and then

considered current out-of-state migration totals and market share, the projections may be achievable. .

Based on the projections provided and the underlying assumptions used by SJMC to project PCI volumes, the department concludes that both emergent and elective/scheduled PCI projections are reasonable and SJMC 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.

SJMC 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, SJMC 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, SJMC provided a copy of the Admission Policy that would be used upon approval of the project. The policy outlines the process/criteria that SJMC uses to admit patients for treatment or care at the hospital. However, though stated in the application, the policy does not contain any non-discrimination language that would assure that any patient requiring care is accepted for treatment at SJMC without regard to items such as low-income persons, racial and ethnic minorities, women, handicapped persons, other underserved groups, and the elderly. [Application, p23 & Exhibit 7]

Based on the review of the attached Admission policy, the department concludes the policy does not completely satisfy the necessary standards and requirements. To ensure that the policy enacted would meet the standards and requirement stated under this sub-criterion, the Applicant must accept a term to provide a copy of a revised Admission policy to the department for review and approval. If the applicant agrees to this term, this sub-criterion would then 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.

SJMC 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 SJMC identifies the facility's financial resources as including both Medicare and Medicaid revenues. [Application, p5 & 24; Exhibit 9]

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

SJMC's current charity care policy outlines the process a patient would use to access this service and the eligibility requirements. Further, the applicants included a 'charity care' line item as a deduction from revenue within the pro forma financial documents for the hospital. [Application, p23 & Exhibit 8]

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 Cowlitz County, SJMC is one of 13 hospitals in the Southwest Sound Region. According to 2005-2007 charity care data obtained from HPDS, SJMC has historically provided charity care above the average charity care provided in the region. SJMC's most recent three years (2005-2007) of charity care for gross and adjusted revenues are 3.00% and 7.87%, respectively. The 2005-2007 average for the Southwest Region is 2.74% for gross revenue and 6.16% for adjusted revenue.

SJMC pro forma revenue and expense statements through 2012 indicate that the hospital will provide charity care at approximately 3.90% of gross revenue and 10.55% of adjusted revenue. [HPDS 2005-2007 charity care summaries; Application, p24 & Exhibit 9]

With agreement to the term regarding the hospital's Admission policy, 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, SJMC provided its Statement of Operations for the incremental PCI revenue and expenses projected in years 2010 through

2012. A summary of the Statement of Operations for the PCI cost center only is shown in Table 3 below. [Application, Exhibit 9]

**Table 3**  
**Incremental PCI Projected Statement of Operations Summary**

	<b>Projected Year 1 (2010)</b>	<b>Projected Year 2 (2011)</b>	<b>Projected Year 3 (2012)</b>
Total Operating Revenue	\$ 1,514,788	\$ 4,738,623	\$ 6,825,888
Total Operating Expense	\$ 974,748	\$ 3,318,422	\$ 4,784,769
<b>Net Profit or (Loss)</b>	<b>\$ 540,040</b>	<b>\$ 1,420,201</b>	<b>\$ 2,041,119</b>

Projections for years 2010 through 2012 include emergent and elective PCI services. The ‘Total Operating Revenue’ line item in Table 3 is the result of gross revenue minus any deductions for contractual allowances, bad debt, and charity care directly related to the PCI program. The ‘Total Operating Expense’ line item includes staff salaries/wages and all hospital cost allocations related to the PCI services. Table 3 reflects the steady increase in PCIs projected by SJMC and summarized in Table 2 of this evaluation. As shown, the PCI cost center is projected to be profitable in years 2010 through 2012.

SJMC 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 4 below. [Application, Exhibit 9]

**Table 4**  
**SJMC Hospital Projected Statement of Operations Summary**

	<b>Projected Year 1 (2010)</b>	<b>Projected Year 2 (2011)</b>	<b>Projected Year 3 (2012)</b>
Total Operating Revenue	\$ 218,518,000	\$ 223,882,000	\$ 229,216,000
Total Operating Expense	\$ 208,250,000	\$ 211,408,000	\$ 215,344,000
<b>Net Profit or (Loss)</b>	<b>\$ 10,268,000</b>	<b>\$ 12,474,000</b>	<b>\$ 13,872,000</b>

The ‘Total Operating Revenue’ line item in Table 4 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 4, the hospital as a whole is projected to be profitable in years 2010 through 2012 with the elective PCI program implemented.

To determine whether SJMC 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 5A and 5B on the following page. [HPDS analysis, p2; Application, Exhibit 9]

**Table 5A**  
**SJMC Balance Sheet for Year 2008**

<b>Assets</b>		<b>Liabilities</b>	
Current	\$ 41,148,767	Current	\$ 24,956,441
Board Designated	\$ 72,770,476	Long Term Debt	\$ 58,293,478
Property/Plant/Equipment	\$ 115,506,910	Other	-
Other	\$ 10,001,778	Equity	\$ 156,178,012
<b>Total</b>	<b>\$ 239,427,931</b>	<b>Total</b>	<b>\$ 239,427,931</b>

**Table 5B**  
**SJMC Balance Sheet for Year 2012**

<b>Assets</b>		<b>Liabilities</b>	
Current	\$ 47,920,000	Current	\$ 29,169,000
Board Designated	\$ 21,720,000	Long Term Debt	\$ 69,351,000
Property/Plant/Equipment	\$ 215,454,000	Other	\$ 196,575,000
Other	\$ 10,001,000	Equity	-
<b>Total</b>	<b>\$ 295,095,000</b>	<b>Total</b>	<b>\$ 295,095,000</b>

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 provide 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 6 on the following page. [HPDS analysis, p2]

**Table 6  
Current and Projected HPDS Debt Ratios for SJMC PCI Program**

Category	Trend <sup>13</sup>	State 2007	Current 2008	Projected 2010	Projected 2011	Projected 2012
Long Term Debt to Equity	B	0.523	0.373	0.295	0.312	0.315
Current Assets/Current Liabilities	A	2.135	1.649	1.422	1.359	1.309
Assets Funded by Liabilities	B	0.419	0.348	0.330	0.335	0.334
Debt Service Coverage	A	6.041	4.615	-	-	-
<b>Definitions:</b>	<b>Formula</b>					
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 SJMC most current (2008) ratios with the statewide ratios (2007) revealed that SJMC is outside the normal range in two of the four categories. The ratios outside the normal range reflect any construction, remodel, or upgrade projects that have occurred at the hospital. SJMC has engaged in a variety of these types of projects in the most recent years, which is demonstrated in its current ratios.

After evaluating the hospital’s projected ratios and statement of operations for years 2010-2012, HPDS states, “[SJMC] 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 [SJMC]”. [HPDS analysis, p2]

HPDS also compared SJMC’s operating expense to operating revenue ratio for the PCI project only. SJMC projects its operating revenues to exceed its operating expenses for its PCI project. This is demonstrated by the revenue to expense ratios of 0.643, 0.700, and 0.701 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.

SJMC identified a capital expenditure for this project of zero, as a result there are no construction costs for this project. This sub-criterion also requires the department to consider

<sup>13</sup> A is better if above the ratio, and B is better if below the ratio.

the operational costs of the project and the impact of those costs on the costs and charges for health services. SJMC did not provide any additional documentation or discussion to demonstrate compliance with this sub-criterion.

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

(3) *The project can be appropriately financed.*

SJMC identifies a capital expenditure for this project to be zero. While SJMC acknowledges a recent expansion and renovation of its current catheterization laboratories, including purchase of upgraded equipment, They assert that the expansion of the cardiology and radiology facilities has been taking place over the past few years independent of this application. The department notes that SJMC’s initial renovation of the catheterization lab was completed in May 2009 and the subsequent remodel of the existing lab is expected to be completed and returned to service in October 2009. [Application, p9; April 29, 2009 Supplemental Information, p3]

The department acknowledges that the dollars already spent for the renovation and equipment project are reflected in SJMC’s historical and financial health and were included in the review of the previous sub-criterion. The department will not review any capital expenditure directly related to this project.

**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, SJMC states, “Currently, the nursing component of the catheterization lab has been established with fully trained RNs from the Ambulatory Care Surgical Unit. This has provided the depth and breadth of access to a number of nurses with Advanced Cardiac Life Support [ACLS] services and catheterization lab experience”. Table 7 shows the breakdown of SJMC’s expected incremental increases for the three years following implementation of the program. [Application, p31]

**Table 7**  
**Projected Incremental Increases in FTE Totals**

<b>FTEs</b>	<b>Current</b>	<b>Partial Year</b>	<b>Year 1 Increase</b>	<b>Year 2 Increase</b>	<b>Year 3 Increase</b>	<b>Total in 2012</b>
Nursing (RN)	1.40	2.00	0.00	0.50	0.50	4.40
Technicians	3.00	1.00	0.00	0.50	0.50	5.00
<b>FTE Total</b>	<b>4.40</b>	<b>3.00</b>	<b>0.00</b>	<b>1.00</b>	<b>1.00</b>	<b>9.40</b>

As shown, SJMC anticipates adding three FTE’s upon CN approval. With assistance from a joint education exchange with OHSU, SJMC expects to begin educating existing staff on procedural responsibilities required with the addition of the PCI program. The remaining support will be added in the second and third year of operation as the program reaches its projected volumes. Regarding the eventual need to hire additional support, SJMC expects to be successful in the traditional recruiting methods for notifying and attracting health care workers. The applicant does not anticipate this staffing increase to affect the program currently at SWMC and states “active recruitment from this existing program will not be a focus, or intent, for program initiation”. [Application, p32; April 29, 2009 Supplemental Information, p4]

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, SJMC provided a description of the primary equipment utilized in their cardiac catheterization labs. SJMC states, “Both the catheterization labs are equipped

with optimum digital cardiac imaging capabilities/systems”. Specifically, “SJMC has purchased a GE 3100 unit fully equipped to perform cardiac procedures including PCI”. This cited equipment also includes intra-aortic balloon pumps, fully stocked crash carts for emergency care, intubation equipment, and defibrillators. [Application, p40; April 29, 2009 Supplemental Information, p4]

Documentation provided demonstrates that the catheterization laboratory 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.*

SJMC does not currently perform emergent or elective PCI procedures at the hospital. Upon approval, the hospital intends to utilize Joaquin Cigarroa, MD for coverage as the program begins and grows. As the Applicant describes the plan cover emergent cases, “In year one of our program start-up, coverage will be delivered at 33% for emergent (primary) PCI. By year two, a second evasive cardiologist will allow expansion of coverage to 66%. By the end of year three (3), it is the intent of SJMC to have 100% coverage 24/7 for emergent PCI”. Further, SJMC states, “This ramp-up will be accelerated based on successful recruitment of a second interventional cardiologist”. [Application, p32; April 29, 2009 Supplemental Information, p5 & 11]

The description of 24/7 coverage required under this sub-criterion is not explicit regarding when a hospital is required to be able to support 24/7 emergent care. SJMC is unique in that it has not previously offered the emergent PCI treatments that other comparable facilities perform. Rather, past practice at SJMC has been to rely upon a strong working relationship and transfer protocol with OHSU to address patients requiring emergent PCI care. The department considered these factors, the staffing model presented, and the 3-year implementation schedule outlined above, and has determined that combining the newly available on-site coverage with the traditional OHSU back-up would be sufficient to satisfy the requirements.

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 Dr. Cigarroa as the physician who will be performing PCI procedures within SJMC at the start of the program. Dr. Cigarroa currently performs elective and emergent PCI procedures at OHSU and is available to SJMC through a long-standing relationship between the two hospitals. Joint recruitment efforts between the hospitals are currently directed towards placing two additional cardiologists to be based out of SJMC. The new physicians will have medical staff relationships with both hospitals and each will be assigned a separate cardiac call team for coverage of SJMC’s emergent cases. Volume statistics for Dr. Cigarroa are reported through data available from OHSU. These records

indicate that Dr. Cigarroa has met the volume standards prescribed. [Application, p32 & 35; April 29, 2009 Supplemental Information, p4 & 11]

Due to the need to place two additional cardiologists to support the proposed program, as a condition, SJMC must provide the new physician's name, credential information, and verifiable three year tally of PCI procedures to the Certificate of Need Program for review and approval. This must occur prior to the physician performing any elective PCI services within the hospital.

Based on the information above, and the acceptance of the stated condition, 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.

SJMC does not currently employ any cardiologists. Upon approval, the hospital intends to utilize Dr. Cigarroa for coverage as the program begins and grows. The applicant plans to maintain the relationship with OHSU for physician recruitment and cross-training purposes. [Application, p32; April 29, 2009 Supplemental Information, p5 & 11]

As stated above, due to the need to place two additional cardiologists to support the proposed program, SJMC must provide the new physician's qualifying details to the Certificate of Need Program for review and approval.

Based on the information above, and the acceptance of the stated condition, 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 current staff is ACLS trained and certified as a condition of employment. Additional training in relevant procedures is prescribed and defined competency testing is updated annually for each member of the nursing staff. The need for intubation or ventilator procedures while within the hospital will be performed by physicians available 24/7 in the adjacent emergency department with additional support from a nurse anesthetist, anesthesiologist, or a respiratory therapist as needs require. For instances requiring transport, the Applicant states, "Support of endotracheal intubation and ventilator management during ground or air ambulance transport is maintained by the ambulance companies that support the medical center". Based on the information provided, the department concludes that this sub-criterion is met. [Application, p34, Exhibit 11 & 15]

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, SJMC 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 OHSU. The agreement identifies OHSU as the primary hospital for PCI patients requiring a transfer from SJMC. The agreement outlines the responsibilities of SJMC when acting as the transferring Hospital and the expectations of OHSU acting as the receiving hospital. SJMC also supplied a copy of a physician ordered 'ST Elevation Myocardial Infarction Transfers for Angioplasty' [STEMI] flow chart utilized in the instance where emergency surgical intervention and transfer is required. This outlines, by time interval, the information necessary to facilitate a safe transport. [Application, p36 & Exhibit 13 & 14]

Based on the review of the "patient transfer" agreement with OHSU, 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 Patient Transfer Agreement with OHSU. Section 1 of the agreement outlines the responsibilities of SJMC when acting as the transferring hospital and the expectations of OHSU acting as the receiving hospital, and ensures access to cardiac surgery services for elective PCI patients transferred from SJMC Hospital. [Application, p36 & Exhibit 13]

Based on the review of the "patient transfer" agreement with OHSU, 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 Patient Transfer Agreement with OHSU. Section 2 of the agreement outlines the responsibilities of SJMC when 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. The system outlined relies upon a virtual private network (VPN) to facilitate access to all necessary medical information. [Application, p36 & Exhibit 13]

Based on the review of the "patient transfer" agreement with OHSU, 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 Patient Transfer Agreement with OHSU. Section 2 of the agreement outlines the responsibilities of SJMC when acting as the transferring hospital, and ensures communication of medical and clinical data between the physician performing the elective PCI and the cardiac surgeon via the VPN web-based communication links between physicians. [Application, p37 & Exhibit 13]

Based on the review of the “patient transfer” agreement with OHSU, 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 Patient Transfer Agreement with OHSU. Section 1 of the agreement outlines the responsibilities of OHSU, acting as the receiving hospital, and ensures acceptance of all transfers under the agreement. [Application, p37 & Exhibit 13]

Based on the review of the “patient transfer” agreement with OHSU, 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 Agreements with Life Flight Network, LLC (Life Flight) and American Medical Response (AMR). Schedule A of the agreement outline the responsibilities of SJMC and of each transport service to maintain qualified staff to conduct the safe and effective transport of patients from the hospital. [Application, p38 & Exhibits 15 & 16]

Based on the review of the responsibilities outlined in the transfer agreements, 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 OHSU and the STEMI transfer protocols. Together, they outline the responsibilities of SJMC, acting as the transferring hospital, and ensure 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 also provided a copy of executed Transfer Agreement with Life Flight and AMR. The agreement outlines the

obligation for full air or ground ambulance transport service. [Application, p38 & Exhibits 13, 14, 15, & 16]

Based on the review of these provisions with OHSU, 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 OHSU, the Transfer Agreements with Life Flight an AMR, address the use of qualified staff to be available as the situation requires. Schedule A of the agreement assure that all parties involved with the transfer of PCI patients will have their relevant certifications and professional skills to address potential life support or equipment operation. [Application, p38 & Exhibits 13, 15, & 16]

Based on the review of the transfer agreements, 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 draft of the Quality Assurance (QA) plan. The plan presents the responsibilities of SJMC and outlines the hospital's expectation to track and record the STEMI transfers from the time a decision is made to transfer a patient to their arrival to the operating room of the receiving hospital. [Application, 38 & Exhibit 17]

Prior to commencement of the project, SJMC must agree to provide to the Certificate of Need Program for review and approval a final QA Plan. The final Plan will be consistent with the draft plan provided in Exhibit 17 of the application and specifically address the timelines required under this sub-criterion.

Based on the process described above, and the acceptance of the stated term, 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 draft of the Quality Assurance (QA) plan. The plan presents the responsibilities of SJMC and outlines the hospital's expectation to conduct periodic assessments regarding PCI transfers and the process to evaluate patient transportation time. [Application, 38 & Exhibit 17]

Supporting the efforts to adhere to this standard, the applicant provided a copy of executed transfer agreements with Life Flight and AMR. Section 9 outlines the obligation for the

transport service to document and provide reporting of departure, arrival, and door to balloon times. [Application, 39 & Exhibit 15 & 16]

Prior to commencement of the project, SJMC must agree to provide to the Certificate of Need Program for review and approval a final QA Plan. The final Plan will be consistent with the draft plan provided in Exhibit 17 of the application and specifically address the requirement to conduct timed transportation drills.

Based on the information above, and the acceptance of the stated term, 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. The executed copy of a Partner Agreement with OHSU outlines the responsibilities of SJMC, acting as the transferring hospital, and Section 2 of the agreement obligates the hospital secure the patient's signed informed consent.

To demonstrate the efforts to adhere to this standard, the applicant provided a draft PCI 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, p39 & Exhibit 18]

Based on the review of the transfer policy and 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 PCI 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 reported that a Catheterization Conference program is being developed. According to SJMC, the program will focus upon, "surgical outcome data related to SJMC patients". This data is expected to be presented at conferences between cardiologists representing SJMC and OHSU. [Application, 39]

Prior to commencement of the project, SJMC must agree to provide to the Certificate of Need Program for review and approval a final Catheterization Conference program description. The final program will detail who will be represented in on the conferences and the projected meeting schedule.

Based on the information above, and the acceptance of the stated term, the department concludes that 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.).

In response to this sub-criterion, the applicant provided a copy of an executed Partner Agreement with OHSU. Section 1 of the agreement includes the details regarding patient selection and the relative availability of necessary space or services available at SJMC. It also outlines the obligations of OHSU to accept the transfers and the procedures surrounding the use of existing capacity and additional staff. [Application, p40, Exhibit 13]

Based on the review of the “patient transfer” agreement with OHSU, 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 SJMC will continue to provide Medicare and Medicaid services at the hospital to the residents of Cowlitz 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 SJMC Hospital in full compliance with all applicable standards following the most recent on-site survey in August 2006.<sup>14</sup>

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 SJMC in December 2006. The survey revealed deficiencies which are typical for the size and type of facility and SJMC submitted a plan of corrections and implemented the required actions. [Compliance survey data provided by Investigation and Inspection’s Office]

SJMC identifies one physician to initially provide emergent and elective PCIs at the hospital. Dr. Cigarroa is employed as an interventional cardiologist with OHSU and is qualified to perform PCIs under the department’s standards and guidelines. Quality of care for SJMC’s 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 Dr. Cigarroa reveals no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

Based on the information above, and the acceptance of the previously stated condition regarding the placement of additional cardiologists, the department concludes that this sub-criterion is met.

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<sup>14</sup> <http://www.qualitycheck.org> – The site does not contain any updated information regarding the recent passing of the three-year period since the last on-site survey at the time of this evaluation.

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 a QA plan that is designed to facilitate, “a process for ongoing review of the outcomes of the adult elective PCI’s. Outcomes will be compared and benchmarked against state or national quality of care standards indicators for elective PCIs”. The sources listed by SJMC include Washington State COAP data, the American College of Cardiology (ACC) guidelines and AMI Core Measures produced by the Joint Commission and CMS. [Application, p40, Exhibit 17]

Based on the review of the draft QA 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 QA 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

SJMC provided an outline of the data elements for patient selection in the draft QA Plan. This includes elements addressing elective PCI criteria and the appropriate informed consent. The elements intend to be based upon benchmarks and standards published in ACC guidelines and Washington State rule.

Based on the review of the draft QA Plan, the department concludes the draft plan satisfies the cited standards and requirements. To ensure this plan would continue to meet the standards and requirements as identified, the applicant must agree to provide a copy of the final QA 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(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

SJMC provided an outline of the data elements for case reviews in the draft QA Plan. SJMC 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 QA Plan is the partnering agreement with OHSU. 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 13 & 17]

Based on the review of the draft QA Plan, the department concludes the draft plan satisfies the cited standards and requirements. To ensure this plan would continue to meet the standards and requirements as identified, the applicant must agree to provide a copy of the

final QA 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(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 QA Plan addresses this standard by identifying the data that SJMC will collect and report to ensure quality outcomes. The application identifies a Catheterization Conference program. The conference program is expected to meet regularly and identifies particular representatives from the both SJMC and OHSU. The necessary members are identified and currently include surgeons, interventional cardiologists, and invasive cardiologists from both SJMC and OHSU. [Application, p39, Exhibit 17]

Based on the review of the draft QA Plan and proposed committee, the department concludes the application satisfies the cited standards and requirements. To ensure that each would continue to meet the standards and requirements as identified, the applicant must agree to provide a copy of the final QA Plan and Catheterization Conference program 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.

SJMC states that the additional service in the planning area will directly benefit the planning area residents. Rates of out-of-state 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 being used by the planning area residents. SJMC notes, "patients in Longview currently must travel 44 miles, or 46 minutes, to reach the closest PCI provider in Vancouver". In addition, due to their rural location and potential delays in a patient's decision to seek medical assistance, "once we receive the heart attack victim at SJMC, even if that patient resides in Cowlitz County, we are often approaching the 90-minute window already". In addition to these issues, SJMC cites factors relating to area poverty rates and the degree to which the area residents exhibit high risk factors that contribute to heart disease. [Application, p16-18]

SJMC's reasoning for adding elective PCI services at the hospital are reasonable. SJMC has been providing health care to the residents of Cowlitz 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 and may work to improve the timeliness of an area resident's necessary care.

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, SJMC's 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, SJMC has met the review criteria under WAC 24-6310-210 through 230. Additionally, SJMC 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, SJMC considered the disadvantages of the current system in relation to the potential advantages of the proposed PCI program. As the applicant summarizes the current situation, “the options being exercised are the most expensive in terms of cost, lack of efficiency, and lack of effectiveness for both patients and staff”. Specifically for PCI patients, SJMC states, “Staff must identify and prepare the patient for transport which is an added cost to medical care and procedural inefficiency”. [Application, p42]

The advantages that SJMC cite in support of the proposed program include beneficial impacts in areas such as the hospitals operating costs, cost to the patient, quality of care received, and overall access. Specifically, SJMC claims the proposed program would provide the following to the residents of the planning area and the staff of the hospital: [Application, p43]

- Better access to emergent and elective PCI services;
- The ability to provide a more consistent and comprehensive cardiology program;
- An improved ability to recruit cardiologists at SJMC, and
- Improved conditions for staff retention

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 #5. Even though SWMC receives the majority of Cowlitz 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 SJMC 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.

(2) In the case of a project involving construction:

(a) The costs, scope, and methods of construction and energy conservation are reasonable; and

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

There is no construction directly related to the program proposed in this application. The costs associated with the hospital expansion are addressed in the financial feasibility criteria above and 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 Cowlitz 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