



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

December 16, 2011

CERTIFIED MAIL # 7009 2250 0001 8669 5999

Richard W. Linneweh, Jr., President & CEO
Yakima Valley Memorial Hospital
2811 Tieton Drive
Yakima, Washington 98902

RE: CN11-19

Dear Mr. Linneweh:

We have completed review of the Certificate of Need application submitted by Yakima Valley Memorial Hospital proposing to establish an adult elective percutaneous coronary intervention program within space at the hospital serving residents in PCI planning area #4-Kittitas, Yakima, and East Klickitat counties. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Need	WAC ¹ 246-310-210 WAC 246-310-745 WAC 246-310-720(1) and (2)
Cost Containment	WAC 246-310-240

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

Appeal Option 1:

You or any interested or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

¹ Washington Administrative Code



Richard Linneweh, President & CEO
Yakima Valley Memorial Hospital
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Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail
Department of Health
Certificate of Need Program
310 Israel Road SE
Tumwater, WA 98501

Appeal Option 2:

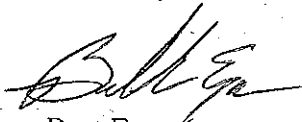
You or any affected person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610.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

Mailing Address:
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

Other Than By Mail
Adjudicative Clerk Office
310 Israel Road SE, Building 6
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,



Bart Eggen
Executive Director
Health Professions and Facilities

Enclosure

cc: Linda Foss, Department of Health, Investigations and Inspections Office
Karen Stricklett, Department of Health, Customer Service Office

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED
ON BEHALF OF YAKIMA VALLEY MEMORIAL HOSPITAL (MEMORIAL)
PROPOSING TO ESTABLISH AN ADULT ELECTIVE PERCUTANEOUS
CORONARY INTERVENTION PROGRAM IN THE
YAKIMA PCI PLANNING AREA #4**

APPLICANT DESCRIPTION

Yakima Valley Memorial Hospital (Memorial) is currently a provider of Medicare and Medicaid acute care services to the residents of Yakima County and surrounding areas. Memorial is a not-for-profit corporation and a 501(c)(3) exempt organization. Memorial owns and manages the facilities listed below:

Yakima Valley Memorial Hospital	2811 Tieton Drive, Yakima, WA 98902	Yakima County
Psychiatric Unit	2811 Tieton Drive, Yakima, WA 98902	Yakima County
Home Health	1019 S. 40 th Ave, Yakima. WA 98902	Yakima County
Hospice	1019 S. 40 th Ave, Yakima. WA 98902	Yakima County
Genetic Counseling	2811 Tieton Drive, Yakima, WA 98902	Yakima County
Children’s Village	3801 Kern Road, Yakima, WA 98902	Yakima County
Maternal Health Services	2903 W. Walnut, Yakima, WA 98902	Yakima County

[Source: Application, p8]

Memorial is currently licensed for 226 acute care beds.

PROJECT DESCRIPTION

Memorial is requesting approval to provide adult elective percutaneous coronary interventions (PCIs) without on site cardiac surgery at the existing hospital located in the city of Yakima.

Memorial has a partnering agreement with Kadlec Regional Medical Center to provide the back-up cardiac surgery capability required under WAC 246-31-735. The applicant provided information shown below regarding the 3 closest hospitals providing elective PCI and open heart surgery.

Name of Hospital	Distance from Memorial	Driving Distance (Time)
Yakima Regional Medical & Cardiac Center (Regional)	1.3 miles	1.4 miles (6 min.)
Central Washington Hospital	57.7 miles	110 miles (1 hr. 6 min.)
Kadlec Medical Center	64.3 miles	77.4 miles (1hr. 21 min.)

Memorial has a previous Cardiac surgery transfer agreement with Yakima Regional signed in 2005 and submitted with its application for level I cardiac center categorization submitted to DOH. Memorial and Yakima Region Medical Center have received their level I cardiac center categorization designations as part of the Washington State Emergency Cardiac and Stroke System.

Memorial has been providing emergent PCI services for over 10 years. PCI means invasive, but non-surgical, mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:

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

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

Memorial anticipates that the elective PCI services would be available as soon as the certificate of need is approved. No additional construction or new equipment is required for this project. As a result no capital expenditure is associated with this project. (Source: Application, p2-10

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).¹ Where applicable, the applicant must demonstrate compliance with the above criteria by meeting the Adult Elective Percutaneous Coronary Interventions (PCI) Without On-Site Cardiac Surgery Standards and Forecasting Method outlined in WAC 246-310-700 through 755.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-710 the department accepted this project under the year 2010 PCI Concurrent Review Cycle. Below is a chronologic summary of the project.

January 31, 2011	Letter of Intent Submitted
February 28, 2011	Application Submitted
February 28, 2011 through July 19, 2011	Department’s Pre-Review activities, including screening responses received from applicant
July 20, 2011	Department Begins Review; no Public Hearing Requested or Conducted
August 24, 2011	End of Public Comment
September 12, 2011	Rebuttal Documents Received
October 24, 2011	Department's Anticipated Decision Date Department's Anticipated Decision Date
November 23, 2011	(with 30 day Extension)
December 16, 2011	Department's Actual Decision Date

¹ 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).

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. Memorial is located in planning area #4 as defined in WAC 246-310-705(5), which includes Yakima, Kittitas and East Klickitat (zip codes 98620, 99356, and 99322). 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.

Yakima Regional Medical and Cardiac Center – located in Yakima and currently a provider of both PCI and heart surgery.

SOURCE INFORMATION REVIEWED

- Yakima Valley Memorial Hospital's Certificate of Need Application submitted February 28, 2011
- Yakima Valley Memorial Hospital's supplemental information dated May 12, 2011
- Yakima Valley Memorial Hospital's supplemental information dated July 12, 2011
- Public comments submitted by community members and healthcare providers
- Rebuttal comments provided by Yakima Regional Medical and Cardiac Center dated September 12, 2011
- Rebuttal comments provided by Yakima Valley Memorial Hospital dated September 8, 2011
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Hospital and Patient Data Systems
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2007, 2008, and 2009 summaries)
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems received October 11, 2011
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Department of Health 2009 PCI utilization survey data related to inpatient and outpatient PCIs obtained in year 2010

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Yakima Valley Memorial Hospital proposing to establish an adult elective percutaneous coronary intervention program is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

There is no capital expenditure associated with this project.

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, the department determines that Yakima Valley Memorial Hospital's project has not met the need criteria in WAC 246-310-210 and the PCI methodology and standards in WAC 246-310-715(1) and (2), WAC 246-310-720(2), and WAC 246-310-745.

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

WAC 246-310-700 requires the department to evaluate all adult elective PCI applications based on the populations 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) and WAC 246-310-720(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 Appendix A attached to this evaluation.

For PCI programs, Washington State is divided into 14 separate planning areas.² Memorial is located the PCI Planning Area #4, which includes all of Yakima and Kittitas counties and also East Klickitat county (zip codes 98620, 99356, and 99322).

The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation is limited to Planning Area #4. Memorial is one of six hospitals that are operating in Planning Area #4. The six hospitals including Memorial that are operating in PCI Planning Area #4 are identified in Table 1.

² WAC 246-310-705.

**Table 1
Planning Area 4 Hospitals**

Hospital	Elective PCI's provided	# of PCIs performed³
Kittitas Valley Community Hosp.	No	0
Klickitat Valley Hospital	No	0
Sunnyside Community Hosp.	No	0
Toppenish Community Hosp.	No	0
Yakima Regional	Yes	338
Yakima Valley Memorial Hosp.	No	175*

*Emergent PICs provided in 2009

Memorial

WAC 246-310-745 clearly defines the data that must be used by the department in calculating the need for PCI services in the defined PCI planning areas. The applicant has taken the position that the data set used by the department undercounts the number of PCIs performed in the State of Washington for the time period relevant to this application. The initial application contained a PCI need calculation for 2008; however in the screening process the department advised Memorial that since 2009 data was available it would be the base year for calculations. In response to the initial screening questions, Memorial provided their calculations for 2009 and also calculations for 2008.

In order to provide a numeric need methodology, data from existing Washington State hospitals must be obtained. Memorial relied on the department's utilization survey for outpatient PCIs and CHARS data for inpatient PCIs. In addition to this data, Memorial used PCI records from their hospital, CHARS observation database records, OAHHS Inpatient database records, and estimations from Thomas Reuters.

The following is the calculation of need for PCIs in the PCI Planning Area #4 as presented in the Response to Screening Questions submitted by Memorial.

The Step 1 calculation is as follows:

Step 1: Compute the planning area's PCI use rate for persons age 15+ including inpatient and outpatient PCI case counts.

- (a) Take the total planning area's base year population age 15+ and divide by 1,000.*
- (b) Divide the total number of PCIs performed on planning area residents age 15+ by the result of Step 1(a). This number represents the base year use rate.*

³ As reported on the Department of Health's 2009 PCI Utilization Survey conducted in 2010.

Table 2
Step 1: Planning Area PCI Use Rate
Base Year = 2009

<i>Population Age 15+ (1a)</i>	<i>Divide by 1,000</i>	<i>Resident Inpatient PCI</i>	<i>Resident Inpt. PCI from OR Hosp.</i>	<i>Total Resident Opt. PCI (All Sites)</i>	<i>Total Resident PCI</i>	<i>Use Rate (1b)</i>
215,702*	215.702	494	10**	194***	698	3.24
		<i>Total Includes:</i>				
		440	<i>WA DOH CN Program website</i>			
		39	<i>CHARS records outside MS_DRGs 246-251 with procedure codes 00.66,36.06,36.07</i>			
		3	<i>Yakima Valley Memorial Hospital reporting omissions</i>			
		8	<i>Records already counted above, with code 00.66 occurring twice</i>			
		4	<i>CHARS observation database records with procedure codes 00.66, 36.06, & 36.07</i>			

* WA DOH CN Program website
 **OAHHS Inpatient database
 ***Thomson Reuters Estimates

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 and over.⁴*

Table 3
Step 2: Planning Area Forecasted PCI
Forecast Year = 2014

<i>Use Rate from Step 1</i>	<i>Population</i>	<i>Divide by 1,000</i>	<i>Projected Demand (a)2</i>
3.24	229,012	229.012	741

The “forecast year” is the fifth year after the base year. Therefore for this application, the forecast year is 2014. Memorial used the same OFM population data source for 2014 as they used for the 2009 population.

⁴ Residents 15 years of age and older.

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

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

Table 4
Step 3: Current PCI Capacity (3d)

Regional	Source
430	
Total Includes	
282	WA DOH CN Program website
24	CHARS records outside MS_DRGs 246-251 with procedure codes 00.66,36.06,36.07
7	Records already counted above, with code 00.66 occurring twice
2	CHARS observation database records with procedure codes 00.66, 36.06, & 36.07
115	Thomson Reuters Estimates

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.

Table 5
Step 4: Planning Area Net Need for PCI Procedures

Projected Demand (Step 2)	Current Capacity (Step 3)	Projected Net Need
741	430	311

Step 5: If Step 4 is greater than 300, calculate the need for additional programs.

- (a) Divide the number of projected procedures from Step 4 by 300.
- (b) Round the results down to identify the number of needed programs.

Table 6

Step 5: Planning Area Need for Additional PCI Programs

Projected Need/300 (5a)	# of New Programs (5b)
1.03	1

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.*
- (b) *Divide the total number of PCIs performed on the planning area residents over fifteen years of age⁵ by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.*

Table 7

**Step 1: Planning Area PCI Use Rate
Base Year = 2009**

<i>Population Age 15+ (1a)</i>	<i>Divide by 1,000</i>	<i>Resident Inpatient PCI</i>	<i>WA Resident Inpt. PCI from OR Hosp.</i>	<i>Total Resident Opt. PCI (All Sites)</i>	<i>Total Resident PCI</i>	<i>Use Rate (1b)</i>
215,702	215.702	440	10	76	526	2.44

For PCI programs, 'base year' is defined as the most recent calendar year that December 31 data is available from the department's Comprehensive Hospital Abstract Reporting System (CHARS) reports (or successor reports) as of the first day of the application submission period. For this project, the first day of the application submission period was February 1, 2011. The base year data is year 2009.⁶

⁵ Residents 15 years of age and older.

⁶ Although year 2010 CHARS data became available in early August 2011, WAC 246-310-745 directs the department to use specific CHARS data. Therefore, the 2010 data will not be discussed in this evaluation.

The Department used year 2009 PCI survey data and planning area population data obtained from population forecasts produced by OFM. ⁷ The results produced a Planning Area #4 PCI use rate of 2.44 per 1,000 residents [2.44/1,000].

Step 2: Forecasting the demand for PCIs to be performed on the residents of the planning area.

- (a) *Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.⁸*

Table 8
Step 2: Planning Area Forecasted PCI
Forecast Year = 2014

<i>Use Rate from Step 1</i>	<i>Population</i>	<i>Divide by 1,000</i>	<i>Projected Demand (a)2</i>
2.44	229,012	229.012	559

For PCI programs, ‘forecast year’ is defined as the fifth year after the base year. For this project, the forecast year is year 2014. In this step, the department multiplied the use rate of 2.44 calculated in Step 1 by the OFM projected planning area population of 229,012. The results are 558,789. This number is then divided by 1,000, which produced a need for 558.8 or 559 procedures for Planning Area #4 residents in 2014.

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

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

This step requires computation of the planning area’s current capacity. Table 9 shows the CN approved PCI providers located in Planning Area #9 and their PCIs for 2009.

Table 9
Hospital Capacity PCI Planning Area #4

Hospital	Inpatient	Outpatient	Total PCIs
Regional	282	56	338
Yakima PCI Planning Area #4	282	56	338

⁷ County & Age Population Projections OFM Sept 2007 update, Released Nov. 2007

⁸ Residents 15 years of age and older.

“WAC 246-310-745(10)

This step requires computation of the PCI planning area’s current capacity. There is one elective PCI provider located in PCI planning area #4. The capacity for 2009 was 338 procedures.

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.

Table 10
Step 4: Planning Area Net Need for PCI Procedures

Projected Demand (Step 2)	Current Capacity (Step 3)	Projected Net Need
559	338	221

A subtraction of 338 (current capacity from step 3) from 559 (projected need from step 2), results in a net need of 221 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.)

Table 11
Step 5: Planning Area Need for Additional PCI Programs

Projected Need/300 (5a)	# of New Programs (5b)
0.74	0

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 #4, this calculation is 221 / 300 resulting in a value of 0.74. This number is rounded down as directed in WAC 246-310-745 to 0. No new programs could be approved.

Department Conclusion Numeric Methodology Review

The department’s review of the Memorial’s need calculation finds that Memorial included data from sources (Thomson Reuters) that are not included in WAC 246-310-745 (4), (7) and (9) as acceptable data. The addition of the estimated PCIs from Thomson Reuter’s changes

the need projection from the no need found by the department to a need for one program as calculated by Memorial. Table 12 illustrates this difference.

Table 12
Department of Health and Memorial
Comparison of Need Projection Methodology Results

	Projected Need	Capacity	Projected Net Need	# of Programs Needed
Department	559	338	221	.74 or 0
Memorial	741	430	311	1.03 or 1

Public Comment

The department received approximately 1,049 letters regarding Memorial’s application to provide adult elective PCI Services. Of these letters, 637 were in support of the project and 412 were in opposition to the project. Both hospitals in the community solicited support for their position regarding this project. Table 13 includes a breakdown of the letters submitted to the department.

Table 13
Public Comment Letters Memorial PCI Project

Letter Type	Quantity
Support	
Form Letter	537
Form Letter with Comments	71
Original Letter	29
Oppose	
Form Letter	256
Form Letter with Comments	78
Original Letter	78
Total	1,049

Common themes among the letters of support are summarized below:

- Accessibility – Patients would have choice with the establishment of the elective PCI program at Memorial.
- Manpower – The interventional cardiologists provide services at both hospitals.
- Facilities – Memorial has already invested in the cardiology facilities and no added facilities or equipment is needed.
- Controlling Costs - The public comment proposed that Memorial has lower costs and that the competition between the 2 hospitals would foster even lower costs.
- Quality/Prevention – Public comment supported the concept that quality and efficiency improves with volume. Public comment that Memorial invests in health education programs.

Common themes among the letters of opposition are summarized below:

- Access – Concern expressed in some letters regarding potential impact on access to Regional's other cardiac services. No increase in geographical access.
- Quality – Concern expressed that patient volume could be split between the two hospitals reducing volume for both. Potential to affect quality of care and clinical outcomes.
- Safety – Concern about PCI patients needing to be transferred from Memorial if the patient needs services beyond those provided at Memorial.

The public comments indicate to the department that some members of the community acknowledge the concept of each hospital specializing in certain tertiary services and other members of the community do not.

Rebuttal

Both Memorial and Yakima Region Medical Center submitted rebuttal comments to the department. Both sets of rebuttal comments focused on reinforcing their positions regarding the application submitted by Memorial for adult elective PCI services.

The department distributed the rebuttal comments to both hospitals for their information. In a letter submitted to the department September 28, 2011 from Richard W. Linneweh Jr., CEO of Memorial, an issue was raised that Regional had introduced new information regarding the 2008 data prepared by the department. The department identified 2009 as the base year for this application in the screening questions sent to the applicant. [Source: April 1, 2011 Screening Questions p3] In addition two new letters of support were included. The department will not consider the two letters submitted with the rebuttal comments submitted by Regional.

Based on review of information submitted by the applicant and the need methodology calculated by the department, the department concludes, **this sub-criterion is not met.**

Further PCI specific 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.

To demonstrate compliance with this standard, Memorial provided a table showing the number of Planning Area #4 PCIs performed at University of Washington (UWMC) in year 2009. For year 2009, UWMC performed a total of 4 PCIs on Planning Area #4 patients. For year 2009, UWMC performed a total of 312 PCIs. Their market share for PCI Planning Area #4 was 0.7%. Memorial reports that no direct referrals were made by their cardiologists to the University of Washington Medical Center. Memorial provided a copy of the letter sent to

the University of Washington Medical Center advising of the Memorial PCI project. [Source: Application, pp26]

Department’s Evaluation

Although most of the previous PCI applications had a condition applied to monitor their impact on PCIs performed at the University of Washington, it does not appear that this would be necessary for this project. The four PCIs performed at the University of Washington Medical Center appear to be incidental utilization. The department has determined that if approved this project would not have significant impact on the University of Washington PCI program. **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.

There are two parts to parts to this sub-criterion Part one is the projections provided by the applicant and part evaluates the if the number of projected procedures is sufficient if all of the physicians working only at the applicant hospital will be able to meet the volume standards of seventy-five PCIs per year.

Memorial provided a table showing the projected number of PCIs it expects to perform through the first three years of the proposed program. Table 14 below summarizes the projected PCIs for Memorial [Source: Application, p14]

Table 14
2012-2014 Projected PCI Procedures for Memorial

	2012	2013	2014
Total	225	275	305

Memorial reports having 4 physicians on their medical staff who will be performing PCI procedures at Memorial. They are projecting sufficient procedures at their facility to meet this requirement.

The department is projecting a total of 559 procedures for PCI planning area #4. Since all four of the physicians perform PCIs at both Yakima Regional and at Memorial, the second requirement does not apply to this application. There are sufficient PCIs projected for the planning area for the physicians to meet their 75 PCI procedures per year. **This sub-criterion is met.**

WAC 246-310-720(1) Hospitals with an elective PCI program must perform a minimum of three hundred adult PCIs per year by the end of the third year of operation and each year thereafter

The department is projecting only 221 PCI procedures will be available to Memorial in 2014, therefore does not anticipate that Memorial will be achieve the minimum of 300 adult PCIs by the end of the third year of operation. **This sub-criterion is not met.**

WAC 246-310-720(2)The department shall only grant a certificate of Need to new programs within the identified planning area if

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

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

The PCI forecasting methodology forecasts a need for zero new programs in PCI planning area #4 for the target year 2014. Therefore the department is not able to approve a certificate of need for this project. **This sub-criterion is not met.**

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

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

To demonstrate compliance with this sub-criterion Memorial provided a copy of the Admission Policy used by their staff. The Admission Policy does not provide the language regarding non-discrimination but the Charity Care Policy states that Memorial admits any patient without regard to race, color, gender, age, religious creed, ancestry, disability/handicap, payer source, or inability to pay. The document submitted defines procedure for admission rather than policy. The document does not take the place of a patient admission policy; rather it would be used to supplement their Admission Policy. [Source: Application, Exhibit 3] The department concludes that a condition requiring Memorial to submit an Admission Policy is necessary if this project is approved.

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.

Memorial 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 Memorial identifies the facility's financial resources as including both Medicare and Medicaid revenues. [Source: Application, p7 & Exhibit 4]

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.

Memorial demonstrated that it currently provides charity care to the residents of the service area and surrounding communities at its existing campuses and intends to maintain this status. Memorial’s policy outlines the process one would use to access this service. The charity care policy was revised in March 2008 and approved by the department’s Hospital and Patient Data Systems office. [Source: Application, Exhibit 3] Memorial also included a ‘charity care’ line item as a deduction from revenue within the pro forma income statement documents. [Source: Application, Exhibit 4]

For charity care reporting purposes, HPDS divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Memorial is located in the Central Region. Currently there are 21 hospitals located within the region. According to 2007 - 2009 charity care data obtained from HPDS, Memorial has historically provided more than the average charity care provided in the region.⁹ Memorial’s most recent three-year (2007 - 2009) average percentages of charity care for gross and adjusted revenues are 1.94% and 4.69%, respectively. The 2007 - 2009 average for the Central Region is 1.91% for gross revenue and 4.43% for adjusted revenue. [Source: HPDS 2007-2009 charity care summaries]

Table 18
Memorial Charity Care Comparison

	3-Year Average for Central Region	3 Year Average for Memorial
% of Gross Revenue	1.91%	1.94%
% of Adjusted Revenue	4.43%	4.69%

Memorial submitted pro forma revenue and expense statements with proposed PCI project. [Source: Exhibit 4] RCW 70.38.115(2)(j) requires hospitals to meet or exceed the regional average level of charity care. Since Memorial’s historical charity care is currently more than the average for the region and Memorial projects to provide more than the regional average the department will not need to condition this project. The department concludes that all residents, including low income, racial and ethnic minorities, handicapped, and other underserved groups would have access to the services provided by the hospital. Provided that SHS agreed with the condition related to the Admission Policy, **this sub-criterion is met.**

⁹ IBID

B.FINANCIAL FEASIBILITY (WAC 246-310-220)

Based on the source information reviewed, the department determines that the Yakima Valley Memorial 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, Memorial provided its Statement of Operations for the PCI cost center only for projected years 2012 through 2015. [Source: May 9, 2011 Response to Screening Questions, Attachment 5] A summary of the Statement of Operations for the PCI cost center only is shown in Table 13.

Table 13
PCI Cost Center Projected Statement of Operations Summary
Years 2013 through 2015

	Projected Year 1 (2012)	Projected Year 2 (2013)	Projected Year 3 (2014)
Total Operating Revenue	\$25,956,380	\$27,247,726	\$28,027,353
Total Operating Expenses	\$12,415,168	\$12,770,127	\$12,992,274
Net Profit or (Loss)	\$13,541,212	\$14,477,599	\$15,035,079

The total operating revenue’ line item in Table 6 is the result of gross revenue minus any deductions for contractual allowances, bad debt, and charity care directly related to the PCI cost center. The ‘total operating expenses’ line item includes staff salaries/wages and all hospital cost allocations related to the PCI cost center. Table 3 reflects the gradual increase in both emergent and elective PCIs projected by Memorial. As shown in Table 6, the PCI cost center is projected to be profitable in years 2012 through 2014.

Memorial also provided its Statement of Operations for the hospital as a whole with PCI services for projected years 2012 through 2014. [Source: Application, Exhibit 4] A Statement of Operations summary is shown in Table 14.

Table 14
Memorial Projected Statement of Operations Summary
Years 2012 through 2014

	Projected Year 1 (2012)	Projected Year 2 (2013)	Projected Year 3 (2014)
Total Operating Revenue	\$314,266,444	\$331,551,098	\$349,786,408
Total Expenses	\$301,119,456	\$318,121,759	\$336,012,812
Net Profit or (Loss)	\$13,146,988	\$13,429,339	\$13,773,596

The ‘total operating revenue’ line item in Table 7 is the result of gross revenue, and non-operating revenue minus any deductions for contractual allowances, bad debt, and charity care. The ‘total expense’ line item includes all hospital staff salaries/wages, other direct expenses, and all cost allocations. As shown in Table 7, the hospital as a whole is projected to be profitable in years 2012 through 2014 with the elective PCI program.

To determine whether Memorial would meet its immediate and long range capital costs with an elective PCI program, HPDS reviewed projected balance sheets. Memorial’s balance sheet for 2010 is shown in Table 15. [Source: October 11, 2011 HPDS analysis, p2]

**Table 15
Memorial Balance Sheet for 2010**

Assets		Liabilities	
Current Assets	\$78,376,722	Current Liabilities	\$42,375,749
Board Designated Assets	\$42,377,971	Long Term Debt	\$57,899,563
Fixed Assets	\$120,549,721	Other	\$39,036,833
Other Assets	\$6,184,878	Total Liabilities	\$139,312,145
Total Assets	\$247,489,292	Equity	\$108,177,147
		Total Liabilities and Equity	\$247,489,292

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 2009 data for comparison. The ratio comparisons are shown in Table 16. [Source: October 11, 2011 HPDS analysis, pp2-3]

Table 16
Current and Projected HPDS Debt Ratios for Memorial

Category	Trend ¹⁰	State 2009	Memorial 2009	Projected 2010	Projected 2011	Projected 2012
Long Term Debt to Equity	B	0.545	0.535	N/A	N/A	N/A
Current Assets/Current Liabilities	A	2.262	1.850	N/A	N/A	N/A
Assets Funded by Liabilities	B	0.430	0.430	N/A	N/A	N/A
Operating Expense/Operating Revenue	B	0.945	1.012	0.478	0.469	0.464
Debt Service Coverage	A	6.169	2.987	N/A	N/A	N/A
Definitions:	Formula					
Long Term Debt to Equity	Long Term Debt/Equity					
Current Assets/Current Liabilities	Current Assets/Current Liabilities					
Assets Funded by Liabilities	Current Liabilities + Long term Debt/Assets					
Debt Service Coverage	Net Profit+Depr. and Interest Exp/Current Mat. LTD and Interest Exp					

Comparing Memorial's 2010 ratios with the statewide ratios (2009) revealed that Memorial is slightly outside the normal range on Current Assets/Current Liabilities and Operating Expense/Operating Revenue. This is due to the hospital being slightly below average in overall financial health.

HPDS also compared operating expense to operating revenue ratio for the PCI project only. Memorial projects its operating revenues to exceed its operating expenses for its PCI project. This is demonstrated by the revenue to expense ratios of 0.478, 0.469, and 0.464 for years 2010, 2011, and 2012, respectively. The PCI program should improve the hospital's overall financial health if the project is approved. [Source: October 11, 2011, 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.

Memorial identified a capital expenditure for this project of zero; as a result there are no construction costs for this project. The Cath. Lab is currently operating and the applicant is projecting minimal incremental costs. This sub-criterion also requires the department to consider the operational costs of the project and the impact of those costs on the costs and charges for health services. The revenue and expense statement for the PCI project indicates that the project will be profitable in the first full year and for the following two years of the project. Literature reviewed by the department indicates that reimbursement for the PCI

¹⁰ A is better if above the ratio, and B is better if below the ratio.

procedures is very profitable for hospitals so the additional PCIs would contribute to the profitability of Memorial.

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

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

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. If approved Memorial has a reasonable chance of improving its financial objectives for the hospital with this project. **This sub-criterion is met.**

(3) The project can be appropriately financed.

Memorial identified the capital expenditure for this project of zero. Therefore, this certificate of need project does not require additional construction and requires no additional capital expenditures. The total original cost identified with the catheterization lab was \$4,549,000.

The department acknowledges that the Cath. Lab is already operational and the capital expenditures are reflected in Memorial’s historical financial statements and were included in the review of the previous sub-criterion. The department will not review any capital expenditure directly related to this project. As a result, this sub- criterion is **not applicable to Memorial’s application.**

C. STRUCTURE AND PROCESS (QUALITY) OF CARE (WAC 246-310-230), GENERAL (PCI PROGRAM) REQUIREMENTS (WAC 246-310-715(3), (4), AND (5); PHYSICIAN VOLUME STANDARDS (WAC 246-310-725; STAFFING REQUIREMENTS (WAC 246-310-730); PARTNERING AGREEMENTS (WAC 246-310-735) AND QUALITY ASSURANCE (WAC 246-310- 740)

Based on the source information reviewed, the department determines that the Yakima Valley Memorial Hospital 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, Memorial 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 staff the elective program. Memorial provided a table, summarized below, showing the current and projected nursing and technical staff for the emergent and elective PCI programs. Memorial also provided the professional license number for each of the current staff, including the cardiologists.

**Table 17
Memorial
Current Year (2009) and Projected FTEs Cath. Lab**

Staff/FTEs	Current FTEs	Year 1 2012	Year 2 Increase	Year 3 Increase	Total FTEs
Technologists	6.75	0	0	0	6.75
Nurses	3.6	0	0	0	3.6
Management	1.5	0	0	0	1.5
Unit Secretary	1.0	0	0	0	1.0
Total	12.85	0	0	0	12.85

Memorial states that no new staff will added to provide the additional PCIs if this project is approved. **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.

Memorial reports having 2 cardiac catheterization labs both used for diagnostic and therapeutic procedures. [Source: Application, p10] To demonstrate compliance with this sub-criterion, Memorial provided a listing of equipment that is provided in the each of their Cath. Labs. [Source: May 9, 2011 Response to Screening Questions, Exhibit 10]. Memorial has provided job descriptions and skills review documents for the PCI program nurses and technical staff. [Source: Application, Exhibit 5]

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.

Memorial currently provides emergent PCIs and both the interventional cardiologists and cardiac lab staff are available 24 hours per day 7 days per week. Memorial has three cardiac teams that provide on-site staffing of the 2 cath. Labs from 6am to 5:30 pm Monday through Friday. An on-call team provides coverage after hours and on weekends. Table 18 shows the cardiac catheterization staffing for Memorial

**Table 18
Memorial Cath. Lab Staffing**

Hours	Staffing
0600 to 1630 Monday - Friday	1 RN 1 Technician
0700 to 1730 Monday - Friday	1 RN 3 Technicians 1 Unit Secretary (0730 to 1630)
0800 to 1630 Monday - Friday	1 RN 2 Technicians
On-Call 1730 to 0700 Monday – Friday 24 hours Saturday and Sunday	1 RN 2 Technicians

The current staff has demonstrated competencies in operating PCI related technologies. Memorial has provided job descriptions and skills review documents for the PCI program nurses and technical staff.

Based on the documentation provided, the department concludes that all identified staff will be available 24/7 and will be appropriately trained as required by the standards. **This sub-criterion is met.** [Source: Application, p35]

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.

Memorial currently has 13 cardiologists on its active medical staff. Of the 13, four are board certified or otherwise credentialed to perform PCIs. Table 19 lists the 4 physicians and their credentials.

Table 19
Memorial Physicians Qualified to Perform PCIs

Physician	Board Certification
Mark S. Berman, MD	ABIM-Cardiovascular Disease ABIM-Interventional Cardiology
Ralph (Thomas) McLaughlin, MD	ABIM-Cardiovascular Disease
Douglas A. Morrison, MD	ABIM-Internal Medicine ABIM-Pulmonary Disease ABIM-Interventional Cardiology ABIM-Cardiovascular Disease
Omer A El-Amin, MD	ABIM-Internal Medicine ABIM-Interventional Cardiology ABIM-Cardiovascular Disease Cert/Board of Nuclear Cardiology

Memorial provided documentation to demonstrate each physician performed at least 75 procedures per year for years 2008, 2009, and 2010. The numbers are substantiated and consistent with the numbers reported to the HPDS data system. As a result, all three physicians have met the volume standards prescribed. [Source: Application, p39; May 9, 2011 Response to Screening Questions, Attachment 9]

Based on the information above, the department concludes **this sub-criterion is met.**

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

Memorial has identified 4 physicians currently providing emergent PCIs at Memorial who have demonstrated the necessary qualifications to provide elective PCIs

Based on the information above, the department concludes, **this sub-criterion is met.**

WAC 246-310-730(2) Staff its catheterization laboratory with a qualified, trained team of technicians experienced in interventional lab procedures.

- a. Nursing staff should have coronary care unit experience and have demonstrated competency in operating PCI related technologies.
- b. Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary

To demonstrate compliance with these sub-criteria, Memorial provided names and professional license numbers of all nursing and technical staff associated with the current emergent and proposed elective PCI program. The nurses, RTs and RCISs all demonstrate competency in operating PCI-related technologies. Memorial has provided job descriptions for each of the positions.

All nursing staff are ACLS certified and which ensures that they have been trained in performing endotracheal intubation and ventilator management. [Source: Application, p37, Exhibit 5]

Documentation provided demonstrated that catheterization laboratory staff will be required to meet the standards outlined in WAC 246-310-730(2) but since the staff has not been hired, the department concludes **this sub-criterion is met.**

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

As an operating facility, Memorial 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.

To demonstrate compliance with this standard, Memorial provided a copy of its Elective PCI Patient Transfer and Surgical Partnering Agreement with Kadlec Regional Medical Center (KRMC), Richland. The agreement identifies KRMC as the receiving hospital for PCI patients requiring a transfer from Memorial.

The agreement acknowledges that KRMC will coordinate availability of surgical teams and will coordinate backup if needed during peak periods of OR use. [Source: May 9, 2011 Response to Screening Questions, Attachment 11

Based on the review of the Memorial and KRMC Partner agreement, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(1). **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.

The agreement acknowledges that KRMC will provide cardiac surgery during all hours that elective PCIs are being performed at Memorial. [Source: May 9, 2011 Response to Screening Questions, Attachment 11

Based on the review of the Memorial and KRMC agreement, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(2). **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.

To demonstrate compliance with this standard, Memorial agrees to transfer all clinical data, including images and videos with the patient to KRMC. Memorial and KRMC agree to maintain clinical records of sufficient content to ensure continuity of care, and copies of these records will accompany the patient. [Source: May 9, 2011 Response to Screening Questions, Attachment 11

Based on the review of the Memorial and KRMC Partner agreement, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(3). **This sub-criterion is met.**

WAC 246-310-735(4) Communication by the physician(s) performing the elective PCI to the backup hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.

The executed Memorial and KRMC Partner agreement addresses this standard. Section 1 of the agreement ensures communication between cardiac surgeons at each hospital. [Source: May 9, 2011 Response to Screening Questions, Attachment 11]

Based on the review of the Memorial and KRMC Partner agreement, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(4). **This sub-criterion is met.**

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

The executed Memorial and KRMC Partner agreement addresses this standard. Section 3 of the agreement ensures KRMC will accept all referred patients from Memorial. [Source: May 9, 2011 Response to Screening Questions, Attachment 11]

Based on the review of the Memorial and KRMC Partner agreement department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(5). **This sub-criterion is met.**

WAC 246-310-735(6) The applicant hospital's mode of emergency transport for patients requiring urgent transfer. The hospital must have a signed transportation agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery.

To demonstrate compliance with this standard, Memorial provided a copy of its executed "Transportation Agreement" with Advanced Life Systems. The agreement outlines roles and responsibilities for both entities, including maintaining qualified staff to conduct the safe and effective transport of patients from Memorial. The Agreement includes an automatic renewal clause. [Source: Application, Exhibit 7]

Based on the review of the Transportation Agreement with Advanced Life Systems. The department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(6). **This sub-criterion is met.**

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

The executed Memorial and KRMC Partner agreement addresses this standard. Section 7b of the agreement ensures beginning of transport within 20 minutes after Memorial identifies complications with the patients. In addition, the Transportation Agreement with Advanced Life Systems also addresses this standard. Schedule A of the agreement states that the ambulance will commence transportation of the patient within 20 minutes of the request to

transport. [Source: Application, Exhibit 7, and May 9, 2011 Response to Screening Questions, Attachment 11]

Based on the review of the Memorial Partner agreement with KRMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(7). Based on the review of the Transportation Agreement with Advanced Life Systems, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(7). **This sub-criterion is met.**

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

The executed Memorial Partner agreement with KRMC, addresses this standard. Section 7 of the agreement addresses the qualifications of the emergency transport staff. In addition, the Transportation Agreement with Advanced Life Systems also addresses this standard. Exhibit A of this agreement assures the patient will be transported with appropriately qualified personnel. [Source: Application, Exhibit 7, and May 9, 2011 Response to Screening Questions, Attachment 11]

Based on the review of the Memorial Partner agreement with KRMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(8). Based on the review of the Transportation Agreement with Advanced Life Systems, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(8). **This sub-criterion is met.**

WAC 246-310-735(9) The hospital documenting the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of the backup hospital. Transportation time must be less than one hundred twenty minutes.

The executed Memorial Partner agreement with KRMC, addresses this standard. Section 7c of the agreement ensures that the transport time will be less than 120 minutes. In addition, the Transportation Agreement with Advanced Life Systems also addresses this standard. Schedule A of the agreement states that the ambulance will commence transportation within 20 minutes of the request to transport and the transport shall be completed within 90 minutes. [Source: Application, Exhibit 7, and May 9, 2011 Response to Screening Questions, Attachment 11]

Based on the review of the Memorial Partner agreement with KRMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(9). Based on the review of the Transportation Agreement with Advanced Life Systems, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(9). **This sub-criterion is met.**

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

The executed Memorial Partner agreement with KRMC addresses this standard. Section 1 of the agreement ensures Memorial and KRMC will participate in at least two timed emergency transport drills. Outcomes of the drills will be reported to transferring hospital's quality

assurance program. In addition, the Transportation Agreement with Advanced Life Systems also addresses this standard. Schedule A. of the agreement ensures that the ambulances and personnel will participate in the drills with both hospitals. [Source: Application, Exhibit 7, and May 9, 2011 Response to Screening Questions, Attachment 11]

Based on the review of the Memorial and KRMC agreement, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(10). Based on the review of the Transportation Agreement with Advanced Life Systems, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(10). **This sub-criterion is met.**

WAC 246-310-735(11) Patient signed informed consent for adult elective (and emergent) PCIs. Consent forms must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements

To demonstrate compliance with this standard, Memorial provided a draft copy of their Percutaneous Coronary Intervention (PCI) Informed Consent. The form is specific to cardiac catheterization. The document further discusses potential risks and complications related to the procedure. The document provides the following language related to this sub-criterion:

“Should emergency transfer to an open heart surgery hospital be needed, Yakima Valley Memorial Hospital has an established agreement with a qualified emergency transport agency that will ensure a total transportation time of less than 120 minutes, which is the ideal standard. I understand that a transport team will be en route with me that include staff certified in advance cardiac life support who have the skills and experience, and equipment to monitor and treat me and to manage an intra-aortic balloon pump. Yakima Valley Memorial Hospital will immediately notify both the open-heart hospital and the emergency transport in the rare case a complication should arise. Emergency transport occurs in less than 3 out of 1,000 cases.” [Source: Application, Exhibit 8]

Memorial also points out that in the rare event that the patient may need emergency open-heart surgery because of the PCI procedure; it might be performed more quickly if the procedure was scheduled at such facility first.

Based on the review of the draft Percutaneous Coronary Intervention (PCI) Informed Consent, the department concludes that if this project is approved Memorial will need to submit a copy of the approved form that satisfies the standard and requirement under WAC 246-310-735(11). With the applicants agreement to the above condition **this sub-criterion is met.**

WAC 246-310-735(12) Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases.

The executed Memorial Partner agreement with KRMC addresses this standard. Section 1 of the agreement ensures Memorial and KRMC will participate in joint quarterly conferences in

which a significant number of preoperative and postoperative cases, including all transport cases, are reviewed. [Source: Application, Exhibit 7]

Based on the review of the Memorial Partner agreement with KRMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(12). **This sub-criterion is met.**

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

The executed Memorial Partner agreement with KRMC addresses this standard. Section 1b and 3 of the agreement ensures Memorial and KRMC will coordinate transfer of patients at peak volume periods. KRMC will assist in securing alternative back-up surgical services when necessary.

Based on the review of the Memorial Partner agreement with KRMC, the department concludes this agreement satisfies the standards and requirements under WAC 246-310-735(13). **This sub-criterion is met.**

In summary with the Memorial's agreement to the condition on the **Percutaneous Coronary Intervention (PCI) Informed Consent form**, all three documents identified above meet the standards and requirements outlined in WAC 246-310-735(1)-(13). **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. As stated earlier, Memorial provides healthcare services to the residents of Yakima and surrounding counties, through its various healthcare facilities. Memorial does not operate any healthcare facilities outside of Washington State.

As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public. Since October 2008, the Department of Health's Investigations and Inspections Office has completed one compliance surveys for Memorial. Memorial had a Joint Commission survey in June 2010 and was approved for deemed status in October 2010.

Memorial's most recent compliance survey in October 2008 revealed minor non-compliance issues related to the care and management at Memorial. These non-compliance issues were typical of the specific type of facility and Memorial submitted and implemented an acceptable plan of correction. [Source: facility survey data provided by the Investigations and Inspections Office]

Memorial provided the names and license numbers for licensed personnel that are staffing the cath. Lab. The department verified licensure and state compliance for these individuals. [Source: Application p40-43, ILERS]

The department concludes that Memorial did provide documentation to demonstrate there is reasonable assurance that its PCI program would operate in compliance with state and federal regulations. **This sub-criterion is met.**

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.

Memorial provided a copy of its Yakima Valley Memorial Hospital, Elective and Emergent PCI Improvement Plan specific to elective and emergent PCI services. The Plan identifies that Memorial will participate in the Washington State Clinical Outcomes Assessment Program (COAP) to ensure quality and quality improvement. For accountability, Memorial will report the results of its performance to the Cardiology Leadership Team, the Cath. Lab Manager, and The Cardiac, Pulmonary, and Critical Care Quality Assurance/Performance Improvement Committee for review, discussion, and performance improvement recommendations. The report will also be forwarded to the Department of Health or their designee as requested. [Source: Application, Exhibit 9]

Based on the review of the Yakima Valley Memorial Hospital, Elective and Emergent PCI Improvement Plan, the department concludes the plan satisfies the standards and requirements under WAC 246-310-735(12). **This sub-criterion is met.**

WAC 246-310-740(2) A system for patient selection that results in outcomes that are equal to or better than the benchmark standards in the applicant's plan

The Yakima Valley Memorial Hospital, Elective and Emergent PCI Improvement Plan addresses this standard by participating in the Washington State Clinical Outcomes Assessment Program (COAP) to ensure quality and quality improvement. [Source: Application, Exhibit 9]

Based on the review of the Yakima Valley Memorial Hospital, Elective and Emergent PCI Improvement Plan,” the department concludes the plan satisfies the standards and requirements under WAC 246-310-740(2). **This sub-criterion is met.**

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

The Yakima Valley Memorial Hospital Elective and Emergent PCI Performance Improvement Plan addresses this standard. [Source: Application, Exhibit 9]

Based on the review of the Yakima Valley Memorial Hospital Elective and Emergent PCI Performance Improvement Plan, the department concludes the plan satisfies the standards and requirements under WAC 246-310-740(3). **This sub-criterion is met.**

WAC 246-310-740(4) A description of the hospital's cardiac catheterization laboratory and elective PCI quality assurance reporting processes for information requested by the department or the department's designee. The department of health does not intend to require duplicative reporting of information.

Memorial provided a copy of its Yakima Valley Memorial Hospital, Elective and Emergent PCI Improvement Plan specific to elective and emergent PCI services. The Plan identifies that Memorial will participate in the Washington State Clinical Outcomes Assessment Program (COAP) to ensure quality and quality improvement. For accountability, Memorial will report the results of its performance to the Cardiology Leadership Team, the Cath. Lab Manager, and The Cardiac, Pulmonary, and Critical Care Quality Assurance/Performance Improvement Committee for review, discussion, and performance improvement recommendations. [Source: Application, Exhibit 9]

Based on the review of the Yakima Valley Memorial Hospital, Elective and Emergent PCI Improvement Plan, the department concludes the plan satisfies the standards and requirements under WAC 246-310-740(4). **This sub-criterion is met.**

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

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

The department recognizes that Memorial is a long-time provider of health care services in Washington State, and as such, has already established long term relationships within the healthcare system. [Source: CN historical files] the applicant has a partnering agreement with Kadlec Medical Center in Richland to transfer those patients needing the heart surgery back-up provided by that facility. Memorial has a health transportation agreement with Advanced Life Systems to provide the transportation for those PCI patients needing this service. **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 met.

D. COST CONTAINMENT (WAC 246-310-240)

Based on the source information reviewed, the department determines that the Yakima Valley Memorial Hospital has not met the cost containment criteria in WAC 246-310-240 (1).

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

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

Step three of this assessment is to apply any service or facility specific criteria (tie-breaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

For this project, Memorial's project does not meet the review criteria under WAC 246-310-210. Therefore, the department concludes this project is not the best available alternative for the community. The department does not review steps two or three below for this project.

- (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 does not involve construction. As a result, this sub-criterion is **not applicable to Memorial's application.**

APPENDIX A

2009 Use
Rate Table

2008

County	2009 PCI POP	2009 PCI POP/1000	2009 PCIs Inpt.	2009PCIs Opt	Oregon Inpt	Use Rate
PSA 1						
Adams	13,029		33	14	0	
Asotin	17,697		44	19	0	
Ferry	6,607		22	1	0	
Grant	63,983		106	43	0	
Lincoln	8,447		22	8	0	
Pend Oreille	11,086		32	10	0	
Spokane	368,626		822	114	1	
Stevens	36,765		117	23	0	
Whitman	36,617		79	16	0	
Total	562,857	562.857	1277	248	1	2.71
PSA 2						
Benton	129,950		182	210	0	
Columbia	3,462		17	10	0	
Franklin	48,347		49	50	0	
Garfield	1,993		7	1	0	
Walla Walla	48,532		101	18	0	
Total	232,284	232.284	356	289	0	2.78
PSA 3						
Chelan	58,206		81	37	0	
Douglas	29,884		51	13	0	
Okanogan	35,520		55	15	0	
Total	123,610	123.61	187	65	0	2.04
PSA 4						
Kittitas	32,864		64	8	0	
Klickitat (E)	6,672		8	3	20	
Yakima	176,166		368	65	4	
Total	215,702	215.702	440	76	10	2.44
PSA 5						
Clark	332,686		449	129	79	
Cowlitz	83,528		40	9	139	
Klickitat (W)	9,804		1	0	37	
Skamania	8,846		2	0	12	
Wahkiakum	3,444		0	0	8	

PSA 14							
	Whatcom						
	Total	157,595	157,595	393	208	0	3.81
				9371	3546	334	

