STATE OF WASHINGTON
DEPARTMENT OF HEALTH

October 23, 2009

CERTIFIED MAIL # 7007 3020 0000 3056 2711

Michael Motte, Chief Executive Officer
Capital Medical Center
3900 Capital Mall Drive SW
Olympia, WA 98502

Dear Mr. Motte:

We have completed review of the Certificate of Need application submitted on behalf of Capital Medical Center proposing to establish an adult elective 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 Capital Medical Center agrees to the following terms and conditions.

TERMS

1. Prior to commencement of the project, Capital Medical Center must provide to the Certificate of Need Program for review and approval a final "Quality Assurance/Quality Improvement Plan" for its PCI program. The final Plan will be consistent with the draft plan provided in Exhibit 6 of the application.

2. Prior to commencement of the project, Capital must provide the Certificate of Need program a finalized Charity Care Policy approved by the Department's Hospital and Patient Data Systems program.

CONDITIONS

1. Capital Medical Center will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Capital Medical Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the regional average amount of charity care provided by hospitals in the Southwest Washington Region. Currently, this amount is 2.74% of gross revenue and 6.16% of adjusted revenue. Capital Medical Center will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.

2. Capital Medical Center 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 Capital Medical Center in any one calendar year is 20.

   3. The University of Washington Medical Center makes a written request to Capital Medical Center for patient referrals. The request must:

   - include the number of patients residing in Capital Medical Center'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 (20) 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 Capital Medical Center.

With the terms and conditions stated above, the Department of Health concludes that the project satisfies the application criteria. Without the terms and conditions, 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 terms and conditions attached to the department's approval. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:	FedEx and UPS:
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	310 Israel Road SE
Olympia, WA 98504-7852	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 COLUMBIA CAPITAL MEDICAL CENTER, LP d/b/a CAPITAL MEDICAL CENTER PROPOSING TO ESTABLISH AN ADULT ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM TO SERVE THE RESIDENTS OF PLANNING AREA #6.

PROJECT DESCRIPTION

Columbia Capital Medical Center, LP d/b/a Capital Medical Center opened its doors in January 1985 as a for-profit limited liability acute care hospital. Capital is operated in partnership with its parent company Capella Healthcare. Capella Healthcare is physician's formed healthcare management organization based in the State of Tennessee. In Washington State, Capital Medical Center (Capital) currently provides Medicare and Medicaid acute care services and also owns or manages two separately licensed multi-purpose clinics. Below is a listing of the two separately-licensed clinics owned and/or operated by Capital. [Source: Application page 4 and CN historical file]

Hospital	**Health Clinics**
Capital Medical Center	Clinic at Elma
	Olympia Family Medicine

Capital is located at 3900 – Capital Mall Drive Southwest in the City of Olympia, Thurston County. Capital is currently licensed for 119 beds[1] and is accredited by the Joint Commission. Capital has been providing emergent PCI[2] services since approximately 1999. PCI intervention involves invasive, but non-surgical mechanical procedure and the devices that are used by the cardiologist to revascularize an obstructed coronary artery or 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)]

Capital's application proposes to establish an adult elective PCI program within space at the hospital.[3] Capital anticipates the elective PCI program would be available in January 2010,

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[1] On February 24, 1995, Capital was issued Certificate of Need #1120 to add 9 transitionary beds to the existing capacity. On March 22, 2007, Capital submitted an application to bank 9 licensed nursing home beds in its Skilled Unit under RCW 70.38.115 (13)(b). The nine-banked beds will expire on March 1, 2015 or until a CN is issued for their replacement.

[2] Emergent PCI means a patient needs immediate interventions 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)]

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

because it does not anticipate any construction or new equipment that would be required for this project. As a result, no capital expenditure is associated with this project. [Source: Application Pages 1and 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 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).[4] 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 2009 PCI Concurrent Review Cycle. Below is a chronological summary of the project.

January 30, 2009	Letter of Intent Submitted
February 27, 2009	Application Submitted
February 28, 2009 through May 17, 2009	Department's Pre-Review activities including screening responses received from the applicant
May 18, 2009	Department Begins Review
July 17, 2009	Public Hearing Conducted/End Public Comment
August 17, 2009	Rebuttal Documents Received
October 1, 2009	Department's Anticipated Decision Date
November 2, 2009	Department's Anticipated Decision Date (with 30 days extension)
October 23, 2009	Department Actual 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. Capital is located in PCI planning area #6 as defined in WAC 246-310-705(5), which includes Grays Harbor, Lewis, Mason, Pacific, and Thurston counties. No other application was submitted proposing to serve this planning area.

For this project, two entities 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.

- Providence St. Peter Hospital a religious affiliated healthcare services provider that provides both Medicare and Medicaid acute care services in the City of Olympia and is located within

[4] 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).

the same planning area as the applicant. Providence is currently the only elective PCI services provider in planning area #6.

SOURCE INFORMATION REVIEWED

- Capital Medical Center Certificate of Need application submitted February 27, 2009
- Capital Medical Center supplemental information received on April 30, 2009
- Public comments provided by University of Washington Medical Center received on July 15, 2009
- Addendum to public comments provided by University of Washington Medical Center received on July 17, 2009
- Public comments provided by Providence received on July 17, 2009
- Public comments received from community members
- Rebuttal comments received from Providence on August 16, 2009
- Rebuttal comments received from Capital Medical Center on August 17, 2009
- 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 (2005, 2006 and 2007 summaries)
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems
- Licensing and/or survey data provided by the Department of Health's Office of Investigation and Inspections Office
- Capella Healthcare quality of care history provided by the State of Arkansas, Tennessee, Oklahoma and Oregon
- The Joint Commission Accreditation Quality Report—Columbia Medical Center Limited Partnership

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Columbia Capital Medical Center, LP d/b/a Capital Medical Center 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 terms and conditions stated below. There is no capital expenditure associated with this project.

TERMS

1. Prior to commencement of the project, Capital Medical Center must provide to the Certificate of Need Program for review and approval a final "Quality Assurance/Quality Improvement Plan" for its PCI program. The final Plan will be consistent with the draft plan provided in Exhibit 6 of the application.
2. Prior to commencement of the project, Capital must provide the Certificate of Need program a finalized Charity Care Policy approved by the Department's Hospital and Patient Data Systems program.

CONDITIONS

1. Capital Medical Center will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Capital Medical Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the regional average amount of charity care provided by hospitals in the Southwest Washington Region. Currently, this amount is 2.74% of gross revenue and 6.16% of adjusted revenue. Capital Medical Center will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.

2. Capital Medical Center 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 Capital Medical Center in any one calendar year is 20.

   3. The University of Washington Medical Center makes a written request to Capital Medical Center for patient referrals. The request must:
      - include the number of patients residing in Capital Medical Center'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 (20) 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) and Need Forecasting Methodology (WAC 246-310-745), and Standards (WAC 246-310-715(1), (2))

Based on the source information reviewed and the applicant agreement to the terms and conditions identified on page 4 of this evaluation, the department determines that Capital project has met the need criteria in WAC 246-310-210 and the PCI methodology and standards in WAC 246-310-715(1) and (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 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 numeric method contained in the WAC 246-310-745(10). The methodology 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 current and 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[5]. Capital Medical Center is located in Olympia within Thurston County. Thurston County is included in Planning Area #6, which also includes the entire counties of Grays Harbor, Lewis, Mason, and Pacific. The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation is limited to Planning Area #6.

Capital is one of six hospitals operating in Planning Area #6. Of the six hospitals in the planning area; Providence is the only provider with an open heart program that can schedule elective PCI's. The six hospitals operating in Planning Area #6 and the corresponding number of elective PCI's performed by each hospital, if applicable, are listed in Table 1 on the following page.

[5] WAC 246-310-705

Table 1
Planning Area #6 Hospitals

Hospital	Elective PCIs provided	# of Elective PCIs performed[6]
Providence Centralia General Hospital	No	0
Capital Medical Center	No	0
Grays Harbor Community Hospital	No	0
Mason General Hospital	No	0
Providence St. Peter Hospital	Yes	975
Public Hospital District #3 Pacific County	No	0

Capital Medical Center

Capital followed the methodology as prescribed while relying upon use rates and population values calculated independently from the department's methodology. To establish the planning area use rate, Capital used 2008-2013 zip codes population estimates for portions of Thurston County. For Mason, Grays Harbor, and Pacific counties, Capital used the Department of Health Office of Financial Management population estimates and population data from Claritas, Inc. Capital projected that in year 2012 the number of residents in Planning Area #6 would be 409,968 and this number was used to project a 3.38 use rate for the planning area.

Using the planning area population use rate, Capital projected a forecasted demand of 1,384 and from this number, Capital deducted Providence St. Peter Hospital's 975 current capacity and this resulted in a demand of 409 additional PCI procedures for the residents of Planning Area #6. When the 409 additional PCI procedures is divided by 300, Capital's results show a need of 1.363, or one additional elective PCI program in the planning area. [Source: Application Pages 14-16]

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 age[7] by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

For PCI programs, 'base year' is defined as the most recent calendar year 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

[6] As reported on the Department of Health's 2007 PCI Utilization Survey conducted in 2008.
[7] Residents 15 years of age and older.

period. For this project, the first day of the application submission period was February 1, 2009. The base year data is year 2007.[8]

The Department used year 2007 PCI survey data and planning area population data obtained from the population forecast published by the Washington State Office of Financial Management (OFM) based on year 2000 census that was updated in November 2007[9]. The results produced a Planning Area #6 PCI use rate of 3.23 per 1,000 residents [3.23/1,000]; which is nearly equal to Capital's use rate of 3.38 per 1,000 residents [3.38/1,000].

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[10].

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 3.23 calculated in Step 1 with the OFM projected planning area population of 409,968. The results are 1,324,196.64. This number is then divided by 1,000, which produced a need for 1,324 procedures for PCI Planning Area #6 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.

This step requires computation of the planning area's available capacity. Providence is the only provider of elective PCI services in the planning area. According to the department's year 2007 PCI survey data, Providence St. Peter performed 975 PCI procedures that was applied as the current capacity in planning area #6.

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.

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

[9] County & Age Pop. Projections OFM Sept 2007 update, Released Nov. 2007

[10] Residents 15 years of age and older

A subtraction of 975 (current capacity from step 3) from 1,324 (projected need from step 2), results in a net need of 349 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 #6, this calculation is 409 / 300 resulting in a value of 1.363 when this number is rounded down per WAC 246-310-745; one additional program could be approved.

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 Medical Center (UWMC) program and how the hospital intends to meet the minimum number of procedures. The criteria and applicant's responses are addressed below.

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

In response to this sub-criterion, Capital provided a zip code listing documentation of planning area #6 residents who had PCI related services at UWMC. In addition, Capital stated,

> *"Further, and probably unique to our project, our affiliation with the UW will serve to strengthen its program as well. As a result of specific legislative intent, WAC 243-310-715 requires applicants for elective PCI programs to demonstrate that they will not reduce the interventional cardiology training volumes within the UW Academic Medical Center's fellowship program. Not only will we not reduce volumes, our proposed affiliation, over time, should result in increased cases from our service area being referred to them (as our cardiologist become more familiar with the UW's systems and they increasingly refer complex cases."*

[Source: Application, Page 47]

Additional information provided by Capital shows that in 2007, UWMC performed 20 PCI's on planning area #6 residents. The 20 PCI's performed by UWMC on planning area #6 residents, equates to about 2% of all PCI's performed by planning area #6 residents in 2007. Incorporated within it future PCI projections, Capital projected that the same number of patients will use UWMC in the future. To preserve UWMC current volumes, Capital deducted 20 or 2% PCI patients from it projections. Furthermore, in order to show that Capital intends to preserve UWMC volumes, an executed partnering agreement with UWMC was provided. The agreement states,

"By choosing to partner with UWMC, our goal is not only to protect the current referral pattern, but to also provide a South Sound location from which they can satellite. Our proposed relationship will afford and provide UWMC with the potential for new referrals and will provide support to Capital patients who require transfer for tertiary or quaternary care services available at UWMC."
[Source: Application, Page 25 and Supplemental Information received April 30, 2009, Attachment 7]

Department's Evaluation

Documentation provided by Capital demonstrates that UWMC performed a total of 20 PCI's on patients from Planning Area #6. In 2007, UWMC performed a total of 402 PCIs. Capital does not assert that 100% of its referrals would be recaptured if this project is approved, rather, Capital asserts that the referral patterns related to UWMC would not change, and UWMC would continue to receive patients from Capital. Public comments provided by UWMC include a letter dated July 10, 2009 from UWMC to Capital's Chief Executive Officer. The letter states,

"As we have discussed, we believe there may be opportunities for Capital Medical Center ("Capital") and University of Washington Medical Center ("UWMC") to collaborate in offering improved quality of, and access to, cardiac care. This proposed objective would have two objectives. First, it would serve to further our mutual goal of providing the best possible care to patients in the region. Second it would help mitigate the potential impact of an elective PCI program at Capital on the UW interventional cardiology fellowship, the only one in the WWAMI[11] *region."*

To ensure that any new PCI programs, including Capital, 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. [Source: University of Washington Medical Center public comment received July 15, 2009, Exhibit E]

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.

Capital Medical Center 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 Capital Medical Center in any one calendar year is 20.
3. The University of Washington Medical Center makes a written request to Capital Medical Center for patient referrals. The request must:

[11] WWAMI region includes the states of Washington, Wyoming, Alaska, Montana, and Idaho.

- include the number of patients residing in Capital Medical Center'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 (20) 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.

Capital provided a projection of the number of both emergent and elective PCI's it expected would be performed at the hospital from years 2010 through 2012. Detailed in the table below is the number of expected PCI's at Capital.

Table 2
2010-2012 Projected PCI Procedures for Capital Medical Center

Type of PCI	2010	2011	2012
Emergent	72	93	114
Elective/Scheduled	92	147	191
Total	**164**	**240**	**305**

Capital provided its methodology and assumptions used to project the PCI procedures in Table 2. The projections are based on the following four factors:

- Used the current and future total planning area PCI volumes directly from the department's methodology
- To ensure no harm to UWMC's training program, UWMC PCIs were "backed out" of the planning area totals before any projections were calculated;
- Baseline assumptions concerning Capital are based on actual CHARS data
- Growth in Capital's PCI volumes due to the new elective program is based on reasonable projections of annual incremental growth to Capital's current emergent market share

Below are the summaries of the many comments provided to the department by Providence St. Peter Hospital regarding Capital Medical Center proposed elective PCI program.

Provide St. Peter Hospital

- Capital fails to establish need for a new program in the planning area. Certificate of Need regulation for new elective PCI programs at hospital without on-site open heart surgery requires that applicant provide detailed analysis of its projected volumes and establish that it will perform a minimum of 300 adult PCI's per year by the end of the third year of operations.

- The forecast methodology when adjusted to reflect eligible patients shows insufficient planning area need. Capital's application as well as the stakeholder's consensus and the Society of Cardiac Angiography Interventions (SCAI) guidelines agree that certain types of patients and lesions that classify the complexity of a proposed PCI should only be treated at a hospital with on-site surgery.
- Providence commented that if one modifies the planning area use rate by adjusting out what they claim are patients not eligible for PCI at non-surgical hospitals, no need would exist in planning area #6.
- Capital cannot reach the minimum quality threshold of 300 PCI's by 2012. The department set the minimum threshold at 300 PCI's based on evidence in the HMA report and patient safety consideration that 300 PCI's annually is essential to assuring patient safety.

[Source: Public comments received on July 17, 2009]

Summarized below are the rebuttal comments provided by Capital in response to the comments made by Providence St Peter Hospital.

Capital's Response

Providence does not believe that there is a need for a second provider in planning area #6 and objects to a second program in Olympia. The need for a second elective PCI provider has been identified by the projection methodology set forth in WAC 246-310-745. The fact is that applications of numeric need methodology set in WAC 246-310-745 demonstrate that in 2012 the planning area residents will generate 1,384 PCI's. The identified net need is 409 cases or 1.363 additional elective programs in the planning area. Providence performed 975 cases in 2007 and in fact, is the 4th largest total volume PCI provider statewide. Capital's methodology and assumptions for projecting its PCI program volume are similar and in some cases identical to those used by other PCI CN applicants.

Without providing any data, assumptions or analysis, Providence states that if Capital is approved, no other provider can be approved before 2020. This is simply not true if one conservatively assume that Capital's projected 305 procedures in 2012 are achievable by treating only 155 or approximately 38% of the 409 projected net need in 2012. Additionally, by redistributing 150 PCI procedures currently performed at Providence, Capital's projected need is achievable, in addition to the remaining net need with ongoing population growth it's possible that an application would be submitted in the planning area by 2013. With regards to Capital cardiologist, Providence neglected to mention that, the three of the four physicians identified in Capital's application have their offices on Capital campus. The three physicians can and will perform the required number of PCI's to meet the volume standards. Consistent with Certificate of Need criteria, Capital has demonstrated that there is need, and its volume projections are reasonable, and that it will reach the minimum quality threshold of 300 PCI's by 2012.

Department's Evaluation

The projections in Table 2 show Capital's emergent PCI cases experiencing marginal growth, which appears to be reasonable. Capital primary source of reaching the required 300 minimum PCI's cases by year three for a new program is derived by adding elective procedures. During the review of this application, Providence claimed an affected party

status and submitted many comments to the department regarding Capital's application of the PCI need methodology.

Providence St. Peter Hospital asserted that the department's need methodology should be revised by discounting certain segments of the population in planning area #6 from the need methodology, the department declines to take that approach. The department notes that its PCI need methodology is in rule and therefore, should not be changed without going through the appropriate change process. Providence further asserted that planning area #6 would not show need until 2020 if Capital's project is approved. The department has not projected need past year 2012 and does not follow why this would be a reason to support the position that Capital has not demonstrated need.

Given that 1,324 PCI's cases were projected by the department PCI need methodology in planning area #6 by year 2012, the department recognizes that a second provider would be available to provide PCI services to the residents of the planning area. With regards to Capital's projected need, the department agrees with Capital that the PCI need methodology projects a need of 409 cases in year 2012. Furthermore, the department agrees that Capital's projections are reasonable and according to the information provided by Capital and the underlying assumptions used, the department concludes the projections appear achievable.

Based on the numeric methodology, a need for one additional PCI program in Planning Area #6 has been projected. In addition, Capital analysis of the potential effects upon UWMC training program, and the deduction of 20 PCI patients from year 2012 volumes appear to have adequately addressed this sub-criterion. This sub-criterion has been met.

(2) <u>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.</u>

To demonstrate compliance with this sub-criterion, Capital provided a copy of its current Admission Policy. The policy outlines the process/criteria that Capital uses to admit patients for treatment or care at the hospital. The policy also states that any patient requiring care is accepted for treatment at Capital without regard to gender, age, disability, race, ethnicity, religion or source of payment. This policy is consistent with Certificate of Need requirements. [Source: Application, Exhibit 1]

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.

Capital 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 by Capital identifies the facility's financial statements as including both Medicare and Medicaid revenues. [Source: Application, Exhibit 1]

To show that Capital would provide charity care, the applicant provided its current charity care policy. The policy describes the process Capital will follow if a patient requests charity [Source: Application, Exhibit 1, Page 53]

During the review of this application, the department received comments from Providence St. Peter Hospital regarding Capital's ability to provide adequate charity for the residents in the planning area #6. Below is a summary of the comments provided by Providence St. Peter Hospital.

Providence St. Peter Hospital comment

For over 120 years, St. Peter Hospital has served the residents of Olympia and the surrounding region and carried out its mission to provide care for all regardless of ability to pay. As a not-for-profit hospital, St. Peter Hospital invests its net revenue into services for the community. In 2008, St. Peter Hospital provided nearly $34 million in charity care (charges) and more than $17.8 million in the community benefit other than charity care. These programs serve and are highly used by the uninsured and underinsured and are supported through programs like PCI and other cardiac care that generate a positive margin. In contrast, Capital is a for-profit hospital that distributes profits to its private equity fund investors.

Capital is an affiliate of Capella Healthcare, which is backed by one of the world's largest private equity firms; Chicago based Golder Rauner, LLC. The stated goal of GTCR Golder Rauner is to create substantial value for [its] investors management partners. In 2008, Capital provided only $207,000 in charity care, or 0.10 percent of gross revenue, which it acknowledges is less than the regional average. [Source: Public comment received July 17, 2009, Page 2 and 3]

Below is the rebuttal comment provided to the department by Capital in response to Providence St. Peter Hospital comments.

Capital's Response

Providence appears to be questioning the ability of a for profit hospital to meet its charity care obligation. Capital is required, as are all hospitals in Washington regardless of whether they are for-profit or nonprofit; to adopt and implement a Department of Health approved charity care policy. Capital has done so. Capital is not publicly traded (as Providence alludes). The fact is, that one of Capella owners, GTCR Rauner (GTCR) is one of the nation's leading investment firms. Despite the fact that Capital's charity is below the regional average, our charity care policy and practices are consistent with the requirements in Washington State regulations and statues; we operate with a Department-approved charity care plan and to our knowledge have never turned away qualified patients in need. Our charity care income guidelines meet and in some instances exceed, the Washington State Hospital Association's voluntary guidelines for members establish in 2007.

In every past CN decision that Capital has reviewed, if an applicant has historically, provided charity care at less than the regional average, and if the department otherwise finds the application consistent with applicable CN review, the department has simply placed a condition on the certificate of need requiring that the applicant agree to provide charity care

in compliance with the policies outlines in its CN. Capital assumes such condition will be placed on its certificate of need, and is fully amenable to such. [Source: Rebuttal comments received on August 17, 2009, Pages 26-27]

Department's Evaluation

Capital provided its current charity care policy that describes the process used to determine a patient's eligibility for charity care. Additionally, Capital included a 'charity care' line item as deduction from both its PCI project specific and the hospital aggregate with the project revenue and expense statements. [Source: Supplemental Information, received April 30, 2009, Attachment 1] In its application Capital states:

> *"Capital is committed to providing health care services to all individuals based on need: we prohibit discrimination on basis of income, race, ethnicity, sex, or handicap...while we believe that Capital's actual charity care is higher than reported (because we may have miscategorized some charity care as bad debt), we do acknowledge that our charity care has been less than the regional average. Capital's percentage of charity care included in our pro-forma financials for this project is higher than the Southwest Washington region."* [Source: Application, Page 26]

The charity care policy provided within the application is not the same as the approved version the department has on file[12]. Therefore, if this project is approved, a term would be added requiring Capital submit to the Certificate of Need program a finalized charity care policy approved by Department's Hospital and Patient Data Systems program.

Capital makes the argument within its application that its charity care level for the PCI only financial projections are higher than the regional average. Whether or not the PCI only charity care numbers are above or below the regional average is not applicable to the department's evaluation of Capital's charity care levels. A hospital's charity care levels are evaluated for the hospital as a whole. 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 Thurston County, Capital Medical Center is one of 14 hospitals in the Southwest Region. According to the 2005-2007[13] charity care data obtained from HPDS, Capital has historically provided significantly less than the average charity care provided in the region. Capital's most recent (2007) percentages of charity care for gross and adjusted revenues is 0.26% and 0.81%, respectively. For the Southwest Region, the 2007 charity care average is 2.74% for gross revenue and 6.16% for adjusted revenue. [Source: HPDS 2005-2007 charity care summaries] The department's review of Capital's pro forma revenue and expense statement shows that the hospital will provide charity care at approximately 0.32% of total revenue and 0.57% of adjusted revenue. [Source: Supplemental Information received April 30, 2009, Attachment 1]

Therefore, the department agrees with Providence's comment that Capital has historically provided charity care that is below the regional average. As was stated earlier, Capital agrees that as a whole it has not been providing the regional average. Therefore, if this project is approved the following condition would be necessary:

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[12] Source: http://www.doh.wa.gov/EHSPHL/hospdata/CharityCare/CharityPolicies/Default.htm

[13] Year 2008 charity care data is not available as of the writing of this evaluation.

> Capital Medical Center will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Capital Medical Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the regional average amount of charity care provided by hospitals in the Southwest Washington Region. Currently, this amount is 2.74% of gross revenue and 6.16% of adjusted revenue. Capital Medical Center will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.

With agreement to the terms and conditions on pages 4 and 5, 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) <u>The immediate and long-range capital and operating costs of the project can be met.</u>

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

To demonstrate compliance with this sub-criterion, Capital provided its Statement of Revenue and Expense for the PCI cost center only for year 2010 through 2012. [Source: Supplemental Information received April 30, 2009, Page 11, Attachment 1] Capital states that because the department did not ask for an existing cardiac catheterization laboratory cost center, it interpreted the application form guidelines to mean that for the PCI project specific financial statements, the department was only interested in new incremental PCI volume, revenues and expenses and not the expenses associated with Capital's current catheterization laboratory. [Source: Rebuttal comment received August 17, 2009, Page 29] A summary of the incremental Statement of Revenue and Expense for the PCI cost center only is shown in Table 3 on the following page.

Table 3
Capital's Incremental PCI Project Specific Revenue and Expense Statement
Years 2010 through 2012

	Projected Year 1 (2010)	**Projected Year 2 (2011)**	**Projected Year 3 (2012)**
Net Patient Revenue	$596,294	$1,005,734	$1,362,852
Total Operating Revenue	$519,915	$827,065	$1,100,962
Net Revenue Expense	**$76,379**	**$178,669**	**$261,890**

Currently Capital provides emergent PCI services therefore, year 2009 cost center financial information was provided with the hospital aggregate Revenue and Expense Statement without the project. As stated before, Table 3 above reflects the incremental increases in PCIs projected by Capital as summarized in Table 2 of this evaluation. As shown in Table 3, Capital's PCI project specific cost center is projected to be profitable starting from years 2010 through 2012. [Source: Supplemental Information received April 30, 2009, Page 11, Attachment 1] Summarized in Table 4, is Capital's entire hospital projected revenue and expenses statement from years 2009 through 2012.

Table 4
Capital Hospital Aggregate Revenue and Expenses Statement
Years 2009 - 2012

	Current Year 2009	**Projected Year 1 (2010)**	**Projected Year 2 (2011)**	**Projected Year 3 (2012)**
Patient Services Revenue	$235,149,794	$250,112,470	$267,355,184	$288,093,878
Total Deduction From Revenue	$159,040,008	$169,600,900	$181,639,258	$196,091,121
Other Operating Revenue	$201,588	$211,667	$224,367	$240,073
Total Operating Revenue	$76,311,374	$80,723,237	$85,940,293	$92,242,830
Total Operating Expense	$65,723,799	$69,476,827	$73,853,493	$79,190,099
Net Operating Revenue	**$10,587,575**	**$11,246,409**	**$12,086,799**	**$13,052,730**

As shown in Table 4 above, the hospital as a whole is profitable in 2009 and also projected to be profitable from years 2010 through 2012 with the addition of elective PCI program. To determine whether Capital would meet its immediate and long range capital costs with an elective PCI program, the applicant provided current balance sheet and its projected hospital balance sheet for years 2010 through 2012. The department's Hospital and Patient Data Systems (HPDS) reviewed the aggregate balance sheet provided by Capital for current year 2009 and year projected years 2010 to 2012 shown in Tables 5A and 5B on the following page. [Source: Supplemental Information received April 30, 2009, Page 15, Attachment 1]

Table 5A
Capital's Aggregate Balance Sheet for Year 2009

Assets		**Liabilities**	
Current	$15,549,999	Current	$4,602,369
Board Designated	-	Deferred Credits	$1,993,211
Property/Plant/Equip.	$38,814,410	Long Term Debt	$32,346,064
Other	$614,704	Other	-
Tangible	$1,840,794	Equity	$17,878,263
Total	**$56,819,907**	**Total**	**$56,819,907**

Table 5B
Capital's Aggregate Balance Sheet for Projected Year 2012

Assets		**Liabilities**	
Current	$15,549,999	Current	$4,602,369
Board Designated	-	Deferred Credits	$1,993,211
Property/Plant/Equip.	$43,518,540	Long Term Debt	$19,286,416
Other	$614,704	Other	-
Tangible	$1,840,794	Equity	$35,642,041
Total	**$61,524,037**	**Total**	**$61,524,037**

To assist the department in its evaluation whether the immediate and long-range and operating costs of the project can be met, 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 compares the projected ratios with the most recent year's financial ratio guidelines for hospital operations. For this project, HPDS used year 2007 data for comparison. The ratio comparisons are shown in Table 6 on the following page. [Source: HPDS analysis September 11, 2009, Page 3]

Table 6
Capital's Current and Projected Debt Ratios by HPDS

Category	Trend[14]	State 2007	Current 2008	Projected 2010	Projected 2011	Projected 2012
Long Term Debt to Equity	B	0.532	2.419	1.108	0.766	0.541
Current Assets/Current Liabilities	A	2.136	2.872	3.379	3.379	3.379
Assets Funded by Liabilities	B	0.422	0.728	0.545	0.465	0.388
Debt Service Coverage	A	6.169	3.483	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 Services Coverage	Net Profit+Depr and Interest Exp/Current Mat. LTD and Interest Exp.

Comparing Capital's most current (2008) ratios with the statewide ratios revealed that Capital is outside the normal range in all except the current assets to current liabilities ratio. The ratios outside the normal range reflect any construction, remodel, or upgrade projects that have occurred at the hospital. Capital recently upgraded its catheterization laboratory equipment within the most recent years, which is demonstrated in the ratios.

After evaluating the hospital's projected ratio's for years 2010-2012, staff from HPDS provided the following analysis. [Source: HPDS analysis, September 11, 2009, Page 2]

> *"The financial ratios for year 3 [2012] are for the project only and show a profit in the third year. Capital did generate a positive net income in 2008 and is improving its financial status [shown in quarterly 2009 data]. The applicant has reserves to sustain this project. The project, when fully implemented, will improve the financial standing of Capital."*

HPDS also compared Capital's operating expense to operating revenue ratio for the PCI project only. Capital projects that its operating revenues will exceed its operating expenses for the hospital PCI project. This is demonstrated by Capitals revenue to expense ratios of 0.901, 0.872, and 0.822 for years 2010, 2011, and 2012, respectively. [Source: HPDS analysis September 11, 2009, Page 2]

During the review of this application, Providence St. Peter Hospital provided comments to the department regarding Capital's financial feasibility below are the comments.

Providence St. Peter Hospital Comments

Provide St. Peter Hospital provided many comments to the department regarding Capital's financial feasibility. The department summarized those comments in order to allow for a coherent reading of the evaluation and the comments. Summarized below are Providence St. Peter Hospital comments.

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

- Capital's proposed program is not financially feasible the PCI regulations expressly include the certificate of need standards relating to financial feasibility set forth in WAC 246-310-220 and WAC 246-310-700. This regulation require the Department to determine whether a proposed project is financially feasible...Capitals pro-forma financial forecast contains several errors and makes evaluation of the proposed project very difficult.
- Capital's proposed project is not financially feasible on a hospital-wide basis if Capital provides the amount of charity care it asserts it will provide at the level it projects in its application or at the regional average. The surprising results is that if capital is to provide charity care at anything greater than 0.95% of its gross revenue...Capital would operate at a net loss.
- Capital's projected wages and salary expenses are unrealistically low and do not accurately reflect the actual cost of staffing a cardiac catheterization lab. Further, Capital did not include depreciation cost in its pro-forma financial statements.
- Payer mix is another key determinant of financial performance...Capital projected payer mix in 2012 for Medicare and Medicaid is inconsistent with both its current PCI payer mix and current pay mix across all inpatient services in planning area #6.
- Capital projected bad debt at 2.3 percent of gross revenue and in screening responses projected a bad debt forecast of 0.48 percent which is nearly 80 percent less than the Washington State average .[Source: Public comment received July 17, 2009, Pages 34-37]

Below is the rebuttal comments provided to the department by Capital in response to the many comments made by Providence St. Peter Hospital.

Capital's Response

Providence erroneously concludes that Capital's elective PCI costs are significantly understated. They made this determination by evaluating only our incremental costs (costs associated with adding the elective program). The Department's PCI CN application form/guidelines identified three financial cost centers that applicant's need to include within their application—PCI project specific, Hospital aggregate without PCI project specific and Hospital aggregate with PCI project specific.

So despite Providence claims, 100% of the costs of our cardiac catheterization cost center were included in our submittal, they were simply reported in aggregate with the rest of the hospital. The same is true of depreciation. Providence argued that Capital did not include existing depreciation of the catheterization laboratory within its PCI project specific statement. Again, Capital provided an incremental revenue and expenses statement for a project that happens to have no incremental capital costs (hence no new incremental depreciation). [Source: Rebuttal comments received August 17, 2009, Pages 30 and 31]

Below is the department's response to public comments provided by Providence and Capital's rebuttal response.

Department's Evaluation.

The department notes that HPDS review of Capital's Revenue and Expense Statements either at the cost center level (PCI project specific and hospital aggregate with the project) did not

show inconsistency or error's as asserted by Providence St. Peter Hospital. In its analysis, HPDS states,

> *"In reviewing PCI procedures in the 2008 Comprehensive Hospital Abstract Reporting System (CHARS) we noted some variation among hospitals regarding billed charges based on the healthcare common procedure coding system (HCPCS). We also reviewed the 0481 Cardiac Catheterization Lab cost center in 2008 CHARS and that review also shows that there are variations among hospitals in the category. However, in both instances the variation is not extremely large since the financial database does not have a cost center that is exclusive to cardiac catheterization. The project costs to the patient and community appears to be similar to current providers."*

[Source: HPDS analysis, September 11, 2009, Page 3]

HPDS analysis of Capital's financial, stated that the hospital has a poorer than average showing on three of the five financial ratios that the Certificate of Need usually uses in its analysis. However, HPDS stated that Capital generated a positive net income in 2008 and is improving its financial status. HPDS concluded that Capital has the reserves to sustain the project since there are no capital expenditures associated with this project and its analysis did not discuss Capital's corporate parent (Capella Healthcare) assets. HPDS noted that Capital has adequate resources to initiate this project and in summary states, *"The project, when fully implemented will improve the financial standing of Capital"*. [Source: HPDS analysis, September 11, 2009, Page 3]

The department agrees with HPDS analysis of Capital's revenue and expense statements and noted the applicant stated that for its PCI specific financial statement, it only included the incremental cost needed to add an elective PCI program. Further, the department also notes that Capital stated that it will not incur any depreciate cost and capital expenditure for this project, because those costs are already included in its overall hospital wide revenue and expense statements. Therefore, the department notes that deprecation cost, capital expenditure, bad debt and other costs alluded to by Providence St. Peter Hospital, are already included in Capital's aggregated revenue and expense financial statement. Additionally, the department notes that Capital provided a project specific and an aggregated hospital wide revenue and expense statements which HPDS reviewed. Based on the information above, the department concludes that the immediate and long-range operating costs of the project can be met. This sub-criterion is met.

(2) <u>*The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.*</u>

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

Capital proposes to begin providing elective PCI services in January 2010 and states there is no capital expenditure associated with this project. [Source: Application, Page 11] Based on the

source information reviewed, the department concludes that since there is no capital expenditure associated with this project, the project will probably not result in an unreasonable impact on the costs and charges for health services within the service area. This sub-criterion is met.

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

Within the application, Capital stated it recently renovated its existing cardiac catheterization laboratory and also upgraded the lab equipment's. Capital asserted that the expenditure associated with the cardiac catheterization laboratory renovation project would have occurred regardless of the outcome of this elective PCI project. Capital states that it spent $1.2 million dollars to replace and upgrade the lab equipments. The department notes Capital disclosed within its application, that in 2008, it upgraded the hospital cardiac catheterization laboratory and replaced some equipments and that project was completed before submitting application to add an elective PCI program. [Source: Application, footnote #1, Page 11]

The department therefore think the $1.2 million dollars already spent for equipment and the cardiac catheterization laboratory upgrade are reflected in Capital's hospital wide aggregated revenue and expense balance sheet which that was reviewed in previous sub-criterion's related to this evaluation. Therefore, since Capital did not state a capital expenditure, the department did not review a capital expenditure directly related to this project. This sub-criterion is met.

C. **Structure and Process (Quality) of Care (WAC 246-310-230), General (PCI Program) Requirements (WAC 246-310-715(3), (4), and (5); Physician Volume Standards (WAC 246-310-725; Staffing Requirements (WAC 246-310-730); Partnering Agreements (WAC 246-310-735) and Quality Assurance (WAC 246-310- 740)**

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

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

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

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

To demonstrate compliance with this sub-criterion, Capital stated that since it already provides both diagnostic and emergent PCIs, the majority of the nursing and technical staff required for elective procedures is already in place. Within its application, Capital stated that it currently has four cardiologists, 2.3 registered nurses and 4.1 catheterization laboratory technicians in house. Capital provided both the current and projected nursing and technical staffs for the emergent and elective PCI program. Shown in the table below is Capital's staffing plan.

Table 7
Capital Medical Center
Current Year (2009) and Projected FTEs

Staff/FTEs	Current Year	Partial Year 2009	Year 1	Year 2	Year 3	Total
Registered Nurses	2.3	0	0.75	0.25	0	3.3
Catha Lab/ Techs	4.1	0	0.75	0	0.25	5.1
Total FTE	**6.4**	**6.4**	**7.9**	**8.15**	**8.4**	**8.4**

In addition to the number of staff identified above, Capital stated it has interventional radiology laboratory staffs that are available to help cover the elective PCI program when needed. Further, Capital stated it would use its day shift staffs to address the additional volume expected. This sub-criterion also requires the applicant to demonstrate within its plan that its staff recruitment will not negatively affect existing providers in the planning area. For planning area #6, Providence St. Peter Hospital is the only existing elective PCI provider located in the planning area and according to the staffing plan provided by Capital, it does not appear that its recruitment plan will impact the healthcare services providers in the planning area. [Source: Application, Page 33 and Supplement Information received April 30, 2009, Page 10]

Public comments provided by Providence St. Peter Hospital regarding Capitals staffing plan stated that Capital failed to meet its burden of showing it will effectively recruit staff. Summarized below is the rebuttal comments provide by Capital in response to Providence concerns.

Capital's Response

Capital in its application, set forth a staffing plan that ensure the highest quality and efficiency in PCI staffing with the least impact of staffing for other providers. Capital already has a staffed catheterization lab the addition of elective PCI program will only require slight additional staffing and it will maximize the efficiency of exiting staff. [Source: Rebuttal comment received August 14, 2009, Page 19]

Department's Evaluation

Within its application, Capital stated that as a current provider of both diagnostic and emergent PCI's the majority of the nursing and technical staffs required for elective procedures are already in place. Capital also stated that it currently has four cardiologists, 2.3 registered nurses and 4.1 catheterization laboratory technicians in-house providing emergent PCI services.

Since the department does not have a minimum number of clinicians that are required to provide services, the department would reply on the applicant experience and better judgment in staffing critical services provided at the facility. Given that Capital currently provides emergent PCIs, the department agrees with the staffing plan proposed by Capital. Based on the documentation provided, the department concludes that Capital has demonstrated that it has, or can recruit all staff necessary to operate the program. This sub-criterion is met.

WAC 246-310-715(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, life sustaining apparati, intra-aortic balloon pump assist device (IABP). The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.

Capital currently provides emergency PCI procedures and recently upgraded its cardiac catheterization laboratory with new equipments. As a comprehensive acute care facility, Capital has a mixed-use diagnostic catheterization laboratory operating with an existing credentialed staffs. Information within Capital's application states that another laboratory is being proposed, but did not elaborate on when that proposed lab will be available for use. Supplemental information by Capital during the application screening provides a listing of its cat-lab equipments. [Source: Application, Page 34 and Supplemental Information received April 30, 2009]

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.

Capital currently provides emergency PCI twenty-four hours per day and seven days a week. Within the application, Capital anticipates that it would have additional staff available by using on-call staffs and increasing part-time staffs workload. [Application, Page 34] Based on source information reviewed, 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.

Capital identified four interventional cardiologists as active staff at the hospital. Of the four interventional cardiologists identified, three currently performs emergency PCI's at Capital and the same three physicians also provide elective PCI's at Providence. The four interventional cardiologists are Phillip Berger, MD, Harton S. Smith, MD, Jimmy Z. Swain, MD and John W. Waggoner, MD.

The department verified through CHARS data and by third party documentation provided by Capital that three of the four interventional cardiologists (with the exception of Harton S. Smith) provided the required minimum number of PCI procedures per year, for the pervious three years prior to Capital's application. [Source: Application, Page 38 and Supplemental Information received April 30, 2009, Attachments 5 and 6]

The documentation provided by Capital demonstrates that the three elective cardiologists identified above, met the standard of providing 75 PCIs per year for the most recent three years. One emergent only cardiologist (Harton S. Smith) does not meet this standard; however, the standard states that physicians performing adult elective PCI procedures must demonstrate 75 procedures per year for the previous three years. The plain reading of the rule suggests that physicians performing emergent PCIs are not required to meet the 75 historical PCI standards. Based on the information above, the department concludes that this sub-criterion is met.

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

Capital identified four interventional cardiologists that would be available to perform PCI procedures at the hospital. Of the four physicians identified, three physicians are credentialed by the hospital to perform both electives and emergency PCI's and one physician (Harton S. Smith) would perform only emergency PCI's at the hospital upon CN approval. [Source: Application, Page 37]

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*

Capital currently provides emergent PCIs and would use the same nursing and technical staff for its elective program. Capital states that it catheterization laboratory nurses are credentialed and have demonstrated balloon pump competency and the credentialing status of the nurse's entails they have training in performing endotracheal intubation and ventilator management. Capital stated that any additional nursing or technical staff assigned to its PCI program in the future will be required to demonstrate competencies in PCI related technologies and have direct coronary care, critical care or equivalent experience. Capital states that it does not reply on the catheterization laboratory staffs to perform emergent PCI procedures rather it relies on its 24/7 in-house board certified emergency room physicians and respiratory therapist to respond immediately when needed. Patients needing ventilator management during transfers are accompanied by qualified trained staffs. [Source: Application, Pages 35 and 36]

(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, Capital 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 Capital provided a copy of its executed Partnering Agreement with UWMC. The agreement identifies UWMC as the primary hospital for PCI patients requiring a transfer from Capital. The agreement outlines the roles and responsibilities of Capital when transferring patients and the expectations of UWMC when receiving patients from Capital. Capital states, *"Partnering with an institution of this magnitude that also includes the Regional Heart Center, the UW's comprehensive integrated delivery system for all aspects of cardiovascular care—including PCI, cardiac surgery, and treatment for advance heart failure—will ensure Capital's elective PCI program and overall cardiology program are of the utmost quality"*. [Source: Application, page 40 and Supplemental Information received April 30, 2009, Attachment 7]

Based on the review of the "Partnering Agreement" with UWMC, 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.

In response to this sub-criterion, the applicant provided a copy of an executed Partnering Agreement with UWMC to show that it met this standard. In summary the agreement states *"UWMC shall serve as Transferring Facility's back up cardiac surgery hospital, providing cardiac surgery during all hours that elective PCIs are being performed at Transferring Facility"*. In addition, the agreement outlines the roles and responsibilities of Capital when transferring patients to UWMC. The executed agreement ensures that planning area #6 patients in need of PCI have access to cardiac surgery services at UWMC. [Source: Application, page 40 and Supplemental Information received April 30, 2009, Page 39, Attachment 7]

Based on the review of the "Partnering Agreement" with UWMC, 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.

In response to this sub-criterion, the applicant provided a copy of an executed Partnering Agreement with UWMC. The agreement states, *"Transferring Facility will transfer all clinical data, including images and videos, with the patient to UWMC. Additionally, a signed*

transfer memorandum (Exhibit A) must accompany the patient". In summary, the executed agreement ensures that planning area #6 patients in need of emergent PCI have access to cardiac surgery services at UWMC. [Source: Supplemental Information received April 30, 2009, Page 39, Attachment 7] Based on the review of the "Partnering Agreement" with UWMC, 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.
In response to this sub-criterion, the Capital provided a copy of its executed Partnering Agreement with UWMC. The partnering agreement states, *"The physician at the Transferring Facility shall immediately notify the cardiac surgeon(s) at UWMC regarding the clinical reasons for urgent transfer and the patient's clinical condition"*. [Source: Supplemental Information received April 30, 2009, Page 39, Attachment 7] Additionally, Capital states, *"Partnering with an institution of this magnitude that also includes the Regional Heart Center, and the UW's comprehensive integrated delivery system for all aspects of cardiovascular care—including PCI, cardiac surgery, and the treatment for advance heart failure—will ensure Capital's elective PCI program and its overall cardiology program is of the utmost quality"*. [Source: Application, Page 40]

Based on the review of the "Partnering Agreement" with UWMC, 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.*
In response to this sub-criterion, the Capital provided a copy of an executed Partnering Agreement with UWMC. The agreement states *"UWMC shall serve as the Transferring Facility's back up cardiac surgery hospital, providing cardiac surgery during all hours that elective PCIs are being performed at the Transferring Facility"*. [Source: Supplemental Information received April 30, 2009, Page 39-40, Attachment 7]

Further, the agreement outlines the roles and responsibilities of Capital when transferring patients and the expectations of UWMC when receiving patients from Capital. Based on the review of Capital's "Partnering Agreement" with UWMC, the 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.
In response to this sub-criterion, Capital provided copies of its executed agreements with American Medical Response (AMR) and Airlift Northwest. In parts the agreement with Airlift Northwest states, "*...Facilitates by air or by ground (as available) the expeditious transfer of patients who experience complications during emergent and elective PCI*

procedures and require transfer from CMC to the University of Washington Medical Center (UWMC) or other hospital with on-site cardiac surgery...". [Source: Supplemental Information received April 30, 2009, Page 48, Attachment 9]

Additionally, the agreements outline the roles and responsibilities of Capital, AMR and Airlift Northwest when transferring patients to UWMC. Based on the review of Capital's "Transportation Agreement" with AMR and Airlift Northwest, the department concludes the agreements satisfy 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.

In response to this sub-criterion, Capital provided copies of its executed agreements with American Medical Response (AMR) and Airlift Northwest. The agreements outline the roles and responsibilities of Capital, AMR and Airlift Northwest when transferring patients to UWMC. Specifically, the agreement with AMR states that all transportation to UWMC will be accomplished in 100 minutes or less. Additional supplemental information provided by Capital to the department states, *"To ensure that the total time from identification of a complication to arrival in the operating room is less than 120 minutes, Capital is committed to beginning emergency transportation within 20 minutes of the identification of a complication"* [Source: Application, page 42] In addition, Capital's agreement Airlift Northwest states in parts, "*...Contractor agrees to provide emergency transportation as available to CMC. CMC will notify Contractor of the need for such services within twenty (20) minutes or less of the initial identification of a complication during an elective percutaneous coronary intervention (PCI)...*" [Source: Supplemental Information received April 30, 2009, Attachment 9, Page 48]

Based on the review of the "Partnering Agreement" with UWMC, 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 American Medical Response (AMR) and Airlift Northwest, the department concludes the agreements 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).

Information included in the partnering agreement with UWMC and the transfer agreement with Airlift Northwest indicates that staff who are Advance Cardiac Life Support (ACLS) credentialed will be part of the hospital personnel that would transfer patients.

Capital's transfer agreement with Airlift Northwest states,

> *"During emergency transport, all staff will be cardiac life support certified (ACLS) and have the skills and experience needed to monitor and treat the patient en route. If the Contractor's staff is unavailable, a critical care team ambulance will transport the patient."*

[Source: Supplemental Information received April 30, 2009, Attachment 9, Page 48]

In addition to the ACLS credentialed staff reference in the agreement, with the application, Capital states it would also make available respiratory therapy staff that will monitor the patient and manage the intra-aortic balloon pump during transfer's en-route to UWMC. [Source: Application, Page 42]

Based on the review of the "Partnering Agreement" with UWMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(8). Based on the review of the "Transfer Agreement" with Airlift Northwest 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.

In response to this sub-criterion, Capital provided a copy of its executed agreements with American Medical Response (AMR) and Airlift Northwest. Both agreements outline the roles and responsibilities of Capital, AMR and Airlift Northwest when transferring patients to UWMC. Capital's agreement with Airlift Northwest states all transportation to UWMC will be accomplished in 100 minutes or less. Information provided to the department by Capital states, *"To ensure that the total time from identification of a complication to arrival in the operating room is less than 120 minutes, Capital is committed to beginning emergency transportation within 20 minutes of the identification of a complication."*
[Source: Supplemental Information received April 30, 2009, Page 6]

Further Capital's agreement with Airlift Northwest states in parts, *"...Contractor agrees to make every attempt to meet the requirement that total time from the decision to transfer the patient to patients arrival in the operating room of the backup hospital is less than one hundred and twenty (120) minutes...The parties agrees to meet or exceed transportation time, from the notification of the need to transport to the arrival in the operating room at UWMC or other hospital with on-site cardiac surgery, in 120 minutes or less. The parties additionally will cooperate to document the actual time of each case..."*
[Source: Supplemental Information received April 30, 2009, Attachement9, Page 48]

Based on the review of the "Partnering Agreement" with UWMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(9). Based on the review of the "Transfer Agreement" with American Medical Response (AMR) and Airlift Northwest, the department concludes both agreements 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.

In response to this sub-criterion, Capital provided a copy of its executed agreement with American Medical Response (AMR) and Airlift Northwest. The agreement outlines the roles and responsibilities of Capital, AMR and Airlift Northwest when transferring patients to UWMC.

Specifically the agreement with Airlift Northwest states, "*The parties agrees to participate in at least two emergency transportation drills annually to ensure the timelines and processes referenced within the agreement continue to be met. The outcomes of the drills will be reported to CMC's quality assurance director"*. [Source: Supplemental Information received April 30, 2009, Attachment 10, Page 48]

Based on the review of the "Partnering Agreement" with UWMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(10). Based on the review of the "Transfer Agreement" with American Medical Response (AMR) and Airlift Northwest, 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

In response to this sub-criterion, Capital provided a copy of its "Patient Consent Form" that would be provided to patients seeking PCI care at the hospital. Capital's patient consent form, is also known as the *"Consent for Cardiovascular Invasive or Interventional Procedure and Sedation if Applicable"* and it provides the outlines for catheterization procedure and the relative risks related to PCI procedures. The Consent for Cardiovascular Invasive or Interventional Procedure and Sedation if Applicable document includes information regarding patients transfer policy and the associated risks. [Source: Supplemental Information received April 30, 2009, Attachment 3]

Based on the review of the "Patient Consent Form" specific to cardiac catheterization and angiography, the department concludes Capital's Consent for Cardiovascular Invasive or Interventional Procedure and Sedation if Applicable satisfies the standard and requirement under WAC 246-310-735(11). 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.

In response to this sub-criterion, Capital states its PCI quality assessment team including representatives from UWMC will participate in quarterly meetings and would prepare written reports. These reports would include the results of all performance monitoring activities and it will be forwarded to Capital board of trustees to resolve any identified problems. The final reports from the board of trustee will be reviewed according to Capital's Practitioner Peer Review Policy and written report including all findings, data and performance improvement activities from all quality assessments meetings would recorded. [Source: Application, Page 45]

Based on the review of the draft "Quality Assurance/Quality Improvement Plan the department concludes the draft plan satisfies the standards and requirements under WAC 246-310-735(12). 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 Quality

Assurance/Quality Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be met.

WAC 243-310-735(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, Capital provided a copy of an executed Partnering Agreement with UWMC. The agreement states that the back-up facility will provide cardiac surgery during all hours that elective PCIs are being performed at the transferring facility and it identifies the roles and responsibility of both Capital and UWMC in addressing peak volume periods and the capacity to temporarily increase staffing. [Source: Supplemental Information received April 30, 2009, Attachment 7]

Based on the review of the "Partnering Agreement" with UWMC, the department concludes the agreement satisfies the standards and requirements under WAC 246-310-735(13). This sub-criterion is met.

In summary, the documents identified above meet the standards and the requirements outlined in WAC 246-310-735(1)-(13). However, since one of the documents was submitted as a draft, the department would attach a term to this approval requiring Capital to provide the final document for review and approval. With Capital's agreement to the term above, 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.
Capital will continue to provide Medicare and Medicaid services to the residents of planning area #6. Quality of care history for Capital is verified through the Department of Health's Investigations and Inspections Office (IIO). For the most recent three years, IIO completed three quality of care and fire life safety surveys at the hospital and one survey for the Clinic at Elma owned and/or operated by Capital[15]. There were no adverse licensing actions as a result of these surveys. [Source: facility survey data provided by DOH Investigations and Inspections Office]

As stated earlier, Capital is owned by Capella Healthcare a physician management group entity located in the State of Tennessee. Capella Healthcare also own or operates healthcare facilities in the following states Alabama, Arkansas, Missouri, Oklahoma and Oregon. [Source: Application, Appendix 1] 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[16]. To accomplish this task, in March 2009 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for surveying the healthcare facilities where Capella Healthcare or any of its subsidiaries has health care facilities. Of the 6 states, the department received responses from 5 states or 83% of the 6 states. The State of Alabama did not provide a response therefore; the compliance history of that state is unknown.

[15] Surveys completed May 2005, December 2006 and October 2008. The Clinic at Elma was surveyed May 2007.
[16] WAC 246-310-230(5).

The 5 states responding to survey indicated that significant or minor non-compliance deficiencies had been cited at the healthcare facilities operated or owned by Capella Healthcare within the past three years. None of the deficiencies resulted in fines or enforcement action and those facilities were reported as currently in compliance with applicable regulations. Given that the out-of state quality of care survey's provided to the department did not indicate any significant deficiencies the department is satisfied that Capital and its parent entity Capella Healthcare has demonstrated compliance. Therefore, the department concludes the out-of-state compliance surveys are acceptable. Information provided by Capital indicated that currently, there are five cardiologists within its active medical staff.

As of February 2009, when this application was submitted, only four physicians are identified by the hospital as credentialed to perform. Capital provided the professional license number for each of the physicians to assist the department in its quality of care review. [Source: Application, Page 8]

Quality of care for Capital'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 all medical staff associated with Capital's emergent PCI and proposed elective PCI program reveals no recorded sanctions for all. [Source: compliance history provided by Medical Quality Assurance Commission]

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

WAC 246- 310-740(1) A process for ongoing review of the outcomes of adult elective WAC 246-310 PCI's. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.

Capital responses to this sub-criterion states that it currently participates in the Washington State Clinical Outcomes Assessment Program (COAP) and scheduled or elective PCIs performed at the hospital would be benchmarked against statewide outcome data. Capital would also establish a quality of care joint case review meeting between the hospital and University of Washington. Capital stated that it has adopted an organizational wide Quality/Risk Management and Performance Improvement Plans (PIP) that would be used in systems performance and improvement. Capital provided the PIP plan documentation with its application. [Application, Page 44, Exhibit 6]

Based on the review of the draft "Quality Assurance/Quality Improvement Plan," the department concludes the draft plan satisfies the standards and requirements under WAC 246-310-740(1). 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 Quality Assurance/Quality Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be met

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

In response to the sub-criteria, Capital states that its cardiologist will use the Society for Cardiac Angiography Interventions (SCAI) guidelines for patient lesion and cases selection to determine which patients are suitable for elective PCIs. Capital stated within the application that, *"Only low-risk patients with low-risk lesions will be eligible for elective PCI."* Capital provided a copy of the SCAI guidelines that would be use to select PCI patients. [Source: Application, Page 44, Appendix 3]

The department received comments from Providence St. Peter Hospital stating that Capital would not provide care to all PCI patients in the planning area. Summarized below are the comments provided to the department.

Providence St. Peter Hospital

Capital would provide elective PCI only to low-risk patients with low-risk lesions. Candidate for elective PCIs in facilities without on-site surgical backup are typically selected based on patient and lesion risk. Capital's application specifically limits the elective PCIs that it will perform to patients meeting the SCAI definition of a low-risk patient with a low-risk lesion.

Capital's 2008 PCI volume is inconsistent with SCAI guidelines. Capital proposed PCI program will threaten the quality of PCI services in the planning area. In recent years, capital cardiac care has been below the national standard. [Source: Public comments received July 17, 2009, Pages 34-37] Summarized below are the rebuttal comments provided by Capital.

Capital's Response

Capital cardiologist will use the Society for Cardiac Angiography Interventions (SCAI) guidelines for patients, lesion, and case selection to determine which patents are suitable candidates for elective PCI. Only low-risk patients with low-risk lesions will be eligible for elective PCI.

Capital is fully committed to ongoing compliance with the SCAI guidelines on emergent PCI volume. In 2008, Capital volume was temporarily reduced due to planned equipment upgrade. Capital cat lab is now fully operational with the highest quality of PCI care provided with state of the art technology. The 2008 COAP data shows that Capital is within the range of, or better than the average performance regardless of volume level. Washington PCI hospitals with inpatient PCI volume in 2008 ranged from 32 to 1,560 procedures are demonstrably capable of maintaining high quality programs. The state multi-year (2006-2008) COAP data shows that Capital program provides high quality care or significantly better than the state average. [Source: Application, Pages 14-16 & 44 and Appendix 3 & 6]

Department's Evaluation

The department accepts Capital's position that SCAI is a good tool for patient selection. A review of Capital "Quality Assurance/Performance Improvement Plan" provided to the department states, *"CMC acknowledge the special circumstances of performing certain high-risk procedures including adult elective Percutaneous Coronary Intervention (PCI) without*

on-site cardiac surgery. By this plan, CMC through its hospital leaders will implement a focused quality assurance/performance improvement plan for elective PCI to:

1) *Provide a process for ongoing review of the outcomes for adult elective PCI's. Outcome will be benchmark against state or national indicators for elective PC.*
2) *Provide a system of patient selection that will result in outcomes that are equal to or better than benchmark standards.*
3) *Provide for a process of formalized review of pre-operative patient care with partner surgical backup hospital including all patients transferred for surgical intervention; and ,*
4) *Provide a process for reporting elective PCI information to the Washington State Department of Health (DOH) or entity designated by the DOH".*

[Source: Application Exhibit 6, Pages 110 and 111]

Based on the review of the draft "Quality Assurance/Quality Improvement Plan" the department concludes the draft plan satisfies the standards and requirements under WAC 246-310-740(2). 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 Quality Assurance/Quality Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be met.

WAC 246-310-740(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

Capital's responses to this sub-criterion indicated that it will send representatives vested with quality performance authority to meet jointly with University of Washington representatives on a quarterly basis to review transfer cases. The results of the joint meeting will be forwarded to the hospital quality improvement committee and clinical outcomes involving individual practitioners. [Source: Application, Page 45]

Based on the review of the draft "Quality Assurance/Quality Improvement Plan" the department concludes the draft plan satisfies the standards and requirements under WAC 246-310-740(3). 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 Quality Assurance/Quality Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be met.

WAC 246-310-740(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.

In response to this sub-criterion, Capital states its PCI quality assessment team including representatives from UWMC will participate in quarterly meetings and would prepare written reports. These reports would include the results of all performance monitoring activities and it will be forwarded to Capital board of trustees to resolve any identified problems. The final reports from the board of trustee will be reviewed according to Capital's Practitioner Peer Review Policy and any written report including all findings, data and performance improvement activities from all quality assessments meetings would be provided to the

department or its designee upon request. The frequency of the report that would be provided to the department would be determined by the department or its designees. [Source: Application, Page 45] Based on the review of the draft "Quality Assurance/Quality Improvement Plan" the department concludes the plan satisfies the standards and requirements under WAC 246-310-740(4). 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 Quality Assurance/Quality Improvement Plan to the department for review and approval. If the applicant agrees to this term, this sub-criterion would be met.

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

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

Capital provided documentation to demonstrate that it's an acute care comprehensive hospital with accreditation from the Joint Commission. The department verified that Capital's credentialed status with the Joint Commission did not show any adverse information. Capital asserts the addition of elective procedures at the hospital will have benefits by improving the overall operating efficiencies within planning area #6.

Capital also states that its elective program would enhance efficiency and the best use of its interventional cardiologist and would increase volume such that it can sustain its lifesaving 24/7 emergency program. Capital's rationale for adding elective PCI services at the hospital are reasonable because the hospital has been providing health care services to the residents of Thurston County and surrounding communities for many years. Presently, Capital participates in relationships with community facilities to provide a variety of services and approval of this project will not change the relationships in place with the health care providers in the planning area #6.

The department notes that there is reasonable assurance that approval of this project would afford the residents of planning area #6, an additional option to seek necessary care without leaving the planning area. Further, Capital's relationships with some of the health care systems in the planning area would continue and is not likely to result in an unwarranted fragmentation of services planning area #6. 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.

Based on the above information, the department concludes that Capital will continue to promote continuity in the provision of health care services in the community, and this sub-criterion is met.

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

Based on the source information reviewed and the applicant's agreement to the terms and conditions identified on pages 4 of this evaluation, the department determines that the applicant has 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 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 246-310-200(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, Capital has met the review criteria under WAC 246-310-210, 220, and 230. Additionally, Capital has met the service specific review criteria identified in WAC 246-310-715, 720, 725, 730, 735, and 740. Therefore, the department moves to step two below.

Step Two

For this project, Capital states that being located in a large planning area with only one provider of elective PCI services, the establishment of a second provider will provide the residents with a second choice.

Further, Capital stated the addition of elective PCI procedures at the hospital will have numerous benefits including:

- Improving overall operating efficiencies within its PCI program
- Reducing and minimizing the inefficiencies and higher costs inherent in the current delivery system by reducing delays in treatment for patients
- Enhancing the efficiency and the use of its current interventional cardiology by increasing volumes such that the hospital can sustain its lifesaving 24/7 emergency program.

Capital anticipates increased overall operational efficiencies with the addition of elective PCI. Capital indicated that the additional volume can easily be accommodated with existing ancillary and support services at the hospital. [Source: Application, Page 48] Given that the only other option to this project is do nothing, taking into account the community support, and the results of the numeric need methodology, the department concludes that the project described is the best available alternative for the community.

Step Three

This step is used to determine between two or more approvable projects which is the best alternative. There was no other projected submitted under the year 2009 Adult Elective PCI Concurrent Review timeline for Planning Area #6. As a result, this step is not applicable to this project.

Based on the information above, the department concludes this project is the best available alternative for PCI Planning Area #6. This sub-criterion is met.

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

This project has the potential to improve delivery of PCI services to the residents in planning area #6 and according to the need methodology, has unmet need. The department is satisfied the project is appropriate and needed because the project would:

- Does not have capital expenditure and no innovative financing
- Would improve the delivery of services in planning area #6
- The project would reduced cost because there is no unnecessary duplication of procedure
- The project would increase scheduling for PCI doctors that promote quality assurance
- The project would involve the efficient use of existing equipment and staff by increasing volumes

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