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Check #: _____

Initials _____

**Application for Certificate of Need
Adult Elective Percutaneous Coronary Interventional Services**

(Do Not Use this form for any other type of hospital project)

Certificate of Need applications must include the appropriate fee (WAC 246-310-990.)

This is an application for a Certificate of Need under state law and rules. (RCW Chapter 70.38 and WAC 246-310). I hereby certify that the statements in this application are correct to the best of my knowledge and belief. I understand that any misrepresentation, misleading statements, evasion, or suppression of material fact in this application may be used to take actions identified in WAC 246-310-500.

My signature authorizes the Department of Health to check the credit of the corporation or business and its principals; to obtain a credit report; and to verify any responses provided. The department will use such information as appropriate to further program purposes. The department may disclose this information when requested by a third party to the extent allowed by law.

Applicants(s)

Owner:

Operator:

Legal Name of Owner:

Legal Name of Operator:

Address of Owner:

Address of Operator:

Name and Title of Responsible Officer: **(Print)**

Name and Title of Responsible Officer: **(Print)**

Signature of Responsible Officer

Signature of Responsible Officer

Date: _____ Telephone: _____

Date: _____ Telephone: _____

Type of Ownership:

- District
- Private Non-Profit
- Proprietary - Corporation
- Proprietary - Individual
- Proprietary - Partnership
- State or County

Operation of Facility:

- Owner Operated
- Management Contract
- Lease

Project Description Summary:

Estimated Capital Expenditure as defined in WAC 246-310-010(10): _____

Intended Project Start Date: _____ Intended Project Completion Date: _____

Application Contacts:

Primary:

Name: _____

Title: _____

Address: _____

Phone: (____) _____

Financial Projections/Statements

Name: _____

Title: _____

Address: _____

Phone: (____) _____

Other:

Role: _____

Name: _____

Title: _____

Address: _____

Phone: (____) _____

Application Instructions
Adult Elective Percutaneous Coronary Intervention (PCI) services

The department will use the information in your application to determine if your project meets the applicable review criteria. These criteria are included in state law and rules. (RCW 78.38.115, WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, WAC 246-310-240, and WAC 246-310-700 thru 750).

PCI projects are reviewed under a Concurrent Review schedule. Key dates include:

- **Letter of Intent:** Accepted between the 1st working day of January and the last working day of January of each year.
- **Application Submission:** Accepted between the 1st working day of February and last working day of February of each year. If a letter of intent has not been received in January, an application will not be accepted in February.

- Include a table of contents for major application sections and appendices.
- Number **all** pages consecutively.
- **Do not** bind or 3-hole punch the application.
- Make the narrative information complete and to the point.
- Cite all data sources.
- Provide copies of articles, studies, etc., cited in the application.
- Place extensive supporting data in an appendix.
- Provide detailed descriptions of assumptions used for all projections.
- Use **non-inflated** dollars for **all** cost projections
- **Do not** include a general inflation rate for these dollar amounts.
- **Do** include current contract cost increases such as union contract staff salary increases. You must identify each contractual increase in the description of assumptions in the application.
- **Do not** include a capital expenditure contingency.

Application Submission

Number of Copies:

- Submit an **original, one copy, and an electronic (pdf) version**
- All subsequent submissions associated with this application must be submitted with an **original, one copy and an electronic (pdf) version.**

To be accepted, the application must include:

- A completed and signed Certificate of Need application face sheet
- The review fee of **\$34,457**. Make check payable to ***Department of Health***
- Received between the 1st working day of February and the last working day of February and a letter of intent was received by the department in January.
- Send application to:

Physical Address:

**Department of Health
Certificate of Need Program
P O Box 47852
Olympia, Washington 98504-7852**

To mail overnight, UPS or FedEx:

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

If you have questions, call (360) 236-2955

I. Applicant Description

"Applicant" means:

a. Any person proposing to engage in any undertaking subject to review under chapter 70.38 RCW

OR

b. Any person or individual with a 10 percent or greater financial interest in a partnership or corporation or other comparable legal entity engaging in any undertaking subject to review under provisions of RCW 70.38.

A. Owner Description

1. Legal name(s) of owner(s)
2. Address of each owner(s)
3. Provide the following information about each owner
 - a. Identify each person or individual with a 10 percent or greater financial interest and the percent of financial interest.
 - b. For out-of-state corporations or partnerships, provide proof of registration with Secretary of State, Corporations, Trademarks, and Limited Partnerships Division.
 - c. Show relationship to any organization as described in 42 CFR 413.17.
 - d. Provide a chart showing organizational relationship to any related organizations as described in 42 CFR 413.17.

B. Operator Description

1. Provide the legal name and address of operating entity, unless same as owner.
 - a. For out-of-state corporations or partnerships, submit:
 - i. Proof of registration with Secretary of State, Corporations, Trademarks, and Limited Partnerships Division.
 - ii. A chart showing organizational relationship to any related organizations as described in 42 CFR 413.17.
2. Is the applicant currently reimbursed for services Medicare?
3. If no to question 2, does the applicant propose to be reimbursed by Medicare for services?
4. Is the applicant currently reimbursed by Medicaid for services?
5. If no to question 4, does the applicant propose to be reimbursed for services by Medicaid?
6. List the following for each Washington and out-of-state health care facility owned or managed by the applicant or related party:
 - a. Name
 - b. Address
 - c. Medicare provider number
 - d. Medicaid provider number
 - e. Specify whether facility is owned or managed.
7. For each out-of-state health care facility owned or managed by the applicant or related party, provide the following contact information for the state entity responsible for the licensing or certification of each facility.
 - a. Entity Name

- b. Address
- c. Phone number
- d. Contact person
- e. Applicant or related party facility name

II. General Information

A. Site Information

1. Location where the PCI services will be provided.

Facility name: _____

Address: _____

2. Submit a copy of either an environmental impact statement **or** a declaration of non-significance from the appropriate governmental authority if:

- This project involves construction of 12,000 square feet or more, or
- Construction associated with parking for 40 or more vehicles.

Note: Under the provisions of WAC 246-03-030, the department may not issue a Certificate of Need until the requirements of SEPA have been met.

3. Identify the PCI planning area. WAC 246-310-705 lists PCI planning areas for the State of Washington.
4. Identify all other hospitals in the PCI planning area providing either PCI or open heart surgery services.
5. Identify in statute miles -- straight line measurement -- the three closest hospitals authorized to perform either PCIs or open heart surgery from the applying hospital.

Name of Hospital	Distance from Applicant Hospital

B. Capacity Information

1. Provide the following information:

	Current	Proposed
Cardiac Cath. Labs		
Dedicated Diagnostic	_____	_____
Dedicated Therapeutic	_____	_____
Mixed used	_____	_____

2. Identify the number of emergent PCIs performed in the last three calendar years. If no emergent PCIs were performed in any of the years, use N/A.

CY _____ CY _____ CY _____
 _____ _____ _____

3. List, by specialty, the number of physicians who are now employed by the hospital and properly credentialed to perform emergent and elective PCIs. The term "employed" is interpreted to mean traditional

employment relationships and traditional privileging practices that formally allow physicians to practice in a hospital.

III. General Project Description

1. Describe the proposed project. This should include:

- a. A description of changes to the hospital’s current cardiac catherization services operations.
- b. An identification and description of changes to the other hospital support services operations.
- c. A description of any proposed conversion or renovation of existing space, or new construction.

2. Projected number of PCIs for the first three years of operation following project completion:

Type of PCIs	Year _____	Year _____	Year _____
Emergent			
Scheduled			
Total			

3. Percent of patient revenue, by payor source:

Source of Revenue	Hospital as whole	Current Cardiac Catherization Services	Cardiac Catherizations Services with PCI Services
Medicare			
Medicaid			
Private (no Insurance)			
Insurance-Other			
HMO			
Other (Specify)			

4. Total estimated capital expenditures necessary to provide PCI services.

5. Source of financing for capital costs for the PCI services.

6. Equipment proposed:

- a. List of new and replacement equipment
- b. Description of equipment to be replaced. This includes the cost of equipment and salvage value, if any, or disposal or use of the equipment to be replaced.

7. If construction or alterations to existing space is involved, provide single line drawings to scale of current locations that identify current department or services.

8. If construction or alterations to existing space are involved, provide single line drawings to scale of proposed locations that identify proposed departments or services.

9. Timetable for implementing the proposed project.

a. Projects involving construction:

- i. Month/Year for obtaining construction financing
- ii. Month/Year for obtaining permanent financing
- iii. Month/Year for obtaining funds necessary to undertake the project.

- iv. Month/Year submission of preliminary drawings to Construction Review Services.
 - v. Month/Year submission of final drawings to Construction Review Services.
 - vi. Month/Year construction contact award.
 - vii. Month/Year 25% of construction completed
 - viii. Month/Year 50% of construction completed
 - ix. Month/Year 75% of construction completed
 - x. Month/Year construction completed
- b. Projects without construction **and** projects following completion of construction:
- i. Month/Year 25% toward service implementation completed
 - ii. Month/Year 50% toward service implementation completed
 - iii. Month/Year 75% toward service implementation completed
 - i. Month/Year services implementation complete and offering services.

Note: This information is used to monitor an approved project as required by WAC 246-310-590 and may be used for actions stated in WAC 246-310-600.

IV. Project Specific Criteria

Reminder: Follow application instructions on page 3 of this form

Need (WAC 246-310-210 and WAC 246-310-745)

A. Numeric Need

1. Compute the numeric need using the method in WAC 246-310-745.

B. PCI Planning Area Need

2. Identify and analyze the unmet need addressed by this project. The analysis should include:
 - a. The problems this project will address.
 - b. The negative impact and consequences of these unmet needs.
 - c. Identification of any deficiencies

C. Applicant Hospital Volumes

1. Submit a detailed analysis of the projected volume of adult elective PCIs the hospital expects to perform in the first three years of operation.
2. Hospitals with elective PCI programs must perform a minimum of 300 adult PCIs per year by the end of the third year of operation and each year thereafter. Provide documentation that demonstrates:
 - a. How the hospital intends to comply with state of Washington annual PCI volume standard of 300 by the end of year three and each year thereafter.
 - b. How the hospital intends to assure that all physicians working **only** at the applicant hospital will be able to meet volume standards of 75 PCIs per year

D. Existing Hospital Volumes

1. Document that all existing PCI and open heart surgery programs in the PCI planning area meet or exceed the minimum volume standard.
2. New programs may not reduce current volumes at the University of Washington fellowship training program. Submit a detailed analysis that:
 - a. Evaluates the impact your new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington
 - b. Identifies the opportunity given to the U of W to respond.
 - c. Includes any U of W response.

E. Access to Services

1. Document the manner in which the hospital intends to assure access to needed PCI services by:
 - a. Low income persons
 - b. Racial and ethnic minorities
 - c. Women
 - d. Disabled persons
 - e. Other underserved groups
2. Provide the following:
 - a. Copy of the hospital’s admissions policy
 - b. Copy of the hospital’s community service policy
 - c. Copy of the hospital’s charity care policy. If the hospital has more than one charity care policy based on type of service, provide a copy of all charity care policies.
 - d. Other information as appropriate

Financial Feasibility (WAC 246-310-220)

A. Financial Statements

1. Provide detailed descriptions of each assumption used to develop the financial projections.
2. Estimated Start-up and Initial Operating Expenses
 - a. Total Estimated Start-up costs (Expenses incurred prior to opening such as staff training, inventory, etc.) \$ _____
 - b. Estimated Period of Time Necessary for Initial Start up: (Period of time after construction is completed but prior to serving patients.) _____ “months”
 - c. Total Estimate initial operating deficits (Operating deficits occurring during operating period.) \$ _____
 - d. Estimated initial operating period (Period of time from receipt of first patient until total revenues equal total expenses.) _____ “months”

3. Complete the financial statements in the format provided below:

Hospital Information Comparison Statement of Revenue & Expense-Unrestricted Funds- PCI Project Specific Only				
	Current YR _____	Projected YR _____	Projected YR _____	Projected YR _____
Operating Revenue:				
Inpatient Revenue				
Outpatient Revenue				
Total Patient Service Revenue				
Deductions From Revenue:				
Provision for Bad Debt				
Contractual Adjustments				
Charity and Uncompensated Care				
Other Adjustments and Allowances				
Total Deductions From Revenue				
Net Patient Service Revenue				
Other Operating Revenue				
Other Operating Revenue				
Tax Revenues				
Total Other Operating Revenue				
Total Operating Revenue				
Operating Expenses				
Salaries and Wages				
Employee Benefits				
Professional Fees				
Supplies				
Purchased Services - Utilities				
Purchased Services - Other				
Depreciation				
Rentals and Leases				
Insurance				
License and Taxes				
Interest				
Other Direct Expenses				
Allocated Expenses				
Total Operating Expenses				
Net Operating Revenue				
Non-Operating Revenue-Net of Expenses				
Net Revenue Before Items Listed Below				
Extraordinary Item				
Federal Income Tax				
Net Revenue or (Expense)				
Explanation:				

Hospital Information
 Comparison Statement of Revenue & Expense-unrestricted
 Funds-**Hospital Aggregate-Without Project**

Current Projected Projected Projected
 YR _____ YR _____ YR _____ YR _____

Operating Revenue:

Inpatient Revenue				
Outpatient Revenue				
Total Patient Services Revenue				

Deductions From Revenue

Provision for Bad Debt				
Contractual Adjustments				
Charity and Uncompensated Care				
Other Adjustments and Allowances				
Total Deductions from Revenue				
Net Patient Service Revenue				

Other Operating Revenue

Other Operating Revenue				
Tax Revenues				
Total Other Operating Revenue				
Total Operating Revenue				

Operating Expenses

Salaries and Wages				
Employee Benefits				
Professional Fees				
Supplies				
Purchased Services - Utilities				
Purchased Services - Other				
Depreciation				
Rentals and Leases				
Insurance				
License and Taxes				
Interest				
Other Direct Expenses				
Total Operating Expenses				
Net Operating Revenue				

Non-Operating Revenue-Net of Expenses

--	--	--	--	--

Net Revenue Before Items Listed Below

Extraordinary Item				
Federal Income Tax				

Net Revenue or (Expense)

--	--	--	--	--

Explanation:

Hospital Information
 Comparison Statement of Revenue & Expense-unrestricted
 Funds-**Hospital Aggregate-With Project**

	Current YR _____	Projected YR _____	Projected YR _____	Projected YR _____
Operating Revenue:				
Inpatient Revenue				
Outpatient Revenue				
Total Patient Services Revenue				
Deductions From Revenue				
Provision for Bad Debt				
Contractual Adjustments				
Charity and Uncompensated Care				
Other Adjustments and Allowances				
Total Deductions from Revenue				
Net Patient Service Revenue				
Other Operating Revenue				
Other Operating Revenue				
Tax Revenues				
Total Other Operating Revenue				
Total Operating Revenue				
Operating Expenses				
Salaries and Wages				
Employee Benefits				
Professional Fees				
Supplies				
Purchased Services - Utilities				
Purchased Services - Other				
Depreciation				
Rentals and Leases				
Insurance				
License and Taxes				
Interest				
Other Direct Expenses				
Total Operating Expenses				
Net Operating Revenue				
Non-Operating Revenue-Net of Expenses				
Net Revenue Before Items Listed Below				
Extraordinary Item				
Federal Income Tax				
Net Revenue or (Expense)				
Explanation:				

Hospital Information
Deductions From Revenue-
PCI Project Specific

Current Projected Projected Projected
YR _____ YR _____ YR _____ YR _____

Acct: Item:

5800	Provision For Bad Debts				
Contractual Adjustments					
5810	Medicare				
5820	Medicaid				
5830	Workers Compensation				
5840	Other Government Programs				
5850	Negotiated Rates				
5860	Other				
	Total Contractual Adjustments				
Charity Care					
5900	Inpatient				
5910	Outpatient				
	Total Charity Care				
5970	Administrative Adjustments				
5980	Other Deductions (Specify)				
	Total Deductions From Revenue				

Explanation:

Hospital Information
Deductions From Revenue Hospital **Aggregate Without the Project**

Current Projected Projected Projected
YR _____ YR _____ YR _____ YR _____

Acct: Item:

5800	Provision For Bad Debts				
Contractual Adjustments					
5810	Medicare				
5820	Medicaid				
5830	Workers Compensation				
5840	Other Government Programs				
5850	Negotiated Rates				
5860	Other				
	Total Contractual Adjustments				
Charity Care					
5900	Inpatient				
5910	Outpatient				
	Total Charity Care				
5970	Administrative Adjustments				
5980	Other Deductions (Specify)				
	Total Deductions From Revenue				

Explanation:

Hospital Information
Deductions From Revenue- Hospital Aggregate-With The PCI Project

Current Projected Projected Projected
YR _____ YR _____ YR _____ YR _____

Acct: Item:

5800	Provision For Bad Debts				
Contractual Adjustments					
5810	Medicare				
5820	Medicaid				
5830	Workers Compensation				
5840	Other Government Programs				
5850	Negotiated Rates				
5860	Other				
	Total Contractual Adjustments				
Charity Care					
5900	Inpatient				
5910	Outpatient				
	Total Charity Care				
5970	Administrative Adjustments				
5980	Other Deductions (Specify)				
	Total Deductions From Revenue				

Explanation:

Hospital Information
Balance Sheet – Unrestricted Fund-Hospital **Aggregate**

Assets	Current YR _____	Projected YR _____	Projected YR _____	Projected YR _____
Current Assets:				
Cash				
Marketable Securities				
Accounts Receivable				
Less-Estimated Uncollectable & Allowances				
Receivables From Third Party Payors				
Pledges And Other Receivables				
Due From Restricted Funds				
Inventory				
Prepaid Expenses				
Current Portion Of Funds Held In Trust				
Total Current Assets				
Board Designated Assets:				
Cash				
Marketable Securities				
Other Assets				
Total Board Designated Assets				
Property, Plant and Equipment:				
Land				
Land Improvements				
Buildings				
Fixed Equipment - Building Service				
Fixed Equipment - Other				
Equipment				
Leasehold Improvements				
Construction In Progress				
Total Property, Plant & Equipment				
Less Accumulated Depreciation				
Net Property, Plant & Equipment				
Investments and Other Assets:				
Investments In Property, Plant & Equipment				
Less - Accumulated Depreciation				
Other Investments				
Other Assets				
Total Investments & Other Assets				
Intangibles Assets:				
Goodwill				
Unamortized Loan Costs				
Preopening And Other Organization Costs				
Other Intangible Assets				
Total Intangible Assets				
Total Assets				

Hospital Information
Balance Sheet - Unrestricted Fund-**Hospital Aggregate**

Liabilities and Fund Balances-Unrestricted	Current YR_____	Projected YR_____	Projected YR_____	Projected YR_____
Current Liabilities:				
Notes and Loans Payable				
Accounts Payable				
Accrued Compensation and Related Liabilities				
Other Accrued Expenses				
Advances from Third Party Payors				
Payables to Third Party Payors				
Due to Restricted Funds				
Income Taxes Payable				
Other Current Liabilities				
Current Maturities of Long Term Debt				
Total Current Liabilities				
Deferred Credits:				
Deferred Income Taxes				
Deferred Third Party Revenue				
Other Deferred Credits				
Total Deferred Credits				
Long Term Debt:				
Mortgage Payable				
Construction Loans - Interim Financing				
Notes Payable				
Capitalized Lease Obligations				
Bonds Payable				
Notes and Loans Payable to Parent				
Noncurrent Liabilities				
Total t				
Less Current Maturities of Long Term Debt				
Total Long Term Debt				
Unrestricted Fund Balance				
Equity (Investor Owned)				
Preferred Stock				
Common Stock				
Additional Paid In Capital				
Retained Earnings (Capital Account for Partnership or Sole Proprietorship)				
Less Treasury Stock				
Total Equity				
Total Liabilities and Fund Balance or Equity				

B. Projects Involving Construction

1. Identify all applicable estimated capital costs

a. Land Purchase	\$ _____
b. Land Improvements	\$ _____
c. Building Purchase	\$ _____
d. Residual Value of Assets Replaced	\$ _____
e. Construction Costs	\$ _____
f. Movable Equipment	\$ _____
g. Fixed Equipment (not in construction costs)	\$ _____
h. Architect & Engineering Fees	\$ _____
i. Consulting Fees	\$ _____
j. Site Preparation	\$ _____
k. Supervision & Site Inspection	\$ _____
l. Costs of Securing Financing	\$ _____
m. Cost of financing to include cons. Financing	\$ _____
n. Washington State Sales Tax	\$ _____
o. Other-costs not identified above. (itemize these costs in an appendix)	\$ _____
p. Total Estimated Capital Cost	\$ _____

2. Provide a copy of a signed nonbinding contactor's estimate of the project's construction cost, movable equipment, fixed equipment, consulting fees, site preparation, and supervision and inspection of the site. These are items e, f, g, i, j, and k, above.

3. Using the chart below, breakdown the estimated capital cost for each service (cost center) affected by this project. For each service (cost center) provide, gross square feet affected by construction, and estimated costs for items.

Cost Center	Estimated Gross Square Feet (GSF)	Const. Cost/ GSF (use e,f,g, i, j, and k)	Total Cost/GSF (Use p)

4. Use the chart below to identify the increase in capital costs per patient day that would result from this project.

	Current Year	Partial Year	Year 1	Year 2	Year 3
Tot. Deprec. Exp.					
Tot. Int. Exp.					
Total Cap. Exp.					
Patient Days					
Cap. Cost/PD					

C. Project Financing-All Projects

1. Identify the sources and amounts of financing for the project

Source of Financing	Amount
a. Public Campaign	\$ _____
b. Bond Issue	\$ _____
c. Commercial Loans	\$ _____
d. Government Loans	\$ _____
e. Grants	\$ _____
f. Bequests and Donations	\$ _____
g. Private Foundations	\$ _____
h. Accumulated Reserves	\$ _____
i. Internal Loans	\$ _____
j. Capital Allowance	\$ _____
k. Other – specify	\$ _____
l. Total (Should equal Total Project Cost)	\$ _____

2. For projects to be totally or partially funded from capital allowance, identify the amount(s) of capital allowance and budget year(s) during which the funds would be used.

3. Evidence of Availability of Financing for the Project. Submit one of the following:

- a. Copies of letter(s) from lending institutions stating a willingness to finance the proposed project. The letter(s) should include:
 - i. Status of loan application(s)
 - ii. Purpose of the loan(s)
 - iii. Proposed interest rate(s) (Fixed or Variable)
 - iv. Proposed term (period) of the loan(s)
- b. Copies of Hospital Board minutes authorizing the proposed project.

4. Copies of letter(s) from the appropriate source(s) indicating the availability of financing for the initial start-up costs.

5. Copies of each lease or rental agreement related to the proposed project. These agreements may be in draft form if all parties identified in the draft agreements provide a signed “Letter of Intent to finalize” the agreement.

6. For projects involving construction, identify:

- a. The anticipated interest rate on the construction loan. _____%
- b. Whether the long-term loan will have a fixed or a variable interest rate and the rate of interest:
 - i. Fixed Interest rate. _____%
 - ii. Variable interest rate beginning at _____ and ending at _____%

7. Provide amortization schedule(s) for each financing arrangement including long-term and any short-term start-up or initial operating deficit loans. Identify the:

- a. Principal
- b. Term (number of payment periods) (long term loans may be annualized)
- c. Interest
- d. Outstanding balance at end of each payment period

8. Provide a cost comparison analysis. Include a discussion of the advantages, disadvantages, and costs of each of the following alternative financing methods:
 - a. Purchase
 - b. Lease
 - c. Capital Allowance
 - d. Board designated reserves
 - e. Interfund loan
 - f. Commercial loan

Structure and Process (WAC 245-310-230 and WAC 246-310 715, 725, 730, and 740)

A. Staffing-General

1. For the cardiac catheterization lab ONLY identify the number of FTEs proposed by this project.

Staff Position	Current FTEs	Additional FTEs Each Year				Total FTEs
		Partial Yr	Yr 1	YR 2	YR3	

2. Identify the number of FTEs in all other cost centers affected by this project.

Staff Position	Current FTEs	Additional FTEs Each Year				Total FTEs
		Partial Yr	Yr 1	YR 2	YR3	

3. The hospital must be prepared and staffed to perform emergent PCIs 24 hours per day, seven days per week, in addition to the scheduled PCIs. Provide a staff model that demonstrates how the hospital will meet this standard.
4. Submit a plan detailing how the applicant hospital will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists. The plan must explain how this will be accomplished without harming existing staffing at PCI programs in the same planning area.

B. Staffing-Nursing and Technical

1. The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies to treat acutely ill patients. Provide job descriptions that show how the hospital will comply with this standard.
2. The hospital must staff its catheterization laboratory with a qualified, trained team of technicians experienced in interventional lab procedures. Document how the hospital will ensure the following:
 - a. Nursing staff will have coronary care unit experience and have demonstrated competency in operating PCI-related technologies.
 - b. Staff will be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary

B. Staffing-Physician

1. The hospital must employ enough properly credentialed physicians so that both emergent and elective PCIs can be performed. Provide a listing of currently employed physicians who meet this standard. Include their license numbers. If a physician is licensed in other states, provide the license number for those states. The term “employ” is interpreted to mean traditional employment relationships and traditional privileging practices that formally allow physicians to practice in a hospital.
2. If the hospital does not currently employ physicians, identify the physicians who have made a commitment in writing to come to the applicant hospital, if the hospital is awarded a certificate of need. Include their license numbers. The term “employed” is interpreted to mean traditional employment relationships and traditional privileging practices that formally allow physicians to practice in a hospital.
3. Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of 75 PCIs per year. Applicant hospitals must provide documentation that physicians performed 75 PCI procedures per year for the previous three years prior to the applicant's CON request. Documentation must be in the form of a signed third party affidavit, attestation, or like document.

C. Impact on Other Hospital Services

1. Describe the changes in ancillary and support services to be made in support of the proposed project.

D. Continuity of Care and Unwarranted Fragmentation of Services

1. The applicant hospital must have a signed written agreement with a hospital providing on-site cardiac surgery. This agreement must include, at minimum, provisions for:
 - a. 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 24 hours, seven days a week.
 - b. Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.
 - c. Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.
 - d. 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.
 - e. Acceptance of all referred patients by the backup surgical hospital.
 - f. 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.

- g. Emergency transportation beginning within 20 minutes of the initial identification of a complication.
- h. Evidence that the emergency transport staff are certified. These staff must be certified in advanced cardiac life support (ACLS) and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).
- i. The process for 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 120 minutes.
- j. At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.
- k. 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.
- l. Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly. They must review a significant number of preoperative and post-operative cases, including all transport cases.
- m. Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).

This agreement may be in draft form, if the all hospitals identified in the draft provided a signed "Letter of Intent to finalize" the agreement.

- 2. Provide a written quality assurance/quality improvement plan specific to the elective PCI program. At a minimum, this plan must include:
 - a. A process for on-going review of the outcomes of adult elective PCI's. Outcomes must be benchmarked against state or national quality of care standards indicators for elective PCIs.
 - b. A system for patient selection that will result in outcomes that are equal to, or better than, the benchmarked standards in your plan.
 - c. Process for formal case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases.
- 3. 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.
- 4. Identify if the owner, operator, or physician identified in this application has had any other of the following in this state or other states:
 - a. Decertification from Medicare
 - b. Decertification from Medicaid
 - c. Convictions related to the competency to practice medicine or own or operate a hospital
 - d. Denial of a license
 - e. Revocation of a license
 - f. Voluntary withdrawal from Medicare or Medicaid while decertification processes were pending.
- 5. If yes to any part of question 4, describe the incident and provide clear, sound, and convincing evidence that the occurrence is not likely to re-occur.

Cost Containment (WAC 246-310-240)

1. Identify each option considered before submitting the current application.
2. For each option identified in question 1, provide at least the following information:
 - a. Advantages
 - b. Disadvantages
 - c. Impact on operating costs to the hospital
 - d. Impact on staffing
 - e. Impact on costs to the patient
 - f. Impact on physical hospital space
 - g. Legal restrictions
 - h. Other-Specify
 - i. Reason for rejecting each option
3. Identify the specific ways this project will promote staff efficiency and productivity.
4. Identify the specific ways this project will promote system efficiency.
5. For projects involving construction, provide an analysis focused on the reasonableness of the construction costs. This should include these costs's impact on costs and charges.