



Certificate of Need Percutaneous Cardiac Intervention (PCI) Application Packet

Application submission must include:

- Submit one electronic copy of your application, including any applicable addendum, to CN@doh.wa.gov. No paper copy is required.
- Mail a check or money order for the review fee of **\$40,470** payable to **Department of Health**. Mail your check using a service that issues a tracking number (e.g. USPS, FedEx, etc.) and email the tracking number to the program.
 - NOTE: If you physically drop off your fee to the department, scan and email a copy of the receipt to CN@doh.wa.gov. Not completing this step may delay the processing of your application.
- Include copy of the signed cover sheet when you mail the fee. This allows us to connect your application to your fee.

Mail the review fee to:

Mailing Address:

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

Other Than By Mail:

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

Contact Us:

Certificate of Need Program Office 360-236-2955 or CN@doh.wa.gov

Application Instructions

The Certificate of Need Program 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. Revised Code of Washington ([RCW 70.38](#)) and Washington Administrative Code ([WAC 246-310](#)).

General Instructions:

- Include a table of contents for application sections and appendices/exhibits.
- Number **all** pages consecutively.
- 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 a detailed listing of the assumptions you used for all of your utilization and financial projections, as well as the bases for these assumptions.
- Under no circumstance should your application contain any patient identifying information.
- 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 included in the application.
- **Do not** include a capital expenditure contingency.
- If any of the documents provided in the application are in draft form (templates submitted will be treated as drafts), a draft is only acceptable if it includes the following elements:
 - a. identifies all entities associated with the agreement,
 - b. outlines all roles and responsibilities of all entities,
 - c. identifies all costs associated with the agreement,
 - d. includes all exhibits that are referenced in the agreement, and
 - e. any agreements in draft form must include a document signed by both entities committing to execute the agreement as submitted following CN approval.

Do not skip any questions in this application. If you believe a question is not applicable to your project, explain why it is not applicable.

Answer the following questions in a manner that makes sense for your project. In some cases, a table may make more sense than a narrative. The department will follow up in screening if there are questions.

Program staff members are available to provide technical assistance (TA) at no cost to you before submitting your application. While TA isn't required, it's highly recommended and can make any required review easier. To request a TA meeting, [Submit a TA Request](#).

Certificate of Need Application Hospital PCI Projects

Certificate of Need applications must be submitted with a fee in accordance with Washington Administrative Code [\(WAC\) 246-310-990](#).

Application is made for a Certificate of Need in accordance with provisions in Revised Code of Washington [\(RCW\) 70.38](#) and [WAC 246-310](#), rules and regulations adopted by the Washington State Department of Health. I attest that the statements made in this application are correct to the best of my knowledge and belief.

Signature and Title of Responsible Officer	Date
Email Address	Telephone Number
Legal Name of Applicant	Provide a brief project description, including the name of the hospital and the location.
Address of Applicant	Estimated capital expenditure: \$ _____

Identify the Hospital PCI Planning Area
Application type (check all that apply):
☐ Regular Review ☐ Non-Numeric Review

Applicant Description

Answers to the following questions will help the department fully understand the role of the applicant(s). Your answers in this section will provide context for the reviews under Financial Feasibility ([WAC 246-310-220](#)) and Structure and Process of Care ([WAC 246-310-230](#)).

1. Provide the legal name(s) and address(es) of the applicant(s).
Note: The term “applicant” for this purpose includes any person or individual with a ten percent or greater financial interest in the partnership or corporation or other comparable legal entity as defined in [WAC 246-310-010\(6\)](#).
2. Identify the legal structure of the applicant (LLC, PLLC, etc.) and provide the unified business identifier (UBI).
3. Provide the name, title, address, telephone number, and email address of the contact person for this application.
4. Provide the name, title, address, telephone number, and email address of the consultant authorized to speak on your behalf related to the screening of this application (if any).
5. Provide an organizational chart that clearly identifies the business structure of the applicant(s).
6. Identify all healthcare facilities owned, operated, or managed by the applicant. This should include all facilities in Washington State as well as any out-of-state facilities. Include applicable license and certification numbers.

Facility Description

1. Provide the name and address of the facility.
2. Confirm that the facility is licensed and certified by Medicare and Medicaid by providing the existing identification numbers.

HAC.FS. _____

Medicare #: _____

Medicaid #: _____

3. Is the facility operated under a management agreement? If yes, provide a copy of the management agreement.
Yes ☐ No ☐

4. Is the applicant currently providing emergent PCI? If yes, provide the number of PCIs performed at the applicant hospital for the most recent three calendar years.

Project Description

1. WAC 246-310-715(2)(a) states an approved PCI provider must:
Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, life sustaining apparatus.

Provide documentation and a discussion demonstrating that this proposal meets this requirement.

2. Describe how this project will comply with WAC 246-310-715(2)(b), which requires that the facility be available to perform emergent PCIs twenty-four hours a day, seven days a week in addition to scheduled PCIs?

Certificate of Need Review Criteria

A. Need ([WAC 246-310-210](#), [WAC 246-310-715](#), [WAC 246-310-720](#), and [WAC 246-310-745](#))

1. The department will use the posted need forecasting methodology available as of the application submission date. Confirm that you understand this methodology will be used in reviewing your project.
2. Provide the projected number of adult elective PCIs starting in the implementation calendar year and following the initiation of the service, including at least three full calendar years. All new elective PCI programs must comply with the state of Washington annual PCI volume standard of 200 (two hundred) by the end of year three. WAC 246-310-715(1)(a) and WAC 246-310-720(1)(a)
3. **Non-Numeric Need: *Complete this section only if you are applying under the non-numeric need criteria.***

WAC 246-310-760 states:

The department may grant a certificate of need for a new adult elective PCI program in a planning area where the forecasting methodology does not identify numeric need. The department may also grant, at its sole discretion, a certificate of need in a concurrent or comparative review process to more programs than the forecasting methodology projects as needed.

- a. If the forecasting methodology does not identify numeric need in the planning area, demonstrate the proposed project's ability to address at least one of the non-numeric need criteria in WAC 246-310-760(1)(d).
- b. Confirm your understanding that approval under non-numeric need is granted at the sole discretion of the department, and the department may grant a certificate in a concurrent or comparative review process to more programs than the forecasting methodology projects as needed.

B. Financial Feasibility ([WAC 246-310-220](#))

1. Provide revenue and expense statements for the PCI cost center that show the implementation calendar year and three calendar years following initiation of the service.
2. Provide pro forma revenue and expense statements for the hospital with the PCI project that show the implementation year and three calendar years following initiation of the service.
3. Provide pro forma revenue and expense statements for the hospital without the proposed PCI project that show the same calendar years as provided in response to the two questions above.
4. Provide the proposed payer mix specific to the proposed unit using the example table below. If the hospital is already providing emergent PCIs, also provide the current unit's payer mix for reference. Medicare and Medicaid managed care plans should be included within the Medicare and Medicaid lines, respectively. If "other" is a category, define what is included in "other."

Payer Mix	Percentage of Gross Revenue	Percentage by Patient
Medicare		
Medicaid		
Other Payers (list in individual lines)		
Total		

5. If there is no estimated capital expenditure for this project, explain why.

C. Structure and Process of Care ([WAC 246-310-230](#) and [WAC 246-310-715](#))

1. Provide the name and professional license number of the current or proposed medical director for the PCI program. If not already disclosed, clarify whether the medical director is an employee or under contract.
2. If the medical director is/will be an employee rather than under contract, provide the medical director's job description.
3. If the medical director is/will be under contract rather than an employee, provide the medical director contract.
4. Submit a plan detailing how the applicant 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. WAC 246-310-715(1)(b)
5. Provide a list of all credentialed staff proposed for the PCI program, including their names, license numbers, and specialties. WAC 246-310-715(1)(b)
6. Provide copies of the following policies:
 - a. Admissions policy
 - b. Charity care or financial assistance policy
 - c. Patient rights and responsibilities policy
 - d. Non-discrimination policy
7. Provide an attestation that the physicians who would perform adult elective PCI procedures at this hospital have performed a minimum of fifty PCI procedures per year for the previous three years prior to submission of this application. WAC 246-310-720(2).
8. WAC 246-310-735 requires a partnering agreement to include specific information. Provide a copy of the agreement.
9. Identify where, within this partnering agreement or any other agreement provided in this application, the requirements of WAC 246-310-735(1) through (9) below are addressed.
 - (1) *The nonsurgical hospital shall coordinate with the backup surgical hospital about the availability of its surgical teams and operating rooms.*
 - (2) *The backup surgical hospital shall provide an attestation that it can perform cardiac surgery during the hours that elective PCIs are being performed at the applicant hospital.*

- (3) *In the event of a patient transfer, the nonsurgical hospital shall provide access to all clinical data, including images and videos, to the backup surgical hospital.*
- (4) *The physician(s) performing the elective PCI shall communicate to the backup surgical hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.*
- (5) *The backup surgical hospital shall accept all referred patients.*
- (6) *The applicant hospital shall have a signed transportation agreement with a vendor who will transport by air or land all patients that require transfer to a backup surgical hospital.*
- (7) *The transportation vendor shall provide an attestation that its emergency transport staff are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route.*
- (8) *The applicant hospital shall maintain quality reporting of the total transportation time, calculated as the time that lapses from the decision to transfer the patients to arrival in the operating room of the backup surgical hospital. The total transportation time must be less than 120 minutes.*
- (9) *The applicant hospital shall provide a patient consent form that communicates that the intervention is being performed without on-site surgical backup. The patient consent form shall address the risks and mitigations including, but not limited to, emergent patients transfer, surgery by a backup surgical hospital, and the established emergency transfer agreements.*

10. WAC 246-310-740 requires a hospital to submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application. Provide a copy of this document.

D. Cost Containment ([WAC 246-310-240](#))

Projects are evaluated based on the criteria in [WAC 246-310-240](#) in order to identify the best available project for the planning area.

1. Identify all alternatives considered prior to submitting this project. Provide a comparison of this project with alternatives rejected by the applicant. Include the rationale for considering this project to be superior to the rejected alternatives. Factors to consider can include, but are not limited to: patient access to healthcare services, capital cost, legal restrictions, staffing impacts, quality of care, and cost or operation efficiency.

2. If the project involves construction, provide information that supports conformance with WAC 246-310-240(2):
 - The costs, scope, and methods of construction and energy conservation are reasonable; and
 - The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.
3. Identify any aspects of the project that 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.

Certificate of Need Program Revised Code of Washington (RCW) and Washington Administrative Code (WAC)

Certificate of Need Program laws [RCW 70.38](#)

Certificate of Need Program rules [WAC 246-310](#)

Commonly Referenced Rules for Hospital PCI Projects:

WAC Reference	Title/Topic
246-310-010	Certificate of Need Definitions
246-310-160	Regular Review Process
246-310-200	Bases for findings and action on applications
246-310-210	Determination of Need
246-310-220	Determination of Financial Feasibility
246-310-230	Criteria for Structure and Process of Care
246-310-240	Determination of Cost Containment

Certificate of Need Contact Information:

[Certificate of Need Program Web Page](#)

Phone: (360) 236-2955

Email: CN@doh.wa.gov

Construction Review Services Resources:

[Construction Review Services Program Web Page](#)

Phone: (360) 236-2944

Email: CRS@doh.wa.gov

Licensing Resources:

[Hospital Laws, RCW 70.41](#)

[Hospital Rules, WAC 246-320](#)

[Hospital Program Web Page](#)

Hospital Charity Care and Financial Data (HCCFD) Program Resources

[HCCFD Web Page](#)

Email: CharityCare@doh.wa.gov