Certificate of Need
Hospital Application Packet

Contents:

Application submission must include:

- One electronic copy of your application, including any applicable addendum – no paper copy is required.
- A check or money order for the review fee of **$40,470** payable to **Department of Health.**

  Include copy of the signed face sheet with the fee if you submit the application and fee separately. This allows us to connect your application to your fee.

Mail or deliver the application and 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 FSLCON@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, 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.

Washington State Department of Health

Certificate of Need Application
Hospital Projects

Exclude hospital projects for sale, purchase, or lease of a hospital, or skilled nursing beds. Use service-specific addendum, if applicable.

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 Email Address	Date Telephone Number
Legal Name of Applicant Address of Applicant	☐New hospital ☐Expansion of existing hospital (identify facility name and license number) Provide a brief project description, including the number of beds and the location. Estimated capital expenditure: $_____

Identify the Hospital Planning Area				
_____				
Identify if this project proposes the addition or expansion of one of the following services:				
☐NICU Level II	☐ NICU Level III	☐ NICU Level IV	☐ Specialized Pediatric (PICU)	☐ Psychiatric (within acute care hospital)
☐ Organ Transplant (identify)	☐ Open Heart Surgery	☐ Elective PCI	☐ PPS-Exempt Rehab (indicate level)	☐ Specialty Burn Services

Applicant Description

1. Provide the legal name and address of the applicant(s) 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).

Facility Description

1. Provide the name and address of the existing facility.

2. Provide the name and address of the proposed facility. If an address is not yet assigned, provide the county parcel number and the approximate timeline for assignment of the address.

3. Confirm that the facility will be licensed and certified by Medicare and Medicaid. If this application proposes the expansion of an existing facility, provide the existing identification numbers.

   HAC.FS._____

   Medicare #:_____

   Medicaid #:_____

4. Identify the accreditation status of the facility before and after the project.

5. Is the facility operated under a management agreement?

   Yes ☐ No ☐

   If yes, provide a copy of the management agreement.

6. Provide the following scope of service information:

Service	Currently Offered?	Offered Following Project Completion?
Alcohol and Chemical Dependency	☐	☐
Anesthesia and Recovery	☐	☐
Cardiac Care	☐	☐
Cardiac Care – Adult Open Heart Surgery	☐	☐
Cardiac Care – Pediatric Open Heart Surgery	☐	☐
Cardiac Care – Adult Elective PCI	☐	☐
Cardiac Care – Pediatric Elective PCI	☐	☐
Diagnostic Services	☐	☐
Dialysis – Inpatient	☐	☐
Emergency Services	☐	☐
Food and Nutrition	☐	☐
Imaging/Radiology	☐	☐
Infant Care/Nursery	☐	☐
Intensive/Critical Care	☐	☐
Laboratory	☐	☐
Medical Unit(s)	☐	☐
Neonatal – Level II	☐	☐
Neonatal – Level III	☐	☐
Neonatal – Level IV	☐	☐
Obstetrics	☐	☐
Oncology	☐	☐
Organ Transplant - Adult (list types, if applicable)	☐	☐
Organ Transplant - Pediatric (list types, if applicable)	☐	☐
Outpatient Services	☐	☐
Pediatrics	☐	☐
Pharmaceutical	☐	☐
Psychiatric	☐	☐
Skilled Nursing/Long Term Care	☐	☐
Rehabilitation (indicate level, if applicable)	☐	☐
Respiratory Care	☐	☐
Social Services	☐	☐
Surgical Services	☐	☐

Project Description

1. Provide a detailed description of the proposed project. If it is a phased project, describe each phase separately. For existing facilities, this should include a discussion of existing services and how these would or would not change as a result of the project.

2. If your project involves the addition or expansion of a tertiary service, confirm you included the applicable addendum for that service. Tertiary services are outlined under WAC 246-310-020(1)(d)(i).

3. Provide a breakdown of the beds, by type, before and after the project. If the project will be phased, include columns detailing each phase.

	Current	Proposed
General Acute Care		
PPS Exempt Psych		
PPS Exempt Rehab		
NICU Level II		
NICU Level III		
NICU Level IV		
Specialized Pediatric		
Skilled Nursing		
Swing Beds (included in General Acute Care)		
Total		

4. Indicate if any of the beds listed above are not currently set-up, as well as the reason the beds are not set up.

5. With the understanding that the review of a Certificate of Need application typically takes six to nine months, provide an estimated timeline for project implementation, below. For phased projects, adjust the table to include each phase.

Event	Anticipated Month/Year
Anticipated CN Approval	
Design Complete	
Construction Commenced	
Construction Completed	
Facility Prepared for Survey	
Facility Licensed - Project Complete WAC 246-310-010(47)	

6. Provide a general description of the types of patients to be served as a result of this project.

7. Provide a copy of the letter of intent that was already submitted according to WAC 246-310-080.

8. Provide single-line drawings (approximately to scale) of the facility, both before and after project completion. For additions or changes to existing hospitals, only provide drawings of those floor(s) affected by this project.

9. Provide the gross square footage of the hospital, with and without the project.

10. If this project involves construction of 12,000 square feet or more, or construction associated with parking for 40 or more vehicles, submit a copy of either an Environmental Impact Statement or a Declaration of Non-Significance from the appropriate governmental authority. [WAC 246-03-030(4)]

11. If your project includes construction, indicate if you've consulted with Construction Review Services (CRS) and provide your CRS project number.

    The Certificate of Need program highly recommends that applicants consult with the office of Construction Review Services (CRS) early in the planning process. CRS review is required prior to construction and licensure (WAC 246-320-500 through WAC 246-320-600). Consultation with CRS can help an applicant reliably predict the scope of work required for licensure and certification. Knowing the required construction standards can help the applicant to more accurately estimate the capital expenditure associated with a project. Note that WAC 246-320-505(2)(a) requires that hospital applicants request and attend a presubmission conference for any construction projects in excess of $250,000.

Certificate of Need Review Criteria

A. Need (WAC 246-310-210)

WAC 246-310-210 provides general criteria for an applicant to demonstrate need for healthcare facilities or services. Documentation provided in this section must demonstrate that the proposed project will be needed, available, and accessible to the community it proposes to serve. Do not skip any questions. If you believe a question is not applicable to your project, explain why it is not applicable.

1. List all other acute care hospitals currently licensed under RCW 70.41 and operating in the hospital planning area affected by this project. If a new hospital is approved, but is not yet licensed, identify the facility.

2. For projects proposing to add acute care beds, provide a numeric need methodology that demonstrates need in this planning area. The numeric need methodology steps can be found in the Washington State Health Plan (sunset in 1989).

3. For existing facilities proposing to expand, identify the type of beds that will expand with this project.

4. For existing facilities, provide the facility's historical utilization for the last three full calendar years. The first table should only include the type(s) of beds that will increase with the project, the second table should include the entire hospital.

Project-Specific Only	Identify Year	Identify Year	Identify Year
Licensed beds			
Available beds			
Discharges			
Patient days			

Entire Hospital	Identify Year	Identify Year	Identify Year
Licensed beds			
Available beds			
Discharges			
Patient days			

5. Provide projected utilization of the proposed facility for the first seven full years of operation if this project proposes an expansion to an existing hospital. Provide projected utilization for the first ten full years if this project proposes new facility. For existing facilities, also provide the information for intervening years between historical and projected. The first table should only include the type(s) of beds that will increase with the project, the second table should include the entire hospital. Include all assumptions used to make these projections.

Project-Specific Only	Identify Year	Identify Year	Identify Year	Identify Year	Identify Year	Identify Year	Identify Year
Licensed beds							
Available beds							
Discharges							
Patient days							

Entire Hospital	Identify Year	Identify Year	Identify Year	Identify Year	Identify Year	Identify Year	Identify Year
Licensed beds							
Available beds							
Discharges							
Patient days							

6. For existing facilities, provide patient origin zip code data for the most recent full calendar year of operation.

7. Identify any factors in the planning area that currently restrict patient access to the proposed services.

8. Identify how this project will be available and accessible to underserved groups.

9. If this project proposes either a partial or full relocation of an existing facility, provide a detailed discussion of the limitations of the current location.

10. If this project proposes either a partial or full relocation of an existing facility, provide a detailed discussion of the benefits associated with relocation,

11. Provide a copy of the following policies:
    - Admissions policy
    - Charity care or financial assistance policy
    - Patient rights and responsibilities policy
    - Non-discrimination policy
    - End of life policy
    - Reproductive health policy
    - Any other policies directly associated with patient access

B. Financial Feasibility (WAC 246-310-220)
Financial feasibility is based on the criteria in WAC 246-310-220.

1. Provide documentation that demonstrates the immediate and long-range capital and operating costs of the project can be met. This should include but is not limited to:
    - Utilization projections. These should be consistent with the projections provided under the Need section. Include all assumptions.
    - A current balance sheet at the facility level.
    - Pro forma balance sheets at the facility level throughout the projection period.
    - Pro forma revenue and expense projections for at least the first three full calendar years following completion of the project. Include all assumptions.
    - For existing facilities, provide historical revenue and expense statements, including the current year. Ensure these are in the same format as the pro forma projections. For incomplete years, identify whether the data is annualized.

2. Identify the hospital's fiscal year.

3. Provide the following agreements/contracts:
    - Management agreement
    - Operating agreement
    - Development agreement
    - Joint Venture agreement

    Note, all agreements above must be valid through at least the first three full years following project completion or have a clause with automatic renewals. Any agreements in draft form must include a document signed by both entities committing to execute the agreement as submitted following CN approval.

4. Provide documentation of site control. This could include either a deed to the site or a lease agreement for the site. If a lease agreement is provided, the terms must be for at least five years with options to renew for a total of 20 years.

5. Provide county assessor information and zoning information for the site. If zoning information for the site is unclear, provide documentation or letter from the municipal authorities showing the proposed project is allowable at the identified site. If the site must undergo rezoning or other review prior to being appropriate for the proposed project, identify the current status of the process.

6. Complete the table on the following page with the estimated capital expenditure associated with this project. If you include other line items not listed below, include the definition of the line item. Include all assumptions used to create the capital expenditure estimate.

Item	Cost
a. Land Purchase	$
b. Utilities to Lot Line	$
c. Land Improvements	$
d. Building Purchase	$
e. Residual Value of Replaced Facility	$
f. Building Construction	$
g. Fixed Equipment (not already included in the construction contract)	$
h. Movable Equipment	$
i. Architect and Engineering Fees	$
j. Consulting Fees	$
k. Site Preparation	$
l. Supervision and Inspection of Site	$
m. Any Costs Associated with Securing the Sources of Financing (include interim interest during construction)	
1. Land	$
2. Building	$
3. Equipment	$
4. Other	$
n. Washington Sales Tax	$
Total Estimated Capital Expenditure	**$**

7. Identify the entity responsible for the estimated capital costs . If more than one entity is responsible, provide breakdown of percentages and amounts for all.

8. Identify the start-up costs for this project. Include the assumptions used to develop these costs. Start-up costs should include any non-capital expenditure expenses incurred prior to the facility opening or initiating the proposed service.

9. Identify the entity responsible for the start-up costs. If more than one entity is responsible, provide a breakdown of percentages and amounts for all.

10. Provide a non-binding contractor's estimate for the construction costs for the project.

11. Provide a detailed narrative supporting that 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 in the planning area.

12. Provide the projected payer mix for the hospital by revenue and by patients using the example table below. 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 by Revenue	Percentage by Patient
Medicare		
Medicaid		
Commercial		
Other Government (L&I, VA, etc.)		
Self-Pay		
Charity Care		
Other Payers (please list)		
Total		

13. If this project proposes the addition of beds to an existing facility, provide the historical payer mix by revenue and patients for the existing facility. The table format should be consistent with the table shown above.

14. Provide a listing of all new equipment proposed for this project. The list should include estimated costs for the equipment. If no new equipment is required, explain.

15. Identify the source(s) of financing and start-up costs (loan, grant, gifts, etc.) and provide supporting documentation from the source. Examples of supporting documentation include: a letter from the applicant's CFO committing to pay for the project or draft terms from a financial institution.

    If this project will be debt financed through a financial institution, provide a repayment schedule showing interest and principal amount for each year over which the debt will be amortized.

16. Provide the most recent audited financial statements for:
    - The applicant, and
    - Any parent entity.

C. Structure and Process of Care (WAC 246-310-230)

Projects are evaluated based on the criteria in WAC 246-310-230 for staffing availability, relationships with other healthcare entities, relationships with ancillary and support services, and compliance with federal and state requirements. Some of the questions within this section have implications on financial feasibility under WAC 246-310-220.

1. Identify all licensed 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.

2. Provide a table that shows full time equivalents (FTEs) by type (e.g. physicians, management, technicians, RNs, nursing assistants, etc.) for the facility. If the facility is currently in operation, include at least the most recent full year of operation, the current year, and projections through the first three full years of operation following project completion. There should be no gaps. All FTE types should be defined.

3. Provide the basis for the assumptions used to project the number and types of FTEs identified for this project.

4. Identify key staff (e.g. chief of medicine, nurse manager, clinical director, etc.) by name and professional license number, if known.

5. Describe your methods for staff recruitment and retention. If any barriers to staff recruitment exist in the planning area, provide a detailed description of your plan to staff this project.

6. For **new** facilities, provide a listing of ancillary and support services that will be established.

7. For **existing** facilities, provide a listing of ancillary and support services already in place.

8. Identify whether any of the existing ancillary or support agreements are expected to change as a result of this project.

9. If the facility is currently operating, provide a listing of healthcare facilities with which the facility has working relationships.

10. Identify whether any of the existing working relationships with healthcare facilities listed above would change as a result of this project.

11. For a new facility, provide a listing of healthcare facilities with which the facility would establish working relationships.

12. Provide an explanation of how the proposed project will promote continuity in the provision of health care services in the planning area, and not result in an unwarranted fragmentation of services.

13. Provide an explanation of how the proposed project will have an appropriate relationship to the service area's existing health care system as required in WAC 246-310-230(4).

14. Identify whether any facility or practitioner associated with this application has a history of the actions listed below. If so, provide evidence that the proposed or existing facility can and will be operated in a manner that ensures safe and adequate care to the public and conforms to applicable federal and state requirements.
    a. A criminal conviction which is reasonably related to the applicant's competency to exercise responsibility for the ownership or operation of a health care facility; or
    b. A revocation of a license to operate a healthcare facility; or
    c. A revocation of a license to practice as a health profession; or
    d. Decertification as a provider of services in the Medicare or Medicaid program because of failure to comply with applicable federal conditions of participation.

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. At a minimum include a brief discussion of this project versus no project.

2. 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.

3. 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.

4. 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.

Addendum for Hospital Projects
Certificate of Need Application
All Tertiary Services EXCEPT Percutaneous Coronary Intervention (PCI)

The following questions are applicable to ALL tertiary service projects except for elective PCI. There are service-specific sections that follow.

General Questions – Applicable to ALL Tertiary Service Projects except for PCI

Project Description

1. Check the box corresponding with the tertiary service proposed by your project:

☐NICU Level II	☐ Organ Transplant (identify)
☐ NICU Level III	☐ Open Heart Surgery
☐ NICU Level IV	☐ Elective PCI*
☐ Specialized Pediatric (PICU)	☐ PPS-Exempt Rehab (indicate level)
☐ Psychiatric (within acute care hospital)	☐ Specialty Burn Services

*If you selected "Elective PCI" above, **skip this section** and move on to the PCI-specific Addendum.

Need

2. If there is a numeric need methodology specific to your service in WAC, provide the WAC-based methodology. If there is no numeric need methodology in WAC, provide and discuss a service-specific numeric need methodology supporting the approval of your project. Include all assumptions and data sources.

3. Are there any service/unit-specific policies or guidelines? If yes, provide copies of the policies/guidelines.

Financial Feasibility

4. Provide the proposed payer mix specific to the proposed unit or service. If this project represents the expansion of an existing unit, provide the current unit's payer mix for reference.

Payer Mix	Percentage by Revenue	Percentage by Patient
Medicare		
Medicaid		
Commercial		
Other Government (L&I, VA, etc.)		
Self-Pay		
Charity Care		
Other Payers (please list)		
Total		

5. Provide pro forma revenue and expense statements for the proposed unit or service. If this project proposes the expansion of an existing unit, provide both with and without the project.

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

Structure and Process of Care

7. If applicable for the service proposed, provide the name and professional license number of the proposed medical director. If not already disclosed under WAC 246-310-220(1) above, identify if the medical director is an employee or under contract.

8. If the medical director is/will be an employee rather than under contract, provide the medical director's job description.

9. If the medical director is/will be under contract rather an employee, provide the medical director contract.

10. Provide the names and professional license numbers of current and proposed credentialed staff for this service/unit.

11. If applicable for the service proposed, provide the existing or proposed transfer agreement with a local hospital.

12. Will the service/unit proposed comply with any state or national standards? If yes, provide the applicable standard, the rationale for selecting the standard selected, and a detailed discussion outlining how this project will comply with the standard.

13. After discharge, what steps are taken to ensure continuity of care for each patient?

14. If the proposed service type is already offered in the same planning area, provide a detailed description of the steps that will be taken to avoid unwarranted fragmentation of care within the existing healthcare system.

Psychiatric Unit Projects ONLY

1. Confirm that the existing or proposed facility will accept ITA patients.

2. Identify if the existing or proposed facility will provide pediatric or geriatric psychiatric services. If yes, identify the number of beds dedicated to each service.

Rehabilitation Unit Projects ONLY

1. What trauma designation is being proposed for this rehabilitation unit?

2. Will there be separate units for separate diagnoses requiring rehabilitation?

NICU Projects ONLY

1. Describe how this project will adhere to the most recent Washington State Perinatal Level of Care Guidelines.

Addendum for Hospital Projects
Certificate of Need Application
Percutaneous Coronary Intervention (PCI)
WAC 246-310-700 through 246-310-755

Facility Description

1. Is the applicant currently providing emergent PCI?

2. If no, what facilities are these patients being sent to in the most recent calendar year?

3. If yes, provide the number of PCI's performed at the applicant hospital for the most recent three calendar years?

Project Description

4. WAC 246-310-715(4) states:

   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).

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

5. Describe how this project will comply with WAC 246-310-715(5), 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)

6. 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.

7. 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(2)

8. WAC 246-310-720(2) states:

The department shall only grant a certificate of need to new programs within the identified planning area if:
(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and
(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.

Provided documentation that this standard is met for the planning area.

B. Financial Feasibility (WAC 246-310-220)

9. 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.

10. 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.

11. 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.

12. Provide the proposed payer mix specific to the proposed unit. If the hospital is already providing emergent PCIs, also provide the current unit's payer mix for reference.

Revenue Source	**Emergent PCI Program** (if applicable)	**Proposed PCI Program**
Medicare		
Medicaid		
Commercial		
Other Government (L&I, VA, etc.)		
Self-Pay		
Charity Care		
Other Payers (please list)		
Total		

13. 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)

14. Provide the name and professional license number of the current or proposed medical director. If not already disclosed, clarify whether the medical director is an employee or under contract.

15. If the medical director is/will be an employee rather than under contract, provide the medical director's job description.

16. If the medical director is/will be under contract rather an employee, provide the medical director contract.

17. Provide a list of all credentialed staff proposed for this service (including the catheterization lab staff) including their names, license numbers, and specialties. WAC 246-310-715(4)

18. For existing facilities, provide names and professional license numbers for current credentialed staff (including the catheterization lab staff) including their names, license numbers, and specialties. WAC 246-310-715(4)

19. Provide any unit-specific policies or guidelines for the proposed PCI service.

20. Submit a detailed analysis of the impact the proposed adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington Medical Center. WAC 246-310-715(1)

21. Provide discussion and any documentation that the new PCI program would not reduce current volumes below the hospital standard at the University of Washington fellowship training program. WAC 246-310-715(1)

22. Provide a copy of any response from the University of Washington Medical Center.

23. Provide documentation 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 246-310-725.

24. Provide projected procedure volumes by physician for each of the physicians listed in the previous question.

25. Provide a discussion on how the projected PCI volumes will be sufficient to assure that all physicians staffing the program will be able to meet volume standards of fifty PCIs per year. WAC 246-310-715(2)

26. 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(3)

27. Provide documentation that the catheterization lab will be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients. The answer to this question should demonstrate compliance with WAC 246-310-730.

28. WAC 246-310-735 requires a partnering agreement to include specific information. Provide a copy of the agreement.

29. Identify where, within this agreement or any other agreement provided in this application, numbers (1) through (13) below are addressed.

    (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.
    (2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.
    (3) Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.
    (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.
    (5) Acceptance of all referred patients by the backup surgical hospital.
    (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.
    (7) Emergency transportation beginning within twenty minutes of the initial identification of a complication.
    (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).
    (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.

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

(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.

(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.

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

30. WAC 246-310-740 requires this document to include specific information. Provide a copy of the agreement

31. Identify where, within the agreement, numbers (1) through (4) below are addressed.

(1) A process for ongoing review of the outcomes of adult elective PCIs. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.

(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.

(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.

(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.

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 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
246-03-030(4)	State Environmental Policy Act – Guidelines

Certificate of Need Contact Information:
Certificate of Need Program Web Page
Phone: (360) 236-2955
Email: FSLCON@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

Psychiatric Hospital Laws, RCW 71.12
Psychiatric Hospital Rules, WAC 246-322
Psychiatric Hospital Program Web Page

Hospital Charity Care and Financial Data (HCCFD) Program Resources
HCCFD Web Page
Email: CharityCare@doh.wa.gov