Certificate of Need Program
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Certificate of Need Review Criteria for Percutaneous Coronary Intervention (PCI)

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(2)

3. 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)

4. 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.

5. 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.

6. 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.

7. 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		

8. 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)

9. 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.

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

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

12. 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)

13. 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)

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

15. 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)

16. 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)

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

18. 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.

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

20. 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)

21. 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)

22. 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.

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

24. 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.).

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

26. 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.