Ambulatory Surgical Facility (ASF)
Ambulatory Surgery Center (ASC)
Certificate of Need Application Packet

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Submission Instructions:
Provide one paper copy of the application and one electronic copy on a CD or thumb drive.

To be accepted, the application must include:

- A completed and signed Certificate of Need application, including the face sheet
- A check or money order for the review fee of $20,427 payable to Department of Health.
- 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

Washington State Department of Health

Definitions

The Certificate of Need (CN) Program will use the information you provide 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.

"Ambulatory surgical facility" or "**ASF**" means any free-standing entity, including an ambulatory surgery center that operates primarily for the purpose of performing surgical procedures to treat patients not requiring hospitalization. This term does not include a facility in the offices of private physicians or dentists, whether for individual or group practice, if the privilege of using the facility is not extended to physicians or dentists outside the individual or group practice. WAC 246-310-010(5)

"Ambulatory surgical center" or "**ASC**" is also a term used interchangeably with "ASF" to describe a facility that provides ambulatory surgical procedures. The Centers for Medicare and Medicaid Services state that an ASC is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients.

"Ambulatory surgical facility" or "**ASF**" as defined by licensing rules, and relied on by the CN Program for consistency, means any distinct entity that operates for the primary purpose of providing specialty or multispecialty outpatient surgical services in which patients are admitted to and discharged from the facility within twenty-four hours and do not require inpatient hospitalization, whether or not the facility is certified under Title XVIII of the federal Social Security Act. An ambulatory surgical facility includes one or more surgical suites that are adjacent to and within the same building as, but not in, the office of a practitioner in an individual or group practice, if the primary purpose of the one or more surgical suites is to provide specialty or multispecialty outpatient surgical services, irrespective of the types of anesthesia administered in the one or more surgical suites. An ambulatory surgical facility that is adjacent to and within the same building as the office of a practitioner in an individual or group practice may include a surgical suite that shares a reception area, restroom, waiting room, or wall with the office of the practitioner in an individual or group practice. WAC 246-330-010(5)

"Assumptions," as referred to in this application, means the basis for any projection you provide.

"Invasive procedure" as defined by licensing rules means a procedure involving puncture or incision of the skin or insertion of an instrument or foreign material into the body including, but not limited to, percutaneous aspirations, biopsies, cardiac and vascular catheterizations, endoscopies, angioplasties, and implantations. Excluded are venipuncture and intravenous therapy. WAC 246-330-010(20)

“Operating room” as defined by licensing rules means a room intended for invasive procedures. WAC 246-330-010(29)

“Procedure room” for Certificate of Need purposes has the same meaning as “operating room,” but is often used by providers in reference to rooms dedicated to specific procedure types, such as endoscopy or pain management.

“Person” means an individual, a trust or estate, a partnership, any public or private corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district. WAC 246-310-010(42)

Application Instructions

The Certificate of Need (CN) 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.
- 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 a detailed description of the basis used for all projections.
- Do not include a general inflation rate for any dollar amounts.
- Include known contract cost increases.
- 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, provide rationale as to why it is not applicable.

Please 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, call 360-236-2955 or email us at FSLCON@doh.wa.gov.

Date Stamp Here

Certificate of Need Application
Ambulatory Surgical Facilities
Ambulatory Surgery Centers

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.

Name, Title, and Signature of Responsible Officer:	Phone Number:
Dated:	Email Address:
Legal Name of Applicant:	Number of Operating Rooms requested – include procedure rooms:
Address of Applicant:	Estimated Capital Expenditure:

Identify the Planning Area for this project as defined in WAC 246-310-270(3):

Applicant Description

Answers to the following questions will help the department fully understand the role of applicants. 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. WAC 246-310-010(6)

2. Identify the legal structure of the applicant (LLC, PLLC, etc.) and if known, provide the UBI number.

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 any other representatives 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) and the role of the facility in this application.

Project Description

Answers to the following questions will help the department fully understand the type of facility you are proposing as well as the type of services to be provided. Your answers in this section will provide context for the reviews under Need (WAC 246-310-210) and Structure and Process of Care (WAC 246-310-230)

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. Provide a detailed description of the proposed project.

4. With the understanding that the review of a Certificate of Need application typically takes at least 6-9 months, provide an estimated timeline for project implementation, below:

Event	Anticipated Month/Year
Design Complete	
Construction Commenced	
Construction Completed	
Facility Prepared for Survey	
Project Completion	

5. Identify the surgical specialties to be offered at this facility by checking the applicable boxes below. Also attach a list of typical procedures included within each category.

☐ Ear, Nose, & Throat
☐ Gastroenterology
☐ General Surgery
☐ Gynecology
☐ Maxillofacial
☐ Ophthalmology
☐ Oral Surgery
☐ Orthopedics
☐ Pain Management
☐ Plastic Surgery
☐ Podiatry
☐ Urology

☐ Other? Describe in detail:____

6. If you checked gastroenterology, above, please clarify whether this includes the full spectrum of gastroenterological procedures, or if this represents a specific sub-specialty:

☐ Endoscopy ☐ Bariatric Surgery ☐ Other:_____________

7. For existing facilities, provide a discussion of existing specialties and how these would or would not change as a result of the project.

8. Identify how many operating rooms will be at this facility at project completion. Note, for certificate of need and credentialing purposes, “operating rooms” and “procedure rooms” are one and the same.

9. Identify if any of the operating rooms at this facility would be exclusively dedicated to endoscopy, cystoscopy, or pain management services. WAC 246-310-270(9)

10. Provide a general description of the types of patients to be served by the facility at project completion (e.g. age range, etc.).

11. If you submitted more than one letter of intent for this project, provide a copy of the applicable letter of intent that was submitted according to WAC 246-310-080.

12. Provide single-line drawings (approximately to scale) of the facility, both before and after project completion.

13. Confirm that the facility will be licensed and certified by Medicare and Medicaid, which is a requirement for CN approval. If this application proposes the expansion of an existing facility, provide the existing facility's identification numbers.

    License #: ASF.FS.______________________

    Medicare #:__________________________

    Medicaid #:__________________________

14. Identify whether this facility will seek accreditation. If yes, identify the accrediting body.

15. **OPTIONAL –** 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 246-330-500, 246-330-505, and 246-330-510). 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.

    If your project includes construction, please indicate if you've consulted with CRS and provide your CRS project number.

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 in the planning area. WAC 246-310-270 provides specific criteria for ambulatory surgery applications. Documentation provided in this section must demonstrate that the proposed facility will be needed, available, and accessible to the community it proposes to serve. Some of the questions below only apply to existing facilities proposing to expand. For any questions that are not applicable to your project, explain why.

Some of the questions below require you to access facility data in the planning area. Please contact the Certificate of Need Program for any planning area definitions, facility lists, and applicable survey responses with utilization data.

1. List all surgical facilities operating in the planning area – to include hospitals, ASFs, and ASCs.

2. Identify which, if any, of the facilities listed above provide similar services to those proposed in this application.

3. Provide a detailed discussion outlining how the proposed project will not represent an unnecessary duplication of services.

4. Complete the methodology outlined in WAC 246-310-270, unless your facility will be exclusively dedicated to endoscopy, cystoscopy, or pain management. If your facility will be exclusively dedicated to endoscopy, cystoscopy, or pain management, so state. If you would like a copy of the methodology template used by the department, please contact the Certificate of Need Program.

5. If the methodology does not demonstrate numeric need for additional operating rooms, WAC 246-310-270(4) gives the department flexibility. WAC 246-310-270(4) states: "Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need."

   These circumstances could include but are not limited to: lack of CN approved operating rooms in a planning area, lack of providers performing widely utilized surgical types, or significant in-migration to the planning area. If there isn't sufficient numeric need for the approval of your project, please explain why the department should give consideration to this project under WAC 246-310-270(4). Provide all supporting data.

6. For existing facilities, provide the facility's historical utilization for the last three full calendar years.

7. Provide projected surgical volumes at the proposed facility for the first three full years of operation, separated by surgical type. For existing facilities, also provide the intervening years between historical and projected. Include the basis for all assumptions used as the basis for these projections.

8. Identify any factors in the planning area that could restrict patient access to outpatient surgical services. WAC 246-310-210(1) and (2)

9. In a CN-approved facility, WAC 246-310-210(2) requires that "all residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services." Confirm your facility will meet this requirement.

10. Provide a copy of the following policies:
    - Admissions policy
    - Charity care or financial assistance policy
    - Patient Rights and Responsibilities policy
    - Non-discrimination policy
    - Any other policies directly related to patient access to care.

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

Financial feasibility of a project is based on the criteria in WAC 246-310-220.

1. Provide documentation that demonstrates that 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 "Need" in section A. Include the basis for all assumptions.
    - Pro Forma revenue and expense projections for at least the first three full calendar years of operation. Include the basis for all assumptions.
    - Pro Forma balance sheet for the current year and at least the first three full calendar years of operation. Include the basis for all assumptions.
    - For existing facilities, provide three years of 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. Provide the following applicable agreements/contracts:
    - Management agreement
    - Operating agreement
    - Medical director agreement
    - Development agreement
    - Joint Venture agreement

    Note that all agreements above must be valid through at least the first three full years following completion of the project 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.

3. Certificate of Need approved ASFs must provide charity care at levels comparable to those at the hospitals in the ASF planning area. You can access charity care statistics from the Hospital Charity Care and Financial Data (HCCFD) website. Identify the amount of charity care projected to be provided at this facility, captured as a percentage of gross revenue, as well as charity care information for the planning area hospitals. The table below is for your convenience but is not required. WAC 246-310-270(7)

Planning Area Hospital 3-year Average Charity Care as a Percentage of Total Revenue	
Projected Facility Charity Care as a Percentage of Total Revenue	

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 following project completion. The costs identified in these documents should be consistent with the Pro Forma provided in response to question 1.

5. For new facilities, confirm that the zoning for your site is consistent with the project.

6. Complete the table below with the estimated capital expenditure associated with this project. Capital expenditure is defined under WAC 246-310-010(10). If you have other line items not listed below, please include the items with a definition of the line item. Include all assumptions used as the basis 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 or entities responsible for funding the capital expenditure identified above. If more than one entity is responsible, provide breakdown of percentages and amounts for all.

8. Please identify the amount of start-up costs expected for this project. Include any assumptions that went into determining the start-up costs. If no start-up costs are needed, explain why.

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

10. Explain how the proposed project would or would not impact costs and charges to patients for health services. WAC 246-310-220

11. Provide documentation that the costs of the project, including any construction costs, will not result in an unreasonable impact on the costs and charges to patients for health services in the planning area. WAC 246-310-220

12. Provide the **projected** payer mix by gross revenue and by patients using the example table below. If "other" is a category, define what is included in "other."

Payer	**Percentage by Revenue WAC 246-310-220(1)**	**Percentage by Patient WAC 246-310-210(2)**
Medicare		
Medicaid		
Other Payers (please list in individual lines)		
Total		

13. If this project proposes CN approval of an existing facility, provide the historical payer mix by revenue and patients for the existing facility for the most recent year. The table format should be consistent with the table shown above.

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

15. Provide a letter of financial commitment or draft agreement for each source of financing (e.g. cash reserves, debt financing/loan, grant, philanthropy, etc.). WAC 246-310-220.

16. 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. WAC 246-310-220

17. Provide the applicant's audited financial statements covering the most recent three years. WAC 246-310-220

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 and will be marked as such.

1. Identify all licensed healthcare facilities owned, operated by, or managed by the applicant. This should include all facilities in Washington State as well as out-of-state facilities, and should identify the license/accreditation status of each facility.

2. Provide a table that shows FTEs [full time equivalents] by classification (e.g. RN, LPN, Manager, Scheduler, etc.) for the proposed facility. If the facility is currently in operation, include at least the last three full years of operation, the current year, and the first three full years of operation following project completion. There should be no gaps in years. All staff classifications should be defined.

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

4. Provide the name and professional license number of the current or 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.

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

6. Identify key staff by name, if known (e.g. nurse manager, clinical director, etc.)

7. Provide a list of physicians who would use this surgery center, including their names, license numbers, and specialties. WAC 246-310-230(3) and (5).

8. For existing facilities, provide names and professional license numbers for current credentialed staff. WAC 246-310-230(3) and (5).

9. 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. WAC 246-310-230(1)

10. For existing facilities, provide a listing of ancillary and support services already in place. WAC 246-310-230(2)

11. For new facilities, provide a listing of ancillary and support services that will be established. WAC 246-310-230(2)

12. Identify whether any of the existing ancillary or support agreements are expected to change as a result of this project. WAC 246-310-230(2)

13. If the ASF is currently operating, provide a listing of healthcare facilities with which the ASF has working relationships. WAC 246-310-230(4)

14. Identify whether any of the existing working relationships with healthcare facilities listed above would change as a result of this project. WAC 246-310-230(4)

15. For a new facility, provide a listing of healthcare facilities with which the ASF would establish working relationships. WAC 246-310-230(4)

16. Provide a copy of the existing or proposed transfer agreement with a local hospital. WAC 246-310-230(4)

17. 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. WAC 246-310-230(4)

18. 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).

19. 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. WAC 246-310-230(3) and (5)
    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.

2. Provide a comparison of the 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. Identify any aspects of the facility's design that lead to operational efficiency. This could include but is not limited to: LEED building, water filtration, or the methods for construction, etc. WAC 246-310-240(2) and (3).

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 Ambulatory Surgery 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
246-310-270	Ambulatory Surgery

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:
Ambulatory Surgical Facilities Laws, RCW 70.230
Ambulatory Surgical Facilities Rules, WAC 246-330
Ambulatory Surgical Facilities Program Web Page

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