Special Circumstance Kidney Disease Treatment Facility Certificate of Need Application Packet

Contents:

To request this document in another format, call 1-800-525-0127.

Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

Application submission must include:

- One electronic copy of your application, including any application addendum – no paper copy is required.
- A check or money order for the review fee of **$25,054** payable to **Department of Health.**

Include a copy of the signed cover sheet with the fee if you submit the application and fee separately. This allows us to connect your application to your fee. We also strongly encourage sending payment with a tracking number.

- If this application is submitted under a concurrent review cycle, the application and review fee must be received on or before the due date. [WAC 246-310-806(1)]. 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

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
- **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 listing of the assumptions you used for all of your utilization and financial projections, as well as the basis for these assumptions.
- 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 known 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 your rationale.

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 are available to provide technical assistance (TA) at no cost to you before submitting your application. While TA is not required, it's highly recommended and can make any required review easier. To request a TA meeting, call 360-236-2955 or e-mail us at fslcon@doh.wa.gov.

Certificate of Need Application
Kidney Disease Treatment Facilities
Special Circumstance 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 Email Address	Date Telephone Number
Legal Name of Applicant Address of Applicant	Provide a brief project description (example: # of stations/location) Estimated capital expenditure: $_____
This application is submitted under (check **one** box only): [ ] Concurrent Review **Cycle 1** – Special Circumstances: [ ] Concurrent Review **Cycle 2** – Special Circumstance	
Identify the Planning Area for this project as defined in WAC 246-310-800(15). _____ If this facility has previously been approved to add special circumstance stations, provide the Certificate of Need number(s) for the approval.	

Applicant Description

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.

2. Identify the legal structure of the applicant (LLC, PLLC, etc.) and 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 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 by, or managed by the applicant. This should include all facilities in Washington State as well as out-of-state facilities. The following identifying information should be included:
   - Facility Name(s)
   - Facility Location
   - Facility CMS Certification Number
   - Facility Accreditation Status
   - Operational date of most recent CN approval or exemption

Project Description

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

2. If this facility has previously been approved to add special circumstance stations, explain why this project is consistent with WAC 246-310-818(3).

3. Provide a detailed description of the proposed project.

4. Identify any affiliates for this project, as defined in WAC 246-310-800(1).

5. With the understanding that the review of a Certificate of Need kidney dialysis Special Circumstance application typically takes three and a half months, provide an estimated timeline for project implementation using the table on the following page.

Event	Anticipated Month, Day, and Year
Assumed Completion of CN Review	
Design Complete	
Construction Commenced	
Construction Completed	
Facility Prepared for Survey	

Note that WAC 246-310-818(10) requires station(s) approved under special circumstance one- or two-station expansion must be operational within six months of approval.

6. Identify the Month/Day/Year that the additional station(s) are expected to be operational as defined in WAC 246-310-800(12).

7. Provide a detailed discussion of existing services and how these would or would not change as a result of the project. Services can include but are not limited to: in-center hemodialysis, home hemodialysis training, peritoneal dialysis training, a late shift (after 5:00 pm), etc.

8. Fill out the table below identifying the current and proposed configuration of dialysis stations. Note – an exempt isolation station defined under WAC 246-310-800(9) is not counted in the methodology, but is included in the total count of certified in-center stations.

	Before		After	
	CMS Certified Stations	Stations Counted in the Methodology	CMS Certified Stations	Stations Counted in the Methodology
General Use In-center Stations				
Permanent Bed Stations				
Exempt Isolation Stations				
Isolation Stations (not exempt)				
Total Stations				

9. Provide a general description of the types of patients to be served by the facility at project completion.

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

11. Provide single-line drawings (approximately to scale) of the facility, both before and after project completion. Reference WAC 246-310-800(11) for the definition of maximum treatment area square footage. Ensure that current and new stations are clearly labeled with their square footage identified, and specifically identify future expansion stations (if applicable)

12. Provide the gross and net square feet of this facility. Treatment area and non-treatment area should be identified separately (see explanation above re: maximum treatment area square footage).

13. Provide the existing facility's Medicare and Medicaid numbers.

    Medicare #:_____

    Medicaid #:_____

Certificate of Need Review Criteria

A. Need (WAC 246-310-210)

1. List all other dialysis facilities currently operating in the planning area, as defined in WAC 246-310-800(15).

2. Consistent with WAC 246-310-818(1), provide the facility's historical utilization data for the most recent six months preceding the letter of intent period. This data should show each month separately and be acquired from the Northwest Renal Network / Comagine ESRD Network 16. Provide the original source correspondence with the monthly data from Comagine.

	Identify Month	Identify Month	Identify Month	Identify Month	Identify Month	Identify Month
Total in-center stations						
Total in-center patients						
Patients per Station						

3. Consistent with WAC 246-310-818(3) and (4) confirm that the facility proposing to add stations with this application:
   a. Has not been approved to add two stations under special circumstance review or that since approval to add two special circumstance stations a facility in the planning area has been approved to add nonspecial circumstances stations.
   b. Has not operationalized relocated stations within the last three years.

4. Consistent with WAC 246-310-818(5) or (6) provide the most recent six months utilization data for all facilities approved to operate in the planning area and owned, operated, or affiliated with the applicant.

5. Provide both historical and projected utilization of the facility for the first three full years of operation with additional stations. Be sure to include the intervening years between historical and projected. Include all assumptions used to make these projections.

	Identify Year	Identify Year	Identify Year
Total in-center stations			
Total in-center patients			
Total in-center treatments			
Total home patients			
Total home treatments			

6. Identify any factors in the planning area that could restrict patient access to dialysis services. WAC 246-310-210(1), (2).

7. Identify how this project will be available and accessible to low-income persons, racial and ethnic minorities, women, mentally handicapped persons, and other under-served groups. WAC 246-310-210(2)

8. 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 associated with patient access (example, involuntary discharge)

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

Financial feasibility of a dialysis project is based on the criteria in WAC 246-310-220 and WAC 246-310-815.

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.
   - Pro Forma financial projections for at least the first three full calendar years of operation. Include all assumptions.
   - For existing facilities proposing a station addition, 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. Provide the following agreements/contracts:
   - Management agreement
   - Operating agreement
   - Medical director agreement
   - Development agreement
   - Joint Venture agreement

Note, all agreements above must be valid through at least the first three full years following 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.

3. 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.

4. 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.

5. Complete the table below with the estimated capital expenditure associated with this project. Capital expenditure for the purposes of dialysis applications is defined under WAC 246-310-800(3). If you have 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	**$**

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

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

8. Provide a detailed narrative regarding how the project would or would not impact costs and charges for services. WAC 246-310-220.

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

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

Payer Mix	Percentage by Revenue	Percentage by Patient
Medicare		
Medicaid		
Other Payers (please list)		
Total		

11. If the payer mix is expected to change as a result of this project, provide the projected payer mix by revenue and patients for the existing facility using the same table format shown above.

12. 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.

13. Identify the source(s) of financing (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.

14. 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

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

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

1. Provide a table that shows FTEs [full time equivalents] by category for 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 categories should be defined.

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

3. Identify the salaries, wages, and employee benefits for each FTE category.

4. Provide the name and professional license number of the current or proposed medical director. If not already disclosed under 210(1) identify if the medical director is an employee or under contract.

5. Identify key staff, if known. (nurse manager, clinical director, etc.)

6. Provide names and professional license numbers for current credentialed staff.

7. 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.

8. Provide a listing of ancillary and support service vendors already in place.

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

10. Provide a listing of ancillary and support services that would be provided on site and those provided through a parent corporation off site.

11. Provide a listing of healthcare facilities with which the dialysis center has working relationships.

12. Provide a copy of the existing transfer agreement with a local hospital.

13. Clarify whether any of the existing working relationships would change as a result of this project.

14. Fully describe any history in the last three calendar years of the applicant concerning the actions noted in Certificate of Need rules and regulations WAC 246-310-230(5)(a). If there is such history, provide documentation that the proposed project will be operated in a manner that ensures safe and adequate care to the public to be served and in conformance with applicable federal and state requirements. This could include a corporate integrity agreement or plan of correction.

15. 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 professional; 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.

16. Provide documentation that 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

17. Provide documentation that the proposed project will have an appropriate relationship to the service area's existing health care system as required in WAC 246-310-230.

D. Cost Containment (WAC 246-310-240)

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

End Stage Renal Disease / Kidney Dialysis rules

WAC Reference	Title/Topic
246-310-800	Kidney disease treatment centers—Definitions
246-310-803	Kidney disease treatment facilities—Data reporting requirements
246-310-806	Kidney disease treatment facilities—Concurrent review cycles
246-310-809	One-time exempt isolation station reconciliation
246-310-812	Kidney disease treatment facilities—Methodology
246-310-815	Kidney disease treatment facilities—Financial feasibility
246-310-818	Special circumstances one- or two-station expansion—Eligibility criteria and application process
246-310-821	Kidney disease treatment facilities—Standards for planning areas without an existing facility
246-310-824	Kidney disease treatment centers—Exceptions
246-310-827	Kidney disease treatment facilities—Superiority criteria
246-310-830	Kidney disease treatment facilities—Relocation of facilities
246-310-833	One-time state border kidney dialysis facility station relocation