



Certificate of Need Program
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Nonspecial Circumstance Kidney Disease Treatment Facility 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. [WAC 246-310-800 through WAC 246-310-833](#) provide specific criteria for kidney disease treatment center 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. If this does not apply to your project, so state.

1. List all other dialysis facilities currently operating in the planning area, as defined in [WAC 246-310-800\(15\)](#).
2. Provide utilization data for the facilities listed above, according to the most recent Northwest Renal Network / Comagine ESRD Network 16 modality report. Based on the standards in [WAC 246-310-812\(5\) and \(6\)](#), demonstrate that all facilities in the planning area either:
 - a) have met the utilization standard for the planning area;
 - b) have been in operation for three or more years; or
 - c) have not met the timeline represented in their Certificate of Need application.

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3. Complete the methodology outlined in [WAC 246-310-812](#). For reference, copies of the [ESRD Methodology](#) for every planning area are available on our website. Please note, under [WAC 246-310-812\(1\)](#), applications for new stations may only address projected station need in the planning area where the facility is to be located, unless there is no existing facility in an adjacent planning area. If this application includes an adjacent planning area, station need projections for each planning area must be calculated separately.
4. For existing facilities, provide the facility's historical utilization for the last three full calendar years.

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

5. Provide projected utilization of the proposed facility for the first three full years of operation. For existing facilities, also provide 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. 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 could restrict patient access to dialysis services. [WAC 246-310-210\(1\), \(2\)](#).
8. 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\(2\)](#)
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 site consistent with [WAC 246-310-210\(2\)](#).
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 consistent with [WAC 246-310-210\(2\)](#).

11. 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 and projected 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	Historical		Projected	
	Percentage by Revenue	Percentage by Patient	Percentage by Revenue	Percentage by Patient
Medicare				
Medicaid				
Other Payers (please list)				
Total				

11. If this project anticipates changes in payer mix percentages from historical to project, provide a brief explanation of why the changes are anticipated and any underlying assumptions.
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 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 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. For existing facilities, 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 proposed ancillary and support agreements for the facility. For existing facilities, provide a listing of the vendors.
9. For existing facilities, provide a listing of ancillary and support service vendors already in place.
10. For new facilities, provide a listing of ancillary and support services that will be established.
11. Provide a listing of ancillary and support services that would be provided on site and those provided through a parent corporation off site.
12. Identify whether any of the existing ancillary or support agreements are expected to change as a result of this project.
13. If the dialysis center is currently operating, provide a listing of healthcare facilities with which the dialysis center has working relationships.
14. For new a new facility, provide a listing of healthcare facilities that the dialysis center would establish working relationships.
15. Provide a copy of the existing or proposed transfer agreement with a local hospital.
16. Clarify whether any of the existing working relationships would change as a result of this project.
17. 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.

18. 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 criminal conviction which is reasonably related to the applicant's competency to exercise responsibility for the ownership or operation of a healthcare facility; or
 - A revocation of a license to operate a healthcare facility; or
 - A revocation of a license to practice as a health professional; or
 - Decertification as a provider of services in the Medicare or Medicaid program because of a failure to comply with applicable federal conditions of participation.
19. 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](#)
20. 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. For existing facilities, identify your closest two facilities as required in [WAC 246-310-827\(3\)\(a\)](#).
4. For new facilities, identify your closest three facilities as required in [WAC 246-310-827\(3\)\(b\)](#).
5. Do any other applications you submitted under this concurrent review cycle rely on the same facilities listed in response to questions 3 or 4? If yes, identify the applications. [WAC 246-310-827\(3\)\(c\)](#). (Note: A maximum of two applications can rely on the same three facilities.)
6. Identify whether any aspects of the facility's design could lead to operational efficiency. This could include but is not limited to: LEED building, water