



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH

May 9, 2011

CERTIFIED MAIL # 7008 1300 0000 7202 9539

Mr. Palmer Pollock  
Vice President of Planning  
Northwest Kidney Centers  
700 Broadway  
Seattle, WA 98122-4302

RE: CN11-08

Dear Mr. Pollock:

We have completed review of Northwest Kidney Centers' Certificate of Need (CoN) application to establish a five station dialysis facility in Enumclaw within King County planning area 12. For the reasons stated in the enclosed decision, the department has concluded that the project as described below is consistent with the applicable CoN review criteria. The Department is prepared to issue a CoN for this project provided Northwest Kidney Centers agrees to the following in its entirety:

Project Description:

Establish a 5-station facility providing the following services hemodialysis, peritoneal dialysis and training/support for dialysis patients. At project completion, NKC Enumclaw Dialysis Center would be approved to certify and operate a total of five dialysis stations. The stations are listed below.

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	3
<b>Total</b>	<b>5</b>

Terms:

1. NKC will provide the Department with a finalized lease that is consistent with the rates and terms outlined in the letter of intent provided with the application.

2. NKC will provide the Department with a copy of the executed medical director agreement with Dr. Ahmed prior to commencement of services consistent with the draft agreement provided within the application.
3. NKC will provide the Department with an executed copy of a Patient Transfer Agreement for Department review and approval prior to commencement of services consistent with the draft agreement provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is \$1,566,470.

You have two options, either accept or reject the above in its entirety. If you accept the above in its entirety, your application will be approved and a Certificate of Need sent to you. If you reject any provision of the above, you must identify that provision, and your application will be denied because approval would not be consistent with applicable Certificate of Need review criteria. Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety.

Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:

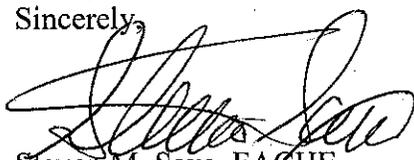
Department of Health  
Certificate of Need Program  
Mail Stop 47852  
Olympia, WA 98504-7852

Other Than By Mail:

Department of Health  
Certificate of Need Program  
310 Israel Road SE  
Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerely,



Steven M. Saxe, FACHE  
Director, Health Professions and Facilities

Enclosure

cc: Linda Foss, Department of Health, Investigations and Inspections Office  
Karen Stricklett, Department of Health, Customer Service Office

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION FROM  
NORTHWEST KIDNEY CENTERS PROPOSING THE ESTABLISHMENT OF A  
5-STATION DIALYSIS FACILITY IN KING COUNTY PLANNING AREA #12**

**APPLICANT DESCRIPTION**

NKC is a private, not-for-profit corporation, incorporated in the State of Washington that provides dialysis services through its facilities. Established in 1962, NKC operates as a community based dialysis program working to meet the needs of dialysis patients and their physicians.

NKC is governed by a volunteer Board of Trustees. The Board is comprised of medical, civic and business leaders from the community. An appointed Executive Committee of the Board oversees operating policies, performance and approves capital expenditures for all of its facilities.

In Washington State, NKC owns and operates a total of fourteen kidney dialysis facilities. Of these, thirteen reside within King County. Below is a listing of the NKC facilities in Washington. [Historical Files, NKC website]

**King County**

Auburn Kidney Center	Scribner Kidney Center
Broadway Kidney Center <sup>1</sup>	Seattle Kidney Center
Elliot Bay Kidney Center	SeaTac Kidney Center
Kent Kidney Center	Snoqualmie Ridge Kidney Center
Lake City Kidney Center	Totem Lake Kidney Center
Lake Washington Kidney Center	West Seattle Kidney Center
Mount Rainier Kidney Center	

**Clallam County**

Port Angeles Kidney Center

**PROJECT DESCRIPTION**

NKC proposes to establish a new 5-station facility to be located at 857 Roosevelt Avenue East in the city of Enumclaw. The new dialysis center would be known as NKC-Enumclaw Kidney Center and would serve the residents of King County planning area #12.

Services to be provided at the Enumclaw facility include hemodialysis, peritoneal dialysis, and training/support for dialysis patients. The 5-station facility would include a permanent bed station and an isolation station. [Application, p6]

The capital expenditure associated with the establishment of the 5-station facility is \$1,566,470. Of that amount 68% is related to construction; 24% for fixed/moveable equipment; and the remaining 8% is related to applicable taxes. [Application, p4]

---

<sup>1</sup> Formerly the Haviland Kidney Center

If this project is approved, NKC anticipates all 5 stations would be completed by April 2012. Under this timeline, year 2013 would be the facility's first full calendar year of operation and 2015 would be year three. [Application, p6 & p8]

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

The project is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

### **CRITERIA EVALUATION**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the Department must make for the application. WAC 246-310-200(2) provides additional direction in how the Department is to make its determinations. It states:

*“Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the Department in making the required determinations.*

*(a) In the use of criteria for making the required determinations, the department shall consider:*

- (i) The consistency of the proposed project with service or facility standards contained in this chapter;*
- (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
- (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.”*

In the event the WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

*“The department may consider any of the following in its use of criteria for making the required determinations:*

- (i) Nationally recognized standards from professional organizations;*
- (ii) Standards developed by professional organizations in Washington state;*
- (iii) Federal Medicare and Medicaid certification requirements;*
- (iv) State licensing requirements;*
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.”*

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment). Additionally, the applicant must

demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.<sup>2</sup>

**APPLICATION CHRONOLOGY**

As directed under WAC 246-310-282(1) the Department accepted this project under the year 2010 Kidney Disease Treatment Centers-Concurrent Review Cycle #4. Below is a chronologic summary of the project.

Action	NKC
Letter of Intent Submitted	October 29, 2010
Application Submitted	November 30, 2010
Department’s pre-review Activities including screening and responses	December 1, 2010 through February 17, 2011
Beginning of Review <ul style="list-style-type: none"> <li>• public comments accepted throughout review (no public comments were submitted);</li> <li>• no public hearing conducted under the expedited review rules</li> </ul>	February 18, 2011
End of Public Comment	March 25, 2011
Department's Anticipated Decision Date	May 27, 2011
Department's Actual Decision Date	April 28, 2011

**CONCURRENT REVIEW AND AFFECTED PERSONS**

Washington Administrative Code 246-310-010(2) defines “affected person as:

“...an “interested person” who:

- (a) Is located or resides in the applicant's health service area;
- (b) Testified at a public hearing or submitted written evidence; and
- (c) Requested in writing to be informed of the department's decision.”

Throughout the review of this project, no entities sought and received affected person status under WAC 246-310-010(2).

**SOURCE INFORMATION REVIEWED**

- Northwest Kidney Center’s Certificate of Need application submitted November 30, 2010
- Northwest Kidney Center’s supplemental information dated February 11, 2011
- No Public comment was received during the review
- Years 2004 through 2009 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2010 Northwest Renal Network 2<sup>nd</sup> Quarter Data
- Licensing and/or survey data provided by the Department of Health’s Investigations and Inspections Office
- Data obtained from Northwest Kidney Center’s webpage (www.nwkidney.org)

---

<sup>2</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(3), and WAC 246-310-287, 288, & 289.

- Data obtained from Centers for Medicare and Medicaid Services (CMS) webpage (www.medicare.gov/dialysis)
- Certificate of Need historical files

**CONCLUSIONS**

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Center proposing to establish a 5-station dialysis center in Enumclaw within King County planning area #12 is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Center agrees to the following in its entirety:

Project Description:

Establish a 5-station facility providing the following services hemodialysis, peritoneal dialysis, shifts after 5:00 p.m., and training/support for dialysis patients. At project completion, NKC Enumclaw Dialysis Center would be approved to certify and operate a total of five dialysis stations. The stations are listed below.

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	3
<b>Total</b>	<b>5</b>

Terms:

1. NKC will provide the Department with a finalized lease that is consistent with the rates and terms outlined in the letter of intent provided with the application.
2. NKC will provide the Department with a copy of the executed medical director agreement with Dr. Ahmed prior to commencement of services consistent with the draft agreement provided within the application.
3. NKC will provide the Department with an executed copy of a Patient Transfer Agreement for Department review and approval prior to commencement of services consistent with the draft agreement provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is \$1,566,470.

#### **A. Need (WAC 246-310-210)**

Based on the source information reviewed, the Department concludes Northwest Kidney Center's project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284 and WAC 246-310-286

- (1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

WAC 246-310-284 requires the Department to evaluate kidney disease treatment centers applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

#### **Kidney Disease Treatment Center Methodology WAC 246-310-284**

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.<sup>3</sup>

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.<sup>4</sup> In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations.

---

<sup>3</sup> Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

<sup>4</sup> WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report." For this project, the base year is 2008.

Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

NKC’s Application of the Numeric Methodology

NKC proposes to establish a 5-station center in Enumclaw. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was used to project need. Given that the Enumclaw facility would be located in King County planning area #12, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Application, pA22-24]

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the Department also used linear regression to project need for King County planning area #12. The Department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

Table 1 below shows a summary of the projected net need provided by the applicant and the Department for King County planning area #12.

**Table 1  
King County planning area #12 Numeric Methodology Summaries  
of Projected Net Station Need**

	4.8 in-center patients per station		
	2013 Projected # of stations	Minus Current # of stations	2013 Net Need
<b>NKC</b>	5	0	5
<b>DOH</b>	5	0	5

When comparing the applicant’s and Department’s results shown in Table 1, it shows that the projections of the applicant match the Department’s figures. As a result, the net station need for King County planning area #12 is five.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. Since there is no dialysis center operating in King County planning area #12, this criterion does not apply.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For King County planning area #12, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, the applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

NKC anticipates all 5 stations would become operational by the end of March 2012. Under this timeline, year 2013 would be the facility’s first full calendar year of operation and 2015 would be year three. A summary of the applicant’s projected utilization for the third year of operation is shown in Table 2 below. [Application, p6]

**Table 2**  
**Third Year Projected Facility Utilization**

<b>Facility Name</b>	<b>Year 3</b>	<b># of Stations</b>	<b># of Pts</b>	<b>Pts/Station</b>
NKC-Enumclaw	2015	5	24	4.80

As shown in Table 2 above, this standard is met.

Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. **This sub-criterion is met.**

- (2) 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.

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of the King County planning area #12 service area would have access to an applicant’s proposed services, the Department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion, NKC provided a copy of its current Admission Criteria that would also be used at the new facility. The Admission Criteria outlines the process/criteria that the Enumclaw facility will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Criteria also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, religion, sex, national origin, or age. [Application, Appendix 19]

NKC currently provides services to Medicare and Medicaid eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare reimbursements. [Application, Appendix 19]

NKC demonstrated its intent to provide charity care to King County planning area #12 residents by submitting its current charity policy that outlines the process one would use to access this service. NKC also included a ‘charity’ line item as a deduction from revenue within the pro forma income statements documents. [Application, pA12 & A28]

The Department concludes that all residents of the service area would have adequate access to the health services at the proposed facility. **This sub-criterion is met.**

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

Based on the source information reviewed, the Department concludes that Northwest Kidney Center’s project has met the financial feasibility criteria in WAC 246-310-220

(1) The immediate and long-range capital and operating costs of the project can be met.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the Department evaluates if the applicant’s pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

NKC anticipates the Enumclaw facility will become operational by March 2012. Based on this timeline, calendar year (CY) 2013 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, Table 3 illustrates the projected revenue, expenses, and net income for CY 2013 through 2015 for the Enumclaw facility. [Application, pA12]

**Table 3**  
**NKC-Enumclaw Kidney Center**  
**Projected Revenue and Expenses Calendar Years 2013 - 2015<sup>5</sup>**

	<b>CY 1 - 2013</b>	<b>CY 2 - 2014</b>	<b>CY 3 - 2015</b>
# of Stations	5	5	5
# of Treatments <sup>[1]</sup>	2,808	3,276	3,744
# of Patients <sup>[1]</sup>	18	21	24
Utilization Rate <sup>[1]</sup>	3.60	4.20	4.80
Net Patient Revenue <sup>[1]</sup>	\$1,024,919	\$1,196,189	\$1,366,560
Total Operating Expense <sup>[1,2]</sup>	\$858,194	\$960,929	\$1,065,181
Net Profit or (Loss) <sup>[1]</sup>	\$166,725	\$235,260	\$301,379

[1] Includes in-center patients only; [2] includes bad debt, charity care and allocated costs

As shown in Table 3, at the projected volumes identified in the application, NKC anticipates that the 5-station the Enumclaw facility would be operating at a profit in each of the forecast years.

Planned changes in the Medicare reimbursement system to a new Prospective Payment System, or bundling, has the potential to change the financial projections provided by the applicant in the application. As part of the screening process, the program requested that the applicant consider these planned changes and supply a pro forma forecast that represents their best estimate of how the change would affect the financial forecasts. [February 11, 2011 Supplemental Information, Exhibit 4]

<sup>5</sup> Whole numbers may not add due to rounding.

**Table 4**  
**NKC-Enumclaw Kidney Center – CMS Bundling Forecast**  
**Projected Revenue and Expenses Calendar Years 2013 - 2015<sup>6</sup>**

	CY 1 - 2013	CY 2 - 2014	CY 3 - 2015
# of Stations	5	5	5
# of Treatments <sup>[1]</sup>	2,808	3,276	3,744
# of Patients <sup>[1]</sup>	18	21	24
Utilization Rate <sup>[1]</sup>	3.60	4.20	4.80
Net Patient Revenue <sup>[1]</sup>	\$1,112,376	\$1,298,222	\$1,483,169
Total Operating Expense <sup>[1,2]</sup>	\$866,135	\$970,254	\$1,075,910
Net Profit or (Loss) <sup>[1]</sup>	\$246,241	\$327,968	\$407,259

[1] Includes in-center patients only; [2] includes bad debt, charity care and allocated costs

The results show that the program may improve the expected revenues and are summarized in Table 4.

NKC selected a site for its new facility located at 857 Roosevelt Avenue East in the city of Enumclaw. The executed letter of intent to lease provided in the application outlines the terms and the annual rent for the space for 10 years following commencement of the lease. The annual lease costs are substantiated in the pro forma financial documents used to prepare the summary in Table 3. [Application, pA12 & A19]

If approved, the Department would add a term requiring NKC to provide the program with a finalized lease that is consistent with the rates and terms outlined in the letter of intent provided with the application.

Additionally, NKC provided a copy of a draft Medical Director Agreement expected to be used between itself and Suhail Ahmed, M.D. The medical director service costs are also substantiated in the pro forma documents. [February 11, 2011 Supplemental Information, p2 & Exhibit 1]

If approved, the Department would add a term requiring NKC to provide a copy of the executed medical director agreement with Dr. Ahmed prior to commencement of services which is consistent with the draft agreement provided within the application.

Based on the above information, and acceptance of the terms outlined above, the Department concludes that NKC's projected revenues and expenses are reasonable and can be substantiated. **With the term, this sub-criterion is met.**

(2) 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.

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the Department compared the proposed project's costs with those previously considered by the Department.

<sup>6</sup> Whole numbers may not add due to rounding.

The capital expenditure associated with the establishment of NKC’s proposed Enumclaw facility is \$1,566,470 of which 68% is related to leasehold improvements; 24% for both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, and application fees. The capital cost breakdown is shown below. [Application, pA12]

**Table 5**  
**Estimated Capitals Costs of Enumclaw Facility**

<b>Item</b>	<b>Cost</b>	<b>% of Total</b>
Construction	\$ 1,069,000	68%
Fixed Equipment	\$ 159,575	10%
Moveable Equipment	\$ 209,873	13%
Architect, Engineering & Fees	\$ 128,022	8%
<b>Total Estimated Capital Costs</b>	<b>\$ 1,566,470</b>	<b>100%</b>

NKC intends to finance the project entirely from available board reserves. A review of the financial statement provided in the application indicates that NKC had sufficient cash assets in both 2009 and 2010 to fund the project. [Application, pA30]

The Department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, NKC also provided the sources of patient revenue shown in Table 6 below. [Application, p7]

**Table 6**  
**NKC-Enumclaw Kidney Center**  
**Sources and Percentages of Revenue**

<b>Source of Revenue</b>	<b>% of Revenue</b>
Medicare	73%
State	9%
Blue Cross	3%
Group Health	1%
Other Insurance	13%
Private Pay	1%
<b>Total</b>	<b>100%</b>

As shown above, the Medicare and State entitlements are projected to equal 82% of the revenue at the Enumclaw facility. The Department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. The remaining 18% will be derived through other or private insurance reimbursements. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is met.**

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the Department compared the proposed project's source of financing to those previously considered by the Department.

As previously stated, the capital expenditure associated with the establishment of NKC's 5-station facility in Enumclaw is \$1,566,470. NKC states that the project will be funded from NKC's available board reserves. A review of NKC's statements of financial position show the funds necessary to finance the project are available. [Application, pA31]

Based on the information provided, the Department concludes that approval of this project would not adversely affect the financial stability of NKC as a whole. **This sub-criterion is met.**

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

Based on the source information reviewed, the Department concludes Northwest Kidney Center's project has met the structure and process of care criteria in WAC 246-310-230

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size. Therefore, using its experience and expertise the Department concludes that the planning would allow for the required coverage.

To staff its proposed 5-station facility, NKC intends to have 4.65 FTEs in full year one and increase the FTEs to 6.34 by the end of full calendar year three (2015). A breakdown of the proposed FTEs is shown in Table 7 below. [Application p15]

**Table 7**  
**2012 – 2015 Projected Total FTEs**

<b>Staff/FTEs</b>	<b>2012 Part Yr.</b>	<b>2013 Total</b>	<b>2014 Total</b>	<b>2015 Total</b>
Medical Director	Professional Services Contract			
RNs	2.00	2.00	2.00	2.00
Patient Care Tech	2.00	2.45	3.12	3.94
Social Wk	0.10	0.10	0.20	0.20
Dietician	0.10	0.10	0.20	0.20
Total FTE's	<b>4.20</b>	<b>4.65</b>	<b>5.52</b>	<b>6.34</b>

As shown in Table 6, after the initial recruitment of FTEs, NKC expects a minimal increase in FTEs. NKC states that it expects no difficulty in recruiting staff for the Enumclaw facility due to its location and past success in attracting qualified health personnel. Further, NKC states that a

high employee retention rate<sup>7</sup> and low position vacancy rate support this assertion and that “NKC has not had to refuse admission to new patients due to staffing shortages”. [Application, p16]

Based on the information reviewed, the Department concludes adequate staffing for the 5-station facility is available or can be recruited. **This sub criterion is met.**

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

WAC 246-310 does not contain specific WAC 246-310-230(2) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the Department assessed the applicant’s history in meeting these standards at other facilities owned or operated by the applicant.

Information provided in the application confirms that NKC maintains the appropriate relationships with ancillary and support services for its 14 operating dialysis centers. For its proposed Enumclaw facility, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, human resources, material management, administration, and technical services would be provided by “one of our support offices in Seattle, Lake Forest Park, SeaTac, or Bellevue” which already provide services daily or on demand for the existing NKC facilities. [Application, p17]

Since this would be a new facility in King County planning area #12, transfer agreements would need to be established. Prior to providing services at the Enumclaw Kidney Center, NKC must provide an executed copy of a Patient Transfer Agreement for the Department’s review and approval.

Based on this information, the Department concludes NKC currently has access to the necessary ancillary and support services for the proposed facility. If this project is approved, the Department would include a term requiring NKC to provide a copy of the executed transfer agreement with a local hospital. **With the term, this sub-criterion is met.**

- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the Department assessed the applicant’s history in meeting these standards at other facilities owned or operated by the applicant.

As stated earlier, Northwest Kidney Center is currently a provider of dialysis services within Washington State, and operates 14 kidney dialysis treatment centers in two separate counties. As part of its review, the Department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.<sup>8</sup>

---

<sup>7</sup> NKC reports a current average employee length of service of 9.5 years

<sup>8</sup> WAC 246-310-230(5).

Since January 2008, the Department of Health's Investigations and Inspections Office has completed certification and compliance surveys for a number the operational facilities that NKC operates. Of the surveys completed, four revealed minor non-compliance issues related to the care and management of the facilities which required plans of correction<sup>9</sup>. These non-compliance issues were typical of a dialysis facility and the plans of correction were fully implemented. [Facility survey data provided by the Investigations and Inspections Office]

For medical director services, NKC provided a copy of its draft contract with Suhail Ahmad, M.D. Under the contract, Dr. Ahmad is designated as medical director for the Enumclaw facility. A review of the compliance history for Dr. Ahmad revealed no recorded sanctions. As stated above in the review of WAC 246-310-220(1), if approved, the Department would add a term requiring NKC to provide a copy of the executed medical director agreement with Dr. Ahmed prior to commencement of services consistent with the draft agreement provided within the application. [February 11, 2011 Supplemental Information, Exhibit 1]

Given the compliance history of NKC and that of the proposed medical director, and acceptance of the term regarding the medical director contract, the Department concludes that there is reasonable assurance that the Enumclaw facility would operate in compliance with state and federal regulations. **With the term, this sub-criterion is met.**

- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the Department assessed the materials in the application.

The Department considered NKC's history of providing care to residents in Washington State. The Department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Application, Supplement 2 & 3, CN historical files]

Additionally, the Department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 5 dialysis stations in King County planning area #12. This project proposes to establish a 5 station facility in Enumclaw.

Approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. Further, NKC

---

<sup>9</sup> Broadway Kidney Center, May, 2009; Lake City Kidney Center, July, 2009; Port Angeles Kidney Center, April, 2010; and the Snoqualmie Ridge Kidney Center, June, 2010

demonstrated it is likely to develop the appropriate relationships to the service area's existing health care system within the planning area. **This sub-criterion is met.**

- (5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This sub-criterion is addressed in sub-section (3) above. **This sub-criterion is met.**

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

Based on the source information reviewed, the Department concludes Northwest Kidney Center's project has met the cost containment criteria in WAC 246-310-240 (1) and (2).

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.  
To determine if a proposed project is the best alternative, the Department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met WAC 246-310-210 through 230 criteria, the Department would move to step two in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the Department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific (tie-breaker) criteria contained in WAC 246-310. The tie-breaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2)(a)(i), then the Department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the Department would assess the competing projects and determine which project should be approved.

#### **Step One**

For this project, NKC's project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the Department moves to step two below.

#### **Step Two**

Within the application, NKC identified six considerations before submitting this application. A summary of each and NKC's rationale for rejection is below. [Application, p18]

#### Alternative 1-Postponment

NKC states it rejected this option because a postponement would “bring no relief to the underserved dialysis population in King County planning area #12”.

#### Alternative 2-Night time services

NKC states that in-center nocturnal dialysis is an option in existing facilities to leverage treatment capacity. But with no existing facility in the planning area, this is not an option to meet the established numeric need.

#### Alternative 3-Shortened treatment times

NKC states that additional treatment capacity at existing facilities by shortening the treatment times in order to turn stations more quickly during the hours of operation, but that this practice can negatively affect the overall care and outcome of the treatments. And, with no existing facility in the planning area, this is not an option to meet the established numeric need.

#### Alternative 4-Increased home dialysis

NKC advocates for home dialysis for both hemodialysis and peritoneal treatments. In October 2010, NKC reports a combined census of 224 patients using their home dialysis program. NKC states, “We continue to try to grow our home programs, but we do not believe this strategy will substantially address the needs of the underserved dialysis population in King County planning area #12”.

#### Alternative 5-Kidney transplantation

NKC states that it advocates for kidney transplantation for all patients whom show interest and for “whom it is not contradicted”. Currently, 22 NKC patients have been placed on waiting lists, but “the supply of available donor organs has not kept pace with the demand”.

#### Alternative 6-Shared/Contract services agreement

There are no existing dialysis facilities in the planning area to establish such an agreement with.

The Department did not identify any additional options for consideration and the numeric need portion of this evaluation resulted in need for dialysis stations in the planning area. The Department did not receive any letters of opposition related to this project. Given the options considered, the Department concludes that the project described is the best available alternative for the community. **This sub-criterion is met.**

#### **Step Three**

NKC was the only entity who submitted an application to address dialysis service in King County planning areas #12. As a result, step three is not evaluated under this sub-criterion

#### (2) *In the case of a project involving construction:*

##### (a) *The costs, scope, and methods of construction and energy conservation are reasonable;*

WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable. However, the

department, through its experience knows that construction projects are usually built to exceed these minimum standards. Therefore, the department considered information in the applications that addressed the reasonableness of their construction projects that exceeded the minimum standards.

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). **This sub-criterion is met.**

(b) *The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.*

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). **This sub-criterion is met.**