



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

September 27, 2012

CERTIFIED MAIL 7011 1570 0002 7809 5261

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

RE: CN12-34

Dear Mr. Pollock:

We have completed review of Northwest Kidney Center's application proposing to add three stations to its Totem Lake Dialysis Center. For the reasons stated in this evaluation, the application submitted by Northwest Kidney Center is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Center agrees to the following in its entirety.

Project Description:

This Certificate approves the addition of three new kidney dialysis stations. At project completion, NKC Totem Lake Kidney Center is approved to certify and operate twenty dialysis stations. Services provided at NKC Totem Lake Kidney Center include in-center hemodialysis, peritoneal dialysis and shifts beginning after 5:00 p.m. The station breakdown at the kidney center is listed below:

Private Isolation Room	0
Permanent Bed Station	0
Home Training Station	0
Other In-Center Stations	20
Total	20

Condition:

1. Approval of the project description as stated above. Northwest Kidney Centers further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

Approved Capital Costs:

The approved capital expenditure associated with this project is \$260,366



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
111 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

EVALUATION DATED SEPTEMBER 27, 2012 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING THE ADDITION OF THREE DIALYSIS STATIONS TO THE EXISTING TOTEM LAKE KIDNEY CENTER IN KING COUNTY PLANNING AREA #6

APPLICANT DESCRIPTION

Northwest Kidney Centers (NKC) is a private, not-for-profit kidney dialysis provider incorporated in the state of Washington. NKC was established in 1962, and it operates its facilities as community based kidney centers working to meet the needs of dialysis patients and their physicians.

NKC is governed by a volunteer Board of Trustees and it's 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 17 kidney dialysis facilities. Of these, 14 facilities are located within King County and one in Clallam County. Below is a listing of NKC facilities in Washington. [Source: Historical Files and Supplemental information received July 17, 2012, Exhibit 1]

King County

Auburn Kidney Center	Renton Kidney Center
Broadway Kidney Center	Scribner Kidney Center
Enumclaw Kidney Center	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

Clallam County

Port Angeles Kidney Center

PROJECT DESCRIPTION

NKC proposes to add three dialysis stations to its existing 17-station Totem Lake Kidney Center located at 12303 NE 130th Lane in the city of Kirkland, within King County planning area #6. Services provided include in-center hemodialysis, peritoneal dialysis and treatments shifts beginning after 5:00 p.m. [Source: Application, page 7]

The capital expenditure associated with the expansion of the kidney center is \$260,366. Of that amount 57% is related to leasehold improvement; 18% for fixed and moveable equipment; and the remaining 25% is related to taxes and fees. [Source: Application, Appendix 8]

If this project is approved, NKC anticipates the three new stations would be available by the end of June 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation with 20 stations and 2016 would be year three. [Source: Application summary page]

APPLICABILITY OF CERTIFICATE OF NEED LAW

The project is subject to Certificate of Need review as the expansion of a dialysis facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-02(1)(e).

EVALUATION CRITERIA

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 284.¹

¹ 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 246-310-286, 287, 288, and 289.

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #2. No other kidney disease treatment center applications were reviewed for the King County planning area #6 during the cycle. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

APPLICATION CHRONOLOGY

Action	Dates
Letter of Intent Submitted	April 30, 2012
Application Submitted	May 31, 2012
Department’s pre-review Activities including screening and responses	June 1, 2012 through July 22, 2012
Beginning of Review	July 23, 2012
End of Public Comment/No Public Hearing Requested or Conducted	August 27, 2012 ²
Rebuttal Comments	September 12, 2012
Department's Anticipated Decision Date	October 29, 2012
Department's Actual Decision Date	September 27, 2012

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 May 31, 2012
- Northwest Kidney Center’s supplemental information dated July 17, 2012
- No public comment was received during the review
- Years 2006 through 2011 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 4th Quarter Utilization Data
- Licensing and/or survey data provided by the Department of Health’s Investigations and Inspections Office
- Certificate of Need historical files
- Medicare.gov – Dialysis Facility Compare

² The department did not receive any public comment. Therefore no rebuttal comments from the applicant were submitted

CONCLUSIONS

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Center proposing to add three dialysis stations the Totem Lake Kidney Center is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Center agrees to the following in its entirety.

Project Description:

This Certificate approves the addition of three new kidney dialysis stations. At project completion, NKC Totem Lake Kidney Center is approved to certify and operate twenty dialysis stations. Services provided at NKC Totem Lake Kidney Center include in-center hemodialysis, peritoneal dialysis and shifts beginning after 5:00 p.m. The station breakdown at the kidney center is listed below:

Private Isolation Room	0
Permanent Bed Station	0
Home Training Station	0
Other In-Center Stations	20
Total	20

Condition:

1. Approval of the project description as stated above. Northwest Kidney Centers further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

Approved Costs:

The approved capital expenditure associated with this project is \$260,366.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the condition identified in the "Conclusion" section of this evaluation, the department concludes that Northwest Kidney Center 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.³

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.⁴ 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.

³ 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]

⁴ 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 2010.

For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. 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 add three dialysis stations to the existing Totem Lake Kidney Center. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was applied to project need. Given that the Totem Lake facility is located in King County planning area #6, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, page A-18]

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 #6. 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).

The table below shows a summary of the projected net need provided by the applicant and the department for King County planning area #6.

**Table 1
King County Planning Area #6 Numeric Methodology Summary
of Projected Net Station Need**

	4.8 in-center patients per station		
	2015 Projected # of stations	Minus Current # of stations	2015 Net Need
NKC	20	17	3 ⁵
DOH	20	17	3

The table above demonstrates that the projections of the applicant match the department’s figures. As a result, the net station need for King County planning area #6 is three.

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. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for this project is May 1, 2012. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2011. NKC operates the only dialysis center in the planning area. The table below shows the reported utilization of the existing 17-station Totem Lake kidney Center.

⁵ Numbers are rounded up

Table 2
December 31, 2011 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
NKC -- Totem Lake	17	86	5.06

The table above demonstrates that Totem Lake Kidney Center satisfies this utilization requirement. **This sub-criterion is met.**

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 #6, 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 the three new stations would become operational by the end of June 2013. Under this timeline, year 2014 would be the center's first full year of operation and 2016 would be year three. A summary of the applicant's projected utilization for the third year of operation is shown in the table below. [Source: Application, page 7]

Table 3
Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
NKC-Totem Lake Kidney Center	2016	20	96	4.80

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 #6 service area would have access to an applicant's proposed services, the department requires an applicant to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the center as to the types of patients that are appropriate candidates to use the kidney center and any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion, NKC provided a copy of the Admission Criteria currently used at the Totem Lake Kidney Center. The Admission Criteria outlines the process and criteria that the center uses to admit patients for treatment and ensures that patients will receive appropriate care. The Admission Criteria also states that any patient with end stage renal

disease needing chronic hemodialysis will be accepted for treatment without regard to race, color, religion, sex, national origin, or age. [Source: Application, Page A-24]

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination.

NKC currently provides services to Medicaid eligible patients receiving treatments at the kidney center. Information provided within the application shows that NKC intends to maintain this status. A review of the anticipated revenue indicates that the center expects to continue to receive Medicaid reimbursements. [Source: Application, page 8]

To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination. NKC currently provides services to Medicare eligible patients receiving treatments at the kidney center. Information provided within the application shows that NKC intends to maintain this status. A review of the anticipated revenues indicates that the center expects to continue to receive Medicare reimbursements. [Source: Application, page 8]

NKC demonstrated its intent to provide charity care to King County planning area #6 residents by submitting the Charity Care policy currently used at the kidney center. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. NKC also included a 'charity' line item as a deduction from revenue within the pro forma income statements for Totem Lake Kidney Center. [Source: Application, page A-12 & A25]

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

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

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, 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 three new stations at Totem Lake Kidney Center would become operational by June 2013. Based on this timeline year 2014 would be the facility's first full year of operation. Using the financial information provided within the application, the table below illustrates the projected revenue, expenses, and net income for 2013 through 2016 for Totem Lake Kidney Center. [Source: Application, page 7 and A-12]

Table 4
NKC-Totem Lake Kidney Center
Projected Revenue and Expenses Calendar Years 2013 - 2016

	Partial 2013	Year 1- 2014	Year 2- 2015	Year 3- 2016
# of Stations	20	20	20	20
# of Treatments ^[1]	12,348	12,936	13,524	14,112
# of Patients ^[1]	84	88	92	96
Utilization Rate ^[1]	4.20	4.40	4.60	4.80
Net Patient Revenue ^[1,2]	\$5,263,550	\$5,514,195	\$5,765,493	\$6,015,486
Total Direct Expenses ^[3]	\$3,633,543	\$3,852,364	\$4,014,685	\$4,177,241
Net Profit or (Loss) ^[1]	\$1,630,007	\$1,661,831	\$1,750,808	\$1,838,245

[1] in-center patients only; [2] includes bad debt, contractual allowance and charity care; [3] includes overhead contribution and allocated costs.

As shown in Table 4, at the projected volumes identified in the application, NKC anticipates the Totem Lake Kidney Center would be operating at a profit in each of the forecast years. As an existing facility, NKC provided an executed lease agreement between King County Public Hospital District No.2 ("Landlord") and Northwest Kidney Centers ("Tenant"). A copy of a second amendment to the initial lease agreement shows that the amended lease is valid through year 2016 with two five year options to renew.

The department's review of the executed lease agreement shows that rent costs identified in the lease are consistent with the pro-forma financial projections used to prepare the information in table above. NKC identified Dr. Astier Alem as the existing medical director for Totem Lake Kidney Center and provided a copy of an executed medical director agreement. The agreement identifies the annual compensation for the medical director position. [Source: Application, Page A-12 & Supplemental 1]

Based on the information, the department concludes that the proposed expansion of NKC Totem Lake Kidney Center by three new stations is financially feasible. **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.

The capital expenditure associated with the expansion of the Totem Lake Kidney Center is \$260,366 of which 57% is related to leasehold improvements; 18% to fixed and moveable equipment; and the remaining 25% is related to review fees and taxes. The capital cost breakdown is shown below. [Source: Application, page A-12]

Table 5
Estimated Capital Costs of Totem Lake Facility Expansion

Item	Cost	% of Total
Leasehold improvement	\$148,000	57%
Moveable Equipment	\$47,967	18%
Review Fees and Taxes	\$64,399	25%
Total Estimated Capital Costs	\$260,366	100%

NKC intends to finance the project entirely from available board reserves. A review of NKC's financial statement provided in the application indicates that NKC has sufficient cash reserves to fund the project. [Source: Application, page 15 and Appendix 28] To further demonstrate compliance with this sub-criterion, NKC also provided the sources of patient revenue shown in Table 6. [Source: Application, page 8]

Table 6
NKC-Totem Lake Kidney Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	73%
State	9%
Other Insurance	18%
Total	100%

As shown above, the Medicare and Medicaid entitlements are projected to equal 82% of the revenue at Totem Lake Kidney Center. The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. Therefore, the department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement they are not expected to have an unreasonable impact on charges for services. The remaining 18% will be derived through a variety of other reimbursement sources.

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 expansion of NKC's Totem Lake Kidney Center is \$260,366. 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. [Source: Application, page 15 & Appendix 28]

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 and the applicant’s agreement to the condition identified in the “Conclusion” section of this evaluation, 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.

As an existing facility, NKC currently has 18.77 FTEs. With the additional three stations, NKC expects to increase to 21.30 FTEs. The center’s existing and proposed FTEs are shown in the table below. [Source: Supplemental information received July 17, 2012, page 2]

**Table 7
2012 – 2016 Projected Total FTEs**

Staff/FTEs	2012 Current	Total 2013	Total 2014	Total 2015	Total 2016
Medical Director	Professional Services Contract				
RNs	5.36	5.78	6.05	6.33	6.60
Patient Care Tech	9.96	10.73	11.24	11.75	12.26
Clerical	1.00	1.00	1.00	1.00	1.00
Dietician	0.52	0.56	0.59	0.61	0.64
MSW	0.65	0.70	0.73	0.77	0.80
Total FTE’s	17.49	18.77	19.61	20.46	21.30

As shown above, NKC expects a minimal increase in FTEs. NKC states that it expects no difficulty in recruiting staff for Totem Lake Kidney Center due to its location and past success in attracting qualified health personnel. Further, NKC states that a high employee retention rate⁶ and low position vacancy rate support this assertion and that “NKC has not had to refuse admission to new patients due to staffing shortages.” [Source: Application, page 18]

Based on the information reviewed, the department concludes adequate staffing for the Totem Lake Kidney Center 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.

⁶ NKC reports a current average employee length of service of 9.5 years

The information and transfer agreement provided in the application confirms that NKC maintains the appropriate relationships with ancillary and support services for this 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. [Source: Application, page 19].

Based on this information, the department concludes NKC currently has access to the necessary ancillary and support services for the existing facility. **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 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.

As stated earlier, NKC is currently a provider of dialysis services within Washington State, and operates 15 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.⁷

Since January 2008, the Department of Health’s Investigations and Inspections Office has completed fourteen certification and compliance surveys for the operational NKC facilities as the agent for CMS-Medicare certification for Washington State. Of the surveys completed, four revealed minor non-compliance issues related to the care and management of the facilities which required plans of correction⁸. These non-compliance issues were typical of a dialysis facility and the plans of correction were fully implemented. [Source: Facility survey data provided by the Investigations and Inspections Office]

For medical director services, NKC provided a copy of the Totem Lake Kidney Center original and amended Medical Director Agreement. Both documents identified Dr. Astier Alem as the medical director. Additionally, the documents also provided the compensation for the medical director position. A review of Dr. Astier Alem’s compliance history revealed no recorded sanctions. [Source: Application Supplemental 1]

Given the compliance history of NKC and that of the medical director, the department concludes that there is reasonable assurance that, Totem Lake Kidney Center would continue to operate in compliance with state and federal regulations. **This sub-criterion is met.**

⁷ WAC 246-310-230(5).

⁸ 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 and February 2011

- (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 expansion would change these relationships.

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 three dialysis stations in King County planning area #6. This project proposes to add three stations to the existing Totem Lake Kidney Center.

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 demonstrated it is likely to maintain 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 and **is considered met.**

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

Based on the source information reviewed and the applicant's agreement to the condition identified in the "Conclusion" section of this evaluation, 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

Before submitting its application, NKC considered and rejected five alternatives. A summary of the alternatives considered and rejected by NKC are listed below. [Source: Application, page 20]

- Alternative 1-Development of a new facility

NKC states it rejected this option because a projected need of three stations in the planning area is *"not sufficient to justify the development of a new facility nor financially feasible to operate."*

- Alternative 2-Shortened treatment times

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

- Alternative 3-Increased home dialysis

NKC stated it continues to advocate for home dialysis modalities, but the planning area projected unmet need was determined using a regression curve that favors in-center dialysis patients.

- Alternative 4-Kidney transplantation

NKC stated it advocates for kidney transplantation for all patients for *"who it is not contraindicated...supply of available donor organs has not kept pace with demand"*.

- Alternative 5-Shared/Contract services agreement

There are no other dialysis providers in the planning area.

The department did not identify any additional alternatives to those identified by the applicant. Considering that the existing facility's current utilization exceeds 4.8 patients per station, and the results of the numeric methodology show a need for three stations in King County planning area #6, the department concludes the project submitted by NKC is the applicant's best available alternative. Therefore, **this sub-criterion is met.**

Step Three

This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted to add dialysis stations in King County planning area #6, during the Kidney Disease Treatment Centers Review Cycle #2. 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

NKC proposes to expand existing space at center to accommodate the expansion. The cost to expand existing space by the applicant is reflected in the capital expenditure disclosed by the applicant. Within this evaluation, the department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes that **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 evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that **this sub-criterion is met.**

APPENDIX A



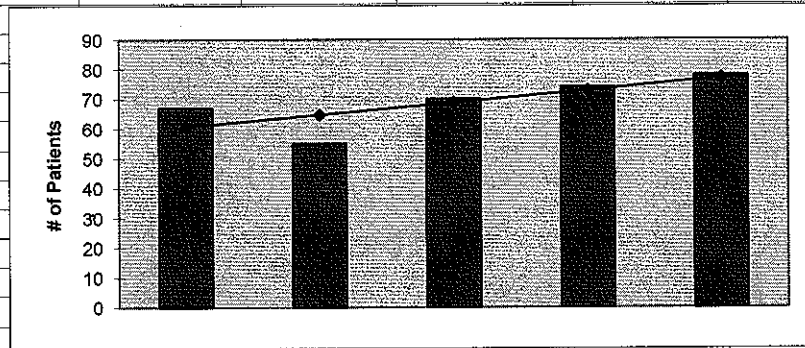
2012
King County 6
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
King Six (6)		2006	2007	2008	2009	2010	2011
	98011	9	10	7	10	10	11
	98033	11	12	11	12	13	9
	98034	15	17	16	21	25	26
	98052	18	17	14	14	14	15
	98053	3	4	5	5	5	8
	98072	8	6	0	4	5	7
	98077	1	1	2	4	2	2
TOTALS		65	67	55	70	74	78
246-310-284(4)(a)	Rate of Change		3.08%	-17.91%	27.27%	5.71%	5.41%
	6% Growth or Greater?		FALSE	FALSE	TRUE	FALSE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2012	Year 2 2013	Year 3 2014	Year 4 2015
Projected Resident Incenter Patients	from 246-310-284(4)(b)			81.10	85.20	89.30	93.40
Station Need for Patients	Divide Resident Incenter Patients by 4.8			16.8958	17.7500	18.6042	19.4583
	Rounded to next whole number			17	18	19	20
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				17	17	17	17
Results of (4)(c) above			-	17	18	19	20
Net Station Need				0	-1	-2	-3
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
NKC - Totem Lake	17	86	5.06				
Total	17	86					
Source: Northwest Renal Network data 2006-2011							
Most recent year-end data: 2011 year-end data as of 02/13/2012							
Most recent quarterly data as of the 1st day of application submission period: 4th quarter 2011 as of 02/13/2012							

x	y	Linear
2007	67	61
2008	55	65
2009	70	69
2010	74	73
2011	78	77
2012		81.10
2013		85.20
2014		89.30
2015		93.40

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.740212098
R Square	0.54791395
Adjusted R Square	0.397218601
Standard Error	6.799509786
Observations	5



ANOVA

	df	SS	MS	F	Significance F
Regression	1	168.1	168.1	3.635904831	0.152605155
Residual	3	138.7	46.23333333		
Total	4	306.8			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-8168.1	4319.740394	-1.890877519	0.155020158	-21915.44185	5579.241854	-21915.44185	5579.241854
X Variable 1	4.1	2.15019379	1.906804875	0.152605155	-2.742876281	10.94287628	-2.742876281	10.94287628

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	62	3
2	64.1	2.9
3	66.2	-11.2
4	68.3	1.7
5	70.4	3.6