



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH

March 25, 2013

CERTIFIED MAIL # 7011 1570 0002 7802 6661

Palmer Pollock, Vice President of Planning  
Northwest Kidney Centers  
700 Broadway  
Seattle, Washington 98122

Re: CN13-16

Dear Mr. Pollock:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers proposing to amend Certificate of Need #1458 because of a change in the site and capital expenditure. For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Centers agrees to the following in its entirety.

**Project Description:**

The NKC Totem Lake Kidney Center is approved to certify and operate seventeen dialysis stations. Services provided at NKC Totem Lake Kidney Center include home dialysis services, hemodialysis dialysis, peritoneal dialysis, visiting patient services, and shifts after 5:00 p.m. The station breakdown at the facility is listed below:

Private Isolation Room	0
Permanent Bed Station	0
Home Training Station	0
Other In-Center Stations	17
<b>Total</b>	<b>17</b>

**Conditions:**

1. Northwest Kidney Centers agrees with 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 for this project is \$423,639.

Palmer Pollock, Vice President of Planning  
Northwest Kidney Centers  
Certificate of Need Application #13-16  
March 25, 2013  
Page 2 of 2

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 March 25, 2013, OF THE CERTIFICATE OF NEED APPLICATION  
SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING TO AMEND  
CERTIFICATE OF NEED #1458**

**APPLICANT DESCRIPTION**

Northwest Kidney Centers (NKC) is a private, not-for-profit corporation, incorporated in the state of Washington that provides dialysis services through its facilities located in King and Clallam counties. 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 15 kidney dialysis facilities. Of these, 14 are located in King County and one is located in Clallam County. Below is a listing of the NKC facilities in Washington. [source: Historical Files, NKC website]

**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

**BACKGROUND INFORMATION AND INITIAL APPROVAL**

This project focuses on Totem Lake Kidney Center [TLKC] listed above. TLKC is currently operating 15 dialysis stations at 12303 Northeast 130<sup>th</sup> Lane in Kirkland. On November 28, 2011, Certificate of Need [CN] #1458 was issued to NKC approving the addition of 2 stations for a facility total of 17 dialysis stations. [source: CN historical files]

Subsequent to the issuance of CN #1458, NKC requested an exemption from CN review for the relocation of TLKC in its entirety as allowed under Washington Administrative Code 246-310-289(9).<sup>1</sup> On December 7, 2012, the department granted NKC's exemption for the relocation of TLKC to a new site at 11327 Northeast 120<sup>th</sup> Street in Kirkland.

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<sup>1</sup> On October 24, 2012, NKC was also issued CN #1491 approving the addition of 3 more stations to TLKC, resulting in a facility total of 20 stations. NKC also submitted an amendment application for CN #1491, which is reviewed in a separate evaluation [App #13-17].

## AMENDMENT PROJECT DESCRIPTION

NKC was required to submit this amendment application for two reasons. First, NKC wanted to preserve the rights to add the 2 stations approved under CN #1458. Second, because of the relocation, the capital costs to add the 2 stations increased beyond the allowable amount identified in Washington Administrative Code 246-310-570.

### Site Change:

Issued CNs are site specific. CN #1458 identifies the 15-station facility and the 2 additional stations would be located at 12023 Northeast 130<sup>th</sup> in Kirkland. In order to preserve the rights to add the two stations granted under CN #1458, NKC must obtain an amended CN #1458 that identifies the 15-station facility and the 2 additional stations would be located at the new site 11327 Northeast 120<sup>th</sup> Street in Kirkland. A change in the approved site requires an amendment under WAC 246-310-570(1)(f).

### Cost Increase:

CN #1458 identifies an estimated capital cost of \$74,401 to add 2 stations to TLKC. The costs were based on minor construction costs and the purchase of moveable equipment. The department allows an increase in capital costs before an amendment CN is required. [Washington Administrative Code 246-310-570]. The increase must be within 12% or \$50,000, whichever is greater, when compared to the approved costs. As a result, the costs associated with CN #1458 could increase to \$124,401 before an amended CN is required.<sup>2</sup> With the relocation of the facility, NKC appropriately allocated a portion of the relocation costs, including construction costs, and all costs associated with the additional moveable equipment to the 2-station addition. These costs totaled to \$423,639, which is well above the limit of \$124,401. An increase in capital expenditure beyond the approved limit also requires an amendment under WAC 246-310-570(1)(f).

Other than the change in site and the increase in capital expenditure, NKC identified no other changes resulting from the relocation of TLKC.

In the initial application that resulted in the issuance of CN #1458, NKC expected the 2 stations would be operational at TLKC by the end of June 2012. [source: November 14, 2011, initial evaluation, p2] If this amendment application is approved, the station addition would be delayed approximately 9 months. NKC expects the 2 stations would be operational by the end of March 2014. [source: Amendment Application, p9]

Issued CN are valid for two years. Issuance of an amended CN does not change the validity period. Specific to CN #1458, the project must commence by November 28, 2013. WAC 246-310-010(13) defines 'commencement of the project' as follows.

*"Commencement of the project" means whichever of the following occurs first: In the case of a construction project, giving notice to proceed with construction to a contractor for a construction project provided applicable permits have been applied for or obtained within sixty days of the notice; beginning site preparation or development; excavating or starting the foundation for a construction project; or beginning alterations, modification, improvement, extension, or expansion of an existing building. In the case of other projects, initiating a health service.*

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<sup>2</sup> \$74,401 + \$50,000 = \$124,401.

NKC expects construction at the new site to begin in January 2013. [source: Amendment Application, p9] If this amendment application is approved, the project authorized under CN #1458A must commence by November 28, 2013, but is not required to be complete by that date. Based on the definition above, the department concludes that NKC could meet this requirement.

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

This project is subject to review under Washington Administrative Code 246-310-570(1)(e) and (f) because the costs for the project have increased beyond the limit and the site for the project has changed.

### **EVALUATION CRITERIA**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each 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.”*

The review for an amendment project is limited to only those criteria that would be affected by the amendment, provided that the amendment does not significantly alter the project. While NKC’s costs and site have changed and the initial timeline is slightly delayed, a significant portion of the approved project has not changed. The services to be provided at TLKC and number of stations to be added have not changed. As a result, the department’s review will focus on applicable portions of financial feasibility

(WAC 246-310-220), structure and process of care (WAC 246-310-230), and cost containment (WAC 246-310-240).<sup>3</sup>

CN #1458 was issued with one condition. The condition focused on the project description, which is restated below.

The NKC Totem Lake Kidney Center is approved to certify and operate seventeen dialysis stations. Services provided at NKC Totem Lake include home dialysis services, hemodialysis dialysis, peritoneal dialysis, visiting patient services, and shifts after 5:00 p.m. The station breakdown at the facility is listed below:

Private Isolation Room	0
Permanent Bed Station	0
Home Training Station	0
Other In-Center Stations	17
<b>Total</b>	<b>17</b>

If this amendment application is approved, the project description condition as stated above would not change. [source: CN #1458]

**TYPE OF REVIEW**

As allowed under WAC 246-310-570, the department accepted this project as an amendment to an existing Certificate of Need. This application was reviewed under an expedited review timeline as outlined in WAC 246-310-150.

**APPLICATION CHRONOLOGY**

Action	Northwest Kidney Centers
Letter of Intent Submitted	November 19, 2012
Application Submitted	January 14, 2013
Department's pre-review activities including screening and responses <sup>4</sup>	January 15, 2013, through February 7, 2013
Beginning of Review <ul style="list-style-type: none"> <li>• public comments accepted throughout review;</li> <li>• no public hearing conducted under the expedited review rules</li> </ul>	February 8, 2013
End of Public Comment	February 28, 2013
Rebuttal Comments Submitted <sup>5</sup>	March 15, 2013
Department's Anticipated Decision Date	April 4, 2013
Department's Actual Decision Date	March 25, 2013

<sup>3</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this amendment project: WAC 246-310-210; WAC 246-310-230(1) and (2); and WAC 246-310-240 (3).

<sup>4</sup> During the review of this amendment application, the department determined that no additional information or clarification was necessary. As a result, NKC did not provide screening responses.

<sup>5</sup> There were no public comments received during the review; therefore, NKC did not submit any rebuttal comments.

**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 Centers’ Certificate of Need application submitted January 14, 2013
- Certificate of Need #1458 issued on November 28, 2011
- The department’s November 14, 2011, evaluation approving the issuance of CN #1458
- Quarterly progress reports related to Certificate of Need #1458
- Quarterly progress reports related to Determination of Reviewability #13-17 approving the relocation of Totem Lake Kidney Center under Washington Administrative Code 246-310-289

**CONCLUSION**

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers proposing to amend Certificate of Need #1458 because of a change in the approved site and an increase in the approved capital expenditure is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Centers agrees to the following in its entirety.

**Project Description:**

The NKC Totem Lake Kidney Center is approved to certify and operate seventeen dialysis stations. Services provided at NKC Totem Lake Kidney Center include home dialysis services, hemodialysis dialysis, peritoneal dialysis, visiting patient services, and shifts after 5:00 p.m. The station breakdown at the facility is listed below:

Private Isolation Room	0
Permanent Bed Station	0
Home Training Station	0
Other In-Center Stations	17
<b>Total</b>	<b>17</b>

**Conditions:**

1. Northwest Kidney Centers agrees with 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 for this project is \$423,639.

## **CRITERIA DETERMINATIONS**

### **A. 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 determines that Northwest Kidney Centers 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.

### **Initial Evaluation Summary**

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department concluded that this sub-criterion was met based on the following factors:

- 1) a review of TLKC's number of dialyses and patients for projected years FY2013 through FY2015;
- 2) a review of the current lease agreement for the site at 12303 Northeast 130<sup>th</sup> Lane in Kirkland;
- 3) a review of the current and amended Medical Director Agreement between NKC and Astier Alem, MD;
- 4) a review of TLKC's revenue and expense statements for projected years FY2013 through FY2015; and
- 5) the lease costs and the medical director costs were both substantiated in the pro forma financial documents.

[source: Initial evaluation, pp8-9]

### **Amendment Application**

This application proposes to amend CN #1458 because of a change in the site and an increase in the capital expenditure beyond the allowable amount. Information provided in the application demonstrates that the projected number of patients and dialyses would not change. [source: Application, Appendix 12]

Additionally, Astier Alem, MD would continue to provide medical director services at the new site. NKC provided a copy of the current and amended medical director agreement for these services. [source: Application, Appendix S-1] This agreement is the same agreement provided in the initial application.

NKC provided a copy of the lease agreement for the new site at 11327 Northeast 120<sup>th</sup> Street in Kirkland [98034]. The lease agreement is between H-P Properties Kirkland, LLC and NKC. The 20-year lease agreement commenced on January 1, 2013, and allows for two 5-year options for renewal. Costs associated with the new lease agreement are substantiated in the pro forma revenue and expense statements provided in this amendment application. [source: Application, Appendices 12 and S-2]



NKC provided an amended pro forma revenue and expense statement. The anticipated gross revenues, deductions from revenues, and net revenues are the exactly the same as provided in the initial application. [source: November 14, 2011, initial evaluation, p9] The expense line item includes the additional costs for the lease at the new site. The table below shows a summary of the amended revenue and expense statements for FY2012 through FY2015. [source: Application, Appendix 12]

**Table 1**  
**NKC-Totem Lake Kidney Center**  
**Fiscal Years 2012 through 2015**

	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
# of Stations	17	17	17	17
# of Treatments [1]	11,704	12,012	12,320	12,628
# of Patients [1]	76	78	80	82
Utilization Rate [1]	4.47	4.59	4.71	4.82
Net Patient Revenue [1]	\$ 4,636,486	\$ 4,758,499	\$ 4,880,808	\$ 5,002,526
Total Expenses	\$ 3,116,086	\$ 3,222,661	\$ 3,469,579	\$ 3,431,132
Overhead Expenses	\$ 1,281,003	\$ 1,314,713	\$ 1,348,424	\$ 1,382,135
<b>Net Profit /(Loss)</b>	<b>\$ 239,397</b>	<b>\$ 221,125</b>	<b>\$ 62,805</b>	<b>\$ 189,259</b>

[1] includes in-center patient only; [2] includes bad debt and charity care

The ‘Net Patient Revenue’ line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The ‘Total Expenses’ line item includes salaries and wages, and depreciation. This is the line item that changed based on the lease agreement for the new site. The ‘Overhead Expense’ line item includes all allocated costs for TLKC.

**Department’s Review**

NKC asserted that its projected number of patients, patient days, and revenue would not change because of a change in site, and maintained those numbers from the initial application. NKC also appropriately showed the changes in the expenses based on the lease agreement for the new site. A comparison of the initial projected net profits and the amended net profits show no substantial changes. As shown in the table above, at the projected volumes identified in the application, NKC anticipates that the 17-station facility would be operating at a profit in each of the forecast years.

Based on the above information, the department concludes that NKC’s projected revenues and expenses are reasonable and can be substantiated for this amendment application. The department concludes that the immediate and long-range operating costs of the project can be met. **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.

### Initial Evaluation Summary

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department concluded that this sub-criterion was met based on the following factors:

- 1) a review of NKC's capital expenditure breakdown associated with the additional two stations;
- 2) a review of NKC's anticipated funding sources; and
- 3) a review of NKC's projected sources and percentages of revenue by payer.

[source: Initial evaluation, pp9-10]

### Amendment Application

This application proposes to amend CN #1458 because of a change in the site and an increase in the capital expenditure beyond the allowable amount. Information provided in the application demonstrates that NKC's funding source would not change. NKC is currently in the early stages of relocating TLKC. As a result, some funding has already been expended. The costs associated with the additional two stations would continue to be funded by NKC board reserves. [source: Application, p16]

The new site for TLKC is approximately two miles from the existing site. [source: driving directions found at yahoo.com] As a result, NKC did not anticipate any changes in sources and percentages of revenue by payer. Medicare and Medicaid entitlements continue to be the largest revenue source at 82%. [source: Application, p8]

NKC identified the capital costs associated with the two additional stations to be \$423,629, which includes a percentage of the relocation costs. NKC also provided its formula for determining the amended capital costs for this project. The table below shows the relocation costs for TLKC, including any costs related to construction to build for more than 15 stations. [source: Application, p5]

**Table 2**  
**NKC Relocation Costs**

<b>Item</b>	<b>Cost</b>
Space Construction	\$ 2,938,313
Fixed Equipment	\$ 312,150
Moveable Equipment [furniture, etc]	\$ 140,375
Sales Tax	\$ 322,130
<b>Total Costs</b>	<b>\$ 3,712,968</b>
Plus Indirect Costs	\$ 420,382
<b>Total Costs For Relocation</b>	<b>\$ 4,133,350</b>

NKC then divided the 'Total Costs for Relocation' line item by 20, which is the number of stations that could be housed in the facility at the new site. This results in a per-station cost of \$206,668.

To determine the costs for the addition of two stations, NKC multiplied \$206,668 by 2, and then added any additional costs that are specific to the two-station addition. The table on the following page provides a breakdown of the costs for the 2-station addition as provided in this amendment application.

**Table 3**  
**NKC Estimated Capital Costs**

<b>Item</b>	<b>Cost</b>	<b>% of Total</b>
Portion of relocation of TLKC	\$ 413,336	97.6%
New moveable equipment	\$ 9,400	2.2%
Tax	\$ 893	0.2%
<b>Total Estimated Capital Costs</b>	<b>\$ 423,629</b>	<b>100.0%</b>

**Department’s Review**

As stated in the project description section of this evaluation, one reason NKC submitted this application is because the costs for the project increased beyond the allowable amount. NKC appropriately allocated relocation costs to this project. The formula used by NKC to determine the amount to be allocated is reasonable.

Based on the information provided above, the department concludes that the cost of this project will not result in an unreasonable impact on the costs and charges for health services within the service area. **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.

**Initial Evaluation Summary**

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department noted that NKC intended to use board reserves to fund the project and concluded that this sub-criterion was met based on the following factors:

- 1) a review of NKC’s historical financial health; and
- 2) a review of TLKC’s current financial health.

[source: Initial evaluation, pp10-11]

**Amendment Application**

With this amendment application NKC still intends to fund the entire project with board reserves, even though the costs have increased from the initial cost of \$74,401, to the amendment cost of \$423,629. [source: Application, p16]

To demonstrate compliance with this sub-criterion, NKC provided its historical and projected financial statements, which includes cash flow statements and balance sheets for both NKC as a whole and TLKC. [source: Application, Appendices 24, 25, 26, 27, & 28]

**Department’s Review**

Based on the above information, the department concludes that NKC’s source of financing continues to be appropriate even with the increase in costs for this project. **This sub-criterion is met.**

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

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "Conclusion" section of this evaluation, the department determines that Northwest Kidney Centers has met the structure and process of care criteria in WAC 246-310-230(3), (4), and (5).

(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. 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.

### **Initial Evaluation Summary**

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department concluded that this sub-criterion was met based on the following factors:

- 1) a review of NKC's quality of care history since January 2008; and
- 2) A review of NKC's medical director at TLKC, Astier Alem, MD.  
[source: Initial evaluation, pp12-13]

### **Amendment Application**

NKC owns and operates 15 dialysis centers in two counties, within Washington State. NKC does not own or operate any out-of-state facilities. The Department of Health's Investigations and Inspections Office (IIO) conducts quality of care and compliance surveys for the types of healthcare facilities operated by NKC.

Since January 2008, the Department of Health's Investigations and Inspections Office has completed certification and compliance surveys for a number of the operational NKC facilities. 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>6</sup> 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 Medical Director Agreement and compensation amendment currently in effect between itself and Astier Alem, MD, the current medical director at TLKC. A review of the compliance history for Dr. Alem revealed no recorded sanctions. [source: Compliance history provided by Medical Quality Assurance Commission]

### **Department's Review**

Given the compliance history of NKC and that of the current medical director, the department concludes that there is reasonable assurance that TLKC would continue to operate in compliance with state and federal regulations with the addition of 2 stations. **This sub-criterion is met.**

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<sup>6</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.

(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.

#### **Initial Evaluation Summary**

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department concluded that this sub-criterion was met based on the following factors:

- 1) a review of NKC's history of providing dialysis services to the residents of the state through its long-standing centers; and
- 2) the results of the ESRD numeric methodology [WAC 246-310-284] and NKC's intent to meet the projected dialysis station need by adding dialysis station capacity in the planning area. [source: Initial evaluation, p13]

#### **Amendment Application**

Currently, NKC operates 15 dialysis centers in two separate counties. TLKC has been operating at the same location in Kirkland for approximately 20 years. NKC states that this relocation will allow it to incorporate some of the new technologies at TLKC that could not be added at the existing site. The additional two stations allow TLKC to continue to have the needed station capacity to provide services to patients within the planning area. [source: Application, p19]

#### **Department's Review**

Given the long standing history TLKC in the planning area and the fact that the need for additional stations in the planning area has not changed, the department continues to conclude that approval of this project will not result in an unwarranted fragmentation of services. **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.

#### **Initial Evaluation Summary**

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department concluded that this sub-criterion was met based on the sub-criterion that was addressed in sub-section (3) above. [source: Initial evaluation, p13]

#### **Amendment Application Review**

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

**C. Cost Containment (WAC 246-310-240)**

Based on the source information reviewed and the applicant’s agreement to the conditions identified in the “Conclusion” section of this evaluation, the department determines that Northwest Kidney Centers has met the cost containment criteria in WAC 246-310-240.

*(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 criteria (tie-breaker) contained in WAC 246-310. The tiebreaker 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**

**Initial Evaluation Summary**

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department concluded that this sub-criterion was met based on the applicant’s ability to meet the review criteria in WAC 246-310-210, WAC 246-310-220; and WAC 246-310-230. [source: Initial evaluation, p14]

**Amendment Application**

In this amendment evaluation review, the department concluded that NKC met the review criteria in the applicable sections of WAC 246-310-220 and WAC 246-310-230. Therefore, the department moves to step two below.

**Step Two**

**Initial Evaluation Summary**

In its November 14, 2011, initial evaluation supporting the issuance of CN #1458, the department concluded that this sub-criterion was met based on the a review of the five options considered and rejected before submitting the application. Further, the department did not identify any other options that should have been considered by NKC. [source: Initial evaluation, pp14-15]

### **Amendment Application**

On November 6, 2012, CN Program staff met with representatives of NKC and discussed the 'next steps' if NKC elected to relocate TLKC in its entirety under WAC 246-310-289. Since CNs are site specific, the only option available to NKC is submission of an amendment application. [source: CN historical files]

After the November 6, 2012, meeting, NKC did not consider any other alternatives other than filing this amendment application once the decision was made to relocate TLKC. Instead, NKC immediately began preparation and submission of an amendment application in order to preserve the rights to the 2 additional stations.<sup>7</sup>

### **Department's Review of Alternatives**

Based on the discussion above, other than the option of relinquishing CN #1458, NKC had no other option than to submit this amendment application once the relocation of TLKC was approved. Northwest Renal Network data demonstrates that the additional stations at TLKC are needed. Further, NKC does not intend to reduce any of the dialysis services currently provided at TLKC.

### **Step Three**

This step is used to determine between two or more approvable projects which is the best alternative. This step did not apply to the initial project and does not apply to this amendment project.

No public comments were submitted for this sub-criterion.

Based on the requirement of NKC to submit an amendment application because of a change in the approved site and an increase in the capital costs, the department concludes that that the financing arrangements appropriate. **This sub-criterion is met.**

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<sup>7</sup> NKC submitted a letter of intent approximately 2 weeks after the November 6 meeting [November 19, 2012], and an amendment application approximately 2 months after the November meeting.