



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

August 5, 2015

CERTIFIED MAIL # 7015 0640 0000 6441 5607

Austin Ross, Vice President of Planning
Northwest Kidney Centers
700 Broadway
Seattle, Washington 98122-4302

RE: CN 15-17

Dear Mr. Ross:

We have completed review of the Certificate of Need (CN) application submitted by Northwest Kidney Centers proposing to add three dialysis stations to NKC SeaTac Kidney Center in King County. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Northwest Kidney Centers agrees to the following in its entirety.

Project Description:

This Certificate approves the addition of three new kidney dialysis stations. At project completion, NKC SeaTac Kidney Center is approved to certify and operate thirty-three dialysis stations. Services provided include in-center hemodialysis, training for home and peritoneal dialysis patients, and treatments shifts beginning after 5:00 p.m. In addition the facility has isolation rooms for those patients needing that level of care as well as bed stations. The station breakdown at the kidney center is listed below:

Permanent Bed Stations ¹	2
Isolation Stations ²	3
Other In-Center Stations	28
Total	33

¹ Based on line drawings within the application.

² iBid

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Vice President of Planning
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Condition:

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 Cost:

The approved capital expenditure associated with this project is \$132,144.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response 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

Physical Address:

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, Community Health Systems

Enclosure

**EVALUATION DATED AUGUST 5, 2015 FOR THE CERTIFICATE OF NEED
APPLICATION SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING THE
ADDITION OF THREE DIALYSIS STATIONS TO THE EXISTING NKC SEATAC
KIDNEY DIALYSIS CENTER LOCATED IN KING COUNTY PLANNING AREA #4**

APPLICANT DESCRIPTION

Northwest Kidney Center's (NKC) is a private, not-for-profit corporation, incorporated in the state of Washington. NKC provides dialysis services through its facilities located in King and Clallam counties. Established in 1962, NKC operates as community based dialysis program working to meet the needs of dialysis patients and their physicians. A volunteer board of trustees governs NKC. 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 15 kidney dialysis facilities. Of these, 14 are located within King County. Below is a listing of NKC facilities in Washington. [Source: Certificate of Need Historical Files and <http://www.nwkidney.org/>]

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	Kirkland Kidney Center ¹
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 30-station NKC SeaTac Kidney Center located at 17900 International Blvd, Suite 301 in the city of SeaTac, within King County planning area #4. Services provided include in-center hemodialysis, training for home and peritoneal dialysis patients, and treatments shifts beginning after 5:00 p.m. In addition the facility has three isolation rooms for those patients needing that level of care as well as two bed stations. [Source: Application, page 7 and facility line drawings]

The capital expenditure associated with the expansion of the kidney center is \$132,114. Of that amount 53% is related to building construction; 37% for fixed and moveable equipment; and the remaining 10% is related to taxes and fees. [Source: Application, Page 25]

¹ Formerly Totem Lake Kidney Center

If this project is approved, NKC anticipates the three new stations would be available by the end of June 30, 2016. Under this timeline, year 2017 would be the facility's first full fiscal year of operation with 33 stations and 2019 would be year three. [Source: Application, Page 7]

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) 246-310-020(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 that 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.”*

To obtain CN 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); 246-310-240 (cost containment) and any service/facility specific criteria and standards linked to these four criteria. WAC 246-310 contains specific kidney dialysis specific criteria and standards.

These are contained in WAC 246-310-280 through 289. These facility specific criteria and standards must be used to make the required determinations.²

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 #4. No other applications were submitted for the King County planning area #4 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	October 30, 2014
Application Submitted	November 26, 2014
Department’s Pre-review Activities including <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant’s 1st Screening Responses Received • DOH 2nd Screening Letter • Applicant’s 2nd Screening Responses Received 	December 31, 2014 February 17, 2015 March 9, 2015 April 24, 2015
Beginning of Review	May 4, 2015
End of Public Comment <ul style="list-style-type: none"> • Public comments accepted through 	June 8, 2015
<ul style="list-style-type: none"> • Public hearing conducted³ • Rebuttal Comments Received⁴ 	N/A June 23, 2015
Department's Anticipated Decision Date	August 7, 2015
Department's Actual Decision Date	August 5, 2015

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 entity 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 26, 2014
- Northwest Kidney Centers’ supplemental information received February 17, 2015, and April 24, 2015
- No public comment was received during the review

² Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to the projects: WAC 246-310-210(3), (4), (5), and (6).

³ The department did not conduct a public hearing.

⁴ There were no public comments received for this project. Therefore, the applicant did not provide rebuttal comments.

- Years 2008 through 2013 historical kidney dialysis data obtained from the Northwest Renal Network
- Year end 2013 Northwest Renal Network 4th Quarter Utilization Data
- Licensing and/or survey data provided by the Department of Health’s Investigations and Inspections Office
- Data obtained from Medicare webpage (www.medicare.gov)
- Certificate of Need historical files

CONCLUSION

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

Project Description:

This Certificate approves the addition of three new kidney dialysis stations. At project completion, NKC SeaTac Kidney Center is approved to certify and operate thirty-three dialysis stations. Services provided include in-center hemodialysis, training for home and peritoneal dialysis patients, and treatments shifts beginning after 5:00 p.m. In addition the facility has isolation rooms for those patients needing that level of care as well as bed stations. The station breakdown at the kidney center is listed below:

Permanent Bed Stations ⁵	2
Isolation Stations ⁶	3
Other In-Center Stations	28
Total	33

Condition:

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 Cost:

The approved capital expenditure associated with this project is \$132,144.

⁵ Based on line drawings within the application.

⁶ iBid

CRITERIA DETERMINATION

A. Need (WAC 246-310-210 and WAC 246-310-284)

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 population's 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.⁷

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.⁸ 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.

⁷ 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]

⁸ 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 2013.

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 NKC SeaTac Kidney Dialysis Center located in King County ESRD planning area #4. 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 NKC SeaTac Kidney Dialysis Center is located in King County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, Page 15]

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 #4. 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 by NKC and the department for King County planning area #4.

**Table 1
King County Planning Area #4 Numeric Methodology Summary
of Projected Net Station Need**

	2017 Projected # of stations	Minus Current # of stations	2017 Net Need
NKC	33	30	3
DOH	33	30	3

Table 1 demonstrates that the projections of the applicant match the department’s figures. As a result, the net station need for King County planning area #4 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 used to calculate this standard. The first day of the application submission period for this project was November 1, 2014. [WAC 246-310-282] The department used the September 30, 2014 quarterly modality report from NRN for its determination of this standard. NKC operates the only dialysis center in the planning area. The table 2 shows the reported station use for the existing 30-station NKC SeaTac Kidney Dialysis Center.

**Table 2
September 30, 2014 - Facility Station Use Data**

Facility Name	# of Stations	# of Pts	Pts/Station
NKC – SeaTac	30	151	5.03

Table 2 above shows that NKC SeaTac Kidney Dialysis Center satisfies this station use 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. The King County planning area #4 standard is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)]

NKC anticipates the three new stations would become operational by end of June 30, 2016. Under this timeline, year 2017 would be the facility first full fiscal year of operation and 2019 would be year three. A summary of NKC’s projected station use rate for the third year of operation is shown in the table 3 below. [Source: Application, page 17]

**Table 3
Third Year Projected Facility Station Use Rate**

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
NKC-NKC SeaTac Kidney Dialysis Center	2019	33	163	4.94

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.

To determine whether all residents of the King County planning area #4 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 its New Patients Admission Criteria and Process currently used at the NKC SeaTac Kidney Dialysis Center. The document outlines the process and criteria that the center uses to admit patients for treatment and ensures that patients will receive appropriate care. The document 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 Exhibit 12]

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 intend 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 #4 residents by submitting the Charity Care policy currently used at the facility. The charity care policy outlines the process one would use to access services when they do not have the financial resources to pay for treatments. NKC also included a ‘charity’ line item as a deduction from revenue within the pro forma income statements for the NKC SeaTac Kidney Dialysis Center. [Source: Application, Exhibit 12 & Supplemental information received February 17, 2015, attachment 1]

The department concludes that all residents of the service area would continue to have access to applicant’s 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 additional stations at the NKC SeaTac Kidney Dialysis Center will become operational by June 30, 2016. Based on this timeline, year 2017 is the facility’s first full fiscal year of operation with all 33 stations. Using the financial information provided as part of the completed application, Table 4 illustrates the projected revenue, expenses, and net income for 2016 through 2019 for the NKC SeaTac Kidney Center. [Source: Application, Page 12 & Supplemental information received February 17, 2015, attachment 1]

Table 4
NKC SeaTac Kidney Center
Projected Revenue and Expenses Years 2016 - 2019

	Partial Year 6/30/2016	Fiscal Year 1 – 2016- 2017	Fiscal Year 2 – 2017- 2018	Fiscal Year 3 – 2018- 2019
# of Stations	33	33	33	33
# of Treatments ^[1]	22,792	23,236	23,680	24,124
# of Patients ^[1]	154	157	160	163
Utilization Rate ^[1]	4.67	4.76	4.85	4.94
Net Patient Revenue ^[3]	\$6,945,712	\$7,081,018	\$7,216,324	\$7,351,631
Total Operating Expense ^[2]	\$4,475,364	\$4,579,527	\$4,655,268	\$4,754,871
Contribution to Overhead	\$2,470,348	\$2,501,491	\$2,561,056	\$2,596,760
Overhead ⁹	\$1,934,015	\$1,912,540	\$1,890,613	\$1,868,280
Net Profit or (Loss)	\$536,333	\$588,951	\$670,445	\$728,480

[1] Includes in-center patients only; [2] includes bad debt and charity care [3] in-center revenue

The ‘Net 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 for SeaTac Kidney Center. As shown in Table 4, at the projected volumes identified in the application, NKC anticipates that the 33-station facility would be operating at a profit in each of the projected years.

NKC currently operates NKC SeaTac at 17900 International Boulevard within the city of SeaTac. The executed lease agreement provided in the application outlines the initial terms and the annual rent for space lease for the premises. The agreement was executed in year 2007, and it extends through June 1, 2017. In a letter dated July 17, 2007 from the building landlord, it was confirmed that tenant have the right to extend the ‘Term of the Lease for two (2) separate successive five (5) years period after the lease expiration on June 30, 2017. [Source: Application, Exhibit 10] The current annual lease costs are substantiated in the pro forma financial documents provided. [Source: Supplemental information received February 17, 2015, attachment 1]

NKC provided a copy of the existing Medical Director Agreement for the NKC SeaTac Kidney Center. Within the application, NKC stated effective January 2015, the current medical for the facility would change. The medical director costs identified in the existing agreement are consistent with the amount identified in the pro-forma income statement.

Based on the source documents evaluated, the department concludes that NKC’s projected revenues and expenses are reasonable and can be substantiated. **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

⁹ The department notes that the overhead rate is not held constant through the 3rd year of operation. The rates are projected as follows: 2016-\$84.85; 2017-\$82.31; 2018-\$79.84; and 2019-\$77.44. Even if the overhead rate is held at its highest level, the facility is projected to a profit through the 3rd year of operation with the additional stations.

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 this project is \$132,114. Table 5 shows a breakdown of the \$132,114.

Table 5
Estimated Capital Costs of NKC SeaTac Kidney Dialysis Center Expansion

Item	Cost	% of Total
Building Construction	\$70,285	53%
Fixed and Moveable Equipment	\$49,120	37%
Taxes and Review Fees	\$12,709	10%
Total Estimated Capital Costs	\$132,114	100%

[Source: Application, Page 27]

To further demonstrate compliance with this sub-criterion, NKC provided the sources of its revenue by payer expected at the facility. The breakdown is shown in table 6. [Source: Application, Page 27]

Table 6
Projected Sources of Revenue and Treatments by Payor
NKC-SeaTac Dialysis Center

Payor	% of Total Treatments	% of Revenue
Medicare	76%	76%
Medicaid	12%	11.9%
Commercial	12%	11.9%
Total	100%	100%

As shown in Table 6, the Medicare and Medicaid treatments are projected to equal 88.0%. The percentage of revenue by payor is also equal to 88.1%. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS has recently implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate.

However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Given the department’s understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by NKC about its revenue indicates this project may not have an unreasonable impact on charges for

services within the planning area. Based on the source documents evaluated of the application materials, the department concludes **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.

The capital expenditure associated with the expansion of NKC SeaTac Dialysis Center is \$132,114. The project will be financed through NKC board reserves. NKC provided a letter of financial commitment to the project. [Source: Application, Exhibit 14] This source of financing is appropriate. A review of NKC’s audited financial statements shows that they have the capability to finance this project. Based on the source documents evaluated, the department concludes **this sub-criterion is met.**

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.

NKC SeaTac Dialysis Center is currently in operation with 30 dialysis stations. Table 7 shows the current and projected staffing for NKC SeaTac if the project is approved.

**Table 7
NKC SeaTac Dialysis Center 2016-2019 FTEs**

Staff/FTEs	Current 2015	2016 Increase	2017 Increase	2018 Increase	2019 Increase	Total FTEs
HD Tech	20.80	0.41	0.41	0.41	0.41	22.44
RN	11.20	0.22	0.22	0.22	0.22	12.08
RN –Home Training	0.25	0.03	0.03	0.03	0.04	0.38
Clinical Manager	1.00	0.00	0.00	0.00	0.00	1.00
Facility System	0.50	0.00	0.00	0.00	0.00	0.50
Social Worker	1.28	0.02	0.03	0.02	0.02	1.37
Dietician	1.02	0.02	0.02	0.02	0.02	1.10
Receptionist	1.00	0.00	0.00	0.00	0.00	1.00
Total FTE’s	37.05	0.70	0.71	0.70	0.71	39.87

As shown in Table 7, NKC expects a minimal increase over the three year period. NKC expects the majority if not all of the staffing increases to be accomplished through increase hours of existing part time staff. They currently have minimal vacancies in their system. Based on the source documents evaluated, the department concludes adequate staffing for the three-station increase for the NKC SeaTac Kidney Dialysis 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.

There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure whether the health services proposed in the project 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.

As a provider of dialysis services in Washington State, NKC currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For its SeaTac Dialysis Center, ancillary and support services such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, materials management, administration, and technical services are provided at one of the support offices in Seattle, Lake Forest Park, SeaTac or Bellevue. Adding three dialysis stations is not expected to change these relationships. **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.

The department reviewed information available to the public at Medicare.gov “dialysis facility compare” website to verify the number of Medicare certified stations, services offered at the location such as types of home training and shifts starting after 5 pm at this NKC facility. NKC SeaTac Kidney Dialysis Center is certified for 30 n-center hemodialysis stations, having shifts starting after 5 pm, home hemodialysis training, and peritoneal dialysis. The NKC SeaTac Kidney Dialysis Center Medicare certification is consistent with the CN approvals and records. Therefore, the department concludes that there is reasonable assurance the NKC SeaTac Kidney Dialysis Center will be operated in conformance with all state and federal rules and regulations.

For Washington State, the Department of Health’s Investigations and Inspections Office (IIO) completed 17 compliance surveys as the contractor for Medicare for the operational facilities own or managed by NKC. These reveals minor non-compliance issues typical of a dialysis facility and NKC submitted and implemented acceptable plans of correction. NKC SeaTac was surveyed on September 2014 by IIO. The survey did not reveal any non-compliance issues. [Source: facility survey data provided by the Investigations and Inspections Office]

The department also reviewed information on the Center for Medicare & Medicaid Services (CMS) website related to dialysis facilities star ratings. CMS assigns a one to five ‘star rating’ in two separate categories: best treatment practices, hospitalizations, and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

- **Best Treatment Practices**
This is a measure of the facility’s treatment practices in the areas of anemia management; dialysis adequacy, vascular access, and mineral & bone disorder. This category reviews both adult and child dialysis patients.
- **Hospitalization and Deaths**
This measure takes a facility's expected total number of hospital admissions and compares it to the actual total number of hospital admissions among its Medicare dialysis patients. It also takes a facility's expected patient death ratio and compares it to the actual patient death ratio taking into consideration the patient’s age, race, sex, diabetes, years on dialysis, and any co-morbidities.

NKC currently provides dialysis services within Washington State, and it operates 15 kidney dialysis treatment centers. 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.¹⁰ Below are the facilities operated or own by NKC and of the CMS star ratings.

Facilities	City	Star Rating
NKC Auburn Center	Auburn	4
NKC Broadway Kidney Center	Seattle	3
NKC Elliot Bay Kidney Center	Seattle	3
NKC Enumclaw Kidney Center	Enumclaw	4
NKC Kent Kidney Center	Kent	3
NKC Totem Lake Kidney Center	Kirkland	4
NKC Lake City Kidney Center	Lake Forest Park	5
NKC Port Angeles Kidney Center	Port Angeles	4
NKC Renton Kidney Center	Renton	4
NKC Scribner Kidney Center	Seattle	3
NKC SeaTac	SeaTac	3
NKC Seattle Kidney Center	Seattle	3
NKC Snoqualmie Kidney Center	Snoqualmie	3
NKC West Seattle Center	Seattle	3
NKC Lake Washington Kidney Center	Seattle	4

As shown in the table above, the facilities operated or own by NKC have a rating of 3 (average) or above.

Dr. Suhail Ahmad was identified as the facility’s existing medical director when the application was submitted. However, beginning January 2015, Dr. Daniel Hu was identified as the Medical Director for the SeaTac Kidney Dialysis Center. NKC provided a copy the executed medical

¹⁰ WAC 246-310-230(5).

director agreement between Northwest Kidney Centers, a Washington nonprofit corporation (“NKC”) and Danny Hu, MD (“Doctor”). The agreement identified the roles and responsibilities of the each party involved. Additionally, the agreement also identifies the annual compensation for the medical director position. [Source: Application, Page 4 & Supplemental information received February 17, 2015, attachment 1] A review of the compliance history for Dr. Daniel Hu revealed no recorded sanctions.

Based on the source documents evaluated, the department concludes **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 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 the King County dialysis planning area #4. This project proposes to add three stations to the applicant’s existing NKC SeaTac Kidney Dialysis Center in SeaTac within King County ESRD planning area #4.

NKC also provided the patient transfer agreement currently used at NKC SeaTac Kidney Dialysis Center and at NKC’s existing facilities in Washington. The provided transfer agreement will continue to be used at the expanded NKC SeaTac Kidney Dialysis Center [Source: Application, Exhibit 15]

Based on the source documents evaluated, the department concludes 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. **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 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. First the department determines if the application has met the other criteria of WAC 246-310-210 thru 230. If the project has failed to meet one or more of these criteria then the project cannot be considered to be the best alternative in terms of cost, efficiency, or effectiveness as a result the application would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, the department then assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type. The superiority 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 type superiority 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.

NKC proposed to expand its existing NKC SeaTac Kidney Dialysis Center from 30 to 33 stations within King County dialysis planning area #4. The department concluded that the project met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two.

Within the application NKC stated, "*As noted earlier in this application, after a lengthy appeal, NKC SeaTac received a CN approval in April 2013 to add five stations. Given the current census at NKC SeaTac, NKC did not consider any other options other than submitting this application to expand. For a modest capital expenditure, NKC can, upon certificate of need approval, quickly and economically add three stations*". [Source: Application, Page 31]

Given the applicant statement, the department reviewed criteria for WAC 246-310-210 and concluded that there is a need for three additional stations in the King County dialysis planning area #4 and the applicant's proposal met the applicable criteria. With the NKC SeaTac facility being the only dialysis facility in the King #4 planning area and the small station need projected, the department did not identify any alternatives to the current NKC project. Additionally, the department also concluded that NKC's project met the applicable review criteria under WAC 246-310-220, and 230. Based on the source information evaluated, the department concludes that NKC's project is the best alternative, **this sub-criterion is met.**

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

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

NKC proposes to add three stations to its existing 30 station SeaTac dialysis facility. The total cost of the project is estimated at \$132,114. Of that amount \$112,829 is for new capital costs and \$19,285 is allocated costs of previously building costs.

NKC has also had many years of experience ensuring its existing facilities are compliant with Medicare certification and the local authority construction and energy conservation codes. Based on the information, the department concludes **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 concluded **this sub-criterion is met**

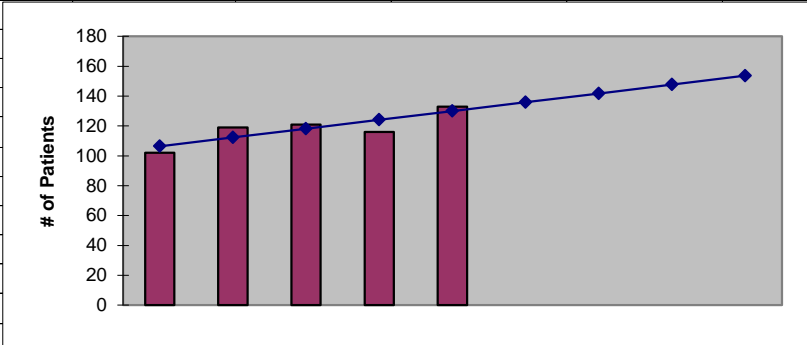
APPENDIX A



**2014
King County 4
ESRD Need Projection Methodology**

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
King Four		2008	2009	2010	2011	2012	2013
	98148	10	10	10	18	13	23
	98158	0	0	0	0	0	0
	98166	22	17	23	21	24	23
	98188	21	32	40	40	35	23
	98198	35	43	46	42	44	64
	TOTALS	88	102	119	121	116	133
246-310-284(4)(a)	Rate of Change		15.91%	16.67%	1.68%	-4.13%	14.66%
	6% Growth or Greater?		TRUE	TRUE	FALSE	FALSE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2014	Year 2 2015	Year 3 2016	Year 4 2017
Projected Resident Incenter Patients	from 246-310-284(4)(b)			135.90	141.80	147.70	153.60
Station Need for Patients	Divide Resident Incenter Patients by 4.8			28.3125	29.5417	30.7708	32.0000
	Rounded to next whole number			29	30	31	33
246-310-284(5)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				30	30	30	30
Results of (4)(c) above				- 29	30	31	33
Net Station Need				1	0	-1	-3
Negative number indicates need for stations							
Planning Area Facilities							
Name of Center	# of Stations						
NKC SeaTac	30						
Total	30						
Source: Northwest Renal Network data 2008-2013							
Most recent year-end data: 2013 posted 01/29/14							

x	y	Linear
2009	102	106
2010	119	112
2011	121	118
2012	116	124
2013	133	130
2014		135.90
2015		141.80
2016		147.70
2017		153.60



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.838758948
R Square	0.703516572
Adjusted R Square	0.604688763
Standard Error	6.992853495
Observations	5

ANOVA					
	df	SS	MS	F	Significance F
Regression	1	348.1	348.1	7.118609407	0.075814836
Residual	3	146.7	48.9		
Total	4	494.8			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-11746.7	4446.994656	-2.641491818	0.077556732	-25899.02171	2405.621712	-25899.02171	2405.621712
X Variable 1	5.9	2.211334439	2.668072227	0.075814836	-1.137453114	12.93745311	-1.137453114	12.93745311

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	106.4	-4.4
2	112.3	6.7
3	118.2	2.8
4	124.1	-8.1
5	130	3