EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING TO ESTABLISH A NEW 38 STATION DIALYSIS CENTER IN KING COUNTY SUBSERVICE AREA #2.

PROJECT 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. Established in 1962, NKC operates as a community based dialysis program working to meet the needs of dialysis patients and their physicians. [Application, p1]

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 twelve kidney dialysis facilities. Of these, eleven reside within King County. Below is a listing of the twelve NKC facilities in Washington. [Application, Appendix 1]

King County

Auburn Kidney Center
Elliot Bay Kidney Center
Haviland Kidney Center
Lake City Kidney Center
Lake Washington Kidney Center
Mount Rainier Kidney Center
Scribner Kidney Center
SeaTac Kidney Center
Snoqualmie Kidney Center
Totem Lake Kidney Center
West Seattle Kidney Center

Clallam County

Port Angeles Kidney Center

This application proposes to relocate 38 of the 53 existing certified dialysis stations from the Haviland facility on 700 Broadway to a new location at 548 15th Avenue. The new location will be called the Seattle Kidney Center.

Specifically, NKC proposes to relocate the Special Care Unit, isolation dialysis and the home hemodialysis and home peritoneal dialysis departments to the new location. The stated purpose is to replace older, less efficient treatment space with new, more efficient space. [Application, Exec. Summary] The Special Care unit will be a, "fully-bedded treatment environment dedicated to provision of dialysis for patients in need of respite care, palliative care and specialized nursing care due to medical, psychiatric, or cognitive issues that make them less suitable…for dialysis in a typical outpatient setting". [June 13, 2007 NKC Rebuttal Comments, p2]

The project costs for the establishment of the new facility is $4,934,998, and is broken down as follows: [Application, p5; Appendix 8]

Item	Cost	% of Total
Construction	$ 3,686,579	75%
Fixed & Moveable Equipment	$ 845,100	17%
Taxes	$ 403,319	8%
Total Estimated Capital Costs	**$ 4,934,998**	**100%**

NKC will lease the site for the Seattle Kidney Center. The building is currently under construction and will be fitted for use as a dialysis facility. As a result, if this project is approved, NKC anticipates the new facility to be operational as early as October 1, 2008.

BACKGROUND

WAC 246-310-289(2) states, "When an existing facility proposes to relocate a portion of its stations to either another planning area or within the same planning area, a new health care facility is considered to be established under WAC 246-310-020(1)". Because NKC plans to relocation only 38 of the 53 stations from the Haviland location, the Seattle Kidney Center is considered to be a new health care facility.

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

CRITERIA EVALUATION

To obtain Certificate of Need (CN) approval, NKC, Inc. 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).[1] Additionally, the applicant must demonstrate compliance for the project according to relevant sections of WAC 246-310-280 through 287.

APPLICATION CHRONOLOGY

January 31, 2007	Letter of Intent Submitted
February 27, 2007	Application Submitted
February 28, 2007 to April 22, 2007	Screening Activities and Responses
April 23, 2007	Department Begins Review of Application No Public Hearing Requested
May 29, 2007	Close of Public Comment
June 13, 2007	NKC Rebuttal received
July 30, 2007	Department's Anticipated Decision Date
July 30, 2007	Department's Decision Date

AFFECTED PARTIES

[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); WAC 246-310-288; and WC 246-310-284.

Throughout the review of this project, one entity sought and received affected person status under WAC 246-310-010 – DaVita, Inc. – manager of the Olympic View facility owned by Group Health Cooperative

SOURCE INFORMATION REVIEWED

- NKC's Certificate of Need Application, received February 27, 2007
- NKC's supplemental information, received April 13, 2007
- Years 2002 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- December 2006 Northwest Renal Network Quarterly Data
- Medical Quality Assurance Commission Credentialing Records
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Public comment submitted by Davita, Inc. May 29, 2007
- NKC Rebuttal Comments received June 13, 2007
- Data obtained from Center for Medicare and Medicaid (CMS) "Dialysis Facility Compare" website (http://www.medicare.gov/Dialysis/home.asp).
- Data obtained from the Internet regarding health care providers
- Population data obtained from the Office of Financial Management
- Data obtained from the Internet regarding mileage and distance
- Information from the Northwest Kidney Centers website (www.nwkidney.org)
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of NKC, Inc. to relocate 38 of the 53 certified dialysis stations from the existing Haviland facility to a new facility called the Seattle Kidney Center is consistent with application criteria of the Certificate of Need Program, and a Certificate of Need is approved. At project completion, Haviland would have a total of 15 stations and the Seattle Kidney Center would have a total of 38.

The total approved costs associated with this project are $4,934,998.

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

Based on the source information reviewed, the department determines that the applicant has met the applicable need criteria in WAC 246-310-210 and the kidney disease treatment standards in WAC 246-310-289.

(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 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology, adopted January 1, 2007, 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.[2]

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. In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last 5 annual change periods), the department 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. 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 in the planning area are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

[2] 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]

Northwest Kidney Center's Application of the Numeric Methodology

The applicant provided the following projected utilization data for dialysis treatments in King County sub-service area #2. [Application, Appendix 17a]

Table 1
NKC cited Utilization Data / Projected Growth Rate

King Two (2)	2001	2002	2003	2004	2005	2006
98101	4	9	12	12	12	11
98102	5	4	4	11	9	12
98104	17	13	15	17	12	17
98108	37	35	39	35	35	33
98109	7	8	11	10	11	12
98111	0	0	0	0	1	2
98112	11	12	13	20	12	13
98118	77	76	74	68	64	63
98119	6	5	7	6	7	7
98121	6	4	4	5	8	5
98122	38	49	53	42	41	37
98134	1	1	1	1	1	0
98144	44	40	39	43	52	56
98199	6	4	6	4	2	4
Totals	**259**	**260**	**278**	**274**[3]	**267**	**272**
Rate of Change	X	0.39	6.92	-1.44	-2.55	1.87

As shown above, the planning area has experienced a six percent growth in only one of the previous five annual change calculations. Therefore linear regression was used in the projection of station need. It should be noted that the applicant included a zip code (98111) not cited in WAC 246-310-284 for inclusion in the King County #2 need methodology and failed to include the training patients reported by NRN for 2002 and 2003. These errors did not alter the determination of the linear regression method.

Table 2 provides the remaining calculations derived by the applicant to determine the number of dialysis stations needed to serve resident in-center patients in the planning area in the projection years. The regression results are divided by the appropriate resident in-center patient per station number cited in WAC 246-310-284(3), or 4.8.

[3] Addition error corrected from application. May affect accuracy of calculations cited.

Table 2
Summary of NKC's Numeric Methodology

	2007	2008	2009	2010
Resident In-center Patients	272	273	274	276
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Divided by 4.8[4]	57	57	57	58
Minus # of CN Approved Stations	91	91	91	91
Net Station Need/(Surplus)	**(34)**	**(34)**	**(34)**	**(33)**

As shown in Table 2, NKC projects a surplus in King County #2 area through the end of 2010. The applicant acknowledges that there is no unmet need for the service area. The proposal made is to relocate existing services to a more modern facility. [Application, p11]

Department's Application of the Numeric Methodology

The Department of Health's CN Program used the same methodology outlined above and used by the applicant for projecting numeric need for dialysis stations within a service area. The department's need projections, based on data obtained from the Northwest Renal Network records on in-center hemodialysis and trainings for years 2001-2006 is contained in Table 3.

Table 3
Utilization Data / Projected Growth Rate

King Two (2)	2001	2002	2003	2004	2005	2006
98101	4	9	12	12	12	11
98102	5	4	4	11	9	12
98104	17	13	15	17	12	17
98108	37	36	39	35	35	33
98109	7	8	11	10	11	12
98112	11	12	13	20	12	13
98118	77	76	75	68	64	63
98119	6	5	7	6	7	7
98121	6	4	4	5	8	5
98122	38	50	54	42	41	37
98134	1	1	1	1	1	0
98144	44	40	39	43	52	56
98199	6	4	6	4	2	4
Totals	**259**	**262**	**280**	**274**	**266**	**270**
Rate of Change	X	1.16%	6.87%	-2.14%	-2.92%	1.50%

Removal of the errant zip code used by the applicant, and the addition of the training patients, results in a slight difference in the totals for years 2002, 2003, 2005 and 2006 and affects the calculated rate of change. The Department also determined that the planning area has experienced six percent growth in only one of the previous five annual change calculations, indicating the use of a linear projection for this project. Table 4 provides the remaining calculations derived to determine the number of dialysis stations needed to serve resident in-center patients in the planning area in the projection year. [Appendix A]

[4] Rounded up to nearest whole number

Table 4
Summary of Department's Numeric Methodology

	2007	2008	2009	2010
Resident In-center Patients	273.1	273.8	274.5	275.2
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	56.896	57.042	57.188	57.333
Total Station Need Rounded Up	57	58	58	58
Minus # of CN Approved Stations	91	91	91	91
Net Station Need/(Surplus)	**(34)**	**(33)**	**(33)**	**(33)**

As shown in Table 4, the department also projects a surplus of 33 stations in King County #2 service area through the end of year 2010. Based on the numeric methodology shown above, there is no need for additional stations in the service area.

Public comment was submitted by the sole affected party, DaVita, Inc. DaVita interprets WAC 246-310-289(2) to require the proposed project be awarded a Certificate of Need to proceed. [May 29, 2007 DaVita Public Comment, p1] Because it is required to obtain a CN before proceeding DaVita also concludes that NKC's application must therefore meet WAC 246-310-284 as "new stations" in the planning area. NKC however contends that its proposal is simply a relocation of existing certified stations from an aging facility and does not constitute an increase in stations for the service area and therefore the numeric need is not applicable.

The department, NKC and DaVita agree that this project is required to obtain a CN before proceeding. The department, NKC and DaVita agree that this project would result in a new health care facility within the planning. What is at issue is whether the stations to be located at the new facility are "new" stations and therefore required to meet all of the review criteria for "new" dialysis stations or whether the stations are existing CN approved capacity and therefore not required to meet these new station requirements.

As stated earlier, in this application the NKC is proposing to take a portion of previously CN approved stations and relocate then approximately 4 blocks away from their current location within the same planning area. If approved the NKC project will not increase the number of CN approved dialysis stations in the planning area.

WAC 246-310-284(1) states that applications for <u>new stations</u> may only address projected station need in the planning area in which the facility is to be located. WAC 246-310-284(2) thru (4) describe the detailed steps then used to calculate the projected station need.

Although the department ran the methodology to verify the applicant's application of it, this proposed project is not requesting new stations in the planning area. The 38 stations to be relocated are currently Medicare certified and patients are being treated in them. Therefore, both NKC and the department included them as CN approved stations when running the numeric methodology. Therefore the department concludes that while a new health care facility would be established, it would not result in new stations to the planning area. Therefore numeric need methodology is not applicable to this project.

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 is February 1, 2007. [source: WAC 246-310-282] The quarterly modality report from NRN available at that time is December 31, 2006, which became available on January 20, 2007. Table 5 calculates the utilization for the existing CN approved stations in King County #2.

Table 5
Station Utilization as of December, 2006

Name of Center	# of Stations	# of Patients	Utilization (Patients per Station)
NKC Elliot Bay	18	101	5.61
NKC Haviland	53	216	4.08
DaVita Olympic View	20	66	3.30
Total	**91**	**383**	

As indicated above, both the Haviland and Olympic View facilities are currently operating below the minimum utilization standard of 4.8 patients per approved station. On first impression this would suggest that this standard is not met and therefore the proposed project should fail this standard. However on closer review of the standard it states that all CN approved stations within the planning must be at the applicable utilization standard before new stations are added to the planning area. The 38 stations involved in this project are already CN approved and located within the planning area. Since the project does not propose to add any new stations to the planning area the department concludes that this sub-criterion is not applicable this project.

Furthermore, the Olympic View dialysis facility is a Group Health controlled facility established by a CN exemption issued in 1989. DaVita was to be the managing entity for Group Health. This exemption was re-affirmed in 2002, after an AAG review, when Group Health reassigned its Medicare number to DaVita to be able to address some Medicare reporting issues. The exemption for the Olympic View allowed 25% of the patients to be non-Group Health enrollees. Therefore as the number of Group Health dialysis patients fluctuates at Olympic View the number of non-Group Health patients will also fluctuate.

The applicant also provided a post-relocation table with the projected utilization recalculated according to the proposed change. [Application, p4] Table 6 includes these projections with the addition of the Olympic View utilization.

Table 6
Projected Station Utilization in 2009—Post Relocation

Name of Center	# of Stations	# of Patients	Utilization (Patients per Station)
NKC Elliot Bay	18	87	4.83
NKC Haviland	15	72	4.80
NKC Seattle	38	158	4.16
DaVita Olympic View	20	66	3.30
Total	**91**	**383**	

WAC 246-310-284(6)(a) indicates that by the third full year of operation, new in-center kidney dialysis stations must reasonably project to be operating at 4.8 in-center patients per station. NKC provided projections for 2010 through 2014 based upon the 38 stations requested in this application. NKC uses a patient count of 158 for the new Seattle Kidney Center facility which includes the patients which NKC believes will transfer to the new location. Using this patient count the Seattle Kidney Center would be operating at 4.15 patients per approved stations.

Public comment submitted by the sole affected party, DaVita, Inc., reaffirms the information outlined above. Utilization for Olympic View is confirmed to be 3.3 patients per station and reaffirms that the application indicates showing the proposed new facility is projected to be below the minimum utilization expected in the third year of operation. [May 29, 2007 DaVita Public Comment, p1] The applicant contends that its proposal is simply a relocation of existing certified stations from an aging facility and does not constitute an increase in stations for the service area and therefore is not required to meet these criteria. [Application, p11 June 13, 2007 Rebuttal Comment, p1]

As stated above, the standard requires that all new in-center kidney dialysis stations must reasonably project to be operating at 4.8 patients per station by the third year of operation. The applicant however is not requesting to add new stations to the planning area. Therefore the department concludes NKC is not required to meet the standards regarding utilization rates. NKC must however meet other applicable requirements in WAC 246-310-210(2) regarding access to underserved groups

As a result of these findings, the department concludes that numeric need for additional stations in the service area is not applicable in the review of this application.

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

To 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. 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.

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

To demonstrate compliance with this sub-criterion, NKC provided a copy of its current admission criteria, patient compliancy, and charity care policies that are currently utilized in the NKC facilities. [Application, Appendices 20, 21, 22]

The documents provided by NKC outline the process/criteria that the dialysis center uses to admit patients for treatment. It is intended to ensure that patients will receive appropriate care at the dialysis center. The Admission criteria states that any patient with end stage renal disease needing treatment will be accepted to NKC's facility without regard to race, color, religion, sex, national origin, or age. [Application, Appendix 20]

NKC currently provides services to Medicare and Medicaid eligible patients at its existing twelve dialysis centers and intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive both Medicare and Medicaid reimbursements. Additionally, NKC demonstrated its intent to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the pro forma financial documents. [Application, Appendix 10]

Based on the above information, the department concludes that all residents of the King County #2 service area would continue to 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, the department determines that the applicant 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.

NKC anticipates commencement of services for this facility to be October 1, 2008. Based on this timeline and the projected release of this evaluation, year 2009 would be NKC's first full year of operation for the Seattle Kidney Center.

NKC reports its fiscal years beginning July, 1 of each calendar year. Therefore, the first fiscal year of operation will take place from July 1, 2009 to June 30, 2010. The following analysis will refer to each reporting year in relation to the relative fiscal year dates.

For financial review of applications, the department requests data for the first three full years following project completion. Using the financial information provided in the application, Table

7 below illustrates the projected revenue, expenses, and net income for fiscal years 2009-2011 for the Seattle Kidney Center. [Application, p6]

Table 7
Proposed Seattle Dialysis Center
Projected Revenue and Expenses

	Year 1 - 2009	Year 2 - 2010	Year 3 - 2011
# of stations	38	38	38
# of Treatments[5]	52,847	52,847	52,847
# of Patients	158	158	158
Utilization Rate	4.16	4.16	4.16
Net Patient Revenue	$ 11,456,173	$ 11,456,173	$ 11,456,173
Total Operating Expense	$ 11,360,390	$ 11,359,033	$ 11,357,368
Net Profit or (Loss)	$ 95,783	$ 97,140	$ 98,805
Net Patient Revenue / Treatment	$ 216.78	$ 216.78	$ 216.78
Total Operating Exp. / Treatment	$ 214.97	$ 214.94	$ 214.91
Net Profit per Treatment	$ 1.81	$ 1.84	$ 1.87

As shown in Table 7, at the projected volumes identified in the application, Seattle Kidney Center would be operating at a profit as a 38-station facility throughout the three years following completion of the project.

Based on the above information, the department concludes that the project's revenues are reasonable and 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.*

The capital expenditure associated with the establishment of the Seattle Kidney Center is $4,934,998, of which 75% is related to construction, 17% for both fixed and moveable equipment; and the remaining 8% is related taxes. The capital cost breakdown is shown below. [Application, p5]

Item	Cost	% of Total
Construction	$ 3,686,579	75%
Fixed & Moveable Equipment	$ 845,100	17%
Taxes	$ 403,319	8%
Total Estimated Capital Costs	**$ 4,934,998**	**100%**

The department recognizes that the majority of reimbursements for dialysis services come through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, NKC also provided the sources of patient revenue shown in Table 8 below. [Application, p8]

[5] Treatment totals include all treatments from In-center, training and home dialysis

Table 8
Anticipated Revenue Sources

Source of Revenue	% of Revenue
Medicare	74
State (Medicaid)	7
Blue Cross	2
Group Health	1
Other Insurance	15
Private Pay	1
Total	**100 %**

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 81% of the revenue at NKC's new facility. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis treatment for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

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

(3) <u>The project can be appropriately financed.</u>

NKC proposes two methods of financing for this project. The primary financing pursued will be to gain approval of bonds from the Washington Healthcare Facilities Authority. If these bonds are not approved, alternative funding will be provided from current NKC Board reserves.

To evaluate the primary financing option of bonds from the Washington Healthcare Facilities Authority (WHFA), the program received a copy of the NKC application accepted by the WHFA on February 8, 2007. The application for $12,000,000 proposes two separate disbursements which initially include refinancing existing debt ($3,134,669) and funding planned improvements to the SeaTac Kidney Center. NKC then anticipates receiving funding for the facility proposed in this application in a subsequent disbursement. NKC cites an anticipated rate paid on these funds to be 4.67% on a 10 year amortization schedule. [Application, p15; April 13, 2007 Supplemental Information, Exhibit 4; Terms & Conditions]

The application cites two benefits of the proposed borrowing. NKC estimates an aggregate savings of $1,099,094 on interest payments. This, in turn, will "…allow for a smaller increase in the rates for services over the life of the borrowing". [April 13, 2007 Supplemental Information, Exhibit 4] Also, the applicant asserts that, "the rate of borrowing through the Washington Healthcare Facilities Authority is below the average annual return on investments for Board Reserves, which makes it the more cost effective strategy". [Application, p15] Review of statements for fiscal

years ending June 30, 2005 and 2006, indicate that this is a reasonable assessment. [Application, Appendix 27]

Currently, pursuant to a meeting with the WHFA Bond Counsel, the initial funding disbursement has been reduced to $3.512 million; to pay for the refinancing of existing debt, issuance costs and equipment for the NKC Dialysis Academy. The Dialysis Academy is used for training new dialysis technicians and nurses. [NKC website] The WHFA Bond Counsel determined that the funds for the improvements to the SeaTac facility, or $5,054,769, will be provided through NKC Board reserves.

For NKC to receive the amount requested for the establishment of the Seattle Kidney Center proposed in this application, NKC must submit a second request to the WHFA upon CN approval. At that time, NKC may again request funding of the SeaTac tenant improvements if the related lease has been modified to match the WHFA Bond Counsel's determination that the depreciation should be over a 15 year term rather than the current 10 year plan. [April 13, 2007 Supplemental Information, Exhibit 4]

A review of the Board reserves available to finance this project is outlined in Table 9. The financial health of the organization seems to indicate that there would be sufficient resources to support the proposed project. In the event that bond funding is not forthcoming for either the SeaTac improvements or the Seattle Kidney Center, the Department can be reasonably assured that the funds will be available to complete the project. [Application, Appendix 26 & 27]

Table 9
NKC Board Financial Summary

	FY05	**FY06**
Current Cash & Equiv	$ 17,962,721	$ 21,320,306
Additional Assets	$ 29,010,555	$ 29,544,483
Total	**$ 46,973,276**	**$ 50,864,789**
Total Liabilities	$ 8,600,732	$ 9,964,651
Net Assets	$ 38,372,544	$ 40,900,138
Net Assets w/o restrictions	**$ 35,328,431**	**$ 38,302,178**

Based on the information provided, the department concludes the establishment of the Seattle Kidney Center would not adversely affect the financial stability of NKC as a whole. This sub-criterion is met.

C. Structure and Process (Quality) of Care (WAC 246-310-230)
Based on the source information reviewed, the department determines that the applicant has met the structure and process (quality) of care criteria in WAC 246-310-230.

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

The applicant states that since this is a relocation of stations from a nearby facility, there are no anticipated concerns related to staffing. NKC anticipates transferring those currently employed at the Haviland facility to the Seattle Dialysis Center. NKC also contends that, "because we

anticipate no growth in demand for services in the King County ESRD planning area 2, there is no anticipated change to staffing for Project years 1, 2 and 3". [April 13, 2007 Supplemental Information, p1]

NKC continues, "The fifteen (15) dialysis stations that are remaining at [Haviland] are in our Progressive Care Unit. The staffing of that unit is unaffected by the relocation of the other 38 stations". [April 13, 2007 Supplemental Information, p2] The applicant also provided the vacancy rates for the primary staffing specialties within the organization. The information supports the assertion that staffing in this project will not be difficult. [Application, p16]

The Department accepts the premise that the relocation of 38 stations to the Seattle Kidney Center would have a minimal impact upon staffing demands. The operation of the Haviland facility already requires planning for sufficient, qualified staff outside of the normative turnover of employees.

NKC has identified Dr. Michael R. Kelly as the Medical Director for the new facility. The applicant supplied a current contract that indicates Dr. Kelly's continued service in this capacity. NKC provided a copy of the draft medical director agreement between itself and Dr. Kelly. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation limits for the medical director responsibilities. [Application, Supplement 1]

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.*

Information provided in the April 13 screening responses show that NKC will continue to maintain a relationship with Swedish Medical Center for hospital care and support services for its existing facilities. [April 13, 2007 Supplemental Information, Exhibit 5]

According to the applicant, ancillary and support services, such as; social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided through departments in Seattle and Lake Forest Park. These services are currently provided as required for all operating NKC facilities. [Application, p17]

Therefore, based on this information and NKC's current operating practices, the department concludes that NKC will have an appropriate relationship with ancillary and support services to support the proposed 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.*

As stated earlier, NKC is currently a provider of dialysis services in Washington State. NKC will continue to provide Medicare and Medicaid services to the residents of its service areas throughout the current kidney dialysis treatment centers in operation.

For Washington State, in the most recent 10 years (since January 1997), the Department of Health's Office of Health Care Survey (OHCS) has completed more than 46 compliance surveys for the NKC facilities in operation. The compliance surveys revealed minor non-compliance issues related to the care and management at the NKC facilities. These non-compliance issues were typical of a dialysis facility and NKC submitted and implemented acceptable plans of correction. [Office of Health Care Survey Historical Record]

As stated above, Michael Kelly, MD is the current Medical Director and will continue to provide services at the proposed dialysis center. A review of the compliance history of Dr. Kelly has shown that his credentials are up to date and reveal no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of NKC and the existing medical director, the department concludes that there is reasonable assurance that the dialysis center would continue to operate in conformance with state and federal regulation. This sub-criterion is met.

(4) <u>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.</u>

In response to this criterion, NKC states that, "the NKC-Seattle Kidney Center will be located 4 blocks east of the NKC-Haviland Kidney Center". The applicant believes that because there are no planned changes or reduction in services that there will be no fragmentation experienced by the residents in the service area. [Application, p17]

The department also 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 many years and has been appropriately participating in relationships with community facilities, such as the Swedish Medical Center, to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Office of Health Care Survey Historical Record]

~~Based on this information, the department must reasonably conclude that the existing facilities would have the capacity to serve the patients within this King County service area. Therefore, the department concludes that approval of this project has the potential of fragmentation of dialysis services within the service area, and this sub-criterion is not met.~~

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. As outlined in the Need discussion above, demonstration of need in the numeric methodology is not required for approval of this application. No new stations are being added to the service area. The 38 stations are currently being used by patients at the Haviland facility. Moving these stations 4 blocks away is not expected to change with the new location.

Based on this information, the department concludes that approval of this project would not result in an unwarranted fragmentation of services. Further, NKC demonstrated it has, and will

continue to have, appropriate relationships to the service area's existing health care system within the planning area. This sub-criterion is met.

(5) *<u>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.</u>*

This subsection is addressed in sub section (3) of this evaluation. The department concludes that there is reasonable assurance that the services to be provided will ensure safe and adequate care to the public and in accord with applicable federal and state laws, rules and regulations. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that the applicant has met the cost containment criteria in WAC 246-310-240.

(1) *<u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>.*

Within the application, NKC provided a discussion regarding the two alternatives to this project. [Application, p18]

a) <u>Postponement</u>
NKC states that the project has already been postponed for over 5 years while searching for an affordable space solution in the same neighborhood. Since renovations of the aged Haviland facility cannot occur while the proposed stations are still on site, NKC rejected this option.

b) <u>Shared/Contract Service Arrangements</u>
NKC states that there are no other dialysis facilities in the planning area that could accommodate or absorb the services and clientele of the proposed project. Therefore, this option was rejected by the applicant.

After reviewing the two options cited above, NKC determined that relocating 38 of the 53 stations of the Haviland facility to a new Seattle Dialysis Center was the best option.

The department recognizes that renovations are often necessary to maintain care standards as patient needs and technology advance. The relocation of stations is often necessary to accommodate plans to improve and expand upon the services provided by any ESRD facility. The delay cited (a) would not mitigate the surplus in the service area and existing facility utilization. It would, however, result in patients continuing to receive treatment in a facility that is identified as needing renovation.

Therefore, based on the information above, the department concurs with the applicant that relocating the 38 stations from the Haviland facility to the new Seattle Kidney Center is the best available option for the community. 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;

The department acknowledges that the majority of the capital expenditure for NKC's new 38-station Seattle Kidney Center is related to tenant improvements to leased space and the purchase of additional fixed and moveable equipment. The construction costs are reasonable when compared to construction costs of recent kidney dialysis proposals. Therefore, the department concludes that this criterion is met.

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

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.