

EXECUTIVE SUMMARY

EVALUATION OF THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN KING COUNTY PLANNING AREA #4:

- **DAVITA, INC. PROPOSING ESTABLISH A THIRTEEN-STATION DIALYSIS CENTER IN THE CITY OF DES MOINES**
- **NORTHWEST KIDNEY CENTERS PROPOSING TO ADD THIRTEEN STATIONS TO SEATAC KIDNEY CENTER IN THE CITY OF SEATAC**

BRIEF PROJECT DESCRIPTIONS

DaVita Inc.

This project proposes to establish a 13-station facility in Des Moines to be located at 22545 – 7th Avenue South, #100. The new dialysis center would serve the residents of King County planning area #4. [source: DaVita Application, p1; May 24, 2007, supplemental information, p1]

The capital expenditure associated with the establishment of the 13-station facility is \$1,427,157. [source: Application, p6] If this project is approved, DaVita anticipates all 13 stations would become operational by the end of July 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [source: DaVita Application, p10]

Northwest Kidney Centers

Northwest Kidney Centers currently operates a 12-station dialysis center, known as SeaTac Kidney Center, located at 17900 International Boulevard South #301 in the city of SeaTac, within King County. This project proposes to add 13 stations for a facility total of 25 stations at the dialysis center. Northwest Kidney Centers also proposes that the 25-station facility would serve the residents of King County planning area #4. [source: NKC Application, Executive Summary and Appendix 1]

The capital expenditure associated with the 13-station addition is \$854,081. [source: NKC 2nd Amendment Application, Appendix 8] If this project is approved, Northwest Kidney Centers anticipates commencement of the project immediately and all 25 stations would be available for patient use by the end of January 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation with 25 dialysis stations and 2011 would be year three. [source: NKC 2nd Amendment Application, Executive Summary]

APPLICABILITY OF CERTIFICATE OF NEED LAW

The DaVita, Inc. project is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a). The Northwest Kidney Centers project is subject to review as an increase of dialysis station capacity in an existing dialysis center under RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

CONCLUSIONS

DaVita Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a thirteen-station dialysis center in the city of Des Moines, within King County planning area #4 is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Northwest Kidney Centers proposing to add thirteen dialysis stations to the existing twelve-station facility known as SeaTac Kidney Center is consistent with applicable criteria. The approved capital expenditure associated with the addition of thirteen stations is \$854,081.

EVALUATION OF THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN KING COUNTY PLANNING AREA #4:

- **DAVITA, INC. PROPOSING ESTABLISH A THIRTEEN-STATION DIALYSIS CENTER IN THE CITY OF DES MOINES**
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PROJECT DESCRIPTIONS

DaVita Inc.

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,300 outpatient centers located in 42 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [source: DaVita Application, p4]

In Washington State, DaVita owns or operates a total of fourteen kidney dialysis facilities in six separate counties--Clark, Franklin, King, Kittitas, Pierce, and Yakima. Below is a listing of the fourteen DaVita facilities located in Washington. [source: CN historical files; & Application, p4]

Clark

Vancouver Dialysis Center

Franklin

Mid-Columbia Kidney Center

Pierce

Lakewood Community Dialysis Center
Puyallup Community Dialysis Center
Tacoma Dialysis Center

Kittitas

Ellensburg Dialysis Center

Yakima

Mt. Adams Kidney Center
Union Gap Dialysis Center
Yakima Dialysis Center

King

Bellevue Dialysis Center
Federal Way Community Dialysis Center
Kent Community Dialysis Center
Olympic View Dialysis Center (management only)
Westwood Dialysis Center

This application proposes to establish a sixth dialysis facility in King County. The new facility, to be known as Des Moines Dialysis Center, would have 12 stations and be located at 22545 – 7th Avenue South, #100 in the city of Des Moines. The new DaVita facility would serve the residents of King County planning area #4. [source: DaVita Application, pp 1 and 3; May 24, 2007, supplemental information, p1]

The capital expenditure associated with the establishment of the 13-station facility is \$1,427,157, of which approximately 51% is related to leasehold improvements at the site; 41% is related to both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 7]

If this project is approved, DaVita anticipates all 13 stations would become operational by the end of July 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [source: DaVita Application, p10]

Northwest Kidney Centers

Northwest Kidney Centers (NKC) is a private, not-for-profit entity 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. [source: NKC Application, p1]

NKC is governed by a volunteer Board of Trustees comprised of medical, civic, and business leaders from the community. An appointed Executive Committee of the Board oversees operating policies, performance benchmarks, and approves capital expenditures for all of its facilities. [source: NKC Application, p2]

In Washington State, NKC owns or operates a total of thirteen kidney dialysis facilities, twelve in King County and one in Clallam County. Below is a listing of the thirteen NKC facilities in Washington. [source: NKC Application, Appendix 1 and CN historical files]

Clallam

Port Angeles Kidney Center

King

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
Seattle Kidney Center
SeaTac Kidney Center¹
Snoqualmie Kidney Center
Totem Lake Kidney Center
West Seattle Kidney Center

This application proposes to add 13 dialysis stations to the existing 12-station facility known as SeaTac Kidney Center located at 17900 International Boulevard #301, in the city of SeaTac. If approved, the 25-station facility would also serve the residents of King County planning area #4. [source: NKC Application, Executive Summary and Appendix 1]

The capital expenditure associated with the addition of 13 stations is \$854,081, of which 76% is related to construction costs, 16% is related to fixed and moveable equipment, and the remaining 8% is related to sales tax. [source: NKC 2nd Amendment Application, Executive Summary]

If this project is approved, NKC anticipates commencement of the project immediately and all 25 stations would be available for patient use by the end of January 2008. Under this timeline, year 2009 would be SeaTac Kidney Center's first full calendar year of operation with 25 stations and 2011 would be year three. [source: NKC 2nd Amendment Application, Executive Summary]

APPLICABILITY OF CERTIFICATE OF NEED LAW

The DaVita, Inc. project is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a)

¹ Formerly known as Cascade Kidney Center.

and Washington Administrative Code (WAC) 246-310-020(1)(a). The Northwest Kidney Centers' project is subject to review as an increase of dialysis station capacity in an existing dialysis center under RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

CRITERIA EVALUATION

To obtain Certificate of Need approval, each 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). Additionally, each applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 288.²

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted these projects under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1. A chronologic summary of the review is shown below.

Action	DaVita	NKC
Letter of Intent Submitted	January 31, 2007	January 31, 2007
Application Submitted	February 28, 2007	February 27, 2007
Amendment Application(s) Submitted	N/A N/A	<ul style="list-style-type: none"> • 1st Amendment Application- March 30, 2007 • 2nd Amendment Application- April 16, 2007
Department's Pre-Review Activities including Screenings and Responses	April 30, 2007 through June 17, 2007	
Beginning of Review	June 18, 2007	
End of Public Comment	August 17, 2007, No public hearing requested or conducted	
Rebuttal Comments Received	September 17, 2007	
Department's Anticipated Decision Date	November 1, 2007	
Department's Actual Decision Date	November 1, 2007	

CONCURRENT REVIEW AND AFFECTED PERSONS

The concurrent review process promotes the expressed public policy goal of RCW 70.38 that the development or expansion of health care facilities are accomplished in a planned, orderly fashion and without unnecessary duplication. For dialysis projects, concurrent review allows the department to review dialysis applications proposing the serve the same planning area [as defined in WAC 246-310-280(9)] simultaneously to reach a decision that serves the best interests of the planning area's residents.

² 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); and WAC 246-310-287.

In the case of the projects submitted by DaVita and NKC, the department will issue one single evaluation regarding whether both, any, or none of the projects should be issued a Certificate of Need.

For each application, the other applicant sought and received affected person status under WAC 246-310-010. No other entity sought or received affected person status related to the two projects.

SOURCE INFORMATION REVIEWED

- DaVita, Inc.'s Certificate of Need application submitted February 28, 2007
- Northwest Kidney Centers' Certificate of Need application submitted February 27, 2007
- Northwest Kidney Centers' 1st amendment application submitted March 30, 2007
- Northwest Kidney Centers' 2nd amendment application submitted April 16, 2007
- DaVita, Inc.'s supplemental information dated May 24, 2007
- Northwest Kidney Centers' supplemental information dated May 29, 2007
- DaVita, Inc.'s comments regarding Northwest Kidney Center's project dated August 16, 2007
- Northwest Kidney Centers' comments regarding DaVita, Inc.'s project dated August 16, 2007
- DaVita, Inc.'s rebuttal comments received September 17, 2007
- Northwest Kidney Centers' rebuttal comments received September 17, 2007
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2006 Northwest Renal Network 4th Quarter Data
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from DaVita, Inc.'s webpage (davita.com)
- Data obtained from Northwest Kidney Centers' webpage (nwkidney.org)
- Certificate of Need historical files
- Data obtained from the Washington Secretary of State website
- Medical Quality Assurance compliance data

CONCLUSIONS

DaVita Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a thirteen-station dialysis center in the city of Des Moines, within King County planning area #4 is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Northwest Kidney Centers proposing to add thirteen dialysis stations to the existing twelve-station facility known as SeaTac Kidney Center is consistent with applicable criteria. The approved capital expenditure associated with the addition of thirteen stations is \$854,081.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that both applicants have met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280.

- (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.³

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year. 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. 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)]

DaVita's Application of the Numeric Methodology

DaVita proposes to establish a 13-station dialysis center in Des Moines to serve patients in King County planning area #4. Consistent with WAC 246-310-280(9), DaVita applied the

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

numeric methodology to the planning area using linear regression. Given that the facility would be 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, pp15-17]

NKC’s Application of the Numeric Methodology

NKC proposes to add 13 stations to its existing 12-station dialysis center located in SeaTac to serve patients in King County planning area #4. Consistent with WAC 246-310-280(9), NKC also applied the numeric methodology to the planning area using linear regression. Given that the facility would be 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: Initial application, Appendix 17]

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning areas 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).

Based on the numeric methodology, Table 1 below depicts a summary of the projected net need provided by each applicant and the department’s projected net need for King County planning area #4. The department’s numeric methodology for King County planning area #4 is attached to this evaluation as Appendix A.

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

	4.8 in-center patients per station			
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
NKC	25.00	12	13.00	13.00
DaVita	25.13	12	13.13	14.00
DOH	24.62	12	12.62	13.00

A comparison of each applicant’s results with the department’s results shown in Table 1 above shows that NKC’s projection results match the department’s and DaVita’s projection results calculate one station more than the department’s. A closer review of NKC’s methodology shows that historical data used is different. For its methodology, NKC counted patients in two zip codes (98054 and 98062) not included in the King County planning area #4 zip codes as identified in WAC 246-310-280(9)(b). In addition, NKC failed to include data regarding in-center training station use in the years reviewed. NKC also based its projections on seven consecutive years’ historical data (2000-2006), rather than five consecutive years as directed in WAC 246-310-284(4)(b). However, when all of these differences are applied by NKC and rounded for year 2010, NKC’s final projection results are equal to the department’s projection results. [source: NKC, initial application, Appendix 17]

DaVita’s projections resulted in a net need of one more station (14) than the department’s net need (13). A closer review of DaVita’s methodology reveals that DaVita also included patients in the zip codes of 98054 and 98062. The inclusion additional patients from the two zip codes explains the difference between DaVita’s and the department’s projections for 2010. [source: DaVita application, pp15-17]

In summary, the net station need for King County planning area #4 is 13 stations as shown in Table 1 above. [source: Department’s methodology, Appendix A attached to this evaluation]

As shown in Table 1 above, currently King County planning area #4 has 12 stations operating within the planning area. 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. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2006, which became available on January 20, 2007. All 12 stations are at one facility—NKC’s SeaTac Kidney Center located in SeaTac. Table 2 below shows the December 31, 2006, utilization of NKC’s SeaTac Kidney Center and demonstrates that this capacity requirement is met.

**Table 2
December 31, 2006-Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
NKC’s SeaTac Kidney Center	12	66	5.50

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For King County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] Both DaVita and NKC propose dialysis stations to be located within King County planning area #4, as a result, each applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station. Further, both NKC’s and DaVita’s third full year of operation is year 2011. A summary of each applicant’s projected utilization for year 2011 is shown in Table 3 below.

**Table 3
Year 2011 Projected Facility Utilization**

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita’s Des Moines Dialysis Center	2011	13	72	5.50
NKC’s SeaTac Kidney Center	2011	25	122	4.88

As shown in Table 3 above, both DaVita’s and NKC’s projections meet this standard. [source: DaVita May 24, 2007, supplemental information, Attachment 5; NKC 2nd amended application, Appendix 10]

Based on the above information and standards, the department’s conclusion regarding this sub-criterion follows.

DaVita, Inc.

DaVita proposes to establish a 13-station dialysis center in King County planning area #4. 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.

Northwest Kidney Centers

NKC proposes to add 13 stations to the existing 12-station dialysis center in King County planning area #4 known as SeaTac Kidney Center. Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. This sub-criterion is met.

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

As previously stated, both applicants currently provide dialysis services to residents of specific service areas within Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. 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.

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current admission and indigent care policies that would also be used at the new Des Moines facility. The Admission policy outlines the process/criteria that the new facility will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the dialysis center without regard to race, color, national origin, sex, age, religion, or disability. [source: Application, Appendix 14]

DaVita currently provides services to Medicare and Medicaid eligible patients at its existing fourteen dialysis centers and intends to maintain this status. A review of the Admission and Charity Care policies provided for the Des Moines facility identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. [source: Application, Appendix 14]

Additionally, DaVita demonstrated its intent to provide charity care to residents by submitting its charity care policy that outlines the process a patient would use to access this service. Further, DaVita included a 'charity care' line item as a deduction from revenue

within the pro forma financial documents. [source: Application, Appendix 14 and May 24, 2007, supplemental information, Attachment 5]

Based on the above information, the department concludes that all residents of the service area would have reasonable access to the health services at the proposed DaVita Des Moines Dialysis Center. This sub-criterion is met.

Northwest Kidney Centers

To demonstrate compliance with this sub-criterion, NKC provided a copy of its admission criteria, patient compliancy, and charity care policies that are currently used in the NKC facilities, including the SeaTac Kidney Center. [source: NKC's Initial 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. [source: Application, Appendix 20]

NKC currently provides services to Medicare and Medicaid eligible patients at its existing thirteen 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 continue to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the pro forma financial documents. [source: 2nd Amendment application, Appendix 10]

Based on the above information, the department concludes that all residents of the service area would continue to have adequate access to the health services at the SeaTac Kidney Center, and the addition of 13 stations would not negatively affect this access to services. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.'s project has not met the financial feasibility criteria in WAC 246-310-220; and
- 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.

DaVita Inc.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the 13-station facility would be operational by the end of July 2008. Based on this timeline, year 2009 would be Des Moines Dialysis Center's first full calendar year of operation and 2011 would be year three. [source: Application, p10]

Using the financial information provided in the application, Table 4 on the following page illustrates the projected revenues, expenses, and net income for years 2008-2011 for DaVita's

Des Moines Dialysis Center. [source: DaVita's May 24, 2007, supplemental information, Attachment 5]

Table 4
Des Moines Dialysis Center
Projected Revenues and Expenses Calendar Years 2008 - 2011

	Partial Year 2008	Full Year 1 2009	Full Year 2 2010	Full Year 3 2011
# of Stations	13	13	13	13
# of Treatments ^[1]	4,945	7,655	10,343	11,394
# of Patients ^[2]	32	49	66	72
Utilization Rate ^[2]	2.46	3.76	5.07	5.53
Net Revenue ^[1]	\$ 1,418,930	\$ 2,410,755	\$ 3,465,479	\$ 4,200,528
Total Expense ^[1,3]	\$ 1,394,619	\$ 1,734,879	\$ 2,270,734	\$ 2,693,241
Net Profit or (Loss) ^[1]	\$ 24,311	\$ 675,876	\$ 1,194,745	\$ 1,507,287
Net Patient Revenue/Treatment ^[1]	\$ 286.94	\$ 315.38	\$ 335.06	\$ 368.66
Total Operating Exp./Treatment ^[1]	\$ 282.03	\$ 226.96	\$ 219.54	\$ 236.37
Net Profit (Loss) per Treatment ^[1]	\$ 4.92	\$ 88.42	\$ 115.51	\$ 132.29

[1] includes both in-center and home dialysis patients; [2] in-center patients only; [3] includes deductions for bad debt, charity care and allocated costs

As shown in Table 5 above, at the projected volumes identified in the application, DaVita anticipates that its Des Moines Dialysis Center would be operating at a profit in years 2008 through 2011 as a 13-station facility.

Public comment was submitted by NKC disputing the validity of the location DaVita has identified for this new facility. NKC asserts, in part, that the lack of complete and accurate site information regarding the address identified in the lease, 22545 – 7th Avenue South, Suite #100 in Des Moines, the inherent inaccuracy of application's floor plan for a non-existent site and inconsistencies in the Pro Forma, notably regarding the medical director costs reflected in the draft lease are grounds for denial. On this point, NKC states, "*Any one of the reasons identified above is sufficient to deny DaVita's application.*" [source: NKC August 17, 2007, public comments pp1-5]

In rebuttal, DaVita points out that the site address was provided as requested by the department and since there was no request for further legal descriptions of the site, they fully responded to screening questions. Further, DaVita states, "*NKC easily located and obtained extensive details about DaVita's proposed site using the detailed legal description DaVita provided.*" [source: DaVita September 17, 2007 Rebuttal, p1]

In response to the comments addressing the line drawings of the floor plan, DaVita states, "*NKC criticizes DaVita for not submitting a floor plan as a lease exhibit. This is more meaningless nit-picking, unsupported by any reference to rule. DaVita provided the floor plan in its screening responses. NKC does not contend the draft lease is somehow invalid or that NKC cannot evaluate DaVita's application because [two schedules are omitted].*" DaVita continues by pointing out that unique attributes of a new facility may require minor modifications but that they do not anticipate any changes to the patient treatment area. [source: DaVita September 17, 2007 rebuttal documents, p5]

DaVita did not provide responses to NKC's comments regarding the inconsistency between the medical director agreement annual costs of \$45,000 and the pro forma costs identified at \$40,000 annual, equating to an understatement of 12.5%.

Department's Response

Application guidelines require that the applicant supply documentation regarding the use of the proposed site for dialysis services and that the applicant has sufficient interest in the proposed location. [source: ESRD Application, Questions O & P] DaVita provided a copy of a draft lease agreement between the tenant, Total Renal Care, Inc (DaVita's parent corporation), and the landlord, EDG-DaVita Des Moines, LLC. The lease agreement provided a legal description of the site to be "*lots 6-10, block 67, city of Des Moines, according to the plat thereof recorded in volume 4 of plats, page 33, King County Washington.*" The address for the site, "22545 7th Avenue South, #100 in Des Moines" is not included in the lease agreement, rather it is provided by DaVita in its screening responses. [source: DaVita's May 24, 2007, supplemental information, Attachment 2, pp1-3]

To address the claims presented in comment and addressed in rebuttal, the department initially worked to confirm the address cited in both the screening questions and the applicant's draft lease submitted in response to screening questions. The King County Assessor website does not locate any property with the address of 22545 7th Avenue South. This is also confirmed by documentation submitted with NKC's comments. [source: NKC's public comments, Exhibit B] The department located the site using the legal description in DaVita's draft lease agreement. As verified by NKC's research, using the legal description of "*lots 6-10, block 67, city of Des Moines, according to the plat thereof recorded in volume 4 of plats, page 33, King County Washington*" reveals two different land parcels, and neither has an address of 22545 7th Avenue South in Des Moines. However, using the parcel numbers in the lease agreement and the site information within the screening responses, the department can reasonably determine the site for the project is parcel #2006600385. The department concludes that while the draft lease agreement provided by DaVita does not identify a specific site, the site can be reasonably located.

Once the department located the site, the next step is to determine whether DaVita has submitted documentation demonstrating control of the site. Again, using the King County assessor website, one parcel (#2006600385)—lots 6 and 7—is a boarded-up single family residence owned by two individuals—neither of which is EDG-DaVita Des Moines, LLC. Further, the Secretary of State's website does not include any entity known as EDG-DaVita Des Moines, LLC. Additionally, the draft lease agreement does not demonstrate appropriate control of a site as required under CN application guidelines. The landlord identified in the lease agreement is EDG-DaVita Des Moines, LLC, an entity that does not appear to have legal control of the property to enter into a lease agreement. The department concludes that DaVita does not provide documentation demonstrating it has control of a site as required under CN application guidelines.

Responses regarding the accuracy of the line drawings submitted for the Des Moines facility appear to address concerns raised in comment. The department acknowledges that there may be slight differences in the final layout of the proposed facility, but that tenant improvements are often allowed in commercial buildings, and are economical for the contractor when done in the initial construction period. There are no indications that the drawings submitted would be rejected by the builder.

Costs associated with the medical director agreement and the draft lease agreement versus costs identified in the pro forma submitted by DaVita were also reviewed by the department. Regarding the \$5,000 annual difference in medical director compensation, the department could add another \$5,000 to DaVita's medical director expense line item to determine the impact of the inconsistency. On the surface, this approach is a reasonable solution; however the inconsistency between the two documents raises concerns by the department.

A larger concern, not noted by NKC, is the inconsistency between the lease costs in the draft agreement and the pro forma lease rent expense line item. The amount identified in the rent expense line item cannot be computed using basic information provided in the lease agreement. [source: DaVita's May 24, 2007, supplemental information, Attachment 2, pp1-3] This inconsistency would indicate that the draft lease submitted in response to screening may to be inaccurate in many terms being considered for the lease. The inaccuracies in the stated and projected rent and medical director costs are currently the only means to isolate two, of possible additional, modifications that could affect the viability of this project.

As a result, the proposed Des Moines facility cannot be fully evaluated on its long-range capital and operating costs. Therefore, this sub criterion is not met.

Northwest Kidney Centers

As stated in the project description portion of this evaluation, if this project is approved, NKC anticipates the 13 additional stations would be added to SeaTac Kidney Center immediately and all 25 stations would be operational by the end of January 2008. Based on this timeline, year 2009 would be SeaTac Kidney Center's first full calendar year of operation with 25 stations and 2011 would be year three. [source: Application, Executive Summary]

NKC provided a copy of its current, executed lease agreement for the SeaTac Kidney Center site. The lease costs can be substantiated in the pro forma documents provided by NKC. [source: NKC Application, Supplement 4]

Using the financial information provided in the application, Table 5 on the following page illustrates the projected revenues, expenses, and net income for years 2008-2011 for SeaTac Kidney Center as a 25-station facility. [source: NKC's 2nd Amendment application, Appendix 10]

Table 5
SeaTac Kidney Center
Projected Revenues and Expenses Calendar Years 2008 - 2011

	Partial Year 2008	Full Year 1 2009	Full Year 2 2010	Full Year 3 2011
# of Stations	25	25	25	25
# of Treatments ^[1]	12,948	14,796	17,004	19,032
# of Patients ^[2]	83	96	109	122
Utilization Rate ^[2]	3.32	3.84	4.36	4.88
Net Revenue ^[1]	\$ 2,708,721	\$ 3,132,979	\$ 3,557,237	\$ 3,981,495
Total Expense ^[1,3]	\$ 2,735,088	\$ 3,121,860	\$ 3,497,887	\$ 3,865,320
Net Profit or (Loss) ^[1]	(\$ 26,367)	\$ 11,119	\$ 59,350	\$ 116,175
Net Patient Revenue/Treatment ^[1]	\$ 209.20	\$ 211.74	\$ 209.20	\$ 209.20
Total Operating Exp./Treatment ^[1]	\$ 211.24	\$ 210.99	\$ 205.71	\$ 203.10
Net Profit (Loss) per Treatment ^[1]	(\$ 2.04)	\$ 0.75	\$ 3.49	\$ 6.10

[1] includes in-center only; no home dialysis patients are projected; [2] in-center patients only; [3] includes deductions for bad debt, charity care and allocated costs

As shown in Table 9 above, at the projected volumes identified in the application, NKC anticipates that its SeaTac Kidney Center would be operating at a slight loss in year 2008, and a slight profit in years 2009 through 2011 as a 25-station facility.

During the concurrent review of this project, DaVita did not provide concerns regarding NKC's financial information provided in its application.

Based on the above evaluation, NKC's projections appear to be reasonable for the SeaTac Kidney Center with 25 dialysis stations, 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.

DaVita Inc.

The capital expenditure associated with the establishment of DaVita's 13-station facility is \$1,427,157, of which approximately 51% is related to leasehold improvements at the site; 41% is related to both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 7]

To demonstrate compliance with this sub-criterion, DaVita provided the following statements:

"...Funding from previously allocated operations funds is the least costly approach. Debt financing for this project will not be required since there is sufficient cash on hand. Furthermore, the method of financing would have no impact on the amount charged for each unit of service." [source: Application, p21]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 6 on the following page. [source: Application, p22]

Table 6
DaVita's Des Moines Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	Percentage of Revenue
Medicare	72%
State (Medicaid)	8%
Insurance/HMO	20%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 80% of the revenue at DaVita's Des Moines Dialysis Center. The department concludes that the majority of revenue (80%) is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. The remaining 20% will be derived through other or private insurance reimbursements. The costs and charges per dialysis for the proposed facility cannot be compared to recent kidney dialysis proposals submitted to the department. The department is not able to calculate the average cost per dialysis with any certainty due to in-consistent pro-forma data and the reported lease costs. The department is unable to conclude the average cost per dialysis is reasonable or accurate.

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

Northwest Kidney Centers

The capital expenditure associated with the addition of 13 stations is \$854,081, of which 76% is related to construction costs, 16% is related to fixed and moveable equipment, and the remaining 8% is related to sales tax. [source: NKC 2nd Amendment Application, Executive Summary]

To demonstrate compliance with this sub-criterion, NKC provided the following statements related to its station addition project:

“Construction estimates are based on recent similar dialysis station development project costs. The capital costs indicated for dialysis machines and recliners reflect our contract purchase pricing. The majority of reimbursements for dialysis services flow from Medicare ESRD entitlements, which are not subject to, or affected by, capital improvements and expenditures by providers.” [source: NKC 2nd Amendment Application, p15]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, NKC also provided the sources of patient revenue shown in Table 7 on the following. [source: NKC 2nd Amendment Application, p8]

Table 7
SeaTac Kidney Center
Sources and Percentages of Revenue

Source of Revenue	Percentage of Revenue
Medicare	74%
State (Medicaid)	7%
Insurance/HMO	19%
Total	100.0%

As shown above, the Medicare and State (Medicaid) entitlements are projected to 80% of the revenue at NKC’s SeaTac Kidney Center in King County planning area #4. 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 for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

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

(3) The project can be appropriately financed.

DaVita Inc.

As previously stated, the capital expenditure associated with the establishment of DaVita’s 13-station facility is \$1,427,157, of which approximately 51% is related to leasehold improvements at the site; 41% is related to both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 11] A review of DaVita’s historical financial statements shows the funds necessary to finance the project are available. [Application, Appendix 10]

Based on the information provided, the department concludes the establishment of a 13-station dialysis center in King County planning area #4 would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met

Northwest Kidney Centers

The capital expenditure associated with the addition of 13 stations is \$854,081, of which 76% is related to construction costs, 16% is related to fixed and moveable equipment, and the remaining 8% is related to sales tax. [source: NKC 2nd Amendment Application, Executive summary]

NKC also provided a breakdown of the costs incurred to relocate the dialysis center, formerly known as Cascade Kidney Center, from its site at 19655 First Avenue South in Normandy Park where it was established in 1988, to the current site at 17900 International Boulevard South in the city of SeaTac.⁴ The relocation was complete approximately July 2007. A breakdown of those costs, which includes the costs for this 12-station addition, is shown in Table 8 on the following. [source: NKC 2nd Amendment Application, Appendix 8]

⁴ On October 3, 2006, the Certificate of Need Program provided NKC with a determination of non-reviewability regarding the relocation of the Cascade Kidney Center. After the relocation, Cascade Kidney Center will be renamed SeaTac Kidney Center.

Table 8
Northwest Kidney Center's Capital Costs Breakdown

Item	Entire Relocation Project	12-Station Addition
Space Construction	\$ 1,595,056	\$ 647,992
Fixed Equipment	\$ 181,781	\$ 73,849
Moveable Equipment	\$ 153,699	\$ 62,440
Sales Tax	\$ 171,818	\$ 69,801
Total Capital Costs	\$ 2,102,354	\$ 854,081

A review of NKC's historical financial statements shows the funds necessary to finance the project are available. [source: NKC Initial Application, Appendices 25, 26, 27]

Public comment was submitted by DaVita regarding the capital costs of NKC's project. DaVita points out that the department requires applicants to include capital costs for the entire relocation project and does not allow applicants to avoid reporting capital costs by allocating costs to some other use. DaVita provides a comparison of NKC's SeaTac Kidney Center's costs with two NKC King County projects currently under review. DaVita's comparison shows the following for NKC's SeaTac project:

- smaller space per square foot per station; and
- construction costs per station is less.

Based on these two findings, DaVita concludes that NKC has substantially understated the true total square footage and construction costs for the SeaTac project.

In rebuttal, NKC points out that the new site of SeaTac Kidney Center includes 7-stations to be used in the Dialysis Academy, which accounts for the center's space for 32 stations, rather than the 25 proposed to be used as incenter stations. The 7 stations are located in a "skills lab" which includes dedicated classrooms, a computer training lab, and four full time instructors, offering a combination of didactic and practical training for dialysis professionals. The space was never intended to produce revenue, rather, it is to be used for education and training for staff, or in the case of a disaster, the space would be used to accommodate surge capacity for patients from other dialysis facilities. In summary, NKC states that the Dialysis Academy space is wholly independent of the SeaTac Kidney Center and is not relevant to this application for expansion. [source: NKC September 17, 2007 Rebuttal, pp1-2]

Department's Response

The department acknowledges that NKC leased 27,000 sf to house the existing SeaTac Kidney Center with 13 stations, accommodate an additional 12 station at the kidney center (this project), and house the Dialysis Academy, which was relocated from First Hill. Initially, NKC intended for the SeaTac Kidney Center, including the Dialysis Academy, to be operational by the end of July 2007.⁵ The Dialysis Academy space is not intended to be used for patient overflow for the dialysis center, rather the 13-station SeaTac Kidney Center is separate from the Dialysis Academy. This is confirmed by the services to be offered at the Dialysis Academy when compared to the dialysis center. NKC's responses regarding the Dialysis Academy space appear to address DaVita's concerns raised in public comment.

⁵ As of the writing of this evaluation, the facility has not yet undergone its required Medicare survey from the department's Office of Health Care Survey, nor has the required paperwork to initiate the survey been submitted by NKC.

Based on the information provided, the department concludes the addition of 12 stations to NKC's SeaTac Kidney Center would not adversely affect the financial stability of the dialysis center or 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:

- DaVita, Inc.'s project has not met the structure and process (quality) of care criteria in WAC 246-310-230; and
- Northwest Kidney Center's project has met the structure and process (quality) 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.

DaVita Inc.

To staff its proposed 13-station facility in Des Moines, DaVita intends to recruit 5.5 FTEs in partial year 2008, which would increase to a total of 13 FTEs by the end of full calendar year three (2011). A breakdown of the proposed FTEs is shown in Table 9 below. [source: Application, p22]

**Table 9
DaVita's Des Moines Dialysis Center 2008 – 2011 Projected FTEs**

Staff/FTEs	2008 Partial Year	2009 Increase	2010 Increase	2011 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	0.80	0.20	0.00	0.00	1.00
RN	1.60	0.60	0.60	0.60	3.40
Patient Care Techs	2.00	1.50	1.20	0.80	5.50
Biomedical Techs	0.30	0.00	0.00	0.00	0.30
Re-Use Techs	0.20	0.10	0.20	0.10	0.60
Administrative Assistant	0.00	0.40	0.30	0.30	1.00
MSW	0.30	0.10	0.10	0.10	0.60
Dietitian	0.30	0.10	0.10	0.10	0.60
Total FTE's	5.50	3.00	2.50	2.00	13.00

As shown in Table 9 above, after the initial recruitment of FTEs, DaVita expects a steady increase in FTEs for its Des Moines dialysis facility through year 2011. DaVita states it expects no difficulty in recruiting staff for the new facility because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. In addition, DaVita states that several employees have already expressed interest in working at its proposed facility. [source: Application, p24]

Based on this information, the department concludes that adequate staffing for a new dialysis center in King County planning area #4 is available or can be recruited. This sub criterion is met.

Northwest Kidney Centers

Currently, NKC's SeaTac Kidney Center employs 22.0 FTEs to staff the 12-station facility. With 13 additional stations, NKC proposes to add approximately 11.60 FTEs by the end of year three, based on the projected number of patients in those years. The current FTEs at the SeaTac facility and the proposed increases for years 2008 - 2011 are shown in Table 10 below. [source: NKC's May 29, 2007, supplemental information, p2]

Table 10
SeaTac Kidney Center 2008 – 2010 Projected FTEs

Staff/FTEs	2007 Current Yr	2008 Increase	2009 Increase	2010 Increase	2011 Increase	Total FTEs
Medical Director	Professional Services Contract					
RN	7.00	1.10	1.10	1.10	1.10	11.40
Patient Care Techs	14.00	2.10	2.10	2.10	2.10	22.40
Administrative Assistant	0.00	1.00	0.00	0.00	0.00	1.00
MSW	0.50	0.25	0.00	0.25	0.00	1.00
Dietitian	0.50	0.25	0.00	0.25	0.00	0.00
Total FTE's	22.00	4.70	3.20	3.70	3.20	36.80

As shown in Table 10 above, NKC expects a steady increase in FTEs for the additional 13 stations at SeaTac Kidney Center through year 2011. The staffing at NKC facilities is sufficient, as NKC states that they have not had to refuse admission to new patients due to staffing shortages, nor do they anticipate difficulties in availability or recruitment of qualified staff. [source: Application, p17]

Based on this information, the department concludes that adequate staffing for the 13 additional stations at NKC's SeaTac facility is either available or can be recruited, and 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.

DaVita, Inc.

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing fourteen dialysis centers. For a new facility in King County planning area #4, 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 on site. Additional services would be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: Application, p24]

DaVita acknowledges that since this would be a new facility in King County planning area #4, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [source: Application, p24 and Appendix 12]

Based on this information, the department concludes that DaVita currently has appropriate relationships with ancillary and support services. If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed transfer agreement with a hospital in King County. Provided that DaVita would agree to the term, this sub-criterion would be met.

Northwest Kidney Centers

Documentation provided in the application confirms that NKC maintains appropriate relationships with ancillary and support services for its existing thirteen dialysis centers. For this project, NKC provided documentation to confirm that its SeaTac Kidney Center currently has appropriate relationships with ancillary and support services. Ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, plant operations, and administration and technical services are provided either through NKC's Haviland facility in the central Seattle area or its Lake City facility located in north Seattle area. [source: NKC 2nd Amended Application, p18] Further, NKC has an umbrella hospitalization transfer agreement with Swedish Medical Center in Seattle that incorporates all NKC patients and programs by specific reference, including this facility, formerly known as Cascade Kidney Center.

Based on this information, the department concludes that both NKC, and specifically its SeaTac facility, currently have appropriate relationships with ancillary and support services and approval of 12 additional stations would not negatively affect those 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.*

DaVita, Inc.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,300 outpatient centers located in 42 states (including Washington State) and the District of Columbia. [source: DaVita Webpage] Prior to the October 1, 2005, acquisition of the dialysis operations of Gambro Healthcare US, DaVita operated 665 centers in 37 states and the District of Columbia. Currently within Washington State, DaVita owns and operates fourteen 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 public⁶. To accomplish this task, in January 2007 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the 42 states and the District of Columbia where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Of the 43 entities, the department received responses from 28 states or 66% of the 42 states.⁷ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁸

⁶ WAC 246-310-230(5).

⁷ Alabama, Arizona, Connecticut, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New York, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

⁸ Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

Ten of the 28 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Delaware, one in New York and one in Texas, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2006 due to several condition-level citations, but was operating in compliance at the time of survey. The New York facility was cited with condition-level deficiencies. This facility was voluntarily de-certified and closed by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005. No further fines were identified for this facility.

The department concludes that considering the 1,300 facilities owned/managed by DaVita, few out-of-state facilities listed above demonstrated substantial non-compliance issues, with only three reported as subject to fines or actually decertified. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 32 compliance surveys for the operational facilities that DaVita either owns or manages.⁹ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Office of Health Care Survey]

Fadi Najjar, MD has agreed to provide medical director services at the proposed dialysis center. DaVita provided a copy of the draft medical director agreement between itself and Dr. Najjar. The agreement outlines the roles and responsibilities of both DaVita and the proposed medical director. A review of the compliance history of Dr. Najjar has shown that his credentials are up to date and reveal no recorded sanctions. [source: compliance history provided by Medical Quality Assurance Commission] If this project were approved, the department would attach a term to the approval requiring DaVita to submit a copy of the executed medical director agreement for review and approval.

Based on DaVita's compliance history and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the new dialysis center would be operated in conformance with state and federal regulations. Provided that DaVita would agree to the term regarding the medical director agreement, this sub-criterion would be met.

Northwest Kidney Centers

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, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 45 compliance surveys for the NKC facilities in

⁹ DaVita's Ellensburg Dialysis Center and Tacoma Dialysis Center are not yet operational. Olympic View Dialysis Center is owned by Group Health and managed by DaVita.

operation.¹⁰ 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. [source: facility survey data provided by the Office of Health Care Survey]

Razan Al-Kudsi, MD is the current medical director and will continue to provide services at SeaTac Kidney Center. NKC provided a copy of the executed medical director agreement between itself and Dr. Al-Kudsi. The agreement outlines the roles and responsibilities of NKC and the existing medical director. A review of the compliance history of Dr. Al-Kudsi has shown that his credentials are up to date and reveal no recorded sanctions. [source: 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 SeaTac Kidney Center would continue to operate in conformance with state and federal regulations with the additional stations. 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.*

DaVita, Inc

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [source: Application, p24, Appendices 17 & 18]

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

Additionally, the department must consider 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 13 additional dialysis stations in King county planning area #4. Within its application, DaVita proposes to establish a 13 station dialysis center in the city of Des Moines. However, as stated in the financial feasibility portion of this evaluation, inconsistencies prevent an accurate evaluation of the proposed facility's lease costs and forecasted viability. In the long-term this may lead to the unnecessary opening and closing of a facility, resulting in a loss of service. Therefore, the department concludes that approval of DaVita's additional dialysis station capacity in King County planning area #4 would have the potential of fragmentation of dialysis services within the service area, and this sub-criterion is not met.

¹⁰ NKC's Seattle Kidney Center is not yet operational.

Northwest Kidney Centers

In response to this criterion, NKC states that, “the NKC-SeaTac Kidney Center (previously Cascade Kidney Center) has been providing outpatient dialysis services to the communities of King County planning area #4 since 1987. The additional capacity will allow that commitment to the community to continue and will help prevent the situation in which served persons must leave their community to seek care elsewhere.” [source: Initial application, p18]

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 records]

Additionally, the department must consider 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 13 additional dialysis stations in King county planning area #4. Within its application, NKC proposed to serve the planning area by expanding its existing SeaTac Kidney Center by 13 stations, for a facility total of 25. Therefore, the department concludes that approval of NKC’s additional dialysis station capacity in King County planning area #4 would not have the potential of fragmentation of dialysis services within the service area, and 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.*

For both projects, this sub-criterion is addressed in sub-section (3) above and is considered met.

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.’s project has not met the cost containment criteria in WAC 246-310-240; and
- Northwest Kidney Center’s project 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.*

DaVita, Inc.

Within the application, DaVita provided discussion regarding the following two alternatives to this project. [source: Application, p26]

- Do nothing or status quo

DaVita states that delays and on-going litigation have caused substantial delays for any operator serving south King County patients. The methodology notes that there is a need for 13 stations, approximately double the existing capacity servicing the area. The existing facility [SeaTac Kidney Center] exceeds 4.8 patients per station. Not expanding

existing stations will result in patients having to leave the planning area to receive services.

- The existing provider—NKC—expands its station capacity if it relocates within the service area

Regarding this alternative, DaVita acknowledges that NKC may elect to expand the facility if it is relocated. However, DaVita believes that the tie-breaker methodology within the rules favor a new project because it would add choice and a second location within the service area. DaVita states that based on capital expenditure, its project would be less costly than new construction of the NKC facility.

Based on DaVita's discussion of the two options above, both options were rejected before submitting this project.

Northwest Kidney Centers

Before submitting its application to add 13 stations to SeaTac Kidney Center, NKC considered and rejected the following six alternatives to this project. [source: Application, pp19-20]

- Postponement

NKC states that this option would require patients to travel outside their community to access care, which would not be in alignment with NKC's goals to continuously see opportunities to improve convenience and access to care. This option was rejected.

- Nighttime Services

Since outpatient dialysis involves 3-5 hours of treatment, 3 times weekly, industry standard is typically 3 patient shifts in a dialysis center. Adding a 4th shift would require patients to dialyze between the hours of 11:00pm to 7:00 am. These hours have little appeal to patients, nephrologists, and facility staff. This option was rejected.

- Shortened Treatment Times

It is NKC's intent to continue to provide quality, patient care with favorable outcomes. There is a body of medical evidence suggesting that longer dialysis times, not shorter, result in better overall care and outcomes. This option was rejected.

- Home Dialysis

NKC offers this dialysis modality, however, this has not yet appealed to a larger number of patients. This option was rejected.

- Kidney Transplantation

NKC advocates for kidney transplants for ESRD patients for whom it is not contraindicated and who demonstrate interest. Currently, over 40% of NKC patients are on the waiting list at one or more of the three transplant centers in Seattle. However, the supply of available donor organs has not kept pace with demand.

- Shared/Contract Services Arrangements

NKC states that there are no other dialysis facilities in King County planning area #4.

The department recognizes that both projects would increase the dialysis station capacity in King County planning area #4. Additionally, the numeric portion of the need methodology supports the addition of 13 stations in the planning area.

In determining the best available alternative, the department considered its findings on the other applicable review criteria. The NKC project met all other review criteria. The DaVita project failed to meet the review criteria of Financial Feasibility and Structure and Process of

Care. Base on these factors, the department concludes that the NKC application is the best available alternative.

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

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

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met.

Northwest Kidney Centers

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

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

DaVita, Inc.

As stated in the project description portion of this evaluation, this project involve construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met.

Northwest Kidney Centers

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

E. Kidney Disease Treatment Centers—Tie-breakers (WAC 246-310-288)

This criterion is applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. Once the department evaluates the applications for compliance with the other applicable review criterion, only then can it determine if this criterion is to be applied.

To determine if this criterion applies to the two applications under review, the department considered its findings on the other review criteria. The department previously concluded that the DaVita application did not meet all the applicable review criteria; and the NKC application met the applicable review criteria. As a result, approval of NKC's application addresses the need in King County planning area #4. Given that DaVita's application failed to meet three of the four required universal review criteria, this tie-breaker criterion is not applicable.