

February 26, 2013

CERTIFIED MAIL # 7011 1570 0002 7802 6623

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

Re: CN12-24

Dear Mr. Pollock:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers proposing to add 11 dialysis stations to the 28-station center known as Renton Kidney Center located in ESRD planning area King #9. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Financial Feasibility
Cost Containment

Washington Administrative Code 246-310-220 Washington Administrative Code 246-310-240

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any interested or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

Palmer Pollock Northwest Kidney Centers Certificate of Need Application #12-24 February 26, 2013 Page 2 of 2

Appeal Option 2:

You or any affected person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address: Adjudicative Clerk Office Mail Stop 47879 Olympia, WA 98504-7879 Other Than By Mail
Adjudicative Clerk Office
111 Israel Road SE
Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerely

Steven M. Saxe, FACHE

Director, Health Professions and Facilities

Enclosure

cc: Department of Health, Investigations and Inspections Office

EXECUTIVE SUMMARY

EVALUATIONS DATED FEBRUARY 26, 2013, FOR THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY TO KING COUNTY PLANNING AREA #9:

- NORTHWEST KIDNEY CENTERS PROPOSING TO ADD ELEVEN STATIONS TO RENTON KIDNEY CENTER IN RENTON
- DAVITA, INC. PROPOSING TO ESTABLISH AN ELEVEN STATION DIALYSIS CENTER IN RENTON

BRIEF PROJECT DESCRIPTIONS

Northwest Kidney Centers

Northwest Kidney Centers is a private, not-for-profit corporation, incorporated in the state of Washington that provides dialysis services through its facilities located in King and Clallam counties. Northwest Kidney Centers proposes to add 11 stations to the 28-station facility known as Renton Kidney Center located in Renton. At project completion, the facility would be operating a total of 39 dialysis stations.

The capital expenditure associated with the addition of 11 stations is \$164,040. If this project is approved, Northwest Kidney Centers anticipates the addition of 11 stations would occur immediately after approval or by January 31, 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation with 39 stations and 2016 would be year three. [source: Application, p5, p9 & Appendix 8]

DaVita, Inc.

DaVita, Inc is a publicly held, for-profit corporation, incorporated in the state of Washington that provides dialysis services through its facilities across the nation. For this project, DaVita, Inc. proposes to establish an 11-station dialysis center in the city of Renton, within King County. The new dialysis center would be known as Renton Dialysis Center. Since DaVita, Inc. proposes a new facility, at project completion, the dialysis center would be operating a total of 11 dialysis stations.

The capital expenditure associated with the establishment of the 11-station facility is \$1,786,383. If this project is approved, DaVita, Inc. anticipates all 11 stations would become operational in June 2013. Under this timeline, 2014 would be the facility's first full calendar year of operation and 2016 would be year three. [source: Second Amendment Application, p5, p9, and p13]

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

DaVita, Inc.'s 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).

CONCLUSIONS

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Northwest Kidney Centers proposing to add eleven stations to Renton Kidney Center is not consistent with the applicable criteria of the Certificate of Need Program.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish an eleven-station dialysis center in Renton, within King County ESRD planning area #9, is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of an eleven-station dialysis facility in Renton, within King County. At project completion, the dialysis facility will be approved to certify and operate eleven stations. Services provided include hemodialysis and peritoneal home training, in-center hemodialysis, shifts beginning after 5:00pm., a permanent bed station, and an isolation station. The eleven dialysis stations operated at the facility are listed below.

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	8
Total	11

Conditions:

- 1. DaVita, Inc. agrees with the project description as stated above. DaVita, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. DaVita Inc. will provide the department with an executed copy of a Patient Transfer Agreement for department review and approval prior to commencement of services consistent with the draft agreement provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is \$1,702,475. This amount represents the total capital expenditure of \$1,786,383 minus the landlord's project costs of \$83,908.

EVALUATIONS DATED FEBRUARY 26, 2013, FOR THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY TO KING **COUNTY PLANNING AREA #9:**

- NORTHWEST KIDNEY CENTERS PROPOSING TO ADD ELEVEN STATIONS TO RENTON KIDNEY CENTER IN RENTON
- DAVITA, INC. PROPOSING TO ESTABLISH AN ELEVEN STATION DIALYSIS CENTER IN RENTON

APPLICANT DESCRIPTIONS

Northwest Kidney Centers

Northwest Kidney Centers (NKC) is a private, not-for-profit corporation, incorporated in the state of Washington that provides dialysis services through its facilities located in King and Clallam counties. Established in 1962, NKC operates as a community based dialysis program working to meet the needs of dialysis patients and their physicians.

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

In Washington State, NKC owns and operates a total of 15 kidney dialysis facilities. Of these, 14 are located in King County and one is located in Clallam County. Below is a listing of the NKC facilities in Washington. [source: Historical Files, NKC website]

King County

Auburn Kidney Center Renton Kidney Center Broadway Kidney Center Scribner Kidney Center Enumclaw Kidney Center Seattle Kidney Center Elliot Bay Kidney Center SeaTac Kidney Center Snoqualmie Ridge Kidney Center Kent Kidney Center Lake City Kidney Center Totem Lake Kidney Center Lake Washington Kidney Center West Seattle Kidney Center

Clallam County

Port Angeles Kidney Center

DaVita, Inc.

DaVita Inc. (DaVita) is a for-profit corporation that currently operates or provides administrative services to approximately 1,642 dialysis facilities located in 43 states and the District of Columbia. DaVita also provides acute inpatient kidney dialysis services in over 720 hospitals throughout the country. [source: Application, p5] In Washington State, DaVita owns or operates 30 kidney dialysis facilities in 14 separate counties. Below is a listing of the 30 facilities. [source: CN historical files & Amended Application, pp5-6]

¹ Des Moines Dialysis Center, East Wenatchee Dialysis Center, Kennewick Dialysis Center, and Zillah Dialysis Center are CN approved but not yet operational.

Benton	Pacific
Chinook Dialysis Center	Seaview Dialysis Center
Kennewick Dialysis Center	
	Pierce
Chelan	Graham Dialysis Center
DaVita Dialysis Center ²	Lakewood Dialysis Center
	Parkland Dialysis Center
Clark	Puyallup Dialysis Center
Vancouver Dialysis Center	Tacoma Dialysis Center
Douglas	Snohomish
East Wenatchee Dialysis Center	Everett Dialysis Center ³
	Mill Creek Dialysis Center
Franklin	
Mid Columbia Kidney Center	Spokane
	Downtown Spokane Renal Center
Island	North Spokane Renal Center
Whidbey Island Dialysis Center	Spokane Valley Renal Center
King	Thurston
Bellevue Dialysis Center	Olympia Dialysis Center
Des Moines Dialysis Center	
Federal Way Dialysis Center	Yakima
Kent Dialysis Center	Mt. Adams Dialysis Center
Olympic View Dialysis Center (management only)	Union Gap Dialysis Center
Westwood Dialysis Center	Yakima Dialysis Center
	Zillah Dialysis Center
Kittitas	
Ellensburg Dialysis Center	

PROJECT DESCRIPTIONS

Northwest Kidney Centers

This application proposes to add 11 stations to the existing 28-station dialysis facility known as Renton Kidney Center located at 602 Oakesdale Avenue Southwest in Renton, within King County. [source: Application, p1 & p5]

With the additional stations, services expected to be provided at Renton Kidney Center include hemodialysis, home and peritoneal dialysis, training/support for dialysis patients, and shifts beginning after 5:00pm. The 39-station facility would also include a permanent bed station and an isolation station. [source: Application, p7]

² DaVita recently purchased the dialysis center previously owned by Central Washington Hospital. The new name of the dialysis center is unknown as of the writing of this evaluation.

³ Refuge Dialysis, LLC, whose ownership is 80% DaVita and 20% The Everett Clinic, owns this facility.

The capital expenditure associated with the additional 11 stations is \$164,040. Of that amount, 92% is for fixed/moveable equipment and 8% is for taxes. [source: Application, Exhibit 8]

If this project is approved, NKC anticipates all 11 stations would become operational immediately after approval or by January 31, 2013. Under this timeline, 2014 would be the facility's first full calendar year of operation with 39 stations and 2016 would be year three. [source: Application, p9]

DaVita, Inc.

DaVita proposes to establish an 11-station dialysis facility to be located at 4110-E Northeast 4th Street in Renton, within King County. The new dialysis center would be known as Renton Dialysis Center. [source: Second Amendment Application, p9]

Services provided include hemodialysis and peritoneal home training, in-center hemodialysis, shifts beginning after 5:00pm., a permanent bed station, and an isolation station. [source: Second Amendment Application, p9; Appendix 16]

The capital expenditure associated with the establishment of the 11-station facility is \$1,786,383. Of that amount 65%.% is related to leasehold improvements, 26% for fixed/moveable equipment; and the remaining 9% is related to professional fees and the landlord's portion of costs. [source: Second Amendment Application, Appendix 7]

If this project is approved, DaVita anticipates the 11-station facility would become operational within seven months of approval. Under this timeline, 2014 would be the facility's first full calendar year of operation 2016 would be year three. [source: Application, p13]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Northwest Kidney Centers' project is subject to Certificate of Need review as an increase in dialysis stations capacity at an existing center under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

DaVita, Inc.'s 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).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for the application. WAC 246-310-200(2) provides additional direction in how the department is to make its determinations. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the Department in making the required determinations.

- (a) In the use of criteria for making the required determinations, the department shall consider:
 - (i) The consistency of the proposed project with service or facility standards contained in this chapter;

- (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and
- (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."

In the event the WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

"The department may consider any of the following in its use of criteria for making the required determinations:

- (i) Nationally recognized standards from professional organizations;
- (ii) Standards developed by professional organizations in Washington state;
- (iii) Federal Medicare and Medicaid certification requirements;
- (iv) State licensing requirements;
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application."

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment). Additionally, the applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.⁴

TYPE OF REVIEW

As directed under WAC 246-310-282(1), the department accepted both projects under the year 2012 Kidney Disease Treatment Centers-Concurrent Review Cycle #1. A chronologic summary of both projects is shown on the following page.

⁴ 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 246-310-286, 287, and 289.

APPLICATION CHRONOLOGY

Action	NKC	DaVita	
Letter of Intent Submitted	January 31, 2012	January 31, 2012	
Application Submitted	February 29, 2012	February 29, 2012	
First Amendment Application Submitted	None	March 30, 2012 ⁵	
Second Amendment Application Submitted	None	April 16, 2012	
Department's pre-review activities including screening and responses	April 17, 2012 through June 17, 2012		
Beginning of Review			
public comments accepted throughout review	June 1	8, 2012	
no public hearing conducted			
End of Public Comment	August 17, 2012		
Rebuttal Documents Received	September 17, 2012 September 14, 2		
Department's Anticipated Decision Date	November 1, 2012	November 1, 2012	
Department's Actual Decision Date	February 26, 2013	February 26, 2013	

AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person as:

- "...an "interested person" who:
 - (a) Is located or resides in the applicant's health service area;
 - (b) Testified at a public hearing or submitted written evidence; and
 - (c) Requested in writing to be informed of the department's decision."

Under concurrent review, each applicant is an affected person for the other application. Throughout the review of this project, no other entities sought or received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers Certificate of Need application received February 29, 2012
- DaVita, Inc. Second Amended Certificate of Need application received April 16, 2012
- Northwest Kidney Centers supplemental information received May 31, 2012
- DaVita, Inc. supplemental information received May 31, 2012
- Northwest Kidney Centers public comment received August 16, 2012
- DaVita, Inc. public comments received August 17, 2012
- Northwest Kidney Centers rebuttal comments received September 17, 2012
- DaVita rebuttal comments received September 14, 2012

⁵ DaVita Inc. submitted its initial application on February 29, 2012, consistent with the ESRD concurrent review cycle #1. On March 30, 2012, DaVita Inc. submitted its first amendment application consistent with WAC 246-310-100(6). On April 16, 2012, DaVita submitted its second amendment application consistent with WAC 246-310-100(6). Once the second amendment application was received, the initial and first amendment applications are no longer considered in this review. As a result, neither of these two applications will be further discussed in this evaluation.

- Years 2005 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 3rd Quarter data
- Licensing and survey data provided by the Department of Health's Investigations and Inspections Office
- Certificate of Need historical files

CONCLUSIONS

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Northwest Kidney Centers proposing to add eleven stations to Renton Kidney Center is not consistent with the applicable criteria of the Certificate of Need Program.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish an eleven-station dialysis center in Renton, within King County ESRD planning area #9, is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of an eleven-station dialysis facility in Renton, within King County. At project completion, the dialysis facility will be approved to certify and operate eleven stations. Services provided include hemodialysis and peritoneal home training, in-center hemodialysis, shifts beginning after 5:00pm., a permanent bed station, and an isolation station. The eleven dialysis stations operated at the facility are listed below.

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	8
Total	11

Conditions:

- 1. DaVita, Inc. agrees with the project description as stated above. DaVita, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. DaVita Inc. will provide the department with an executed copy of a Patient Transfer Agreement for department review and approval prior to commencement of services consistent with the draft agreement provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is \$1,702,475. This amount represents the total capital expenditure of \$1,786,383 minus the landlord's project costs of \$83,908.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes:

- Northwest Kidney Centers' project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284 provided the applicant agrees to the conditions identified in the "Conclusion' section of this evaluation.
- DaVita, Inc.'s project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284; and treatment facility methodology and standards in WAC 246-310-284 provided the applicant agrees to the conditions identified in the "Conclusion' section of this evaluation.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

WAC 246-310-284 requires the department to evaluate kidney disease treatment centers applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

Kidney Disease Treatment Center Methodology WAC 246-310-284

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.⁶

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

⁶ 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]

⁷ WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report." For these projects, the base year is 2010.

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 <u>except</u> 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 incenter stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

WAC 246-310-280(9) identifies the ESRD planning areas for the state. Both NKC and DaVita propose to add dialysis station capacity to King County planning area #9. The following zip codes are included in this planning area.

_Zip	City
98055	Renton
98056	Renton
98057	Renton
98058	Renton
98059	Renton
98178	Skyway

Northwest Kidney Centers' Application of the Numeric Methodology

NKC proposes to add 11 stations to its existing dialysis center in the Renton zip code of 98057. Based on the calculation of the annual growth rate in the planning area as described above, NKC used a linear regression to project need. Given that Renton Kidney Center is located in King County planning area #9, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: Application, Appendices 16 and 17]

DaVita, Inc.'s Application of the Numeric Methodology

DaVita proposes to establish an 11-station dialysis facility located in the Renton zip code of 98059. Based on the calculation of the annual growth rate in the planning area as described above, DaVita used the same linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: Second Amendment Application, pp18-19]

Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project need for King County planning area #9. The department also divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

The table below shows a summary of the projected net need provided by both applicants and the department for the planning area.

Table 1
King County Planning Area #9
Numeric Methodology Summary

	4.8 in-center patients per station			
	2014 Projected # of stations	Minus Current # of stations	2014 Net Need	
NKC	39	28	11	
DaVita	38.9	28	10.9	
DOH	39	28	11	

NKC's methodology shows a need for 11 stations in year 2014. When DaVita's results are rounded as required in WAC 246-310-284(4)(c), both applicants and the department's methodology show need for an additional 11 stations in the planning area in year 2014.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 incenter patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for these projects is February 1, 2012. [WAC 246-310-282] The quarterly modality report from NRN available at that time was September 30, 2011, available on November 15, 2011.

For King County planning area #9, there are 28 dialysis stations located in one facility—NKC's Renton Kidney Center. Table 2 shows the utilization of Renton Kidney Center with 28 stations as of September 30, 2011.

Table 2
September 30, 2011 - Facility Utilization Data

Facility Name		# of Pts	Pts/Station
NKC-Renton Kidney Center	28	136	4.86

Table 2 above demonstrates that the current facility satisfies this utilization requirement. This subcriterion is met.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of incenter patients per approved station by the end of the third full year of operation. For King County planning area #9, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, each applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Northwest Kidney Centers

NKC expects to add the 11 stations immediately after CN approval. Under this timeline, Renton Kidney Center would begin operating 39 dialysis stations at the end of January 2013. Calendar year 2014 would be the facility's first full calendar year of operation with all 39 stations and 2016 would be year three. A summary of NKC's projected utilization for the third year of operation is shown in the table below. [source: Application, p7]

Table 3
NKC-Renton Kidney Center - Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of In-Center Patients	Patients/Station
Renton Kidney Center	2016	39	188	4.80

During the review of this project, DaVita submitted comments related to the NKC's projected number of patients per stations shown in the table above. DaVita's comments and NKC's responses to the comments are summarized below.

DaVita Public Comments [source: DaVita public comments, pp4-7]

DaVita is concerned that NKC may have inflated its number of training patients that would be counted in the projected 188 patients above. DaVita recalculated NKC's number of patients for year 2016 and determined it would be 142 in-center patients, rather than 188, which would equate to 3.64 patients per station. At 3.64 patients per station, NKC's project would fail this standard.

NKC Rebuttal Comments [source: NKC rebuttal comments, p6]

In response to DaVita's assertions above, NKC provides the following clarifications.

"Table 4 [of the NKC application] included no home patients in the fiscal year end census and only the estimated number of training dialyses based on current experience, which are and always have been a small component of total projected dialyses in our pro forma. In other words, the projection of 188 patients for the fiscal year end census in 2016 includes only projected in-center patients as required by the regulations."

Department's Evaluation

During the 'screening' phase of this review, the department requested clarification on the types of patients included in the projected number of patents shown in Table 4 of the NKC application. In response, NKC clarified that the Table 4 does not include training or home patients because 'unless a patient is going to be receiving training for home dialysis for a period longer than 30 days, the patient may not be registered at the NKC Renton Kidney Center, and following training, home patients are permanently registered and are followed through NKC's centralized home patient programs at the NKC Seattle Kidney Center.' [source: May 31, 2012, supplemental information, pp2-3]

Additionally, NKC's rebuttal statements clearly state that only in-center patients are included in the 188 patients for year 2016. As a result, there is no reason for DaVita or the department to doubt whether all 188 patients projected in year 2016 should be counted toward this standard.

In conclusion, as shown in Table 3 above, NKC's Renton Kidney Center is expected to meet this standard with 39 dialysis stations and 188 patients. This sub-criterion is met.

DaVita, Inc.

DaVita anticipates its 11-station Renton Dialysis Center would become operational in June 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation and 2016 would be year three. A summary of DaVita's projected in center utilization for the third year of operation is shown in the table below. [source: Application, p17]

Table 4
DaVita's Renton Dialysis Center - Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of In-Center Patients	Patients/Station
Renton Dialysis Center	2016	11	55	5.00

As shown above, the proposed Renton Dialysis Center is expected to meet this standard with 11 dialysis stations. **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.

Northwest Kidney Centers

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of King County planning area #9 would 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. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, NKC provided a copy of its current Admission Criteria for Renton Kidney Center that would continue to be used at the facility. The Admission Criteria outlines the process/criteria that the facility will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Criteria also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, religion, sex, national origin, or age. [source: Application, Appendix 20]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. NKC currently provides services to Medicare eligible patients in this dialysis center. Details provided in the application demonstrate that NKC intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [source: Application, p8]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. NKC currently provides services to Medicaid eligible patients in this dialysis center. Details provided in the application

demonstrate that NKC intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [source: Application, p8]

NKC demonstrated its intent to provide charity care to King County planning area #9 residents by submitting the Charity policy currently used within the facility. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. NKC also included a 'charity' line item as a deduction from revenue within the pro forma income statements for each proposed facility. [source: Application, Appendices 10 and 21]

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

DaVita, Inc.

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of the King County planning area #9 would 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. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current policy for 'Accepting Patients for Treatment' that is currently used in its facilities. The policy outlines the process/criteria that the DaVita facilities will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facilities without regard to race, color, nation origin, sex, age, religion, or disability. [source: Second Amendment Application, Appendix 14]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. DaVita currently provides services to Medicare eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the anticipated revenues indicates that the new facility also expects to receive Medicare reimbursements. [source: Second Amendment Application, p11 and Appendix 9]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. DaVita currently provides services to Medicaid eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the anticipated revenue indicates that the new facility expects to receive Medicaid reimbursements. [source: Second Amendment Application, pll and Appendix 9]

DaVita demonstrated its intent to provide charity care to King County planning area #9 residents by submitting the 'Indigent Care Policy' currently used within its facilities. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. DaVita also included a 'charity' line item as a deduction from revenue within the proforma income statements for the facility. [source: Second Amendment Application, Appendices 9 and 14]

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

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

Based on the source information reviewed, the department concludes:

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

(1) The immediate and long-range capital and operating costs of the project can be met.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

Northwest Kidney Centers

NKC anticipates the additional 11 stations would become operational immediately after approval or by the end of January 2013. Using the fiscal years provided in the application, FY 2013 would be Renton Kidney Center's first full 12 months of operation with 39 dialysis stations. The table on the following page illustrates the projected revenue, expenses, and net income for fiscal years 2013 through 2016 for Renton Kidney Center. [source: Application, Appendix 10]

Page 15 of 32

Table 5
Renton Kidney Center
Projected Revenue and Expenses Fiscal Years 2013 - 2016⁸

	FY 1 - 2013	FY 2 - 2014	FY 3 - 2015	FY 4 - 2016
# of Stations	39	39	39	39
# of Treatments [1]	21,584	23,288	24,992	26,696
# of Patients [2]	152	164	176	188
Utilization Rate [2]	3.90	4.20	4.50	4.80
Net Revenue [1]	\$ 7,508,858	\$ 8,101,662	\$ 8,695,131	\$ 9,287,272
Total Expense [1,3]	\$ 6,996,129	\$ 7,478,530	\$ 7,961,205	\$ 8,444,167
Net Profit or (Loss) [1]	\$ 512,729	\$ 623,132	\$ 733,926	\$ 843,105

^[1] Includes in-center treatments only; [2] in-center patients only; [3] includes bad debt, charity care and allocated costs

The 'Net Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for Renton Kidney Center. As shown in Table 5, at the projected volumes identified in the application, NKC anticipates that the 39-station facility would be operating at a profit in each of the forecast years.

NKC currently operates the Renton facility at 602 Oakesdale Avenue Southwest in the city of Renton [98057]. The lease provided in the application outlines the initial terms and the annual rent for the space and includes a copy of the lease for the premises between Black River Park, LLC [landlord] and NKC [tenant]. The lease was executed October 20, 2010, and notarized on October 26, 2010, and extends for ten years and nine months. The annual lease costs are substantiated in the pro forma financial documents presented. [source: Application, Attachment 10 and Supplement 2]

Additionally, NKC provided a copy of the Medical Director Agreement and compensation amendment currently in effect between itself and Vilma Quijada, MD. The medical director service costs are also substantiated in the pro forma documents. [source: Application, Supplement 1]

Based on the above information, the department concludes that NKC's projected revenues and expenses are reasonable and can be substantiated. This sub-criterion is met.

DaVita, Inc.

DaVita anticipates the 11-station dialysis center would become operational in mid year 2013. Under this timeline, calendar year (CY) 2014 would be Renton Dialysis Center's first full year of operation and 2016 would be year three. The table on the following page illustrates the projected revenue, expenses, and net income for calendar years 2014 through 2016 for Renton Dialysis Center. [source: Second Amendment Application, Appendix 9]

⁸ Whole numbers may not add due to rounding.

Table 6
Renton Dialysis Center
Projected Revenue and Expenses Calendar Years 2014 - 20169

	CY 1 - 2014	CY 2 - 2015	CY 3 - 2016
# of Stations	11	11	11
# of Treatments [1]	3,744	5,841	8,237
# of Patients [2]	25	39	55
Utilization Rate [2]	2.30	3.50	5.00
Net Revenue [1]	\$ 880,406	\$ 2,155,013	\$ 3,165,470
Total Expense [1,3]	\$ 1,176,359	\$ 2,035,175	\$ 2,768,225
Net Profit or (Loss) [1]	(\$ 295,953)	\$ 119,838	\$ 397,245

^[1] Includes in-center treatments only; [2] in-center patients only; [3] includes bad debt, charity care and allocated costs.

The 'Net Revenue' line item is gross revenue minus any deductions for charity care and bad debt. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for Renton Dialysis Center. As shown in the table above, at the projected volumes identified in the application, DaVita anticipates a loss in the first full calendar year of operation, and a profit in years two and three.

In addition to the financial documents summarized above, DaVita also provided a copy of its executed lease agreement for the site at 4110-E Northeast 4th Street in Renton. The lease is between DaVita (Total Renal Care, Inc.) and Harry Buys as his separate estate, Bart Kooyman and Helena Kooyman, as husband and wife, and the Buys Family Partnership, a California General Partnership, as Tenants in Common (collectively and individually 'lesser'). The lease agreement outlines the roles and responsibilities for both the lesser and lessee and outlines the initial terms and the annual rent for the space. The effective date of the agreement is April 10, 2012, and extends for ten years. The executed agreement was notarized on April 9, 2012. [source: Second Amendment Application, Attachment 15]

Additionally, DaVita provided a copy of the executed Medical Director Agreement among itself [Total Renal Care, Inc.], Bellevue Kidney Specialists, PLLC, and Philip King, MD. The agreement identifies roles and responsibilities for all three entities and identifies annual compensation for the services. The medical director service costs are also substantiated in the pro forma documents. [source: Second Amendment Application, Appendices 3 and 9]

During the review of this project, NKC submitted comments related to the pro forma revenue and expense statements provided in the application. Below is a summary of the comments provided by NKC.

NKC Public Comments [source: NKC public comments, pp1-3]

NKC asserts that DaVita's pro forma revenue and expense statements omit two important costs:

• Operating Expenses: DaVita's share of landlord's taxes, insurance, and common area maintenance charges, collectively referred to as 'operating expenses.' NKC estimated these costs to be at least \$30,000 each year.

⁹ Whole numbers may not add due to rounding.

• <u>Start-up Medical Director Costs</u>: NKC reviewed DaVita's medical director agreement and concluded that DaVita is required to pay its medical director for pre-certification expenses [section 6.1 of the agreement]. However, DaVita's pro-forma shows only post-certification expenses, with the medical director line item at \$65,000 for all three years.

NKC concludes that even if the omitted costs identified above do not cause DaVita's pro forma revenue and expense statement to show a loss in the third full year of operation, these omissions cause the statement to be unreliable. DaVita's project should be denied because the financial statements are unreliable.

DaVita provided responses to NKC's comments above which are summarized below.

<u>DaVita Rebuttal Comments</u> [source: DaVita, rebuttal comments, pp1-5]

NKC cites no rule requiring estimates of operating costs and does not dispute such expenses are typically omitted by dialysis facility applications. The department recognized in its recent review of other dialysis projects including:

- 2010 cycle 4 regular review of DaVita [App #11-10];
- 2011 cycle 2 concurrent review of Northwest Kidney Centers [App #11-37] and DaVita [App #11-38A]; and
- 2011 cycle 3 concurrent review of Puget Sound Kidney Centers [App #12-04A] and DaVita [App #12-05].

In all three recent reviews, the department acknowledged and agreed that typically, dialysis applicants have not included estimates for these lease related expenses.

In NKC's 2011 cycle 2 expansion of its Kent Kidney Center [App #11-40], NKC did not provide these estimates for these operating expenses. NKC's rationale used in the Kent application was that the costs are unknown for a new facility. This is the same rationale used by DaVita.

Related to the pre certification medical director costs, NKC relies on nothing but standard language in the agreement. DaVita does not expect to incur any pre-certification medical director expenses because it does not expect to operate prior to certification. This concept is supported by Table 8 in the application that provides expected dates for 'state inspection and certification' and 'facility opens.' The dates for each are the same.

Department's Evaluation

After reviewing the issues raised by NKC and the responses provided by DaVita, the department concludes that both DaVita and NKC have been diligent in providing reasonable estimates in their applications. For this project, DaVita appropriately identified the estimated costs for the new 11-station facility and appropriately did not include pre-certification medical director costs.

Based on the above information, the department concludes that DaVita's projected revenues and expenses are reasonable and can be substantiated. **This sub-criterion is met**.

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

Northwest Kidney Centers

The capital expenditure associated with the addition of 11 stations to Renton Kidney Center is \$164,040 and all costs are for fixed/moveable equipment and associated sales tax. [source: Application, Appendix 8] The capital cost breakdown is shown in the table below.

Table 7
NKC Estimated Capital Costs

Item	Cost	% of Total
Fixed & Moveable Equipment	\$ 150,634	91.8%
Sales Tax	\$ 13,406	8.2%
Total Estimated Capital Costs	\$ 164,040	100.0%

NKC intends to finance the project entirely from available board reserves. A review of the historical financial statement provided in the application indicates that NKC has sufficient cash assets and board approval to fund the project. [source: Application, Appendices 8 & 24]

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

Table 8
NKC-Renton Kidney Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue			
Medicare .	76%			
Medicaid	12%			
Other [1]	12%			
Total	100%			

[1] Other sources include Blue Cross, Group Health, private pay, and other insurances

As shown above, the Medicare and Medicaid reimbursements are projected to equal 88% of the revenue at Renton Kidney Center. The department concludes that since the majority of revenue is dependent upon sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining 12% will be derived through a variety of reimbursement sources.

During the review of this project, DaVita submitted comments related to the capital expenditure identified in Table 7. Below is a summary of the comments provided by DaVita.

<u>DaVita Public Comments</u> [source: DaVita public comments, p2]

DaVita asserts that when a dialysis center has relocated under WAC 246-310-289, the costs for the relocation of the existing facility are appropriately not reviewed. However, after the relocation, if an application is submitted to add stations to the facility, the costs for the additional stations, including construction costs, must be included in the capital expenditure for the project.

NKC Rebuttal Comments [source: NKC rebuttal comments, pp1-5]

NKC asserts that its capital expenditure of \$164,040 is correct because the project is to certify 11 "existing surplus dialysis stations at the NKC Renton Kidney Center." Further, NKC states that the application fully discloses that the surplus stations and space exist and no new space or construction is needed. NKC further explains that it deliberately invested in the additional stations when the facility was built to serve both as surge capacity and for future use by the community. The Renton facility was built out for 41 stations, which includes 6 private rooms. NKC asserts that there is no requirement in rule or otherwise that applicants that have completely relocated and expanded a dialysis facility report and allocate construction costs when later seeking approval for expansion stations.

Department's Evaluation

WAC 246-310-289 allows the relocation of a dialysis center, in its entirety, to a new site in the same planning area, without undergoing CN review as the establishment of a new healthcare facility, provided that there are no new stations added to the replacement facility. NKC relocated Renton Kidney Center under this rule.

The department acknowledges that when a provider builds a new facility for relocation, the facility is typically built to accommodate more stations than the number to be relocated. In the case of NKC's Renton project, NKC received approval to relocate the 28-station facility on September 24, 2010. All costs, including construction costs, for the existing 28 stations were part of the relocation project. These costs were reviewed when the facility was established and during any subsequent projects to add stations.¹⁰

Any costs, including construction costs, beyond the 28 stations are subject to review when an application is submitted to add stations beyond the 28. On February 29, 2012, NKC submitted this application to add 11 stations to the facility. Construction and equipment costs for the additional 11 stations should have been included in this application.

The CN Program's practice of reviewing construction costs for station additions, even when the facility has relocated under WAC 246-310-289, is long standing. NKC and other providers have submitted applications for station additions after relocation and all were required to identity the

¹⁰ Renton Kidney Center [formerly Mt. Rainier Kidney Center] was established in 1985 [CN #818] as a 7-station facility. Subsequent to the initial approval, stations additions were approved in 1987, 1991, 1991, and 2007, under CNs #893, 1057, 1182 and 1355, respectively.

construction costs specific to the additional stations.¹¹ Historical files also show that NKC's representative was reminded of this approach during a telephone conference call with CN Program staff on May 29, 2012.

Based on the information provided, the department concludes that NKC did not provide construction costs related to the additional 11 stations, therefore, the department is unable to determine compliance with this sub-criterion. **This sub-criterion is not met**.

DaVita, Inc.

The capital expenditure associated with the establishment of the 11-station facility is \$1,786,383. Of that amount 65% is related to leasehold improvements, 26% for fixed/moveable equipment; 4% is related to professional fees; and the remaining 5% is the landlord's portion of costs. [source: Second Amendment Application, Appendix 7] The capital cost breakdown is shown in the table below.

Table 9
DaVita Estimated Capital Costs

Item	Cost	% of Total			
Construction/Leasehold Improvements	\$ 1,156,200	65%			
Fixed & Moveable Equipment (w/ tax)	\$ 470,275	26%			
Professional Service Fees	\$ 76,000	4%			
Landlord Project Costs	\$ 83,908	5%			
Total Estimated Capital Costs	\$ 1,786,383	100%			

DaVita intends to finance its portion of the project, which is \$1,702,475, entirely from available board reserves. A review of the historical financial statement provided in the application indicates that DaVita has sufficient cash assets and board approval to fund the project. [source: Second Amendment Application, Appendix 10]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD reimbursements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in the table below. [source: Second Amendment Application, p11]

Table 10
DaVita-Renton Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	61%
Medicaid	9%
Other [1]	30%
Total	100%

[1] Other sources include Blue Cross, Group Health, private pay, and other insurances

¹¹ Examples include Olympic Peninsula Kidney Centers in Bremerton, Puget Sound Kidney Centers in Oak Harbor, and Northwest Kidney Centers in SeaTac.

As shown above, the Medicare and Medicaid reimbursements are projected to equal 70% of the revenue at the Renton Dialysis Center. The department concludes that since the majority of revenue is dependent upon sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining 30% will be derived through a variety of reimbursement sources.

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

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

Northwest Kidney Centers

As previously stated, NKC identified the capital expenditure associated with the addition of 11 stations to Renton Kidney Center to be \$164,040. NKC states that the project will be funded from available board reserves. A review of NKCs historical financial statements show the funds necessary to finance the project are available. [source: Application, Appendices 23, 24, & 25]

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of NKC as a whole. **This sub-criterion is met**.

DaVita, Inc.

As previously stated, the capital expenditure associated with the establishment of the 11-station Renton Dialysis Center is \$1,786,383, and DaVita's portion of the costs is \$1,702,475. DaVita intends to finance its portion entirely from available board reserves. A review of the historical financial statements provided in the application indicates that DaVita has sufficient cash assets to fund the project. [source: Second Amendment Application, Appendix 10]

Based on the information provided, the Department concludes that approval of this project would not adversely affect the financial stability of DaVita 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 concludes:

- Northwest Kidney Centers' project has met the structure and process of care criteria in WAC 246-310-230; and
- DaVita, Inc.'s project has met the structure and process 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>

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of full time equivalents (FTEs) that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

Northwest Kidney Centers

Renton Kidney Center has been operational for many years. It currently operates with 28 dialysis stations. To accommodate the additional patients associated with the 11 new stations, NKC expects to add a total of 7.47 FTEs to the center. A breakdown of the additional FTEs by year is shown in the table below. [source: May 31, 2012, supplemental information, p4]

Table 11
Renton Kidney Center Current and Projected FTEs

Staff/FTEs	2013 Current	2014 Increase	2015 Increase	2016 Increase	Total		
Medical Director		Professional Services Contract					
Registered Nurse	10.01	0.88	0.80	0.80	12.49		
Patient Care Techs	18.75	1.48	1.48	1.48	23.19		
Clerical	1.00	0.00	0.00	0.00	1.00		
Dietician	1.01	0.08	0.08	0.08	1.25		
MSW	1.16	0.11	0.10	0.10	1.47		
Total FTEs	31.93	2.55	2.46	2.46	39.40		

As shown in the table above, NKC plans for small annual increases in FTEs that coincide with the increase in patients and dialyses each year. NKC states that it does not anticipate any difficulty in recruiting staff for Renton Kidney Center due to its location and past success in attracting qualified health personnel. Further, NKC states its employees have an average length of service of 9.5 years. [source: Application, p18]

NKC identified Vilma Quijada, MD as the current medical director for Renton Kidney Center and provided a copy of the executed medical director's agreement.¹² The agreement outlines the roles and responsibilities for both NKC and the medical director. The agreement also identifies the annual compensation for the medical director services. [source: Application, Supplement 1]

¹² It is noted that the medical director agreement references the former name of Mount Rainier Kidney Center.

Based on the information reviewed, the department concludes adequate staffing for the additional 11 stations and the 39-station Renton Kidney Center is available or can be recruited. **This sub-criterion** is met.

DaVita, Inc.

Since Renton Dialysis Center would be a new facility, DaVita provided a breakdown of all proposed staff beginning in full year one (2014) through full year three (2016). [source: Second Amendment Application, p23] A breakdown of the FTEs is shown in the table below.

Table 12
Renton Dialysis Center Projected FTEs

Staff/FTEs	2014 Total	2015 Increase	2016 Increase	Total	
Medical Director	Pro	fessional Se	rvices Con	tract	
Administrator	1.00	0.00	0.00	1.00	
Registered Nurse	2.30	0.70	1.00	4.00	
Patient Care Techs	1.30	2.70	1.00	5.00	
Biomedical Techs	0.30	0.10	0.10	0.50	
Administrative Asst	0.50	0.00	0.50	1.00	
MSW	0.30	0.20	0.10	0.60	
Dietician	0.30	0.20	0.10	0.60	
Total FTEs	6.00	3.90	2.80	12.70	

As shown in the table above, after the initial recruitment in 2014, DaVita expects to more than double its FTEs by the end of year three based on the projected number of patients and dialyses for those years. DaVita states that it does not anticipate any difficulty in recruiting staff for the Renton Dialysis Center due to its location and past success in attracting qualified health personnel. Further, DaVita states that this is aided by their wage and benefit package and that 'DaVita has an extensive employee-traveling program guaranteeing all appropriate staff.' [source: Second Amendment Application, p25]

DaVita identified Philip King, MD as the medical director for the proposed facility and provided a copy of the medical director's agreement that identified Bellevue Kidney Specialists, PLLC, and Philip King, MD. The agreement outlines the roles and responsibilities of DaVita, Bellevue Kidney Specialists, and Dr. King and identifies the annual compensation for the medical director services. [source: Second Amendment Application, Appendix 3]

Based on the information reviewed, the department concludes adequate staffing for the 11-station Renton Dialysis Center is available or can be recruited. **This sub criterion is met**.

(2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

WAC 246-310 does not contain specific WAC 246-310-230(2) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

Northwest Kidney Centers

The information and transfer agreement provided in the application confirm that NKC maintains the appropriate relationships with ancillary and support services for Renton Kidney Center. Ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, human resources, material management, administration, and technical services are currently provided by "one of our support offices in Seattle, Lake Forest Park, or SeaTac" which already provide services daily or on demand for the existing NKC facilities. [source: Application, p19]

Based on this information, the department concludes NKC currently has access to the necessary ancillary and support services for the existing facility. This sub-criterion is met.

DaVita, Inc.

As a provider of dialysis services in Washington State, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For its proposed Renton Dialysis Center, 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: Second Amendment Application, p25]

DaVita acknowledges that since this would be a new facility in King County, transfer agreements must be established. To further demonstrate compliance with this sub-criterion, DaVita provided an example of a draft transfer agreement. [source: Second Amendment Application, Appendix 12]

Based on this information, the department concludes DaVita currently has access to the necessary ancillary and support services that could support the proposed facility. If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed transfer agreement with a local hospital that is consistent with the example presented in the application. With the condition, this sub-criterion is met.

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii)

and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

Northwest Kidney Centers

As stated earlier, NKC is currently a provider of dialysis services within Washington State, and operates 15 kidney dialysis treatment centers in two separate counties. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public. ¹³

Since January 2008, the Department of Health's Investigations and Inspections Office has completed certification and compliance surveys for a number of the operational NKC facilities. Of the surveys completed, four revealed minor non-compliance issues related to the care and management of the facilities which required plans of correction.¹⁴ These non-compliance issues were typical of a dialysis facility and the plans of correction were fully implemented. [source: Facility survey data provided by the Investigations and Inspections Office]

For medical director services, NKC provided a copy of the Medical Director Agreement and compensation amendment currently in effect between itself and Vilma Quijada, MD, the current medical director at Renton Kidney Center. A review of the compliance history for Dr. Quijada revealed no recorded sanctions. [source: Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of NKC and that of the current medical director, the department concludes that there is reasonable assurance that the Renton Kidney Center would continue to operate in compliance with state and federal regulations with the addition of 11 stations. **This sub-criterion is met.**

DaVita, Inc.

As previously stated, DaVita provides dialysis services in over 1,600 outpatient centers located in 43 states and the District of Columbia. For Washington State, DaVita owns or operates 30 kidney dialysis treatment centers in 14 separate counties. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public. To accomplish this task, in February 2010 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the states and the District of Columbia where DaVita, Inc. or any subsidiaries have health care facilities.

¹⁵ WAC 246-310-230(5).

¹³ WAC 246-310-230(5).

¹⁴ Broadway Kidney Center, May, 2009; Lake City Kidney Center, July, 2009; Port Angeles Kidney Center, April, 2010; and the Snoqualmie Ridge Kidney Center, June, 2010.

Of the 45 states and entities, the department received responses from 21 states or 48% of the 44 entities. The compliance history of the remaining 22 states and the District of Columbia is unknown. To

Five of the 21 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 Iowa that decertified and later re-opened as a private ESRD facility, none of the deficiencies are reported to have resulted in fines or enforcement action. All other facilities comply with applicable regulations. [source: Compliance history from state licensing and/or surveying entities]

The department concludes that considering the more than 1,600 facilities owned/managed by DaVita, only one out-of-state facility demonstrated substantial non-compliance issues. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2008, the Department of Health's Investigations and Inspections Office has completed more than 30 compliance surveys for the operational facilities that DaVita either owns or manages.¹⁹ Of the compliance surveys completed, there were some minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues are typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: DOH Investigations and Inspections Office records]

For medical director services, DaVita provided a copy of the medical director agreement with both Philip King, MD and Bellevue Kidney Specialists, PLLC for medical director services at Renton Dialysis Center. A review of the compliance history for Dr. King revealed no recorded sanctions. [source: Second Amendment Application, Appendix 3 and Compliance history provided by Medical Quality Assurance Commission]

During the review of this project, NKC submitted comments related to DaVita's ability to operate a new facility in compliance with state and federal guidelines. NKC's comments and DaVita's responses to the comments are summarized below.

¹⁷ States that did not provide responses are Alabama, Arizona, Arkansas, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Texas, Utah, Virginia and Wisconsin. The department did not send survey to itself. The District of Columbia did not respond to the survey.

¹⁸ The Iowa facility chose voluntarily termination in August 2007 due to its inability to remain in compliance with Medicare Conditions for Coverage rather than undergo the termination process with Medicare. This facility is currently operating as a private ESRD facility.

As of the writing of this evaluation, four facilities—Des Moines Dialysis Center, East Wenatchee Dialysis Center, Kennewick Dialysis Center, and Zillah Dialysis Center—were recently approved by the department and are not yet operational. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita. Everett Dialysis Center is owned and managed by Refuge Dialysis, LLC, whose ownership is 80% DaVita, and 20% The Everett Clinic.

¹⁶ States that provided responses are: California, Colorado, Connecticut, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nevada, New Mexico, North Dakota, Ohio, Oregon, South Carolina, Tennessee, South Dakota, Washington and West Virginia.

NKC Public Comments [source: NKC public comments, pp3-4]

On May 29, 2012, the department denied a station addition at DaVita's Kent Dialysis Center based on historical documentation showing that DaVita had been operating one station more at the facility than approved. NKC asserts that this action calls into question DaVita's ability to operate in compliance with state and federal guidelines.

<u>DaVita Rebuttal Comments</u> [source: DaVita rebuttal comments, pp8-9]

DaVita first points out that it has no history of license revocation or decertification in Washington State. Further, DaVita or its owners have no history of criminal conviction, a denial or revocation of a license to operate a health care facility, or decertification as a provider of services in the Medicare or Medicaid program. Once the non-compliance was discovered, DaVita self-reported the issue to the department. DaVita also implemented and completed an agreed phase-out plan for the one station to bring the Kent facility into compliance. DaVita then applied to Medicare to reduce the certified station count from 13 to 12.

Department's Evaluation

During the review of DaVita's Kent project, the department verified that the Kent Dialysis Center had been operating out of compliance for years 1999, 2005, 2010, and 2012. Since the project under review was a station addition to the Kent facility, the department could not conclude that DaVita would operate that facility in compliance when it had not been operating in compliance. As a result, NKC is correct that DaVita's Kent Dialysis Center project was denied under this sub-criterion based on non-compliance. DaVita is also correct in that they have been working with department staff to get CMS to de-certify the unauthorized station.

The denial of additional stations to DaVita's Kent facility and requiring DaVita to reduce its station count at the Kent facility is the acceptable remedy for that facility during that review. The department has not identified any other DaVita Washington State facilities operating out of compliance which would indicate a pattern of non-compliance by DaVita.

Taking into account DaVita's long history of compliance across the nation, including Washington State, denial of subsequent applications submitted by DaVita based on the non-compliance of the Kent facility as suggested by NKC is excessive and unwarranted.

The department will continue to periodically review the Medicare website for all dialysis providers to ensure compliance with Certificate of Need approval. For this project, given the compliance history of DaVita and that of the proposed medical director, the department concludes that there is reasonable assurance that the Renton Dialysis Center would operate in compliance with state and federal regulations. **This sub-criterion is met.**

²⁰ CN Application #11-41.

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Northwest Kidney Centers

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

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 11 dialysis stations in King County planning area #9. This project proposes to add 11 stations to Renton Kidney Center located in the planning area.

Approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. Further, NKC demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area. **This sub-criterion is met**.

DaVita, Inc.

The department 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.

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 11 dialysis stations in King County planning area #9. This project proposes to establish an 11-station facility in Renton within the planning area.

Approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. This sub-criterion is met.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

Northwest Kidney Centers

This sub-criterion is addressed in sub-section (3) above. This sub-criterion is met.

DaVita, Inc.

This sub-criterion is addressed in sub-section (3) above. This sub-criterion is met.

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

Based on the source information reviewed, the department concludes that

- Northwest Kidney Centers' project does not meet the cost containment criteria in WAC 246-310-240(1) and (2); and
- DaVita, Inc.'s project has met the cost containment criteria in WAC 246-310-240(1) and (2).
- (1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.</u>
 To determine if a proposed project is the best alternative, the department takes a multi-step approach.

 <u>Step one</u> determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met WAC 246-310-210 through 230 criteria, the department would move to <u>step two</u> in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific (tie-breaker) criteria contained in WAC 246-310. The tie-breaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

Northwest Kidney Centers

NKC's project did not meet the review criteria under WAC 246-310-220. As a result, NKC's project fails under this sub-criterion and step two is not reviewed.

DaVita, Inc

DaVita's project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below for DaVita's project.

Step Two

DaVita, Inc

Within the application, DaVita identified and rejected one alternative before submitting this application. A summary of the alternative and DaVita's rationale for rejection is below. [source: Second Amendment Application, p27 and May 31, 2012, supplemental information, p4]

Alternative 1-Do Nothing

DaVita states it rejected this option because there is a current need for 11 additional stations in year 2014.

Once DaVita determined that it would submit an application to add dialysis stations in the planning area, DaVita stated that it also considered two other sites for the facility. DaVita did not identify the location of either site, but stated both sites were rejected because they required the development of a new building, rather than a build-out of an existing building as described in this application. The department did not identify any other alternatives.

In summary, DaVita simply considered do nothing or submit an application for additional stations in the planning area. Considering there was a projected numeric need for additional dialysis station capacity in the planning area and DaVita does not have an existing facility in that planning area, the department concludes that the 'do nothing' option was appropriately rejected.

Step Three

WAC 246-310-288 identifies specific tie-breaker criteria that must be applied if two or more applications meet <u>all</u> applicable review criteria and there is not enough station need projected for all applications to be approved. Since NKC's project failed to meet the financial feasibility criteria under WAC 246-310-220, this tie-breaker criterion does not apply.

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

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

WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable. However, the department, through its experience knows that construction projects are usually built to exceed these minimum standards. Therefore, the department considered information in the applications that addressed the reasonableness of their construction projects that exceeded the minimum standards.

Northwest Kidney Centers

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). **This** sub-criterion is not met.

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). **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.

Northwest Kidney Centers

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). This sub-criterion is not met.

DaVita, Inc.

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). This sub-criterion is met.

APPENDIX A



2012 King County 9 ESRD Need Projection Methodology

			ning Area Nir				
	ESRD N	leed Project	ion Methodo	logy			
	Planning Area				nter Patients	:	
and a second of the second	King Nine (9)	2005	2006	2007	2008	2009	2010
	98055	28	32	28	27	24	24
	98056	22	25	23	22	30	34
	98057*			8	11	12	14
	98058	38	34	25	30	34	34
	98059	18	23	21	18	21	24
*	98178	36	37	37	37	39	41
	TOTALS	142	151	142	145	160	171
240 240 204(4\(-\		! 	0.040/	r 000/		40.040/	0.000
246-310-284(4)(a)	Rate of Change		6.34%		2.11%	10.34%	6.88%
	6% Growth or Greater?	i	TRUE	FALSE	FALSE	TRUE	TRUE
	Regression Method:	Linear	:			:	
		•	1				
			:			· ····	
246-310-284(4)(c)			: :	Year 1	Year 2	Year 3	Year 4
			i 	2011	2012	2013	2014
Projected Resident					:		
ncenter Patients	from 246-310-284(4)(b)		l	170.40	175.80	181.20	186.60
Station Need for							
Patients	Divide Resident Incenter	Patients by	4.8	35.5000	36.6250	37.7500	38.8750
	Rounded to next whole n	umber		36	37	38	39
040 040 00 4/4\/-1\		: 	:	i			
246-310-284(4)(d)	subtract (4)(c) from approv	ed stations		20		20	0.0
Existing CN Approved S	tations			28	28	28	28
Results of (4)(c) above				36	37.	38	39
Net Station Need	: :			: -8	-9	-10	-11
legative number indicates ne	od for stations		F + +	:			
vegative number indicates ne	eu ioi stations		: :				
246-310-284(5)					: :		** * * * * * *
Name of Center	# of Stations	Patients	Utilization (Dationts no	r Station\		
NKC Renton Kidney Cer		136	 	i atients pe	1 Otation)		e e e
formerly Mt. Rainier)		100	7.00				
Tormerry wit. Raimer)							
Cotol	28	136	•				
Fotal		100	ļ				
Source: Northwest Renal	: Network data 2005-2010	<u></u>	·	 :			
	a: 2010 year-end data as of	f 02/16/2011	l ;			i	
	as of the 1st day of applica			 3rd guarter :	2011 as of 1 ²	/15/2011	
		LIGH CUDITIO	1				
8057 added per WAC 24	th=31H=28H(9)						

2012 King County 9 ESRD Need Projection Methodology

