



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

May 29, 2012

CERTIFIED MAIL # 7011 1570 0002 7802 6098

Jason Bosh, Regional Operations Director
DaVita, Inc., North Star, Region 1
1301 A Street, #400
Tacoma, Washington 98402

RE: CN11-41

Dear Mr. Bosh:

We have completed review of the Certificate of Need application submitted by DaVita proposing to add 1 station to the Kent Dialysis Center in King County dialysis planning area 10. 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.

Structure and Process of Care	WAC ¹ 246-310-230
Cost Containment	WAC 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:

<u>Mailing Address:</u>	<u>Other Than By Mail</u>
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

¹ Washington Administrative Code



Jason Bosh
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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:

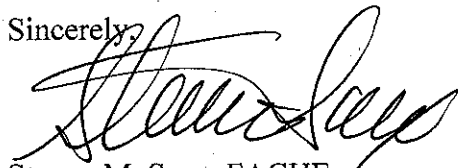
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

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: Karen Stricklett, Department of Health, Customer Service Office

EXECUTIVE SUMMARY

EVALUATIONS DATED MAY 29, 2012 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO KING COUNTY:

- **NORTHWEST KIDNEY CENTERS PROPOSING TO ADD 1 KIDNEY DIALYSIS STATION TO THE EXISTING KENT KIDNEY CENTER IN KING COUNTY**
- **DAVITA, INC. PROPOSING TO ADD 1 KIDNEY DIALYSIS STATION TO THE EXISTING KENT DIALYSIS CENTER IN KING COUNTY**

BRIEF PROJECT DESCRIPTIONS

NKC

Northwest Kidney Centers (NKC) proposes to add one dialysis station to the Kent Kidney Center for a facility total of 18 stations. The facility is located at 25316-74th Avenue South in the city of Kent, within King County. The dialysis center would continue to serve the residents of King County planning area #10. Services currently provided at the Kent facility include hemodialysis, visiting patient dialysis service, home hemodialysis training, special care and treatments scheduled after 5 p.m. [source: Application, p7]

The capital expenditure associated with the expansion of the Kent facility is \$33,397. Of that amount 41% is related to construction; 52% for moveable equipment; and the remaining 7% is related to applicable taxes. [source: Application, p5]

If this project is approved, NKC anticipates the station would be available by July 1, 2012. Under this timeline, year 2013 would be the facility's first full calendar year of operation with 18 stations and 2015 would be year three. [source: Application, Face Page]

DaVita, Inc.

DaVita, Inc. proposes to add one dialysis station to the DaVita Kent Dialysis Center for a facility total of 13 stations. This station will add isolation capability to services already provided at the Kent facility. The facility is located at 21501-84th Avenue South in the city of Kent, within King County. The dialysis center would continue to serve the residents of King County planning area #10. Services currently provided at the Kent facility include hemodialysis, peritoneal home hemodialysis training, visiting patient dialysis service, and treatments scheduled after 5 p.m.

The capital expenditure associated with the expansion of the DaVita Kent facility is \$18,408 and is solely related to construction. DaVita indicated they have the necessary equipment already on hand and that the depreciated value of this equipment is \$4,356. [source: Application, pgs 1 & 8, July 26 Response to Screening Questions, p2]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both projects are subject to Certificate of Need (CN) review as the increase in number of dialysis stations at a dialysis facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

CONCLUSIONS

NKC

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Center proposing to add one dialysis station to the Kent Kidney Center is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Center agrees to the following in its entirety.

Project Description:

NKC proposes to add one dialysis station to the Kent Kidney Center for a facility total of 18 stations. The facility is located at 25316-74th Avenue South in the city of Kent, within King County. The dialysis center would continue to serve the residents of King County planning area #10. Services currently provided at the Kent facility include hemodialysis, visiting patient dialysis service, home hemodialysis training, special care and treatments scheduled after 5 p.m. The station breakdown for the facility at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Home Training ¹	1
Other In-Center Stations	15
Total	18

Condition:

1. Approved project description as described above.

Approved Cost:

The approved capital expenditure associated with this project is \$33,397.

DaVita Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to add one dialysis station to the Kent Dialysis Center is not consistent with applicable criteria and a Certificate of Need is denied.

¹ Includes peritoneal and hemodialysis training

**EVALUATIONS OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS
PROPOSING TO ADD DIALYSIS CAPACITY TO KING COUNTY:**

- **NORTHWEST KIDNEY CENTER PROPOSING TO ADD 1 KIDNEY DIALYSIS TO THE EXISTING KENT KIDNEY CENTER IN KING COUNTY**
- **DAVITA, INC. PROPOSING TO ADD 1 KIDNEY DIALYSIS TO THE EXISTING KENT DIALYSIS CENTER IN KING COUNTY**

APPLICANT DESCRIPTION

NKC

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

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 within King County. Below is a listing of the NKC facilities in Washington. [source: Historical Files, NKC website]

King County

Auburn Kidney Center	Mount Rainier Kidney Center
Broadway Kidney Center ²	Scribner Kidney Center
Elliot Bay Kidney Center	Seattle Kidney Center
Kent Kidney Center	SeaTac Kidney Center
Lake City Kidney Center	Snoqualmie Ridge Kidney Center
Lake Washington Kidney Center	Totem Lake Kidney Center
Enumclaw Kidney Center	West Seattle Kidney Center

Clallam County

Port Angeles Kidney Center

DaVita Inc.

DaVita, Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,598 outpatient centers located in 43 states, the District of Columbia, and San Juan, Puerto Rico. DaVita also provides acute inpatient dialysis services in approximately 700 hospitals throughout the country. [source: Application, p5; DaVita website]

In Washington State, DaVita owns or operates a total of 25 kidney dialysis facilities in 12 separate counties. Below is a listing of the DaVita facilities in Washington. [source: CN historical files; DaVita Application, p5]

² Formerly the Haviland Kidney Center

Clark

Vancouver Dialysis Center
BattleGround Dialysis Center³

Pacific

Seaview Dialysis Center

Island

Whidbey Island Dialysis Center

Pierce

Graham Dialysis Center
Lakewood Community Dialysis Center
Parkland Dialysis Center
Puyallup Community Dialysis Center
Tacoma Dialysis Center

Franklin

Mid-Columbia Kidney Center

Kittitas

Ellensburg Dialysis Center

Douglas

East Wenatchee Dialysis Center⁴

Yakima

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

Thurston

Olympia Dialysis Center

King

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

Snohomish

Everett Dialysis Center
Mill Creek Dialysis Center

Benton

Kennewick Dialysis Center
Chinook Kidney Dialysis Center

PROJECT DESCRIPTION

NKC

NKC proposes to add one dialysis station to the Kent Kidney Center for a facility total of 18 stations. The facility is located at 25316-74th Avenue South in the city of Kent, within King County. The dialysis center would continue to serve the residents of King County planning area #10. Services currently provided at the Kent facility include hemodialysis, visiting patient dialysis service, home hemodialysis training, special care and treatments scheduled after 5 p.m. [source: Application, p7]

The capital expenditure associated with the expansion of the Kent facility is \$33,397. Of that amount 41% is related to construction; 52% for moveable equipment; and the remaining 7% is related to applicable taxes. [source: Application, p5]

If this project is approved, NKC anticipates the station would be available by July 1, 2012. Under this timeline, year 2013 would be the facility’s first full calendar year of operation with 18 stations and 2015 would be year three. [source: Application, Face Page]

DaVita Inc.

³This facility is not yet operational.

⁴This facility is not yet operational.

DaVita proposes to add one dialysis station to the DaVita Kent Dialysis Center for a facility total of 13 stations. This station will add isolation capability to services already provided at the Kent facility. The facility is located at 21501-84th Avenue South in the city of Kent, within King County. The dialysis center would continue to serve the residents of King County planning area #10. Services currently provided at the Kent facility include hemodialysis, home peritoneal hemodialysis training, visiting patient dialysis service, and treatments scheduled after 5 p.m.

The capital expenditure associated with the expansion of the DaVita Kent facility is \$18,408 and is solely related to construction. DaVita stated that the necessary equipment is already available and the depreciated value of this equipment is \$4,356. [source: Application, pp 1 & 8]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they increase the number of dialysis stations at an existing kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

CRITERIA EVALUATION

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 CN approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 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 and 288.⁵

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted these two projects under the year 2011 Kidney Disease Treatment Centers-Concurrent Review Cycle #2. Below is a chronologic summary of the projects.

Action	NKC	DaVita Inc.
Letter of Intent Submitted	April 29, 2011	April 29, 2011
Application Submitted	May 31, 2011	May 31, 2011
Department’s pre-review Activities including screening and responses	June 1, 2011 through August 15, 2011	
Beginning of Review	August 16, 2011	
Public Hearing	October 25, 2011	
End of Public Comment	October 25, 2011	
Rebuttal Comments Received	November 28, 2011	
Department's Anticipated Decision Date	January 12, 2012	
Department's Actual Decision Date	May 29, 2012	

CONCURRENT REVIEW AND 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.*”

The purpose of the concurrent review process is to comparatively analyze and evaluate competing or similar projects to determine which of the projects may best meet the identified need. In the case of the projects submitted by NKC and DaVita, the department will issue one single evaluation regarding whether one, both, or neither of the projects should be issued a CN.

⁵ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(3), and WAC 246-310-287, and 289.

For each application, the other applicant sought and received affected person status under WAC 246-310-010. No other entities sought and received affected person status for either of the two projects.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Center’s Certificate of Need application submitted May 31, 2011
- DaVita, Inc.’s Certificate of Need application submitted May 31, 2011
- Northwest Kidney Center’s supplemental information dated July 27, 2011
- DaVita Inc.’s supplemental information dated July 29, 2011
- Documents received at the public hearing held on October 25, 2011
- Public comment submitted throughout review of the project
- Northwest Kidney Center’s rebuttal submitted November 23, 2011
- DaVita, Inc.’s rebuttal submitted November 28, 2011
- Years 2005 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2010 Northwest Renal Network 4th Quarter Utilization Data
- Licensing and/or survey data provided by the Department of Health’s Investigations and Inspections Office
- Data obtained from Northwest Kidney Center’s webpage (www.nwkidney.org)
- Data obtained from DaVita, Inc.’s webpage
- Data obtained from Medicare webpage (www.medicare.gov)
- Certificate of Need historical files

CONCLUSIONS

NKC

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Center proposing to add one dialysis station to the Kent Kidney Center is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Center agrees to the following in its entirety.

Project Description:

NKC proposes to add one dialysis station to the Kent Kidney Center for a facility total of 18 stations. The facility is located at 25316-74th Avenue South in the city of Kent, within King County. The dialysis center would continue to serve the residents of King County planning area #10. Services currently provided at the Kent facility include hemodialysis, visiting patient dialysis service, home hemodialysis training, special care and treatments scheduled after 5 p.m. The station breakdown for the facility at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Home Training ⁶	1
Other In-Center Stations	15
Total	18

Condition:

⁶ Includes peritoneal and hemodialysis training

1. Approved project description as described above.

Approved Cost:

The approved capital expenditure associated with this project is \$33,397.

DaVita Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to add one dialysis station to the Kent Dialysis Center is not consistent with applicable criteria and a Certificate of Need is denied.

A. Need (WAC 246-310-210)

Based on the source information provided and reviewed, the department concludes:

- NKC'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;
- 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.

(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.⁷

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.⁸ In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan,

⁷ Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

⁸ WAC 246-310-280 defines base year as the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report." For this project, the base year is 2010.

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)]

NKC’s Application of the Numeric Methodology

NKC proposes to add one dialysis station to the Kent Kidney Center. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was applied to project need. Given that the Kent facility is located in King County planning area #10, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: Application, pA18]

DaVita’s Application of the Numeric Methodology

DaVita proposes to add one dialysis station to the DaVita Kent Dialysis Center. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was applied to project need. Given that the Kent facility is located in King County planning area #10, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: Application, p18]

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 #10. The department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

Table 1 below shows a summary of the projected net need provided by the applicant and the department for King County planning area #10. The complete methodology is attached as appendix A.

**Table 1
King County Planning Area #10 Numeric Methodology
Summary of Projected Net Station Need**

	4.8 in-center patients per station		
	2014 Projected # of stations	Minus Current # of stations	2014 Net Need
NKC	29.2	29	1
DaVita	29.3	29	1
DOH	30	29	1

Table 1 demonstrates that the projections of the both applicants match the department’s figures. As a result, the net station need for King County planning area #10 is one.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for these projects is May 1, 2011. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2010. For King County there are 29 stations are located in the King County planning area #10. Table 2 shows the reported utilization of the stations in King County planning area #10.

Table 2
December 31, 2010 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
NKC Kent Kidney Center	17	82	4.82
DaVita Kent Dialysis Facility	12	72	6.00

Table 2 above demonstrates that the current facilities satisfy this utilization requirement. **This sub-criterion is met.**

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For King County planning area #10, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, the applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Both NKC and DaVita anticipate the new station would become operational by March 2012. Under this timeline, year 2013 would be the facility's first full calendar year of operation and 2015 would be year three. A summary of both applicants' projected utilization for their respective third year of operation is shown in Table 3 below. [source: DaVita Application, Appendix 9; NKC Application, p6]

Table 3
Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
NKC Kent	2015	18	96	5.33
DaVita Kent	2015	13	76	5.84

As shown in Table 3 above, this standard is met for both NKC and DaVita.

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

NKC

NKC proposes to add one-station to their dialysis center in Kent within King County planning area # 10. Based on the above standards and criteria, the project is consistent with applicable criteria of the CN Program and **this sub-criterion is met.**

DaVita, Inc.

DaVita proposes to add one-station to their dialysis center in Kent within King County planning area # 10. Based on the above standards and criteria, the project is consistent with applicable criteria of the CN Program and **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.

Both applicants currently provide health care services to residents of Washington State.

NKC

To determine whether all residents of the King County planning area #10 service area 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.

To demonstrate compliance with this sub-criterion, NKC provided a copy of its current Admission Criteria that would continue to be used at the facility. The Admission Criteria outlines the process/criteria that the Kent facility uses to admit patients for treatment, and ensure 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, pA24]

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.

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 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]

NKC demonstrated its intent to provide charity care to King County planning area #10 residents by submitting the Charity Care 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 their facility. [source: Application, p A10-12 & A26 & 27]

DaVita, Inc

To determine whether all residents of the King County planning area #10 service area 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.

To demonstrate compliance with this sub-criterion, DaVita, Inc. provided a copy of its current Admission Criteria that would continue to be used at the facility. The Admission Criteria outlines the process/criteria that the Kent facility uses to admit patients for treatment, and ensure 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 14]

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.

DaVita, Inc. currently provides services to Medicaid eligible patients in this dialysis center. Details provided in the application demonstrate that DaVita, Inc. intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [source: Application, p6 & 10]

DaVita, Inc. currently provides services to Medicare eligible patients in this dialysis center. Details provided in the application demonstrate that DaVita, Inc. intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [source: Application, p 6 &10]

DaVita, Inc. demonstrated its intent to provide charity care to King County planning area #10 residents by submitting the Charity Care 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. DaVita, Inc. also included a 'charity' line item as a deduction from revenue within the pro forma income statements for the facility. [source: Application, Appendixes 9 & 14]

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

NKC

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

DaVita

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

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

Based on the source information provided and reviewed, the department concludes:

- NKC’S project has met the financial feasibility criteria in WAC 246-310-220;
- 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.

NKC

NKC anticipates the new station at the Kent facility will become operational by July 2012. Based on this timeline, fiscal year (FY) 2013 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, Table 4 illustrates the projected revenue, expenses, and net income for FY 2013 through 2015 for the Kent facility. [source: Application, pA12]

Table 4
NKC-Kent Center
Projected Revenue and Expenses Calendar Years 2013 - 2015⁹

	FY 1 - 2013	FY 2 - 2014	FY 3 - 2015
# of Stations	18	18	18
# of Treatments ^[1]	13,524	13,818	14,112
# of Patients ^[1]	92	94	96
Utilization Rate ^[1]	5.11	5.22	5.33
Net Patient Revenue ^[1]	\$5,357,472	\$5,474,221	\$5,590,405
Total Operating Expense ^[1,2]	\$5,215,382	\$5,321,765	\$5,428,261
Net Profit or (Loss) ^[1]	\$142,090	\$152,455	\$162,144

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

As shown in Table 4, at the projected volumes identified in the application, NKC anticipates that the Kent facility would be operating at a profit in each of the forecast years.

NKC currently operates the facility at 25316-74th Avenue South in the city of Kent. The lease provided in the application outlines the initial terms and the annual rent for the space. The annual lease costs are substantiated in the pro forma financial documents presented. [source: Application, pA12 & Supplement 2]

Additionally, NKC provided a copy of the Medical Director Agreement and current compensation between itself and Daniel Hu, MD. The medical director service costs are also substantiated in the proforma revenue and expense statements.

⁹ Whole numbers may not add due to rounding.

During the review of this project, DaVita submitted extensive comments related to three areas: documentation of site control, rent/lease costs, and medical director costs. Below is a summary by topic of the comments provided by DaVita.

DaVita Public Comments

- Site Control [source: DaVita public comment, p2-3 plus supplemental exhibits]
NKC submitted a lease agreement between Northwest Kidney Centers and TRE/Raymor Kent Business Center, LLC. DaVita asserts that NKC may not have submitted the correct lease for their Kent facility. DaVita obtained information from King County that indicates the property was sold in 2007, to a different corporation than is shown on the lease submitted by NKC.
- Rent/Lease Costs [source: DaVita public comment, p2, plus supplemental exhibits]
DaVita asserts that the lease costs in the lease agreement do not agree with the lease costs provided in the pro forma. DaVita also asserts that the current pro forma rent values do not match its rent values from its prior Kent Kidney Center pro forma.
- Medical Director Costs [source: DaVita public comment, p5-6]
DaVita contends that NKC cannot confirm its medical director expense in the third full year since the current medical director agreement is only for one year with automatic renewal for additional unspecified one year renewals.

NKC provided responses to DaVita's assertions above which are summarized below by topic.

NKC Rebuttal Comments

- Site Control [source: NKC rebuttal documents, p1]
The lease submitted in NKC's CN application is the correct and only lease for the premises of the NKC Kent Kidney Center. The purpose of submitting the lease in the application is simply to affirm that the site control and basic lease terms that were established on February 9, 2007 are unchanged.

DaVita's supposition that the subsequent change of property owner somehow invalidates the lease is inconsistent with the facts and the law. Many commercial properties change ownership on a regular basis without disturbing the existing leases and without the new owner entering into a new lease with the existing tenant. Under Washington law, leases run with the land and survive the sale of the property provided they are in writing and acknowledged. The viability of the existing lease for NKC Kent Kidney Center is demonstrated in Exhibit 4 to DaVita's comments which show the conveyance of the property is subject to a number of exceptions in including:

19. THE RIGHTS OF TENANTS IN POSSESSION OF THE PROPERTY

This provision means that the buyer of the property purchased the property subjects to the rights of the tenants in possession at the time of the conveyance, such as NKC, as set forth in the applicable leases. The lease submitted with NKC's application is valid and binding. There is simply no issue of site control.

- Rent/Lease Costs [source: NKC rebuttal documents, p1-2]

There is no rent “mismatch” in the pro forma operating statement. DaVita has attempted to calculate a rent mismatch using a monthly operating expense of \$2,237.56, but does not cite a source for that number—it is simply a guess used to support a faulty conclusion. In fact, the rent figures presented for each fiscal year in the pro forma operating statement represent the sum of monthly base rents, per the rent schedule shown on page one of the lease, plus a placeholder for estimated operating expense based on actual current experience.

DaVita also asserts a rent mismatch because the rent shown for our fiscal years 2012 and 2013 in the pro forma of the original CN application to establish the NKC Kent Kidney Center in 2009 does not include operating expenses and thus is different from what is now shown in the pro forma to expand the facility by one station. In 2009, we had no direct experience to estimate operating expenses associated with the lease, but would certainly have done so if either DaVita or the Department of Health had requested it. Neither did. Today, we have good experience about those operating expenses and felt it would be improper not to include them, which accounts for the difference. There is no mismatch, just better information.

- Medical Director Costs [source: NKC rebuttal documents, pp2-3]

DaVita asserts that the medical director expense shown in the pro forma cannot be accepted because NKC’s Medical Director Agreement offers either NKC or the Medical Director the option of nonrenewal after one year. This is another faulty conclusion. The medical director expense shown on the pro forma is consistent with the Medical Director Agreement which, although it has an initial one year term, automatically renews on an annual basis. In NKC’s entire history, neither it nor a medical director has ever exercised the right to not renew a medical director agreement for multiple one year terms. Nonetheless, NKC believes that it is a prudent business practice to include such an option in an agreement involving a brand-new medical director in the event that either party becomes dissatisfied with the Agreement during the first year, in which case neither party would want the relationship to continue. In the event the Medical Director Agreement is not renewed, NKC is absolutely confident, based on years of experience with other medical director agreements, that it would be able to promptly find and enter into a Medical Director Agreement with a replacement medical director under the same terms. The expenses shown in the pro forma are legitimate.

Department’s Evaluation

After reviewing the issues raised by DaVita and the responses provided by NKC, the department concludes the following.

Site Control

The department concludes DaVita’s assertion that NKC does not have proper site control of the premises where Kent Kidney Center has and is operating is without merit. NKC provided a thorough explanation in its responses and the department agrees with NKC. Based on the information submitted, the department concludes NKC has appropriate site control of the premises.

Rent/Lease Costs

In response to this concern, NKC provided an extensive discussion on how the rent/lease costs are calculated and what is included in the calculations (base amount plus operating expenses). With expansion projects the department expects the applicant to use know expenses of the facility.

Comparison of actual expenses to good faith estimates when a new facility is development would be unreasonable.

Medical Director Costs

DaVita’s concern appears to be two-fold:

- NKC’s medical director agreement is not binding enough, which may result in NKC having to enter into a contract with a new medical director in short notice.
- A new medical director has no obligation to agree to the compensation identified in the current contract; if medical director costs increase, then the pro forma revenue and expense statement would not be accurate as presented.

The current Medical Director’s contract was signed March 1, 2010. This agreement has an initial one year term and then automatic renewal thereafter. The department has accepted similar Medical Director contracts from DaVita in previous applications. The Department finds no justification to treat NKC differently.

DaVita, Inc.

DaVita anticipates the new station at the Kent Dialysis Center will become operational by March 2012. Based on this timeline calendar year (CY) 2013 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, Table 5 illustrates the projected revenue, expenses, and net income for CY 2013 through 2015. [source: Application, Appendix 9]

**Table 5
DaVita’s Kent Dialysis Center
Projected Revenue and Expenses Calendar Years 2013 - 2015¹⁰**

	Full Year 1 2013	Full Year 2 2014	Full Year 3 2015
# of Stations	13	13	13
# of Treatments ^[1]	11,060	11,186	11,310
# of Patients ^[2]	78	78	78
Utilization Rate ^[2]	5.55	5.55	5.55
Net Patient Revenue ^[1]	\$ 3,785,710	\$3,894,980	\$ 3,854,449
Total Operating Expense ^[1,3]	\$ 2,758,790	\$ 2,848,073	\$ 2,942,264
Net Profit or (Loss) ^[1]	\$ 1,026,920	\$ 1,046,907	\$ 912,485

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

As shown in Table 5 above, at the projected volumes identified in the application, DaVita anticipates that the Kent facility will be operating at a profit in full year one, two and three.

DaVita Kent is located at 21501 84th Avenue South in the city of Kent, within King County. The executed lease agreement provided in the application outlines the terms and the annual rent for the space through year 2018. The annual lease costs are substantiated in the pro forma financial documents used to prepare the summary in Table 3. [source: Application, Appendix 9]

¹⁰ Whole numbers may not add due to rounding.

Additionally, DaVita provided a copy of the Medical Director Agreement between itself and Pacific Nephrology Group. The medical director service costs are also substantiated pro forma documents. [source: Application, Appendix 3]

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

NKC

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.

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.

NKC

The capital expenditure associated with the expansion of the Kent Kidney Center is \$33,397 of which 41% is related to leasehold improvements; 52% for additional equipment; and the remaining 7% is related to taxes. The capital cost breakdown is shown below. [source: Application, pA9]

Table 6
Estimated Capitals Costs of NKC Kent Dialysis Center Expansion

Item	Cost	% of Total
Construction	\$ 13,600	41%
Moveable Equipment	\$ 17,294	52%
Sales Tax	\$ 2,502	7%
Total Estimated Capital Costs	\$ 33,396	100%

NKC intends to finance the project entirely from available board reserves. A review of the financial statement provided in the application indicates that NKC had sufficient cash assets in both 2009 and 2010 to fund the project. [source: Application, pA30 & A33]

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

Table 7
NKC-Kent Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	73%
State	9%
Other	18%
Total	100%

As shown above, the Medicare and State entitlements are projected to equal 82% of the revenue at the Kent facility. The department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement; they are not expected to have an unreasonable impact on charges for services. The remaining 18% will be derived through a variety of reimbursement sources.

DaVita, Inc.

The capital expenditure associated with the expansion of the Kent Dialysis Center is \$18,408 and is solely related to construction. DaVita is using existing equipment at the facility that is valued at \$4,356. The capital cost breakdown is shown in Table 8. [source: Application, p8]

Table 8
Estimated Capitals Costs of DaVita Kent Facility Expansion

Item	Cost	% of Total
Construction	\$ 18,408	100%
Total Estimated Capital Costs	\$ 18,408	100%

DaVita intends to finance the project entirely from the DaVita capital expenditures budget. A review of the financial statement provided in the application indicates that DaVita had sufficient cash assets in both 2009 and 2010 to fund the project. [source: Application, Appendix 6]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 9. [source: Application, p10]

Table 9
NKC-Kent Kidney Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	71%
Medicaid/State	3%
Insurance/HMO	26%
Total	100%

As shown above, the Medicare and State entitlements are projected to equal 74% of the revenue at the Kent facility. The department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining 26% will be derived through a variety of reimbursement sources.

NKC

Based on the above information, the department concludes 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.**

DaVita, Inc.

Based on the above information, the department concludes 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.

NKC

As previously stated, the capital expenditure associated with the expansion of NKC's Kent facility is \$33,397. NKC states that the project will be funded from NKC's available board reserves. A review of NKC's statements of financial position show the funds necessary to finance the project are available. [source: Application, p5 & A30]

DaVita, Inc.

As previously stated, the capital expenditure associated with the expansion of DaVita's Kent facility is \$18,408. DaVita states that the project will be funded from DaVita's capital expenditures budget. A review of DaVita's statements of financial position show the funds necessary to finance the project are available. [source: Application, p15 & A30]

Based on the above information, the department's conclusion regarding this sub-criterion is as follows.

NKC

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

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 provided and reviewed, the department concludes:

- NKC's project has met the structure and process of care criteria in WAC 246-310-230
- DaVita, Inc.'s project has not met the structure and process of care criteria in WAC 246-310-230.

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

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

NKC

NKC’s Kent Kidney Center has been operational for many years. To accommodate the additional patients associated with the additional station, NKC intends to add 1.57 FTEs by the end of full calendar year three (2015). A breakdown of the proposed FTEs is shown in Table 10. [source: Application p19]

**Table 10
NKC Kent Kidney Center 2012 – 2015 Projected Total FTEs**

Staff/FTEs	2012 Current	2013 Increase	2014 Increase	2015 Increase	Total FTEs
Medical Director	Professional Services Contract				
RNs	8.80	0.20	0.19	0.20	9.39
Patient Care Tech	13.20	0.30	0.29	0.29	14.08
Clerical	1.00	0.00	0.00	0.00	1.00
Dietician	1.00	0.00	0.00	0.00	1.00
MSW	0.80	0.00	0.10	0.00	0.90
Total FTE’s	24.80	0.50	0.58	0.49	26.37

As shown above, NKC expects a minimal increase in FTEs. NKC states that it expects no difficulty in recruiting staff for the Kent facility due to its location and past success in attracting qualified health personnel. Further, NKC states that a high employee retention rate¹¹ and low position vacancy rate support this assertion and that “*NKC has not had to refuse admission to new patients due to staffing shortages.*” [source: Application, p21]

DaVita, Inc.

DaVita’s Kent Dialysis Center has been operational for many years. To accommodate the additional patients associated with the additional station, DaVita intends to recruit or keep a total of 0.10 additional FTE’s in year one. A breakdown of the proposed FTEs is shown in Table 11. [source: Application, p24]

**Table 11
DaVita Kent Dialysis Center 2012 – 2015 Projected FTEs**

Staff/FTEs	Current 2012 FTE	2013 Increase	2014 Increase	2015 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	1.00	0.00	0.00	0.00	1.00
RN	3.50	0.00	0.00	0.00	3.50
Patient Care Techs	6.60	0.00	0.00	0.00	6.60
Biomedical Techs	0.30	0.00	0.00	0.00	0.30

¹¹ NKC reports a current average employee length of service of 9.5 years

Administrative Assistant	0.80	0.00	0.00	0.00	0.80
MSW	0.70	0.00	0.00	0.00	0.70
Dietitian	0.60	0.10	0.00	0.00	0.70
Total FTE's	13.50	0.10	0.00	0.00	13.60

As shown in Table 11, the increase in staff is minimal and DaVita states the increase is not new staff, rather it is additional hours for existing staff.

Based on the above information, the department's conclusion regarding this sub-criterion is as follows.

NKC

Based on the information reviewed, the department concludes adequate staffing for the one station increase for the Kent Kidney Center is available or can be recruited. **This sub criterion is met.**

DaVita, Inc.

Based on the information reviewed, the department concludes adequate staffing for the one station increase to the Kent 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 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.

NKC

The information provided in the application confirms that NKC maintains the appropriate relationships with ancillary and support services for this facility. Ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, human resources, material management, administration, and technical services are provided by “one of our support offices in Seattle, Lake Forest Park, SeaTac, or Bellevue” which already provide services daily or on demand for the existing NKC facilities. [source: Application, p21]

DaVita

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 Kent 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 are provided on site. Additional services are 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, p25]

Based on the above information, the department's conclusion regarding this sub-criterion is as follows.

NKC

Based on this information, the department concludes NKC currently has appropriate relationships with ancillary and support services and would continue to have appropriate relationships if this project is approved. **This sub-criterion is met.**

DaVita, Inc.

Based on this information, the department concludes DaVita currently has appropriate relationships with ancillary and support services, and would continue to have appropriate relationships if this project is approved. **This sub-criterion is met.**

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

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible.

NKC

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.¹²

The department reviewed information available to the public at Medicare.gov “dialysis facility compare” website to verify the number of Medicare certified stations, services offered at the location such as types of home training and shifts starting after 5 pm at this NKC facility. NKC Kent Kidney Center is certified for 17 dialysis stations, having shifts starting after 5 pm, providing in-center, peritoneal dialysis, and home hemodialysis training. The NKC Kent is consistent with the CN approvals and records. Therefore the Department concludes that there is reasonable assurance the NKC Kent Kidney Center will operate in compliance with be operated in conformance with all state and federal rules and regulations.

For Washington State, since January 2008, the Department of Health’s Investigations and Inspections Office has completed 16 compliance surveys for the operational facilities that NKC either owns or manages. Of the compliance surveys completed, all revealed minor non-compliance issues. 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 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 Daniel Hu, M.D. at the Kent Kidney Center. A review of the compliance history for Dr. Daniel Hu revealed no recorded sanctions. [source: Application, Supplement 1]

¹² WAC 246-310-230(5).

DaVita

DaVita, Inc. is a provider of dialysis services in over 1,500 outpatient centers located in 43 states (including Washington State), the District of Columbia, and San Juan Puerto Rico. [source: DaVita website at www.davita.com] Currently within Washington State, DaVita owns and operates 25 kidney dialysis treatment centers in 12 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 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 each of the states, the District of Columbia, and San Juan Puerto Rico, where DaVita, Inc. or any subsidiaries have health care facilities. The department received responses from 21 states or 47% of the 45 entities.¹⁴ The compliance history of the remaining 24 states, the District of Columbia, and San Juan Puerto Rico is unknown.¹⁵

Ten of the 24 states responding to the survey indicated that minor 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, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported to have no deficiencies and are currently in compliance with applicable regulations. 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.

The department concludes that considering the more than 1,400 facilities owned/managed by DaVita, one out-of-state facility listed above demonstrated substantial non-compliance issues; therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2009, the Department of Health's Investigations and Inspections Office has completed more than 27 compliance surveys for the operational facilities that DaVita either owns or manages.¹⁶ 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 Investigations and Inspections Office]

The department reviewed information available to the public at Medicare.gov "dialysis facility compare" website to verify the number of Medicare certified stations, services offered at the location such as types of home training and shifts starting after 5 pm at this DaVita facility. The information confirmed that the facility is offering a shift starting after 5 pm, in center hemodialysis, peritoneal dialysis, and no home hemodialysis dialysis training. Additionally, the DaVita Kent

¹³ WAC 246-310-230(5).

¹⁴ States that provided responses are: Arizona, California, Colorado, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, Washington, and Wisconsin. San Juan Puerto Rico also provided a response.

¹⁵ States that did not provide responses are: Alabama, Arkansas, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maine, New Mexico, New Jersey, New York, North Carolina, Ohio, South Carolina, South Dakota, Tennessee, and West Virginia. The District of Columbia also did not respond to the survey.

¹⁶ As of the writing of this evaluation, five facilities—East Wenatchee Dialysis Center, Battle Ground Dialysis Center, Whidbey Dialysis Center, Everett Dialysis Center, and Kennewick 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.

Dialysis Center is listed as having 13 certified dialysis stations. Since the DaVita Kent Dialysis Center is CN approved for only 12 stations the department reviewed additional information in the department's files. In 1999, on the dialysis facility's "Application Survey and Certification Report" the facility's authorized official identified 13 stations; in 2005 again the facility's authorized official identified 13 stations, and finally in 2010 the facility's authorized official identified 13 stations. Therefore based on the records reviewed, the Department concludes there is not reasonable assurance that the DaVita Kent Dialysis Center will be operated in conformance with all state and federal rules and regulations.

For medical director services, DaVita provided a copy of its executed contract with Zheng Ge, MD. The term of the contract is ten years, with annual automatic renewals. It outlines the roles and responsibilities of both Dr. Ge and DaVita, and identifies compensation for medical director services. A review of the compliance history for Dr. Ge revealed no recorded sanctions. [source: Application, Appendix 3]

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

NKC

Based on the source information reviewed, the department concludes **this sub-criterion is met.**

DaVita

Based on the source information reviewed, the department concludes **this sub-criterion is not met.**

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

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

NKC

The department considered NK C'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 one dialysis station in King County planning area #10. This project proposes to add one station to the Kent Kidney Center.

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, NK C

demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area

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 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 one dialysis station in King County planning area #10. This project proposes to add one station to the Kent Dialysis Center.

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, DaVita demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area.

Based on the above information, the department's conclusion regarding this sub-criterion is as follows.

NKC

NKC demonstrated that it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. **This sub-criterion is met.**

DaVita

DaVita demonstrated that it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. **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.*

NKC

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

DaVita

This sub-criterion is addressed in sub-section (3) above. **This sub-criterion is not met.**

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

Based on the source information provided and reviewed, the department concludes:

- NKC's project has met the cost containment criteria in WAC 246-310-240(1) and (2);
- DaVita, Inc.'s project has not met the cost containment criteria in WAC 246-310-240

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.
To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

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

Step three of this assessment is to apply any service or facility specific (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

NKC

NKC meets the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below for this projects.

DaVita does not meet the review criteria under WAC 246-310-230, therefore the department concludes the DaVita project is not the best available alternative.

Step Two

NKC

Within the application, NKC identified five considerations before submitting this application. A summary of each and NKC's rationale for rejection is below. [source: Application, p22]

Alternative 1-Development of a new facility

NKC states it rejected this option because a projected need of 1 station in King County planning area #10 is *“not sufficient to justify the development of a new facility.”*

Alternative 2-Shortened treatment times

This alternative would add treatment capacity but this practice can negatively affect the overall care and outcome of the patients, but this is not an option to meet the established numeric need.

Alternative 3-Increased home dialysis

NKC advocates for home dialysis for both hemodialysis and peritoneal treatments. As of December 2010, NKC reports a combined census of over 200 patients using their home

dialysis program. However not all patients opt to use this modality. NKC states, “*We continue to advocate strongly for home dialysis modalities, but the projected unmet need addressed by the application is determined using a regression curve of dialysis patients who specifically choose in-center dialysis.*”

Alternative 4-Kidney transplantation

NKC states that it advocates for kidney transplantation for all patients whom show interest and for “*whom it is not contradicted.*” Currently, 19% of NKC patients have been placed on waiting lists, but “*the supply of available donor organs has not kept pace with the demand.*”

Alternative 5-Shared/Contract services agreement

The only other provider of dialysis services in the planning area is DaVita Kent Dialysis Center, which was operating at 100 percent utilization as of December 31, 2010.

The department did not identify any additional options than those considered by NKC. The need methodology shows a need for one dialysis station in the planning area. The department concludes submission of this 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;

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.

NKC

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.

NKC

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.**

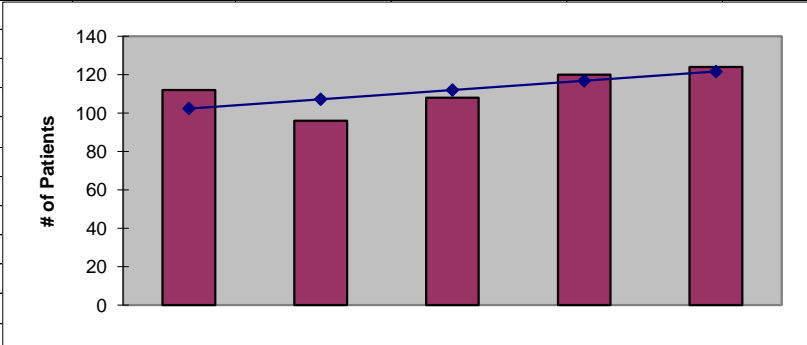
APPENDIX A



2011
King County 10
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
King Ten		2005	2006	2007	2008	2009	2010
98030		6	12	10	15	20	20
98031		36	36	26	30	30	32
98032		39	34	33	31	37	36
98038		6	7	4	8	10	12
98042		23	23	23	24	23	23
98051		2	0	0	0	0	1
TOTALS		112	112	96	108	120	124
246-310-284(4)(a)	Rate of Change		0.00%	-14.29%	12.50%	11.11%	3.33%
	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
				2011	2012	2013	2014
Projected Resident Incenter Patients	from 246-310-284(4)(b)			126.40	131.20	136.00	140.80
Station Need for Patients	Divide Resident Incenter Patients by 4.8			26.3333	27.3333	28.3333	29.3333
	Rounded to next whole number			27	28	29	30
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				29	29	29	29
Results of (4)(c) above			-	27	28	29	30
Net Station Need				2	1	0	-1
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
DaVita Kent Community	12	72	6.00				
NKC Kent	17	82	4.82				
Total	29	154					
Source: Northwest Renal Network data 2005-2010							
Most recent year-end data: 2010 year-end data as of 02/16/2011							
Most recent quarterly data as of the 1st day of application submission period: 1st quarter 2011 as of 05/16/2011							

x	y	Linear
2006	112	102
2007	96	107
2008	108	112
2009	120	117
2010	124	122
2011		126.40
2012		131.20
2013		136.00
2014		140.80



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.692820323
R Square	0.48
Adjusted R Square	0.306666667
Standard Error	9.121403401
Observations	5

ANOVA					
	df	SS	MS	F	Significance F
Regression	1	230.4	230.4	2.769230769	0.194680657
Residual	3	249.6	83.2		
Total	4	480			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-9526.4	5791.959005	-1.644763023	0.198567625	-27958.99853	8906.198535	-27958.99853	8906.198535
X Variable 1	4.8	2.88444102	1.664100589	0.194680657	-4.379578667	13.97957867	-4.379578667	13.97957867

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	98.4	13.6
2	103.2	-7.2
3	108	-20
4	112.8	7.2
5	117.6	6.4