



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

August 19, 2013

CERTIFIED MAIL # 7011 1570 0002 7809 5551

Re: CN12-33

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

Dear Mr. Pollock:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers proposing to add seven dialysis stations to the NKC Kent Kidney Center. 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 (Quality) of Care WAC 246-310-230

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:

Janis Sigman, Manager
Certificate of Need Program
Department of Health
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



Mr. Palmer Pollock
Northwest Kidney Centers
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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
310 Israel Road SE, Building 6
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

EXECUTIVE SUMMARY

EVALUATIONS DATED AUGUST 19, 2013 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO KING COUNTY PLANNING AREA #10:

- **NORTHWEST KIDNEY CENTERS PROPOSING TO ADD 7 KIDNEY DIALYSIS STATIONS TO THE EXISTING KENT KIDNEY CENTER IN KENT**
- **DAVITA, INC. PROPOSING TO ADD 7 KIDNEY DIALYSIS STATIONS TO THE EXISTING KENT DIALYSIS CENTER IN KENT**

BRIEF PROJECT DESCRIPTIONS

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 located in King and Clallam counties. NKC proposes to add seven dialysis stations to the Kent Kidney Center for a facility total of 25 stations. [Source: Second Amended Application, p7]

The capital expenditure associated with this project is \$467,714. This amount represents the total capital expenditure of \$515,730 minus the landlord's project costs of \$48,016. Of the total amount 73% is related to construction; 10% for fixed and moveable equipment; the remaining 8% for taxes, and the remaining 9% for the landlord's project costs. [Source: Second Amended Application, p5]

If this project is approved, NKC anticipates the seven stations would be available by December 31, 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation with 25 stations and 2016 would be year three. [Source: Second Amended Application, Face Page & p7]

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. DaVita, Inc. proposes to add seven dialysis stations to the DaVita Kent Dialysis Center for a facility total of 19 stations.

The capital expenditure associated with this project is \$489,143. This amount represents the total capital expenditure of \$538,752 minus the landlord's project costs of \$48,258. Of the total amount 55% is related to construction; 33% for fixed and moveable equipment; 3% for professional fees and the remaining 9% is the for the landlord's project costs. [Source: Amended Application, p21]

If this project is approved, DaVita, Inc. anticipates the station would be available by July 1, 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation with 19 stations and 2016 would be year three. [Source: Amended Application, P13]

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 Centers proposing to add seven dialysis stations to the Kent Kidney Center is not consistent with applicable criteria and a Certificate of Need is denied.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to add seven dialysis stations to the Kent Dialysis Center is consistent with applicable criteria of the Certificate of Need Program, provided DaVita, Inc. agrees to the following in its entirety.

Project Description:

DaVita, Inc. proposes to add 7 dialysis stations to the Kent Dialysis Center for a facility total of 19 stations. 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, patients requiring isolation, patients requiring a bed 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 Station	1
Other In-Center Stations	16
Total	19

Condition

1. Approval of 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.

Approved Capital Costs

The approved capital expenditure associated with this project is \$489,143 which represents the total capital expenditure of \$538,752 minus the landlord's costs of \$48,258.

EVALUATIONS DATED AUGUST 19, 2013 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO KING COUNTY PLANNING AREA #10:

- **NORTHWEST KIDNEY CENTERS PROPOSING TO ADD 7 KIDNEY DIALYSIS STATIONS TO THE EXISTING KENT KIDNEY CENTER IN KENT**
- **DAVITA, INC. PROPOSING TO ADD 7 KIDNEY DIALYSIS STATIONS TO THE EXISTING KENT DIALYSIS CENTER IN KENT**

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

King County

Auburn Kidney Center	Renton Kidney Center ¹
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. is a for-profit corporation that provides dialysis services in over 1,912 outpatient centers located in 46 states and the District of Columbia. DaVita, Inc. also provides acute inpatient dialysis services in approximately 720 hospitals throughout the country. [Source: Application, p5; DaVita, Inc. website]

¹ Formerly Mount Rainer Kidney Center

² Formerly the Haviland Kidney Center

In Washington State, DaVita, Inc. owns or operates a total of 31³ kidney dialysis facilities in 14 separate counties. Below is a listing of the DaVita, Inc. facilities in Washington. [Source: CN historical files; DaVita, Inc. Application, p2]

Benton

Chinook Dialysis Center
Kennewick Dialysis Center

Chelan

DaVita Dialysis Center⁴
DaVita Dialysis Center

Clark

Vancouver Dialysis Center
Battle Ground Dialysis Center

Douglas

East Wenatchee Dialysis Center

Franklin

Mid Columbia Kidney Center

Island

Whidbey Island Dialysis Center

King

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

Kittitas

Ellensburg Dialysis Center

Pacific

Seaview Dialysis Center

Pierce

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

Snohomish

Everett Dialysis Center⁵
Mill Creek Dialysis Center

Spokane

Downtown Spokane Renal Center
North Spokane Renal Center
Spokane Valley Renal Center

Thurston

Olympia Dialysis Center

Yakima

Mt. Adams Dialysis Center
Union Gap Dialysis Center

PROJECT DESCRIPTION

NKC

NKC proposes to add seven dialysis stations to the Kent Kidney Center for a facility total of 25 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

³ Battle Ground Dialysis Center, Kennewick Dialysis Center, Renton Dialysis Center, and Zillah Dialysis Center are CN approved but not yet operational

⁴ DaVita, Inc. 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.

⁵ Refuge Dialysis, LLC, whose ownership is 80% DaVita, Inc. and 20% The Everett Clinic, owns this facility.

hemodialysis training, patients requiring isolation, patients requiring a bed, and treatments scheduled after 5 p.m. [Source: Amended Application, p7]

The capital expenditure associated with this project is \$467,714. This amount represents the total capital expenditure of \$515,730 minus the landlord's project costs of \$48,016. Of the total capital expenditure 73% is related to construction; 10% for fixed and moveable equipment; 8% is related to applicable taxes, and 9% to the landlord's portion of the costs. [Source: Second Amended Application, p5]

If this project is approved, NKC anticipates the additional stations would be available by December 31, 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation with 25 stations and 2016 would be year three. [Source: Second Amended Application, Face Page & p7]

DaVita

DaVita proposes to add seven dialysis stations to the DaVita Kent Dialysis Center for a facility total of 19 stations. These stations would add isolation capability and a permanent bed station to services already provided at the Kent facility. The facility is located at 21857-84th 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 and hemodialysis training, visiting patient dialysis service, and treatments scheduled after 5 p.m.

The capital expenditure associated with this project is \$489,143. This amount represents the total capital expenditure of \$538,752 minus the landlord's project costs of \$48,258. Of the total capital expenditure, 55% is related to construction; 33% for fixed and moveable equipment; 3% for professional fees and applicable taxes, and 9% for landlord's portion of the costs. [Source: Amended Application, p9]

If this project is approved, DaVita anticipates the seven stations would be available by September, 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation with 19 stations and 2016 would be year three. [Source: Amended Application, p13]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they request to 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).

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, 246-310-220, 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 288.⁶

TYPE OF REVIEW

As directed under WAC 246-310-282(1), the department accepted these two projects under the year 2012 Kidney Disease Treatment Centers-Concurrent Review Cycle #2.

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, Inc. the department will issue one single evaluation regarding whether one, both, or neither of the projects should be issued a CN.

⁶ 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.

APPLICATION CHRONOLOGY

Below is a chronologic summary of the projects.

Action	NKC	DaVita, Inc.
Letter of Intent Submitted	April 30, 2012	April 30, 2012
Application Submitted	May 31, 2012	May 31, 2012
First Amendment Application Submitted	June 29, 2012	June 29, 2012
Second Amendment Application Submitted	July 16, 2012	None
Department's pre-review Activities including screening and responses	July 17, 2012 through September 16, 2012	
Beginning of Review	September 17, 2012	
Public Hearing	October 2, 2012	
End of Public Comment	November 16, 2012	
Rebuttal Comments Received	December 17, 2012	
Department's Anticipated Decision Date	January 31, 2013	
Department's Actual Decision Date	August 19, 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."*

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 Second Amended Certificate of Need application submitted July 16, 2012
- DaVita, Inc.'s First Amended Certificate of Need application submitted June 29, 2012
- DaVita Inc.'s supplemental information dated August 31, 2012
- Public comment submitted prior to end of public comment period
- Northwest Kidney Center's rebuttal documents submitted December 17, 2012
- DaVita, Inc.'s rebuttal documents submitted December 17, 2012
- Years 2007 through 2011 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 4rd 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 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 Centers proposing to add seven dialysis stations to the Kent Kidney Center is not consistent with applicable criteria and a Certificate of Need is denied.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to add seven dialysis stations to the Kent Dialysis Center is consistent with applicable criteria of the Certificate of Need Program, provided DaVita, Inc. agrees to the following in its entirety.

Project Description:

DaVita, Inc. proposes to add 7 dialysis stations to the Kent Dialysis Center for a facility total of 19 stations. 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, peritoneal and 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 Station	1
Other In-Center Stations	16
Total	19

Condition

1. Approval of 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.

Approved Capital Costs

The approved capital expenditure associated with this project is \$489,143 which represents the total capital expenditure of \$538,752 minus the landlord's costs of \$48,258.

CRITERIA DETERMINATION

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 2011.

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 projected 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 seven dialysis stations 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: Second Amended Application, p7]

DaVita, Inc.’s Application of the Numeric Methodology

DaVita, Inc. proposes to add seven dialysis stations 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: Amended Application, p19]

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).

The table below shows a summary of the projected net need provided by the applicants and the department for King County planning area #10. The complete methodology is attached as Appendix A to this evaluation.

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

	4.8 in-center patients per station		
	2015 Projected # of stations	Minus Current # of stations	2015 Net Need
NKC	37	30	7
DaVita, Inc.	36.92	30	7
DOH	37	30	7

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

During the review of this project, NKC submitted comments related to DaVita's compliance with 246-310-210 Need and 246-310-284, specifically Section III.A.3.d and e of the application form. NKC's comments are summarized below.

Compliance with 246-310-210 and 246-310-284

Each applicant is required to demonstrate that its project meets the need criteria in WAC 246-310-210 and WAC 246-310-284. To evaluate the applicant's conformance with these criteria, the Program's application form seeks information concerning utilization experience and utilization projections. DaVita Inc.'s application incorrectly identifies their historical numbers in the table on page 7 of the application. This action should be viewed as purposeful misrepresentation by DaVita, Inc.

DaVita provided a response to NKC's assertion above which is summarized below.

Compliance with 246-310-210 and 246-310-284

DaVita, Inc. reports that the data submitted in table on page 7 was an isolated error which did not affect any need calculations in the application. Table 15 in the application contains the correct utilization for 2011 and is used to demonstrate compliance with the review criteria. [Source: DaVita, Inc. rebuttal comments p2-3]

Department's Review

The department recognized the incorrect numbers in the table on page 7 and determined that these numbers did not affect the outcome of DaVita, Inc.'s utilization projection. The department uses its own calculations and DaVita, Inc.'s utilization projection is consistent with the department's projection.

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, 2012. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2011. For King County there are 30 stations located in the King County planning area #10. The table below shows the reported utilization of the stations in King County planning area #10.

**Table 2
December 31, 2011 - Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
NKC Kent Kidney Center	18	93	5.17
DaVita, Inc. Kent Dialysis Center	12	70	5.83

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.

NKC anticipates their new stations would become operational by December 31, 2013 and DaVita anticipates their new stations would become operational by September 2013. Under this timeline, year 2014 would be each facility's first full calendar year of operation and 2016 would be year three. A summary of each applicant's projected utilization for their respective third year of operation is shown in the table below. [Source: DaVita, Inc. Amended Application, p17; NKC Second Amended Application, p6]

Table 3
2016 Year Projected Facility Utilization

Facility Name	# of Stations	# of Pts	Pts/Station
NKC Kent Kidney Center	25	126	5.04
DaVita Kent Dialysis Center	19	111	5.84

As shown in the table above, this standard is met for both NKC and DaVita, Inc.

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

NKC

NKC proposes to add seven stations to the Kent Kidney Center located in 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, Inc. proposes to add seven-stations to the Kent Dialysis Center in located in 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

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 #10 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 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: Second Amended Application, pA29]

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: Second 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: Second Amended 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: Second Amended Application, p A29 & A30 & 31]

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 #10 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, 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: Amended 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, Inc. currently provides services to Medicare eligible patients at its existing dialysis centers. It expects to also provide

services to these patients at the proposed expanded facility. A review of the anticipated revenues indicates that the expanded facility also expects to receive Medicare reimbursements. [Source: Second Amended 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, Inc. currently provides services to Medicaid eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed expanded facility. A review of the anticipated revenue indicates that the new facility expects to receive Medicaid reimbursements. [Source: Second Amended Application, p11 and Appendix 9]

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: Amended Application, p11]

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: Amended Application, p11]

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: Amended Application, Appendices 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 NKC's Kent Kidney Center. **This sub-criterion is met.**

DaVita, Inc.

The department concludes that all residents of the service area would have adequate access to the health services at DaVita Kent Dialysis Center. **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 7 new stations at the Kent Kidney Center will become operational by July 2013. Based on this timeline, fiscal year (FY) 2014 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, the table below illustrates the projected revenue, expenses, and net income for FY 2014 through 2016 for the Kent Kidney Center. [Source: Second Amended Application, pA12]

Table 4
NKC-Kent Kidney Center
Projected Revenue and Expenses Calendar Years 2014 - 2016⁹

	FY 1 - 2014	FY 2 - 2015	FY 3 - 2016
# of Stations	25	25	25
# of Treatments ^[1]	15,876	17,199	18,522
# of Patients ^[2]	108	117	126
Utilization Rate ^[2]	4.32	4.68	5.04
Net Patient Revenue ^[1]	\$6,471,943	\$7,012,741	\$7,550,601
Total Operating Expense ^[1,3]	\$5,027,111	\$5,405,535	\$5,784,157
Net Profit or (Loss) ^[1]	\$1,444,832	\$1,607,206	\$1,766,444

[1] Includes in-center treatments only; [2] includes 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 Kent Kidney Center. As shown in the table above, at the projected volumes identified in the application, NKC anticipates that the 25-station 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: Second Amended Application, pA12 & Supplement 2]

⁹ Whole numbers may not add due to rounding.

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.

During the review of this project, DaVita submitted extensive comments related to two areas: reduction of capital costs. DaVita, Inc.'s comments are summarized below.

DaVita, Inc. Public Comments

- Failure to Report all Capital Costs [Source: DaVita, Inc. public comment, p2-3 plus supplemental exhibits]
NKC submitted two amendment applications after submitting the initial application on May 31. In the second amendment the capital costs of the project were \$515,730 instead of the \$948,650 submitted in the initial application. DaVita, Inc. commented on the capital costs for the used machines, the landlord's cost for the demising wall, and the dollar amount projected for taxes.

NKC provided responses to DaVita, Inc.'s assertions above which are summarized below.

NKC Rebuttal Comment

- Failure to Report all Capital Costs [Source: NKC rebuttal documents, p1-2]
DaVita's main criticism of NKC's project is that NKC's machines are past their "useful life" (accounting term) and therefore according to DaVita will require substantial repair or replacement in the short term. DaVita also claims that NKC has failed to report its costs of using its existing surplus machines. NKC states that the machines will not need repair or replacement in the short term because NKC constantly maintains its existing machines and they are in excellent working order. NKC is confident that its machines will not require either substantial repair or replacement within the first three years of the project. NKC also will not incur any additional capital expenditure to deploy the machines to the Kent facility.

Related to the assertion by Da Vita that NKC failed to accurately report its construction costs, NKC reports that the cost for the demising wall is more than sufficient since it will be minor construction of an unfinished 100 foot wall. The construction cost also includes the estimated Washington State sales tax.

Department's Evaluation

In reviewing the information submitted in NKC's second amended application, the department concluded that it had sufficient information to continue with the review of the application.

Table 5
DaVita, Inc.'s Kent Dialysis Center
Projected Revenue and Expenses Calendar Years 2014 - 2016¹⁰

	Full Year 1 2014	Full Year 2 2015	Full Year 3 2016
# of Stations	19	19	19
# of Treatments ^[1]	13,010	15,555	17,985
# of Patients ^[2]	81	96	111
Utilization Rate ^[2]	4.26	5.05	5.84
Net Patient Revenue ^[1]	\$3,891,350	\$4,619,604	\$5,504,906
Total Operating Expense ^[1,3]	\$3,041,131	\$3,513,827	\$4,079,941
Net Profit or (Loss) ^[1]	\$850,219	\$1,105,777	\$1,424,965

[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 the table above, at the projected volumes identified in the application, DaVita, Inc. anticipates that the Kent facility will be operating at a profit in full year one, two and three.

DaVita Kent is located at 21857 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: Amended Application, Appendix 9 & 16]

Additionally, DaVita, Inc. 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: Amended Application, Appendix 3 & 9]

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

¹⁰ Whole numbers may not add due to rounding.

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 \$515,713 of which 73% is related to space construction; 10% for additional equipment; 8% related to sales tax and the remaining 9% is related to landlord’s costs. The capital cost breakdown is shown in the table below. [Source: Second Amended Application, p5]

**Table 6
Estimated Capitals Costs of NKC Kent Dialysis Center Expansion**

Item	Cost	% of Total
Space Construction	\$378,878	73%
Fixed Equipment	\$3,150	1%
Moveable Equipment	\$45,108	9%
Sales Tax	\$40,578	8%
Landlord’s Costs	\$48,016	9%
Total Estimated Capital Costs	\$515,713	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 2010 and 2011 to fund the project. [Source: Second Amended Application, pA37 & A38]

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 the table below. [Source: Second Amended Application, p8]

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

Source of Revenue	% of Revenue
Medicare	71%
State	13%
Other	16%
Total	100%

As shown above, the Medicare and State entitlements are projected to equal 84% 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 16% will be derived through a variety of reimbursement sources.

DaVita, Inc.

The capital expenditure associated with the expansion of the Kent Dialysis Center is \$538,752. Of that amount 55% is related to leasehold improvements, 33% for fixed/movable equipment, 3% is

related to professional fees, and the remaining 9% is the Landlord’s portion of the project costs. The capital cost breakdown is shown in the table below. [Source: Amended Application, p9]

Table 8
Estimated Capitals Costs of DaVita Kent Dialysis Center Expansion

Item	Cost	% of Total
Leasehold Improvements	\$295,398	55%
Movable and Fixed Equipment	\$175,000	33%
Professional Fees	\$18,745	3%
Landlord Project Costs	\$49,609	9%
Total Estimated Capital Costs	\$538,752	100%

DaVita, Inc. intends to finance the project entirely from the DaVita, Inc. capital expenditures budget. A review of the financial statement provided in the application indicates that DaVita, Inc. had sufficient cash assets in both 2010 and 2011 to fund the project. [Source: Amended Application, Appendix 10]

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, Inc. also provided the sources of patient revenue shown in the table below. [Source: Amended Application, p23]

Table 9
DaVita Kent Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	85%
Medicaid/State	3%
Insurance/HMO	12%
Total	100%

As shown above, the Medicare and State entitlements are projected to equal 88% 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 12% 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 \$515,730. 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, p8 & A36 & A37]

DaVita, Inc.

As previously stated, the capital expenditure associated with the expansion of DaVita's Kent Dialysis Center is \$538,752. DaVita, Inc. states that the project will be funded from DaVita, Inc.'s capital expenditures budget. A review of DaVita, Inc.'s statements of financial position show the funds necessary to finance the project are available. [Source: Amended Application, p23 & Appendix 10]

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, Inc.

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of DaVita, Inc. 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 not met the structure and process of care criteria in WAC 246-310-230
- DaVita, Inc.'s project has met the structure and process of care criteria in WAC 246-310-230.

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

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

NKC

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 1.90 FTEs by the end of full year one (2014), 1.91 by the end of full year 2 (2015) and 1.89 by the end of full year 3 (2016). A

breakdown of the proposed FTEs is shown in the table below. [Source: Second Amended Application p20]

**Table 10
NKC Kent Kidney Center 2014 – 2016 Projected Total FTEs**

Staff/FTEs	Current	2014 Increase	2015 Increase	2016 Increase	Total FTEs
Medical Director	Professional Services Contract				
RNs	6.81	0.62	0.62	0.61	8.66
Patient Care Tech	12.64	1.15	1.15	1.15	16.09
Dietician	0.66	0.06	0.06	0.06	0.84
MSW	0.83	0.07	0.08	0.07	1.05
Receptionist	1.00	0.00	0.00	0.00	1.00
Total FTE's	21.94	1.90	1.91	1.89	27.64

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: Second Amended 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, Inc. intends to recruit or keep 1.9 FTEs in Year two and 2.3 FTEs in year three. A breakdown of the proposed FTEs is shown in the table below. [Source: Amended Application, p24]

**Table 11
DaVita Kent Dialysis Center 2012 – 2016c Projected FTEs**

Staff/FTEs	Current 2012 FTE	2014 Increase	2015 Increase	2016 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	1.0	0.0	0.0	0.0	1.0
RN	2.9	0.0	0.3	0.5	3.7
Patient Care Techs	7.5	0.0	0.9	1.4	9.8
Biomedical Techs	0.5	0.0	0.0	0.1	0.6
Administrative Assistant	1.4	0.0	0.3	0.3	2.0
MSW	0.8	0.0	0.2	0.0	1.0
Dietitian	0.8	0.0	0.2	0.0	1.0
Total FTE's	14.9	0.0	1.9	2.3	19.1

As shown in the table above, the increase in staff is minimal and DaVita, Inc. 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.

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

NKC

Based on the information reviewed, the department concludes adequate staffing for the seven 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 seven 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: Second Amended Application, p21]

DaVita, Inc. Public Comment

- Failure to Respond to Screening Request [Source: DaVita, Inc. public comment, p4-5 plus supplemental exhibit 4]

NKC Rebuttal Comment

- Failure to Respond to Screening Requests [Source: NKC rebuttal documents, p2-3]
NKC acknowledges that it did not respond in writing to screening questions issued by the Certificate of Need Program but denies that its application was or is incomplete. NKC contends that the requested information is contained in their amended application.

DaVita, Inc. also contends that the NKC application is deficient because NKC did not include a copy of a hospital transfer agreement. NKC states that neither the CN regulations nor the application form specifically requires submission of a transfer agreement.

Department’s Evaluation

Since hospitalization of an ESRD patient would be a service provided by an organization outside of NKC there are specific requirements for the service agreement between the two organizations. The department uses these agreements to confirm that the ESRD provider has established relationships with other agencies in the community. Since NKC did not respond to the screening questions and the requested transfer agreement was not provided

in the second amendment, the department is not able to confirm the relationship and considers the application incomplete.

DaVita, Inc.

As a provider of dialysis services in Washington State, DaVita, Inc. 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, Inc.’s corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland Florida. [Source: Amended 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 not documented the appropriate relationships community providers of ancillary and support services. **This sub-criterion is not met.**

DaVita, Inc.

Based on this information, the department concludes DaVita, Inc. 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) (i) 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 (CN approved for 18), 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.

¹² WAC 246-310-230(5).

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: Second Amended Application, Supplement 1]

DaVita, Inc.

DaVita, Inc. is a provider of dialysis services in over 1,642 outpatient centers located in 43 states (including Washington State), the District of Columbia. [Source: DaVita, Inc. website at www.davita.com] Currently within Washington State, DaVita, Inc. owns and 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.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, Inc. 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, Inc., 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

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.

that DaVita, Inc. 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, Inc. facilities. These non-compliance issues were typical of a dialysis facility and DaVita, Inc. 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, Inc. 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.

The department, in the evaluation of CN 11-41 submitted by DaVita, Inc. for the addition of one station, pointed out that the CMS Compare website reported the DaVita Kent Dialysis Center has 13 stations even though the facility was approved for 12 stations by the Certificate of Need Program. Documentation from the Department of Health’s Investigation and Inspections Office reports that DaVita, Inc. has submitted documentation requesting that the CMS website be changed to 12 stations for their Kent dialysis facility.

During the review of this project, NKC submitted a comment related to compliance with 246-310-230 structure and process of care.

Compliance with 246-240-230

NKC identifies an issue of the DaVita Kent Dialysis Center being CN approved for 12 stations while the Department determined that CMS indicated that the facility was certified for 13 stations. This was identified by the Department as an issue in a recent CN submitted by DaVita, Inc. for the Kent facility.

DaVita provided a response to NKC’s assertion above which is summarized below.

DaVita, Inc. Rebuttal Comment

DaVita, Inc. reports meeting the requirements of the Washington Administrative Code, since they have no adverse history of license revocation or decertification in Washington State. They state that this meets the requirements of the application and rule requirements.

Department’s Evaluation

The department concludes that DaVita, Inc. has met the rule requirements and has submitted documentation to have the CMS Compare website corrected to be in compliance with the CN approved number of stations for their Kent Dialysis Center.

For medical director services, DaVita, Inc. 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, Inc. and identifies compensation for medical director services. A review of the compliance history for Dr. Ge revealed no recorded sanctions. [Source: Amended Application, Appendix 3]

¹⁶ As of the writing of this evaluation, four facilities— 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, Inc.

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, Inc.

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

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

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

NKC

As reported in WAC 246-310-230(2), the department requested a copy of the NKC's hospital transfer agreement to determine that a relationship was established between NKC and local hospital to provide a smooth transition for any ESRD patient that might require transfer from the Kent Kidney Center to a hospital for services. As mentioned previously the department was not able to confirm this relationship with an existing health care provider.

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 seven dialysis stations in King County planning area #10. This project proposes to add seven stations 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, NKC 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, Inc.'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 seven dialysis stations in King County planning area #10. This project proposes to add seven stations 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, Inc. 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 has not 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 not met.**

DaVita, Inc.

DaVita, Inc. 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, 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 provided and reviewed, the department concludes:

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

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.
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's project did not meet the review criteria under WAC 246-310-230. 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

Within the application, DaVita identified two alternatives before submitting this application. A summary of each and DaVita's rationale for rejection is below. [Source: Amended Application, p27-28]

Alternative 1-Add stations to existing dialysis facility

The existing DaVita dialysis facility is too small to expand and is 11 years old. DaVita determined that it would be too expensive to try to expand this space to accommodate the additional dialysis services.

Alternative 2-Establish a new facility in Covington

Historically King Planning Area #10 has been served by two facilities located in Kent. DaVita evaluated a 7 station Covington facility which would have been located over three miles from the existing facilities. This would have provided improved access for some residents of the planning area. The building would have been sized to support existing need as well as future growth. DaVita withdrew this application prior to the beginning of review.

The project chosen by DaVita is to add the additional 7 stations to the relocated Kent facility.

Step Three

WAC 246-310-288 identifies specific tie-breaker criteria that must be applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. 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 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 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