STATE OF WASHINGTON
DEPARTMENT OF HEALTH

October 27, 2014

CERTIFIED MAIL # 7011 1570 0002 7808 8249

Joyce Jackson, President & CEO
Northwest Kidney Centers
700 Broadway
Seattle, Washington 98122-4302

RE: CN14-18

Dear Ms. Jackson:

We have completed review of the Certificate of Need (CN) application submitted by Northwest Kidney Centers to add 5 dialysis stations to its 13 station dialysis facility in King County dialysis planning area #1. For reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Northwest Kidney Centers agrees to the following in its entirety.

Project Description:

Northwest Kidney Centers is approved to add 5 stations to the 13 station NKC Lake City Kidney Center for a total of 18 kidney dialysis stations. The NKC Lake City Kidney Center would serve residents of King County dialysis planning area #1. The NKC Lake City Kidney Center is approved to provide hemodialysis, backup dialysis service, isolation station, home hemodialysis and home peritoneal training, permanent bed station, and shifts after beginning after 5pm at the NKC Lake City Kidney Center.

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	15
Total	**18**

Condition:

1. Approval of project description as stated above. Northwest Kidney Centers 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 Cost:
The approved capital expenditure associated with this project is $77,538.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provision your application will be denied. The department will send you a letter denying your application and provide you information regarding your appeal rights.

Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

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

Physical Address:
Department of Health
Certificate of Need Program
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, Community Health Systems

Enclosure

EXECUTIVE SUMMARY

EVALUATION DATED OCTOBER 27, 2014 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO KING COUNTY PLANNING AREA #1:

- **NORTHWEST KIDNEY CENTERS PROPOSING TO ADD FIVE KIDNEY DIALYSIS STATIONS TO THE EXISTING NKC LAKE CITY KIDNEY CENTER IN LAKE FOREST PARK**
- **FRESENIUS MEDICAL CARE HOLDINGS INC. ON BEHALF OF QUALICENTERS INLAND NORTHWEST, INC. TO ESTABLISH A FIVE STATION KIDNEY DIALYSIS CENTER IN SEATTLE**
- **DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ESTABLISH A FIVE STATION KIDNEY DIALYSIS CENTER IN SEATTLE**

BRIEF PROJECT DESCRIPTIONS

Northwest Kidney Centers

Northwest Kidney Centers (NKC) currently proposes is to add 5 stations to the NKC Lake City Kidney Center for a total of 18 kidney dialysis stations. The NKC Lake City facility is located at 14524 Bothell Way NE, Lake Forest Park, WA.

The NKC Lake City Kidney Center would serve residents of King County dialysis planning area #1. The NKC Lake City Kidney Center proposes to provide hemodialysis, backup dialysis service, isolation station, home hemodialysis and home peritoneal training, permanent bed station, and treatments after beginning after 5pm at the NKC Lake City Kidney Center. [Source: Application, p3 & 81]

The total cost of the project is $128,616 of which $51,078 was incurred in 2002 as construction costs for the facility. For the remaining $77,538, 91% is for equipment and the remaining 9% is related to applicable taxes. [Source: Application, pA8]

If this project is approved, NKC anticipates the additional stations would be available by November 2014. Under this timeline, year 2015 is the facility's first full calendar year of operation with 18 stations and 2017 is year three. [Source: Application, p11]

Fresenius Medical Care Holdings, Inc.

Fresenius Medical Care Holdings, Inc. (Fresenius) proposes to establish a new five station dialysis facility in the King County dialysis planning area #1. FMC Richmond Beach Dialysis Center would be located at 500 Northwest Richmond Beach Road within King County. The applicant is proposing to provide in-center dialysis, peritoneal dialysis training, home hemodialysis training, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station and shifts beginning after 5 pm. [Source: Application, p9-10; February 27, 2014 Supplemental Information, p1]

If this project is approved, Fresenius anticipates the stations would be available by July 2015. Under this timeline, year 2016 is the facility's first full calendar year of operation and 2018 is year three. [Source: Application, Face Page & p10]

The capital expenditure associated with this project is $1,828,952. This amount represents the total capital expenditure of $1,923,388, minus the landlord's project costs of $94,436. Of that $1,932,388, 58% is related to construction; 24% for moveable equipment; 5% for professional fees, 8% for

Washington State sales tax, and the remaining 5% is related to the landlord's portion of the costs. [Source: Application, p27]

DaVita HealthCare Partners, Inc.

DaVita Health Care Partners, Inc. (DaVita) proposes to establish a new five station dialysis facility in the King County dialysis planning area #1. The DaVita North Seattle Dialysis Center would be located at 18503 Firlands Way North in the city of Seattle within King County. This dialysis center would provide in-center dialysis, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station, back-up dialysis services for home dialysis patients, peritoneal dialysis training, home hemodialysis training, shifts starting after 5pm, and renal focused pharmacy services. [Source: Application, pp2 & 10]

If this project is approved, DaVita anticipates the station would be available by May 2015. Under this timeline, year 2016 is the facility's first full calendar year of operation and 2018 is year three. [Source: Application, face page & p10]

The capital expenditure associated with this project is $1,830,931. This amount represents the total capital expenditure of $2,131,188 minus the landlord's project costs of $300,257. Of that $2,131,188, 62% is related to construction; 19% for moveable equipment; 5% for professional fees and the remaining 14% is related to the landlord's portion of the costs. [Source: Application, p9]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they construct, develop, and establish a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a) or they increase the number of dialysis stations in a 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).

CONCLUSIONS

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers is approved to add five new dialysis stations to the existing 13 stations at the NKC Lake City Kidney Center for a total of 18 stations in King County dialysis planning area #1 is consistent with applicable criteria, provided Northwest Kidney Centers to the following in its entirety.

Project Description:

Northwest Kidney Centers is approved to add 5 stations to the 13 station NKC Lake City Kidney Center for a total of 18 kidney dialysis stations. The NKC Lake City Kidney Center would serve residents of King County dialysis planning area #1. The NKC Lake City Kidney Center is approved to provide hemodialysis, backup dialysis service, isolation station, home hemodialysis and home peritoneal training, permanent bed station, and shifts beginning after 5pm at the NKC Lake City Kidney Center.

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	15
Total	**18**

Condition:

1. Approval of project description as stated above. Northwest Kidney Centers 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 Cost:

The approved capital expenditure associated with this project is $77,538.

Fresenius Medical Care Holdings, Inc.

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care Holdings, Inc. proposing to establish a 5-station dialysis center in the King County dialysis planning area #1 is not consistent with applicable criterion and a Certificate of Need is denied.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to construct a new five -station dialysis facility in King County dialysis planning area #1 is not consistent with applicable criteria and a Certificate of Need is denied.

EVALUATION DATED OCTOBER 27, 2014 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO KING COUNTY DIALYSIS PLANNING AREA #1:

- **NORTHWEST KIDNEY CENTERS PROPOSING TO ADD FIVE KIDNEY DIALYSIS STATIONS TO THE EXISTING NKC LAKE CITY KIDNEY CENTER IN LAKE FOREST PARK**
- **FRESENIUS MEDICAL CARE HOLDINGS INC. ON BEHALF OF QUALICENTERS INLAND NORTHWEST, INC. TO ESTABLISH A FIVE STATION KIDNEY DIALYSIS CENTER IN SEATTLE**
- **DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ESTABLISH A FIVE STATION KIDNEY DIALYSIS CENTER IN SEATTLE**

APPLICANT DESCRIPTION

N K C

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

Clallam County

Port Angeles Kidney Center

Fresenius

Renal Care Group Northwest is one of three entities owned by Renal Care Group, Inc. (RCG). RCGNW is responsible for the operation of facilities under four separate legal entities. These four entities are Pacific Northwest Renal Services, Renal Care Group of the Northwest, Inland Northwest Renal Care Group and Renal Care Group of Alaska. On March 31, 2006, thorough stock acquisition, Fresenius Medical Care Holdings, Inc. (FMC) became the sole owner of Renal Care Group, Inc., and

its subsidiaries. Listed below are the five entities owned by FMC. [Source: Department's historical record and Amended Application, page 3-5]

QualiCenters Inland Northwest, LLC
Inland Northwest Renal Care Group, LLC
National Medical Care, Inc.
Pacific Northwest Renal Services
Renal Care Group Northwest, Inc.

In Washington State, Fresenius or one of its four subsidiaries owns, operates or manages 18 kidney dialysis facilities in 13 separate counties. Below is a listing of the 18 facilities in Washington. [Application: p3-6

Adams County
Fresenius Leah Layne Dialysis Center

Benton County/Franklin County
Columbia Basin Dialysis Center

Clark County
Fort Vancouver Dialysis Facility
Salmon Creek Dialysis Facility
Battleground Dialysis Facility

Lewis County
Chehalis Facility

Grant County
Moses Lake Dialysis Facility

Cowlitz County
Fresenius Longview Dialysis center

Grays Harbor County
Aberdeen Dialysis Facility

Spokane County
Northpointe Dialysis Facility
Spokane Kidney Center
North Pines Dialysis Facility
Fresenius Panorama Dialysis Facility

Mason County
Shelton Dialysis Center

Okanogan County
Omak Dialysis Facility

Stevens County
Colville Dialysis Center

Thurston County
Fresenius Lacey Dialysis Center

Walla Walla County
QualiCenters Walla Walla

DaVita

In late 2010, DaVita, Inc. a for-profit end stage renal care provider was acquired by HealthCare Partners Holding, Inc. To reflect the combination of the two companies, DaVita, Inc. changed its name to DaVita HealthCare Partners Inc. For ease of reference, DaVita Healthcare Partners, Inc. will be referred to as 'DaVita'. Currently DaVita operates or provides administrative services in approximately 2,042 outpatient dialysis centers located in the United States. [Source: Application, Page 1] In Washington State, DaVita owns or operates 35[1] kidney dialysis facilities in 17 separate counties. Listed below are the names of the facilities owned or operated by DaVita in Washington State. [Source: CN historical files & Application, pages 5 - 6]

[1] Battle Ground Dialysis Center, Renton Dialysis Center, Marysville Dialysis Center, Zillah Dialysis Center, Tumwater Dialysis Center, Belfair Dialysis Center and Colville Dialysis Center are Certificate of Need approved but not yet operational.

Benton
Chinook Dialysis Center
Kennewick Dialysis Center

Clark
Vancouver Dialysis Center
Battle Ground Dialysis Center

Chelan
Wenatchee Valley 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

Mason
Belfair 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 Center[2]
Mill Creek Dialysis Center
Marysville Dialysis Center[3]

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

Stevens
Colville Dialysis Center

Thurston
Olympia Dialysis Center
Tumwater Dialysis Center

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

PROJECT DESCRIPTION

NKC

Northwest Kidney Centers (NKC) currently proposes to add 5 stations to the NKC Lake City Kidney Center for a total of 18 kidney dialysis stations. The NKC Lake City facility is located at 14524 Bothell Way NE, Lake Forest Park, WA.

The NKC Lake City Kidney Center would serve residents of King County dialysis planning area #1. The NKC Lake City Kidney Center proposes to provide hemodialysis, backup dialysis service, isolation station, home hemodialysis and home peritoneal training, permanent bed station, and shifts beginning after 5 pm at the NKC Lake City Kidney Center. [Source: Application, p3 & 81]

[2] Refuge Dialysis, LLC, is owned 80% by DaVita, Inc. and 20% by The Everett Clinic and managed by DaVita.
[3] Ibid

If this project is approved, NKC anticipates the stations would be available by November 2014. Under this timeline, year 2015 is the facility's first full calendar year of operation and 2017 would be year three. [Source: Application, Face Page & p11]

The capital expenditure associated with this project is $77,538. This amount represents the total capital expenditure of $128,616 minus the expended costs of $51,078. Of the capital expenditure amount of $77,538, 91% is for moveable equipment; and 9% is for taxes. [Source: Application, p6]

Fresenius

Fresenius Medical Care Holdings, Inc. (Fresenius) proposes to establish a new five station dialysis facility in the King County dialysis planning area #1. FMC Richmond Beach Dialysis Center would be located at 500 Northwest Richmond Beach Road within King County. The applicant is proposing to provide in-center dialysis, peritoneal dialysis training, home hemodialysis training, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station and shifts beginning after 5 pm. [Source: Application, p9-10; February 27, 2014 Supplemental Information, p1]

If this project is approved, Fresenius anticipates the stations would be available by July 2015. Under this timeline, year 2016 is the facility's first full calendar year of operation and 2018 is year three. [Source: Application, Face Page & p10]

The capital expenditure associated with this project is $1,828,952. This amount represents the total capital expenditure of $1,923,388, minus the landlord's project costs of $94,436. Of that $1,932,388, 58% is related to construction; 24% for moveable equipment; 5% for professional fees, 8% for Washington State sales tax, and the remaining 5% is related to the landlord's portion of the costs. [Source: Application, p27]

DaVita

DaVita Health Care Partners, Inc. (DaVita) proposes to establish a new five station dialysis facility in the King County dialysis planning area #1. The DaVita North Seattle Dialysis Center would be located at 18503 Firlands Way North in the city of Seattle within King County. This dialysis center would provide in-center dialysis, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station, back-up dialysis services for home dialysis patients, peritoneal dialysis training, home hemodialysis training, shifts starting after 5pm, and renal focused pharmacy services. [Source: Application, pp2 & 10]

If this project is approved, DaVita anticipates the stations would be available by May 2015. Under this timeline, year 2016 is the facility's first full calendar year of operation and 2018 is year three. [Source: Application, face page & p10]

The capital expenditure associated with this project is $1,830,931. This amount represents the total capital expenditure of $2,131,188 minus the landlord's project costs of $300,257. Of that $2,131,188 total amount 62% is related to construction; 19% for moveable equipment; 5% for professional fees and the remaining 14% is related to the landlord's portion of the costs. [Source: Application, p9]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they construct, develop, and establish a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a) or they increase the

number of dialysis stations in a 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 246-310-210, 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 that 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."

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); 246-310-240 (cost containment) and any service/facility specific criteria and standards linked to these four criteria. WAC 246-310 contains specific kidney dialysis specific criteria and standards. These are contained in WAC 246-310-280 through 289. These facility specific criteria and standards must be used to make the required determinations.[4]

TYPE OF REVIEW

[4] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to the projects: WAC 246-310-210(3), (4), (5), and (6).

As directed under WAC 246-310-282(1) the department accepted these three projects under the year 2013 Kidney Disease Treatment Centers-Concurrent Review Cycle #4.

In the case of the projects submitted by NKC, Fresenius and DaVita, the department will issue one single evaluation regarding whether one, all, or neither of the projects should be issued a CN.

APPLICATION CHRONOLOGY

Below is a chronologic summary of the projects.

Action	NKC	Fresenius	DaVita
Letter of Intent Submitted	November 4, 2013	November 4, 2013	November 4, 2013
Application Submitted	November 27, 2013	November 27, 2013	November 27, 2013
1st Amendment Application Submitted	N/A	January 15, 2014	December 31, 2013
Department's pre-review Activities • Department screening letter sent • Public comments accepted through end of public comment	January 31, 2014 February 28, 2014	January 31, 2014 February 27, 2014	January 31, 2014 February 28, 2014
End of Public Comment • No public hearing conducted • Public comments accepted through end of public comment	May 15, 2014		
Rebuttal Comments Received	June 16, 2014		
Department's Anticipated Decision Date	July 31, 2014		
1st Extension Date	September 1,2014		
2nd Extension Date	October 2, 2014		
3rd Extension Date	November 3, 2014		
Department's Actual Decision Date	October 27, 2014		

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 the other project.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers' Certificate of Need application submitted November 27, 2013
- Fresenius Medical Care Holdings, Inc.'s amended Certificate of Need application submitted January 15, 2014

- DaVita HealthCare Partners Inc.'s amended Certificate of Need application submitted December 31, 2013
- Northwest Kidney Centers' supplemental information February 28, 2014
- Fresenius Medical Care Holdings, Inc.'s supplemental information February 27, 2014
- DaVita HealthCare Partners Inc.'s supplemental information submitted February 28, 2014
- Public comment submitted prior to end of public comment period
- Northwest Kidney Centers' rebuttal submitted June 16, 2014
- Fresenius Medical Care Holdings, Inc.'s rebuttal submitted June 16, 2014
- DaVita HealthCare Partners Inc.'s rebuttal submitted June 16, 2014
- Years 2007 through 2012 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2012 Northwest Renal Network 3rd Quarter Utilization Data
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Data obtained from Medicare webpage (www.medicare.gov)
- Certificate of Need historical files

CONCLUSIONS

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers is approved to add five new dialysis stations to the existing 13 stations at the NKC Lake City Kidney Center for a total of 18 stations in King County dialysis planning area #1 is consistent with applicable criteria, provided Northwest Kidney Centers to the following in its entirety.

Project Description:

Northwest Kidney Centers is approved to add 5 stations to the 13 station NKC Lake City Kidney Center for a total of 18 kidney dialysis stations. The NKC Lake City Kidney Center would serve residents of King County dialysis planning area #1. The NKC Lake City Kidney Center is approved to provide hemodialysis, backup dialysis service, isolation station, home hemodialysis and home peritoneal training, permanent bed station, and shifts beginning after 5pm at the NKC Lake City Kidney Center.

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	15
Total	**18**

Approved Cost:

The approved capital expenditure associated with this project is $77,538.

Fresenius Medical Care Holdings, Inc.

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care Holdings, Inc. proposing to establish a 5-station dialysis center in the King County dialysis planning area #1 is not consistent with applicable criterion and a Certificate of Need is denied.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to establish a new five -station dialysis facility in King County dialysis planning area #1 is not consistent with applicable criteria and a Certificate of Need is denied.

CRITERIA DETERMINATION

A. Need (WAC 246-310-210 and WAC 246-310-284)

Based on the source documents evaluated, 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; and
- Fresenius's project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284; and
- 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.[5]

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.[6] 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)]

[5] 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]

[6] 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 2012.

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

NKC's Application of the Numeric Methodology

NKC proposes to add five dialysis stations to the KC Lake City Kidney Center located in Lake Forest Park. 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 Lake City Kidney Center is located in King County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, pA-19]

Fresenius's Application of the Numeric Methodology

Fresenius proposes to establish a five station dialysis facility to be located in Seattle. 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 King County dialysis planning area #1 is located in King County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, pp15-18]

DaVita's Application of the Numeric Methodology

DaVita proposes to establish a five station dialysis facility located in Seattle within King County. Based on the calculation of the annual growth rate in the planning area as described above, DaVita used the same linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, pp17-19]

Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project need for King County dialysis planning area #1. 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 shows a summary of the projected net need provided by the three applicants and the department for King County Planning Area #1. The complete methodology is attached as Appendix A.

Table 1
Summary of King County dialysis planning area #1 Projected 2016 Station Need

	Projected # of Stations	Current # of Stations	Net Need
NKC	40	35	5
Fresenius	40	35	5
DaVita	40	35	5
DOH	40	35	5

Table 1 demonstrates the projections of the three applicants match the department's figures. As a result, the net station need for King County dialysis planning area #1 is five.

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 are 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 was November 29, 2013. [WAC 246-310-282]

The quarterly modality report from NRN available at that time was September 30, 2013. For King County dialysis planning area #1, there are 22 stations located in Seattle and 13 stations located in Lake Forest Park. Table 2 shows the reported utilization of the stations in King County planning area #1.

Table 2
June 30, 2013 - Facility Utilization Data

Facility Name	# of Stations	# of Pts.	Pts./Station
NKC Scribner Kidney Center	22	117	5.32
NKC Lake City Kidney Center	13	64	4.92

Table 2 demonstrates that the two 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, 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.

Fresenius and DaVita anticipate their new dialysis centers would become operational on mid-year 2015. For NKC their new stations would become operational by November 2014. Under this timeline, year 2016 is the first full calendar year of operation for Fresenius and DaVita and 2018 is the third full year of operation. For NKC 2015 would be the first full calendar year of operation and 2017 would be the third full year of operation. A summary of the three applicants' projected utilization for their respective third year of operation is shown in Table 3. [Source: NKC Application, p9; Fresenius Application, p20; & DaVita Application, p16]

Table 3
Third Year Projected Facility Utilization[7]

Facility Name	# of Stations	# of Pts.	Pts./Station
NKC Lake City Kidney Center (2017)	18	88	4.89
FMC Richmond Beach (2018)	5	26	5.2
DaVita North Seattle Dialysis Center (2018)	5	28	5.6

As shown in the Table 3 the department concludes this sub-criterion **is met for NKC, Fresenius and DaVita.**

(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.

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 #1 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 NKC Lake City Kidney Center will use 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, pp18, A23]

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 their Lake City Kidney Center. Details provided in the application demonstrate that Fresenius intends to maintain this status at the expanded facility. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [Source: Application, p20 & A-10]

The department uses the facility's Medicaid certification to determine whether low-income residents would have access to the proposed services. NKC currently provides services to Medicaid eligible patients in their NKC Lake City Kidney Center. Details provided in the application demonstrate that NKC intends to maintain this status at the expanded dialysis facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Application, p20 & A10]

[7] Fractional numbers for patients per station are not rounded up.

NKC demonstrated its intent to provide charity care by submitting the Charity Care policy currently used within the 13-station Lake City Center Kidney Center. It outlines the process a patient would use to access services when they do not have the financial resources to pay for necessary treatments. NKC also included a 'charity' line item as a deduction from revenue within the pro forma income statements for proposed facility. [Source: Application, pp. 21 & A22]

Based on the source documents evaluated, the department concludes **this sub-criterion is met**.

Fresenius

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of King County dialysis planning area #1 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, Fresenius provided a copy of its proposed Admission Criteria that would be used at the facility. The Admission Criteria outlines the process/criteria that the FMC Richmond Beach Dialysis Center will use 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, p20, Exhibit 8 & 9]

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. Fresenius currently provides services to Medicare eligible patients in their existing dialysis centers. Details provided in the application demonstrate that Fresenius intends to maintain this status the proposed new facility. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [Source: Application, p11, Exhibit 10]

The department uses the facility's Medicaid certification to determine whether low-income residents would have access to the proposed services. Fresenius currently provides services to Medicaid eligible patients in their other Washington State dialysis centers. Details provided in the application demonstrate that Fresenius intends to maintain this status at the new dialysis facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Application, p11, Exhibit 10]

Fresenius demonstrated its intent to provide charity care by submitting the Charity Care policy proposed for the Seattle North facility. It outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. Fresenius also included a 'charity' line item as a deduction from revenue within the pro forma income statements for proposed facility. [Source: Application, pg. 20 and Exhibit 9 & 10]

Based on the source documents evaluated, the department concludes **this sub-criterion is met**.

DaVita

As previously stated, DaVita currently provides health care services to residents of Washington State. To determine whether all residents of King County dialysis planning area #1 would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its proposed Admission Criteria that would be used at the facility. The Admission Criteria outlines the process/criteria that the DaVita North Seattle Dialysis Center would use 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, p21, Appendix 14]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. DaVita currently provides services to Medicare eligible patients in their dialysis centers. Details provided in the application demonstrate that DaVita intends to be Medicare certified at its proposed new facility. A review of the anticipated revenues indicates that the facility expects to receive Medicare reimbursements. [Source: Application, p11, Appendix 14]

The department uses the facility's Medicaid certification to determine whether low-income residents would have access to the proposed services. DaVita currently provides services to Medicaid eligible patients in their dialysis centers. Details provided in the application demonstrate that DaVita intends to be Medicaid certified at the new facility. A review of the anticipated revenue indicates that the facility expects Medicaid reimbursement at the proposed new facility. [Source: Application, p11, Appendix 14]

DaVita demonstrated its intent to provide charity care by submitting the Charity Care policy proposed for the new facility. It outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. DaVita also included a 'charity' line item as a deduction from revenue within the pro forma income statements for their proposed facility. [Source: Application, p21, Appendix 14]

Based on the source documents evaluated, the department concludes **this sub-criterion is met.**

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

Based on the source information provided and reviewed, and provided NKC agrees to the condition stated in the 'conclusion' section of this evaluation, the department concludes:

- NKC's project has met the financial feasibility criteria in WAC 246-220;
- Fresenius's project has not met the financial feasibility criteria in WAC 246-310-220; and
- DaVita, Inc.'s project has not 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 5 additional stations at the NKC-Lake City Kidney Center will become operational by November 30, 2014. Based on this timeline, 2015 is the facility's first full Calendar year of operation with 18 stations. Using the financial information provided as part of the completed application, Table 4 illustrates the projected revenue, expenses, and net income for 2015 through 2017 for the NKC-Lake City Kidney Center. [Source: Application: pp10 & A-10

Table 4
NKC Lake City Kidney Center
Projected Revenue and Expenses Years 2015 - 2017[8]

	Year 1 - 2015	Year 2 - 2016	Year 3 - 2017
# of Stations	18	18	18
# of Treatments [1]	10,360	11,248	10,608
# of Patients [1]	70	76	78
Utilization Rate [1]	3.89	4.22	4.56
Net Patient Revenue [3]	$3,549,226	$3,829,428	$4,109,631
Total Operating Expense [2,3]	$3,436,996	$3,651,546	$3,862,753
Net Profit or (Loss)	**$112,230**	**$177,882**	**$246,878**

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

NKC established the NKC Lake City Kidney Center in 2001. NKC initially leased the property and subsequently purchased the facility in 2012. NKC has included depreciation costs in the proformas for the facility. [Source: Application, pA-10]

NKC provided a copy of the existing Medical Director Agreement currently being used at the NKC Lake City Kidney Center. Costs identified in the agreement are consistent with the amount identified in the pro-forma income statement.

[8] Whole numbers may not add due to rounding.

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

Fresenius

Fresenius anticipates the five stations at the FMC Richmond Beach Dialysis Center will become operational by July 2015. Based on this timeline, calendar year 2016 is 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 years 2016 through 2018 for the FMC Richmond Beach Dialysis Center. [Source: Application: Exhibit 10]

Table 5
FMC Richmond Beach-Dialysis Center
Projected Revenue and Expenses Fiscal Years 2016 - 2018[9]

	Year 1 - 2016	Year 2 - 2017	Year 3 - 2018
# of Stations	5	5	5
# of Treatments [1]	2,736	4,032	4,608
# of Patients [1]	15	22	26
Utilization Rate [1]	3.00	4.40	5.20
Net Patient Revenue [3]	$1,583,092	$2,333,886	$2,659,899
Total Operating Expense [2,3]	$1,208,012	$1,554,938	$1,706,746
Net Profit or (Loss)	**$375,080**	**$778,948**	**$953,153**

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

As shown in the Table 5, at the projected volumes identified in the application, Fresenius anticipates that the FMC Richmond Beach Dialysis Center would be operating at a profit in all three years.

The executed lease provided in the application is for 600 Richmond Beach Road, Suite 604 and 612 in the city of Seattle. 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: February 27, 2014 supplemental Materials Exhibit 10]

The draft medical director agreement provided in the application is consistent with the amount identified in the pro-forma income statement. If this project were approved, the department will include a condition requiring Fresenius to provide an executed medical director's agreement consistent with the draft agreement provided in the application.

Based on the source documents evaluated, the department concludes that Fresenius's projected revenues and expenses are reasonable and can be substantiated. If this project is approved, the department will include a condition requiring Fresenius to provide a copy of the executed Medical Director Agreement consistent with the draft provided in the application. **This sub-criterion is met.**

DaVita

[9] Whole numbers may not add due to rounding.

DaVita anticipates the 5 stations DaVita North Seattle Dialysis Center will become operational by June 2015. Based on this timeline, year 2016 is the facility's first full year of operation. Using the financial information provided in the application, Table 6 illustrates the projected revenue, expenses, and net income for full year 2016 through 2018 for DaVita North Seattle Dialysis Center. [Source: Application: P12 & Screening Responses Appendix 9]

Table 6
DaVita North Seattle Dialysis Center
Projected Revenue and Expenses Fiscal Year 2016-2018

	Year 1-2016	**Year 2 - 2017**	**Year 3-2018**
# of Stations	5	5	5
# of Treatments [1]	1,886	3,186	4,594
# of Patients [1]	13	21	28
Utilization Rate [1]	2.6	4.2	5.6
Net Patient Revenue [3]	$563,160	$1,543,763	$2,270,408
Total Operating Expense [2,3]	$1,079,255	$1,530,095	$1,969,376
Net Profit or (Loss)	**($516,095)**	**$13,668**	**$301,032**

[1] Includes in-center patients only; [2] includes bad debt, charity care [3] in-center

As shown in Table 6, at the projected volumes identified in the application, DaVita anticipates that the DaVita North Seattle Dialysis Center will be operating at a loss in the first full year of operation and at a profit in years two and three.

The proposed DaVita North Seattle Dialysis Center will be located at 18503 Firlands Way North in the city of Seattle within King County. The executed lease agreement provided in the application outlines the terms and the annual rent for the space through year 2025. The annual lease costs are substantiated in the pro forma financial documents and the supporting lease cost worksheet. [Source: Supplemental Information Revised Appendix 9 and 15]

The executed medical director agreement is consistent with the amount identified in the pro-forma income statement. [Source: Application, Appendix 15, February 28, 2014 Supplemental Materials, Revised Appendix 11]

Based on the source documents evaluated, 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 this project is $77,538. This amount represents the total capital expenditure of $128,616 minus the expended costs of $51,078. Of the capital expenditure amount of $77,538, 91% is for moveable equipment; 9% is for taxes. [Source: Application, p6]

Table 7
Estimated Capital Costs of NKC-Lake City Kidney Center Expansion

Item	Cost	% of Total
Moveable Equipment	$70,811	91%
Taxes	$6,727	9%
Total Estimated Capital Costs	**$77,538**	**100%**

Public Comment

The public comment regarding the cost of the NKC facility is that the costs allocated to this project from previous years is too low. This results in a very low cost for the project when compared to the other two projects. [May, 15, 2014 Fresenius Public Comment pp7 & 8]

Rebuttal

NKC argues that there is no procedure in rule for calculating historical costs and allocating them to expansion projects. NKC states that they followed guidance provided by department staff and believe that their allocations are correct.

NKC reported the entire historical construction cost of the original project and allocated a portion to this project based on the square footage assigned to the 5 stations being requested in this project. This historical cost was then added to the cost of equipment being added for the new additional 5 stations. [Source: Application, p6 & 6June 16, 2014 NKC rebuttal, pp2 &3]

The department has either met with or had conversations with NKC, DaVita, and Fresenius about how to allocate construction costs when expanding an existing facility. The method used by NKC is consistent with those conversations. The department concludes this is an appropriate way to allocate costs.

NKC provided the following information to show the sources of revenue and the anticipated percentage of revenue from each source. [Source: Application, p9]

Table 8
Estimated Sources of Revenue and Treatments by Payor
NKC-Lake City Dialysis Center

Projected Treatments by Payor		Percentage of Revenues by Payor	% of Revenue
Payor	**% of Total Treatments**		
Medicare	74%	Medicare	74%
Medicaid	11%	Medicaid	11%
Commercial	15%	Commercial	15%
Total	**100%**		**100%**

As shown in Table 8, the Medicare and Medicaid treatments are projected to equal 85.0%. The percentage of revenue by payor is also equal to 85%. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS has recently implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate.

However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Given the department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by NKC about its revenue indicates this project may not have an unreasonable impact on charges for services within the planning area. Based on the source documents evaluated of the application materials, the department concludes **this sub-criterion is met.**

Fresenius

The total capital expenditure associated with the new 5 station FMC Richmond Beach Dialysis Center is $1,923,388. Of that total amount, 58% is related to construction, 24% to equipment, 5% to Architect and Engineering Fees, 8% to sales tax, and 5% for landlord project costs. The capital cost breakdown is shown in Table 9. [Source: Application, p27]

Table 9
Estimated Capital Costs of Fresenius Richmond Beach Dialysis Center

Item	Cost	% of Total
Construction	$1,119,525	58%
Equipment	$467,100	24%
Architect & Engineering Fees	$91,598	5%
Sales Tax	$150,730	8%
Landlord Project Costs	$94,435	5%
Total Estimated Capital Costs	**$1,923,388**	**100%**

Public Comment

The public comment regarding the capital costs of the Fresenius project states that Fresenius has not included all equipment therefore underestimating the cost of the project. It was also stated they are buying enough equipment for six stations rather than the five stations requested in their application. [Source: May 14, 2014 DaVita public comment, pp3-4]

NKC states that FMC is proposing to establish a new dialysis center that will initially house 5 stations but will be built to house 12 stations. FMC anticipates the facility will open in July 2015 and the estimated capital expenditure is $1,923,388. [Source: May 15, 2015 NKC public comment, p3]
DaVita commented that FMC shows a facility shoe-horned into a small storefront space with, an interior treatment floor that would lack both windows and televisions for patients. [Source: May 15, 2014 DaVita public comment, p1]

Rebuttal

Fresenius stated that the equipment (televisions and bio-refrigerator) identified in the public comment is not vital to the operation of the facility. The extra equipment is for back up to the equipment being used for the five stations. Fresenius does not plan on operating more than the five approved stations.

Fresenius did not respond to the comments on the cost of their facility. Fresenius commented that DaVita's criticism about the space for their project was curious since their facility is 8,350 rentable square feet; which is only slightly less than the DaVita figure of 8,800 square feet.

Department's Evaluation

The department reviewed previous applications submitted by Fresenius and other applicants. This review shows that items such as dialysis machines, refrigerators, artwork, computers, chairs, and televisions have been included in the equipment lists. The equipment list should include all items considered to be capital expenditure under WAC 246-310-280(2) and has also included patient comfort items. The department expects all applicants to provide a complete list of equipment for the department to compare with anticipated equipment costs. Fresenius appears to have missed some items of equipment that would be included in a complete equipment list. The department reviewed DaVita's equipment list as well as Fresenius's. If the department were to agree with DaVita's recommendation to fail Fresenius's application because it does not sufficiently identify necessary equipment and therefore should be denied, the same argument would support the denial of DaVita's application on the same grounds. Both applicants generally provided lists of equipment necessary for the facility. Although the level of detail provided by both applicants is not at the level the department expects, the department is not going to deny both these applicants based on this argument in this particular review.

Fresenius provided the following information to show the sources of revenue and the anticipated percentage of revenue from each source. [Source: Application, p11 and 189]

Table 10
Estimated Sources of Revenue and Treatments by Payor
Fresenius- Richmond Beach Dialysis Center

Projected Treatments by Payor		**Percentage of Revenue by Payor**	**% of Revenue**
Payor	**% of Total Treatments**		
Medicare	77%	Medicare	44%
Medicaid	6%	Medicaid	2%
Commercial	10%	Commercial	45%
Other	7%	Other	9%
Total	**100%**	**Total**	**100%**

As shown in Table 10, the Medicare and Medicaid treatments are projected to equal 83%. For this project Medicare and Medicaid revenue make up only 46% of the revenue. Commercial and other revenue sources make up 54%. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS has recently implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare

pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate.

However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider.

Fresenius' project has the second highest capital expenditure of the three projects. In reviewing the line drawing supplied by Fresenius the project is a 12 station dialysis facility rather than a five station facility. The department has historically approved dialysis projects containing shelled-in space for reasonable future expansion. This space has been intended to allow for cost effective expansions when a small number of stations become needed in a planning area. In this case the number of stations for expansion exceeds the needed stations by two times. Also this expansion space is integral to the treatment space proposed for this project. The department generally views expansion space as a separate unfinished space that could be finished in the future for expansion. This project does not seem to fit this concept. It appears from the line drawing that the expansion space would need to be finished as part of this project. This expansion space will need to be paid for by the costs and charges for dialysis treatments provided in the five stations until such time as an expansion would be approved. It does not seem cost effective to over build a project to this extent. The department concludes this project is overbuilt for the projected need in this dialysis planning area. As previously shown in Table 10, 17% of the treatments from non-Medicare/Medicaid patients generate 54% of the total revenue. This revenue is generated through negotiated rates with insurance providers or private patients. It is reasonable to expect these rates are higher than necessary to support the unnecessary capital and operating costs of this over built facility.

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

DaVita

The total capital expenditure associated with the new 5 station FMC Richmond Beach Dialysis Center is $1,923,389. Of that total amount, 62% is related to construction, 19% to equipment, 5% to professional fees, and 14% for landlord project costs. The capital cost breakdown is shown in Table 11. [Source: Application, p27]

Table 11
Estimated Capitals Costs of DaVita North Seattle Dialysis Center

Item	Cost	% of Total
Leasehold Improvements	$1,311,760	62%
Movable and Fixed Equipment	$412,201	19%
Professional Fees	$106,970	5%
Landlord Project Costs	$300,257	14%
Total Estimated Capital Costs	**$2,131,188**	**100%**

Public Comment

Fresenius commented that DaVita is proposing a new five station facility for the King 1 Dialysis planning area. Fresenius states that the proposed lease indicates that the center would be 8,820 sq.

ft. and would require a total capital expenditure of $2.1 million. They state that while DaVita requests approval for only five stations the majority of the treatment area is reserved for future expansion space for an additional 11 stations. Fresenius provided the following concerns regarding the project.

- DaVita does not indicate what space is allocated to its requested stations and what space is allocated for future expansion.
- The department can not evaluate the cost of the project since this is essentially construction of a 16 station facility.
- The cost per station is over $426,000 because of the lack of capital cost break-out.

Rebuttal

DaVita argued that the cost of the project was not unreasonable and that they did not have to allocate costs between the project and expansion space since this is a new facility. [Source: June 15, 2014 DaVita Rebuttal, p4]

The majority of patients 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 12. [Source: Application, p11]

Table 12
Estimated Sources of Revenue and Patients by Payor
Based on DaVita "Company Wide"

Percentages of Patients By Payor Type	% of Patients	Percentage of Revenues by Payor	% of Revenue
Medicare	79%	Medicare	57%
Medicaid/State	8%	Medicaid/State	4%
Insurance/HMO	13%	Insurance/HMO	39%
Total	**100.0%**	**Total**	**100%**

Source: Application, p11

As shown Table 12, the Medicare and Medicaid are projected to equal 61% of the revenue at the DaVita North Seattle Dialysis Center. The Medicare and Medicaid revenues are projected to equal 61% of the revenues. DaVita uses company-wide averages in projecting the payor mix for the new facility. This is a reasonable approach for a new facility.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the DaVita North Seattle Dialysis Center facility, approximately 87% of the patients will have either Medicare or Medicaid. CMS has recently implemented an ESRD PPS. Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive.

What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider.

Department's Evaluation

DaVita's project has the highest capital expenditure of the three projects. In reviewing the line drawing supplied by DaVita, the project is a 16 station dialysis facility rather than a five station facility. The department has historically approved dialysis projects containing some shelled-in space for reasonable future expansion. This space has been intended to allow for cost effective expansions when a small number of stations become needed in a planning area. In this case the number of stations for expansion exceeds the needed stations by three times. Also this expansion space is integral to the treatment space proposed for this project. The department generally views expansion space as a separate unfinished space that could be finished in the future for expansion. This project does not seem to fit this concept. It appears from the line drawing that the expansion space would need to be finished as part of this project. This expansion space will need to be paid for by the costs and charges for dialysis treatments provided in the five stations until such time as an expansion would be approved. It does not seem cost effective to over build a project to this extent. The department concludes this project is overbuilt for the projected need in this dialysis planning area. As previously shown in Table 12, 13% of the treatments from non-Medicare/Medicaid patients generate 39% of the total revenue. This revenue is generated through negotiated rates with insurance providers or private patients. It is reasonable to expect these rates are higher than necessary to support the unnecessary capital and operating costs of this over built facility.

Based on the source documents evaluated, the department concludes the costs of this project will result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is not 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

The capital expenditure associated with the expansion of NKC Lake City Dialysis Center is $77,538. The project will be financed through NKC board reserves. NKC provided a letter of financial commitment to the project. [Source: Application, Appendix 12] This source of financing is appropriate. A review of NKC's audited financial statements shows that they have the capability to finance this project. Based on the source documents evaluated, the department concludes **this sub-criterion is met**.

Fresenius

As previously stated, the capital expenditure associated with the establishment of FHS's Richmond Beach Dialysis Center is $1,828,952. The project will be financed through the parent company, Fresenius. Fresenius intends to finance the project entirely from the Fresenius capital expenditures budget. A review of the financial statement provided in the application indicates that Fresenius had sufficient cash assets in both 2011 and 2012 to fund the project. [Source: Application, Appendix 3]

Fresenius provided a letter of financial commitment to the project. [Source: Screening Responses, Attachment 12] This source of financing is appropriate. Based on the source documents evaluated, the department concludes. **This sub-criterion is met.**

DaVita

As previously stated, the capital expenditure associated with the expansion of DaVita's North Seattle Dialysis Center is $1,830,931. DaVita states that the project will be funded from DaVita's capital expenditures budget. 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 2011 and 2012 to fund the project. [Source: Application, Appendix 10]

DaVita provided a letter of financial commitment to the project. [Source: Application, Appendix 6] This source of financing is appropriate. Based on the source documents evaluated, the department concludes **this sub-criterion is met**.

Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source documents evaluated, the department concludes:

- NKC's project has met the structure and process of care criteria in WAC 246-310-230
- Fresenius's project has the structure and process of care criteria in WAC 246-310-230; and
- 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 Lake City Dialysis Center is currently in operation with 13 dialysis stations. Table 13 shows the current and projected staffing for this facility if the project is approved.

Table 13
NKC Lake City Dialysis Center 2014-2018 FTEs

Staff/FTEs	Current 2014	2015 Increase	2016 Increase	2017 Increase	Total FTEs
RNs	5.94	0.51	0.51	0.51	7.47
Patient Care Tech	8.20	0.71	0.70	0.70	10.31
Clerical.	1.00	0.00	0.00	0.00	1.00
Dietician	0.47	0.04	0.04	0.04	0.59
Social Worker	0.58	0.05	0.05	0.05	0.73
Total FTE's	**16.19**	**1.31**	**1.30**	**1.30**	**20.10**

As shown in Table 13, NKC expects a minimal increase over the three year period of time. NKC states that it expects no difficulty in recruiting staff since they are located in an urban area and they have a history of being able to recruit staff. They currently have minimal vacancies in their system.

Based on the source documents evaluated, the department concludes adequate staffing for the five station increase for the NKC Lake City Kidney Center is available or can be recruited. **This sub criterion is met.**

Fresenius

Fresenius's Richmond Beach Dialysis Center is not operational at this time. For the new five-station facility, Fresenius intends to start with 2.80 staff in 2014, add 1.6 FTEs by the end of 2017. A breakdown of the proposed FTEs is shown in the Table 14. [Source: Application p30]

Table 14
Fresenius Richmond Beach 2015 – 2018 FTEs

Staff/FTEs	2015	2016 Increase	2017 Increase	2018 Increase	Total FTEs
Medical Director	1.00	0.00	0.00	0.00	1.00
Nurse Manager	1.00	0.00	0.10	0.50	1.00
RNs	0.20	0.20	0.50	0.50	1.00
Patient Care Tech	1.00	.25	0.25	.25	1.75
Equipment Tech.[10]	0.20	0.05	0.00	0.00	0.25
Social Worker	0.20	0.00	0.00	0.00	0.25
Dietitian	0.20	0.00	0.00	0.00	0.20
Total FTE's	**2.80**	**0.50**	**0.35**	**0.75**	**4.40**

As shown in Table 14, Fresenius expects a minimal increase over the three year period of time. Fresenius states that it expects no difficulty in recruiting staff for the facility since there has been a steady growth in population in King and Snohomish counties. Fresenius also has a comprehensive documented staff training program that will facilitate filling any staffing needs. [Source: Application, p31]

Based on the source documents evaluated, the department concludes adequate staffing for the 5 station Richmond Beach Dialysis Center is available or can be recruited. **This sub criterion is met.**

DaVita

DaVita's North Seattle Kidney Dialysis Center is not in operation at this time. To accommodate the patients associated with the proposed new stations, For the new five-station facility, DaVita intends to start with 5.00 FTEs in Year 2015 and add a total of 4.70 FTEs. This will result in a total staff of 9.70 FTEs by 2018. A breakdown of the proposed FTEs is shown in Table 15.

[10] Includes BioMed

Table 15
DaVita North Seattle Center 2015 – 2018 Projected FTEs

Staff/FTEs	2015 FTE	2016 Increase	2017 Increase	2018 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	1.00	0.0	0.00	0.00	1.00
RN	1.50	0.60	1.00	0.90	3.10
Patient Care Techs	0.80	0.80	1.00	0.40	2.60
Biomedical Techs	0.20	0.00	0.00	0.00	0.20
Administrative Assistant	0.50	0.00	0.00	0.00	0.50
Social Worker	0.50	0.00	0.00	0.00	0.50
Dietitian	0.50	0.00	0.00	0.00	0.50
Total FTE's	**5.00**	**1.40**	**2.00**	**1.30**	**9.70**

As shown in Table 15, DaVita expects a minimal increase over the three year period of time. DaVita does not anticipate any difficulty in recruiting staff for the new North Seattle Dialysis Center. DaVita offers a competitive wage and benefit package to employees and advertises both locally and nationally. Specific to the DaVita North Seattle Dialysis Center, DaVita states claims it would be located in a desirable geographical location and since it is an urban area recruitment of new staff should not be difficult. [Source: Application, p23 & 24]

Based on the source documents evaluated, the department concludes adequate staffing for the new five-station DaVita North Seattle 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.

There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure whether the health services proposed in the project 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.

NKC

As a provider of dialysis services in Washington State, NKC currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers For its Lake City 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 at one of the support offices in Seattle, Lake Forest Park, SeaTac or Bellevue.

Fresenius

As a provider of dialysis services in Washington State, Fresenius currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. The information provided in the application confirms that Fresenius will maintain the appropriate relationships with ancillary and support services for this facility. FMC Richmond Beach will have

dietary and social services provided within the facility. Other typical ancillary and support services including pharmacy, laboratory and radiology will be provided by existing providers in the service area. Transfer agreements will be established with local hospitals. If this project is approved a copy of the finalized transfer agreement consistent with the draft agreement will need to be submitted prior to offering services. [Source: Application, p32 & Exhibit 11]

If this project is approved, the department would include a condition requiring Fresenius to provide a copy of the executed transfer agreement consistent with the draft agreement provided in the application with Fresenius agreement to submit a finalized transfer agreement, the department concludes this **sub-criterion is met.**

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. The information provided in the application confirms that Fresenius will maintain the appropriate relationships with ancillary and support services for this facility. For its Seattle North 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 will be 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] DaVita provided a template of their proposed transfer agreement, therefore if approved prior to providing services; DaVita will need to submit a final transfer agreement with a local hospital consistent with the draft agreement. [Source: Application Appendix 12]

If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed transfer agreement consistent with the draft agreement provided in the application. Based on this information, the department concludes DaVita will have the appropriate relationships with ancillary and support services. The department concludes **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.[11]

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

[11] WAC 246-310-230(5).

location such as types of home training and shifts starting after 5 pm at this NKC facility. NKC Lake City Kidney Center is certified for 13 dialysis stations, having shifts starting after 5 pm, and providing in-center, peritoneal dialysis. The NKC Lake City Kidney Center Medicare certification is consistent with the CN approvals and records. Therefore the Department concludes that there is reasonable assurance the NKC Lake City Kent Kidney Center will 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 as the contractor for Medicare 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 Jung Jo, M.D. at the NKC Lake City Kidney Center. A review of the compliance history for Dr. Jo revealed no recorded sanctions. [Source: Application Supplement 1] Based on the source documents evaluated, **the department concludes this sub-criterion is met.**

Fresenius

Fresenius Medical Care is the parent company of RCGNW. Information available at Fresenius Medical Care North America's website stated, in the United States, Fresenius Medical Care is the largest provider of dialysis products and services with over 1,800 kidney dialysis clinics, and it provides care for nearly 138,000 patients. [Source:http://www.fmcna.com/fmcna/DialysisCompany/dialysis-company.html] As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.

To accomplish this task, in February 2010 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for conducting surveys where Fresenius Medical Care or any of its subsidiaries have healthcare facilities. Of the 45 states[12] and the non-state entities surveyed, the department received 26 responses or 55% of those surveyed[13].

Six of the 26 states responding to the survey indicated that non-compliance deficiencies were cited at Fresenius facilities in the past three years, but none was reported to have resulted in fines or enforcement action. Fresenius submitted and implemented acceptable plans of correction. Given the results of the out-of-state compliance history of the facilities owned or operated by Fresenius**,** the department concludes that considering that it owns or operates more than 1,800 facilities the number of out-of-state non-compliance surveys is acceptable. [Source: Licensing and/or survey data provided by out of state health care survey programs]

Fresenius is currently a provider of dialysis services within Washington State, and operates 19 kidney dialysis treatment centers in 14 separate counties.

[12] This figure excludes Washington. The department did not send a survey to itself for compliance.

[13] Those not responding are Alabama, Arkansas, District of Columbia, Georgia, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, New Jersey, New York, Oklahoma, Pennsylvanian, Rhode Island, Texas, Vermont, Wisconsin, and Puerto Rico.

For Washington State, since January 2008, the Department of Health's Investigations and Inspections Office has completed 20 compliance surveys as the contractor for Medicare for the operational facilities that Fresenius either owns or manages. Fresenius facilities in Washington have collectively been surveyed 33 times within the last six years. Of the 33 surveys, one survey revealed potentially hazardous condition that was promptly corrected; nine surveys revealed no deficiencies. The remaining 23 surveys revealed minor non-compliance issues and the facilities submitted plans of corrections for the non-compliance issues within the allowable response time. [Source: Facility survey data provided by the Investigations and Inspections Office]

For medical director services, Fresenius provided a copy of the draft Medical Director Agreement proposed between itself and Seth Thaler M.D. A review of Dr. Seth Thaler's compliance history with the Department of Health's Medical Quality Assurance Commission did not revealed any recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

Public Comment
A comment was made regarding the fact that the proposed Medical Director identified by Fresenius has his practice in Olympia.

Rebuttal
Fresenius argued that there is no regulation regarding location of the Medical Director and the distance they work from the dialysis facility.

The department agrees with Fresenius that there is no regulation that the Medical Director must be located in the vicinity of the dialysis facility being monitored by the Medical Director.

If this project is approved, the department would include a condition requiring Fresenius to provide a copy of the executed Medical Director agreement consistent with the draft agreement provided in the application. Based on the source documents evaluated, the department concludes **this sub-criterion is met.**

DaVita
DaVita, Inc. is a provider of dialysis services in over 2,042 outpatient centers located in 43 states (including Washington State), the District of Columbia. [Source: DaVita website at www.davita.com] Currently within Washington State, DaVita owns and operates 34 kidney dialysis treatment centers in 15 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 and in conformance with applicable state licensing requirements and or Medicare/Medicaid certification.[14]

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 or any subsidiaries have health care facilities. The department received responses from 21 states or 47% of the 45 entities.[15] The

[14] WAC 246-310-230(5).
[15] 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.

compliance history of the remaining 24 states, the District of Columbia, and San Juan Puerto Rico is unknown.[16]

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 1,912 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 2010, the Department of Health's Office of Investigations and Inspections as the contractor for Medicare has completed more than 26 compliance surveys for the operational facilities that DaVita either owns or manages.[17] 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]

For medical director services, DaVita provided a copy of the executed Medical Director Agreement proposed between itself, The Polyclinic, and Andrew Somlyo, M.D. A review of Dr. Somlyo's compliance history with the Department of Health's Medical Quality Assurance Commission did not revealed any recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed Medical Director agreement consistent with the draft agreement provided in the application. Based on the source documents evaluated, 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

[16] 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.

[17] 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.

this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

NKC

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

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for five dialysis stations in the King County dialysis planning area #1. This project proposes to add five stations to its existing Lake City Kidney Center in Lake Forest Park.

NKC also provided the patient transfer agreement currently used at the Lake City Kidney Center used at the existing facilities in Washington. The transfer agreement will continue to be used at the expanded Lake City Kidney Center [Source: Application, Supplement 2]

Based on the source documents evaluated, the department concludes approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **This sub-criterion is met.**

Fresenius

The department considered Fresenius'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 new facility would change these relationships and Fresenius has submitted documentation that this facility will cooperate with existing providers.

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 five dialysis stations in the King County dialysis planning area #1. This project proposes a facility designed for 12 stations to establish a five station Dialysis Center.

Fresenius also provided a draft sample of the patient transfer agreement used at the existing facilities in Washington. [Source: Application, Appendix 11] Since the patient transfer agreement is a draft if this project is approved the department would attach a condition to the approval of this project.

Based on the source documents evaluated and with agreement to the condition related to the patient transfer agreement, the department concludes approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **This sub-criterion is met.**

DaVita

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 new facility would change these relationships. Nothing in the materials reviewed by staff suggests that approval of this new facility would change these relationships and DaVita has submitted documentation that this facility will cooperate with existing providers.

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 five dialysis stations in King County dialysis planning area #1. This project proposes to establish a five station Dialysis Center in Seattle.

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.

Additionally, DaVita provided a draft sample of the patient transfer agreement used at the majority owner and managing member existing facilities in Washington. [Source: Application, Appendix 12] Since the patient transfer agreement is a draft if this project is approved the department would attach a condition to the approval of this project.

Based on the source documents evaluated and with agreement to the condition related to the patient transfer agreement, the department concludes approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **This sub-criterion is met.**

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

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

Fresenius
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 met.**

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

Based on the source documents evaluated, the department concludes:

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

A determination that a proposed project will foster cost containment shall be based on the following criteria.

(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. First the department determines if the application has met the other criteria of WAC 246-310-210 thru 230. If the project has failed to meet one or more of these criteria then the project cannot be considered to be the best alternative in terms of cost, efficiency, or effectiveness as a result the application would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, the department then assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type. The superiority 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 type superiority 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.

NKC

NKC proposed to expand its existing Lake City Kidney Center from 13 to 18 stations within King County dialysis planning area #1. The department concluded that the project met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Fresenius

Fresenius proposed to establish a new 5 station kidney dialysis facility in Seattle within King County dialysis planning area #1. The department concluded that the project did not meet the applicable review criteria under WAC 246-310-220(2). This conclusion was based on fact that the project is two times the size for the number of stations needed for King County dialysis planning area #1. The proposed shell-in expansion space is integral to the space for the 5 stations and therefore will have to be completed as part is this project. The department concluded **this sub-criterion is not met.**

DaVita

DaVita proposed to establish a new 5 station kidney dialysis facility in Seattle within King County dialysis planning area #1. The department concluded that the project met the applicable review criteria under WAC 246-310-220(2). This conclusion was based on fact that the project is three times the size for the number of stations needed for King County dialysis planning area #1. The proposed shell-in expansion space is integral to the space for the 5 stations and therefore will have to be completed as part is this project. The department concluded **this sub-criterion is not met.**

The remainder of this section will focus on NKC's application.

NKC

NKC considered eight alternatives to this project before submitting its application. Below are the review of the alternatives and NKC's rationale for rejecting them. [Source: Application, pp26-28]

1. Build a New Facility

Historically King County dialysis planning area #1 has been served by two facilities located in both located in Seattle. NKC rejected this alternative as wasteful and inefficient as it would represent an unnecessary duplication of capacity and an unnecessary capital expenditure. This alternative would also take up to two years to begin providing services.

Expand a Different Facility

The only other adult dialysis facility in the King County dialysis planning area is the NKC Scribner Kidney Center. The leased space at this facility is not suitable for expanding. Any expansion would require additional construction and capital costs and delay opening.

Postponement

NKC reports that both adult dialysis facilities are operating above 80% and the need calculations show additional capacity is needed.

Night Time Services

Outpatient hemodialysis involves 4 to 5 hours of treatment, 3 times weekly, in a staff-assisted environment, with an industry standard operations plan of 3 patient shifts per day. In-center Nocturnal Dialysis is a modality option that can better leverage the treatment capacity of existing dialysis stations. NKC reports that they are not prepared at this time to provide this service in the King County dialysis planning area #1.

Shortened Treatment Times

NKC reports that this could allow for four patient shifts per day instead of three. They report that the medical literature does not support this alternative. The longer treatment times result in better overall care and outcomes.

Home Dialysis

NKC operates both home hemodialysis and home peritoneal dialysis programs with a census of approximately 263 patients from all their facilities as of July 31, 2013. Despite promoting these programs, they don't appear to attract enough patients to reduce the utilization of the in-center patient volume.

Kidney Transplantation

NKC reports that they advocate for transplantation but the supply of available donor organs has not kept up with the demand.

Shared/Contract Service Arrangements
NKC reports that their two facilities in the planning area collaborate to ensure access to care and to avoid overcrowding at both facilities. There are no other providers of adult dialysis services in the planning area.

Department Evaluation
NKC
The department reviewed criteria for WAC 246-310-210 and concluded that there is a need for five additional stations in the King County dialysis planning area #1. NKC also concluded the additional need for dialysis stations in this planning area is five stations. NKC submitted an application to expand their Lake City Dialysis Center from 13 stations to 18 stations. The department did not identify any other alternatives from those identified by NKC.

Based on the source documents evaluated, the department concludes that the NKC project is the best alternative, **this sub-criterion is met.**

(2) In the case of a project involving construction:
(a) *The costs, scope, and methods of construction and energy conservation are reasonable;*
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.

Fresenius
This sub-criterion was evaluated within the financial feasibility criterion under WAC 246-310-220(2). Although Fresenius is the less costly of the two construction projects, the Certificate of Need Program has concluded that the completed space that is twice the size required for the 5 stations will add unnecessary construction costs to this project. **This sub-criterion is not met.**

DaVita
This sub-criterion was evaluated within the financial feasibility criterion under WAC 246-310-220(2). DaVita has included substantial expansion space in their proposed project. Their project is the most costly of the two construction projects. The Certificate of Need Program concluded that he completed space that is three times size required for the 5 stations will add unnecessary construction costs to this project. **This sub-criterion is not 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.

Fresenius

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). The department concluded this project failed to meet 246-310-220(2). Therefore this project also fails this sub-criterion. **This sub-criterion is not met**.

DaVita

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). The department concluded this project failed to meet 246-310-220(2). Therefore this project also fails this sub-criterion. **This sub-criterion is not met**.

APPENDIX A

2013
King County 1
ESRD Need Projection Methodology

	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	King One (1)	2007	2008	2009	2010	2011	2012
	98028	6	7	5	5	8	8
	98103	16	20	22	21	23	16
	98105	14	9	9	9	8	5
	98107	8	8	8	7	6	5
	98115	17	19	17	13	19	16
	98117	15	15	11	11	20	12
	98125	24	24	25	24	21	32
	98133	38	37	42	47	44	49
	98155	28	33	28	30	29	32
	98177	7	10	14	12	8	12
	98195	0	0	0	0	0	0
	TOTALS	173	182	181	179	186	187
246-310-284(4)(a)	Rate of Change		5.20%	-0.55%	-1.10%	3.91%	0.54%
	6% Growth or Greater?		FALSE	FALSE	FALSE	FALSE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
				2013	2014	2015	2016
Projected Resident Incenter Patients	from 246-310-284(4)(b)			187.50	189.00	190.50	192.00
Station Need for Patients	Divide Resident Incenter Patients by 4.8			39.0625	39.3750	39.6875	40.0000
	Rounded to next whole number			40	40	40	40
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				35	35	35	35
Results of (4)(c) above			-	40	40	40	40
Net Station Need				-5	-5	-5	-5
Negative number indicates need for stations							

Planning Area Facilities

Name of Center	# of Stations
NKC - Lake City	13
NKC - Scribner	22
Seattle Children's Hosp	9
Total	35

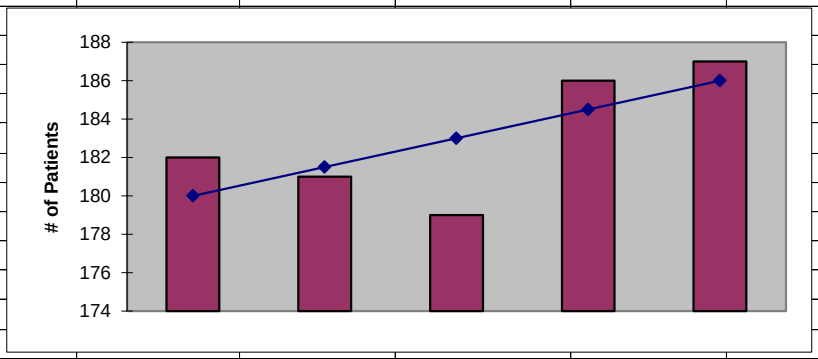
Note: These stations are not counted in the numeric methdology

Source: Northwest Renal Network data 2007-2012

Most recent year-end data: 2012 posted 02/11/2013

2013
King County 1
ESRD Need Projection Methodology

x	y	Linear
2008	182	**180**
2009	181	**182**
2010	179	**183**
2011	186	**185**
2012	187	**186**
2013		**187.50**
2014		**189.00**
2015		**190.50**
2016		**192.00**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.699378606
R Square	0.489130435
Adjusted R Square	0.31884058
Standard Error	2.798809271
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	22.5	22.5	2.872340426	0.188685663
Residual	3	23.5	7.833333333		
Total	4	46			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-2832	1778.973459	-1.591929315	0.20964005	-8493.48751	2829.48751	-8493.48751	2829.48751
X Variable 1	1.5	0.885061203	1.694798049	0.188685663	-1.316659756	4.316659756	-1.316659756	4.316659756

RESIDUAL OUTPUT

Observation	*Predicted Y*	*Residuals*
1	162.2	-8.2
2	168	5
3	173.8	
4	179.6	
5	185.4	185.4