

February 28, 2014

CERTIFIED MAIL # 7011 2000 0000 5081 8647

David D. Natali Regional Operations Director DaVita HealthCare Partners, Inc. North Star Division Office 32275 32<sup>nd</sup> Avenue South Federal Way, Washington 98001

CN: 14-07

Dear Mr. Natali:

We have completed review of the Certificate of Need application submitted by DaVita HealthCare Partners, Inc., proposing to establish a new 10-station kidney dialysis facility in Pierce County planning area #5. For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners, Inc., agrees to the following in its entirety.

#### **Project Description:**

This certificate approves the establishment of a new 10-station dialysis center in Tacoma within Pierce County planning area #5. At project completion, the dialysis center will be approved to certify and operate ten dialysis stations. The dialysis facility will offer at least in-center hemodialysis dialysis. Services to be provided at DaVita Rainier View Dialysis Center includes hemodialysis with treatment shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. A breakdown of all ten stations is below:

#### DaVita Rainier View Dialysis Center

20,100 2002220 , 101, 2 202,	010 0 411441
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	8
Total	10



David D. Natali, Regional Operations Director DaVita HealthCare Partners, Inc. Certificate of Need Application #14-07 February 28, 2014 Page 2 of 3

After the 10 stations are relocated from the 21-station Lakewood Community Dialysis Center, the dialysis center would have 11 stations remaining. A breakdown of the remaining 11 stations is shown below.

Lakewood Community Di	ialysis	Center
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COLLEGE CONTRACTOR DE LOCALITATION DE LOCALITA	
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	9
Total	11

#### **Conditions:**

- 1. DaVita HealthCare Partners, Inc. agrees with the project description as stated above. DaVita HealthCare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. DaVita HealthCare Partners, Inc. must decertify 10 stations from the 21-station Lakewood Community Dialysis Center no later than 30 days following the opening of the new 10-station dialysis center. At project completion, the Lakewood Community Dialysis Center would be approved to certify and operate 11 dialysis stations.
- 3. Prior to providing services, DaVita HealthCare Partners, Inc. will provide a complete copy of its charity care policy with all addendums for review and approval.
- 4. Prior to providing services, DaVita HealthCare Partners, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval. The executed transfer agreement must be consistent with the draft provided in the application.

# **Approved Capital Costs:**

The approved capital expenditure associated with this project is \$1,475,650

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety. 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

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

David D. Natali, Regional Operations Director DaVita HealthCare Partners, Inc. Certificate of Need Application #14-07 February 28, 2014 Page 3 of 3

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, Office of Community Health Systems

Enclosure

EVALUATION DATED FEBRUARY 28, 2014, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA HEALTHCARE PARTNERS, INC., PROPOSING TO ESTABLISH A TEN STATION KIDNEY DIALYSIS FACILITY IN PIERCE COUNTY END STAGE RENAL DISEASE PLANNING AREA #5

#### APPLICANT DESCRIPTION

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 'DaVita'. Currently DaVita operates or provides administrative services in approximately 2,010 outpatient dialysis centers located in the United States. [Source: Application, Page 4] In Washington State, DaVita owns or operates 34<sup>1</sup> kidney dialysis facilities in 15 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]

Benton	Pacific	
Chinook Dialysis Center	Seaview Dialysis Center	
Kennewick Dialysis Center		
	Pierce	
Clark	Graham Dialysis Center	
Vancouver Dialysis Center	Lakewood Dialysis Center	
Battle Ground Dialysis Center	Parkland Dialysis Center	
	Puyallup Dialysis Center	
Chelan	Tacoma Dialysis Center	
DaVita Dialysis Center		
Wenatchee Valley Dialysis Center	Snohomish	
	Everett Dialysis Center <sup>2</sup>	
Douglas	Mill Creek Dialysis Center	
East Wenatchee Dialysis Center	Marysville Dialysis Center <sup>3</sup>	
Franklin	Spokane	
Mid-Columbia Kidney Center	Downtown Spokane Renal Center	
	North Spokane Renal Center	
Island	Spokane Valley Renal Center	
Whidbey Island Dialysis Center		
:	Thurston	
King	Olympia Dialysis Center	
Bellevue Dialysis Center	Tumwater Dialysis Center	
Renton Dialysis Center		
Federal Way Dialysis Center	Yakima	
Kent Dialysis Center	Mt. Adams Dialysis Center	

<sup>&</sup>lt;sup>1</sup> Battle Ground Dialysis Center, Renton Dialysis Center, Marysville Dialysis Center and Zillah Dialysis Center, Tumwater Dialysis Center, Belfair Dialysis Center and Colville Dialysis Center are CN approved but not yet operational.

3 Ibid

<sup>&</sup>lt;sup>2</sup> Refuge Dialysis, LLC, is owned 80% by DaVita, Inc. and 20% by The Everett Clinic and managed by DaVita.

Olympic View Dialysis Center (management only)	Union Gap Dialysis Center
Westwood Dialysis Center	Yakima Dialysis Center '
Mason	
Belfair Dialysis Center	Kittitas
	Ellensburg Dialysis Center

#### PROJECT DESCRIPTION

DaVita proposes to relocate 10 dialysis stations from the existing 21-station Lakewood Community Dialysis Center located at 5919 Lakewood Towne Center Boulevard SW #A, within the city of Lakewood. The new 10-station facility would be located at  $1822 - 112^{th}$  Street East, Suite A, within the city of Tacoma and in the same planning area as the Lakewood facility<sup>4</sup>. The new facility would be known as 'DaVita Rainier View Dialysis Center.' [Source: Application, pages 1 and 6]

Services to be provided at DaVita Rainier View Dialysis Center includes hemodialysis with treatment shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. [Source: Application, page 9]

The capital expenditure associated with the new 10-station kidney dialysis facility is \$1,475,650. Of this amount, approximately 59% is related to leasehold improvements, 33.3% is related to fixed and moveable equipment, 4.3% is related to professional service fees and the remaining 3.4% is related to the property owner expenses, permit, and taxes. [Source: Application Page 8 and Appendix 7]

If this project is approved, DaVita anticipates the new 10 station facility would become operational by the end of November 2014. Under this timeline, calendar year 2015 would be the first full calendar year of operation and 2017 would be the year three. [Source: Application, Page 12]

# APPLICABILITY OF CERTIFICATE OF NEED LAW

WAC 246-310-289(2) states:

"When an existing facility proposes to relocate a portion of its stations to either another planning area or within the same planning area, a new health care facility is considered to be established under WAC 246-310-020(1)."

Because DaVita plans to relocate 10 of the 21 stations from Lakewood Community Dialysis Center, this project is reviewed as the establishment of a new health care 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) and WAC 246-310-289(2).

#### **EVALUATION CRITERIA**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on 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:

<sup>&</sup>lt;sup>4</sup> Floor plans submitted show the facility would be built to house a total of 12 dialysis stations. Two stations would not be certified, but would be for future expansion.

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

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

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

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects that must be used to make the required determinations. To obtain Certificate of Need approval, DaVita must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment)<sup>5</sup>. Additionally, DaVita must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.

#### TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Concurrent Review Cycle #3 for year 2013. No other kidney disease treatment center applications were received for Pierce County planning area #5 during Cycle #3. The review was converted to a regular review. A chronological summary of the review activities is in the table on the next page.

<sup>&</sup>lt;sup>5</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), (6); WAC 246-310-240(3), WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

APPLICATION CHRONOLOGY

Action	DaVita HealthCare Partners, Inc.	
Letter of Intent Submitted	July 31, 2013	
Application Submitted	August 30, 2013	
Department's pre-review activities	September 13, 2013 through	
including screening and responses	November 21, 2013	
Beginning of Review	November 22, 2013	
End of Public Comment/No Public Hearing Requested or Conducted	December 27, 2013	
Rebuttal Comments <sup>6</sup>	January 14, 2014	
Department's Anticipated Decision Date	February 28, 2014	
Department's Actual Decision Date	February 28, 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 this project, no entities sought or received an affected person status.

#### SOURCE INFORMATION REVIEWED

- DaVita HealthCare Partners, Inc.'s Certificate of Need application received on August 30, 2013
- DaVita HealthCare Partners, Inc.'s supplemental information received November 19, 2013
- Years 2007 through 2012 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2012 Northwest Renal Network 4th Quarter Data available on February 11, 2013
- Licensing and/or survey data provided by the Department of Health's Inspections and Investigation Office (IIO)
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission.aspx Medical Quality Assurance compliance data
- http://www.medicare.gov Dialysis Facilities Compare

<sup>&</sup>lt;sup>6</sup> The department did not receive any public comment therefore; no rebuttal comments from the applicant were submitted.

#### **CONCLUSION**

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to establish a new 10-station kidney dialysis center in the city of Tacoma within Pierce County planning area #5 is consistent with applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners, Inc. agrees to the following in its entirety.

#### **Project Description:**

This certificate approves the establishment of a new 10-station dialysis center in Tacoma within Pierce County planning area #5. At project completion, the dialysis center will be approved to certify and operate ten dialysis stations. The dialysis facility will offer at least in-center hemodialysis dialysis. Services to be provided at DaVita Rainier View Dialysis Center includes hemodialysis with treatment shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. A breakdown of all ten stations is below:

DaVita Rainier View Dialysis Center

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Private Isolation Room	. 1
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Other In-Center Stations	8
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After the 10 stations are relocated from the 21-station Lakewood Community Dialysis Center, the dialysis center would have 11 stations remaining. A breakdown of the remaining 11 stations is shown below.

**Lakewood Community Dialysis Center** 

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	9
Total	11

# **Conditions:**

- 1. DaVita HealthCare Partners, Inc. agrees with the project description as stated above. DaVita HealthCare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
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- 4. Prior to providing services, DaVita HealthCare Partners, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval. The executed transfer agreement must be consistent with the draft provided in the application.

<u>Approved Capital Costs:</u>
The approved capital expenditure associated with this project is \$1,475,650

#### **CRITERIA DETERMINATIONS**

# A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s project has met the applicable need criteria in WAC 246-310-210 and the kidney disease treatment standards in WAC 246-310-289.

(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 center 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 in 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.<sup>7</sup>

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

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

<sup>8</sup> 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.

<sup>&</sup>lt;sup>7</sup> 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]

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

# DaVita's Application of the Numeric Methodology

DaVita did not provide a methodology. Instead, it stated, "Because this is a partial relocation, no new stations will be added with this project. In previous certificate of need decisions, wherein a "new" facility is being established by relocation of existing stations, the department has concluded that the methodology in WAC 246-310-284 is not applicable." [Source: Application, Page 17]

# Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning area, the department used linear regression to project need. Given that the facility would be located in Pierce County planning area #5, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. The table below is the department's application of the numeric methodology for the planning area. [Source: Appendix A of this evaluation]

Table 1
Pierce County ESRD Planning Area #5 Numeric Methodology

	3			- · · · · · · · · · · · · · · · · · · ·
	Year	Year	Year	Year
· · · · · ·	2013	2014	2015	2016
In-center Patients	285.70	299.60	313.50	327.40
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need Rounded Up	60	63	66	69
Minus # CN Approved Stations	42	42	42	. 42
Net Station Need / - Surplus	18	21	24	27

<sup>\*</sup>Negative number indicates need for additional stations

Though DaVita is not proposing to add stations to the planning area, the department's projections show a need for 27 additional dialysis stations in year 2016. The department and DaVita agree that this project is required to obtain a CN before proceeding because this project would result in a new health care facility within the planning area. If approved, the project will not increase the number of CN approved dialysis stations in the planning area.

WAC 246-310-284(1) states that applications for <u>new stations</u> may only address projected station need in the planning area in which the facility is to be located. WAC 246-310-284(2) thru (4) describe the detailed steps then used to calculate the projected station need. The department calculated the methodology as prescribed in WAC 246-310-284 that demonstrated a forecasted need in the planning area for additional stations in year 2016. Review of licensing data indicates the ten stations to be relocated are currently Medicare certified and patients are being treated in them.

The department included them as CN approved stations when applying the numeric methodology. Therefore, the numeric need methodology is not applicable to this project.

#### 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 <u>new</u> stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period is August 1, 2013. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 2012, which became available on February 11, 2013. Currently there are two facilities operating in the planning area and both are owned by DaVita. The table below shows the utilization of both facilities

Table 2
NWRN Facility Utilization Data

Facility Name	# of Stations	# of Pts.	Pts./Station
DaVita Lakewood Community Dialysis Center	21	107	5.10
DaVita Parkland Dialysis Center	21	82	3.90

As shown above, DaVita's Lakewood Community Dialysis Center is operating above the required 4.8 standard and DaVita's Parkland Dialysis Center is operating below the 4.8 standard. The standard states that all CN approved stations within the planning area must be at the applicable utilization standard before new stations are added to the planning area. Since the applicant is proposing to relocate CN approved stations already counted as available in planning area, the department concludes that **this sub-criterion is not applicable**.

#### 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. DaVita Rainier View Dialysis Center would be located in the Pierce County ESRD planning area #5; therefore, the standard for this criterion is 4.8 in-center patients per approved station. The table below shows DaVita Rainier View Dialysis Center's projected utilization in the third year of operation. [Source: Application, Appendix 9]

Table 3
DaVita Rainier View Dialysis Center
Third Full Year Projected (2017) Facility Utilization

Facility Name	#of Stations	# of Pts.	Pts./Station
DaVita Rainier View Dialysis Center	10	60	6.0

As shown above, DaVita projected that DaVita Rainier View Dialysis Center would meet this standard in 2017 with all ten stations operational. The department concludes **this sub-criterion** is met.

(2) <u>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.</u>

DaVita is currently a provider of health care services to the residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the planning area would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. 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 Accepting Patients for Treatment Policy used at dialysis centers owned or operated by DaVita or its subsidiaries. The policy outlines the process and guidelines that DaVita uses to admit patients for treatment at its dialysis centers. The policy asserted that any patient needing treatment would be accepted at the dialysis facility without regard to race, creed, color, age, sex, or national origin. [Source: Application Appendix 14]

The department uses a facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. DaVita currently provides services to Medicaid eligible patients at it existing dialysis centers in Washington. A review of the proposed dialysis center anticipated revenue sources indicates that DaVita expects to receive Medicaid reimbursements. [Source: Application Page 10]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. DaVita currently provides services to Medicare eligible patients at its existing dialysis centers. A review of DaVita's anticipated revenue sources indicates that it expects to receive Medicare reimbursements. [Source: Application Page 10]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process a patient would use to access charity care at the facility. DaVita demonstrated its intent to provide charity care to patients receiving treatments at the proposed facility by providing a detailed Projected Financial Operating Statement that shows a 'charity care' line item as a deduction from revenue. [Source: Application Appendix 9] In addition, DaVita also provided a copy of its sliding fee scale from its Patient Financial Evaluation Policy – Addendum B that is used at facilities owned or operated by it.

Based on the department's review, there are pages from the Patient Financial Evaluation Policy that are missing. Given that this particular project is a relocation of 10 stations from an existing 21-station facility and therefore is not competing with another applicant for these stations, the department would attach a condition requiring that DaVita provide a complete copy of its charity care policy with all addendums for review and approval.

With DaVita's agreement to the condition related to charity care, the department expects that dialysis patients in the planning area would have access to DaVita's services. The department concludes that all residents of the planning area would have access to the health services at the facility. **This sub-criterion is met**.

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

Based on the source information reviewed and the applicant's agreement to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s project has met the financial feasibility criteria in WAC 246-310-220.

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

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

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates that the new stations would become operational by the end of November 2014. Under this timeline, calendar year 2015 would be the first full calendar year of operation and 2017 would be the year three. [Source: Application, Page 12] DaVita provided its projected revenue and expense statement for the proposed dialysis center. The table below summarizes that information. [Source: Application Appendix 9]

Table 4
DaVita Rainier View Dialysis Center
Projected Revenue and Expenses for Full Years 2015-2017

	Year -1 2015	Year 2- 2016	Year -3 2017
# of Stations	10	10	10
# of Treatments [1]	8,299	8,447	8,744
# of Patients [2]	56	58	60
Utilization Rate [2]	5,60	5.80	6.0
Net Patient Revenue[1]	\$3,195,192	\$3,317,294	\$3,502,364
Total Operating Expenses [1, 3]	\$1,926,914	\$2,018,601	\$2,113,405
Net Profit or (Loss)[1]	\$1,268,278	\$1,298,693	\$1,388,959

<sup>[1]</sup> Includes both in-center and home dialysis patients; [2] in-center patients only; [3] includes bad debt, charity care.

As shown above, DaVita Rainier View Dialysis Center would be operating at a profit beginning from partial year 2015 through the proposed project third full year of operation or by year 2018. DaVita provided an executed lease agreement between Portland Avenue Business Park, LLC ("Landlord") and Total Renal Care, Inc. ("Tenant"). [Source: Application, Appendix 15]

The department's review of the executed lease agreement shows that rent costs<sup>9</sup> identified in the lease are consistent with DaVita's pro-forma financial projections.

DaVita identified Dr. Zheng Ge as the medical director for DaVita Rainier View Dialysis Center and provided a copy of an executed medical director agreement. The initial terms of the agreement is 5 years with automatic annual renewal. The agreement identifies the annual compensation for the medical director position. Additionally, DaVita's pro-forma also confirms the annual compensation for the medical director. [Source: Application, Appendices 3 and 9] Based on the information reviewed, the department concludes **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 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.

The capital expenditure associated with the establishment of the DaVita Rainier View Dialysis Center is \$1,475,650. [Source: Application, page 8 and Appendix 15]

Table 5
DaVita Rainier View Dialysis Center Capital Cost

Item	Cost	% of Total
Leasehold improvements	\$869,963	59%
Fixed and Moveable Equipment	\$492,223	33.3%
Professional Services Fee	\$113,464	7.7%
Total Project Cost	\$1,475,650	100%

To further demonstrate compliance with this sub-criterion, DaVita provided the sources of its revenue by payer expected at the facility shown in the table below. [Source: Application, page 10]

Table 6
DaVita Rainier View Dialysis Center Revenue Source By Payer

Revenue Source	% of Revenue		
Medicare	56.7%		
Medicaid	4.5%		
Commercial /HMO	38.8%		
Total	100.0%		

The proposed DaVita Rainier View Dialysis Center is expected to obtain 38.8% of its revenue from commercial insurance/HMO. For Medicare and Medicaid, DaVita expects it would obtain 61.2% of its revenue from Medicare and Medicaid. [Source: Application, page 10] Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. Under the new ESRD PPS payment system, 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.

<sup>&</sup>lt;sup>9</sup> DaVita's lease agreement identified costs associated with the property common areas and taxes.

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 quality for Medicare payments, the department concludes that the information presented by DaVita may not have an unreasonable impact on charges for services within the planning area. Based on the information provided, the department concludes that this project would not result in an unreasonable impact on the costs and charges for health services. **This sub-criterion is met**.

# (3) The project can be appropriately financed.

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

The capital expenditure associated with the establishment of the 10-station DaVita Rainier View Dialysis Center is \$1,475,650. DaVita stated the funds needed for the project will be funded from its own reserves. A letter from DaVita chief operating officer was provided confirming the corporate funding. Based on the information provided, the department concludes **this sub-criterion is met.** 

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

Based on the source information reviewed and provided the applicant agrees to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s project has met the structure and process (quality) of care criteria in WAC 246-310-230.

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

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 (full time equivalents) that should be employed for projects of this type or size.

Since DaVita Rainier View Dialysis Center would be a new facility, DaVita provided a breakdown of all proposed staff for the proposed facility beginning from November 2014 (two partial months) and three full calendar years of operation (2015-2017). [Source: Application, page 21] A breakdown of the proposed staffing is summarized in the table below.

Table 7
DaVita Rainier View Dialysis Center proposed FTE's Year 2014 – 2017

Staff/FTEs	Partial Year - 2014	Year 1- 2015 Increase	Year 2- 2016 Increase	Year 3- 2017 Increase	Total FTEs	
Medical Director	Professional Services Contract					
Administrator	1.0	0.0	0.0	0.0	1.0	
Registered Nurses	2.1	0.0	0.0	0.1	2.2	
Patient Care Tech	4.2	0.0	0.0	0.2	4.4	
Biomedical Tech	0.3	0.0	0.0	0.0	0.3	
Administrative Assistant	0.8	. 0.1	0.1	0.0	1.0	
Social Worker	0.6	0.1	0.0	0.0	0.7	
Dietician	0.6	0.1	0.0	0.0	0.7	
Re-Use Tech	0.0	0.0	0.0	0.0	0.0	
Total FTEs	9.6	0.3	0.1	0.3	10.3	

As shown above, DaVita expects to open the facility with 9.6 FTEs and increase staffing as the utilization increases through year 2017. DaVita states it does not anticipate any difficulty recruiting staff because it offers competitive wage and benefit packages to employees. Additionally, the applicant stated that DaVita posts job openings nationally and internally and it has an extensive employee traveling program that guarantees it will maintain staffing at its facilities. [Source: Application Page 22]

DaVita identified Zheng Ge, MD as the medical director for the proposed facility and provided an executed medical director's agreement between Pacific Nephrology Associates the ("Group"), and Total Renal Care, Inc. ("Company"). According to the medical director agreement recitals, Dr. Zheng Ge is a physician employee of the Group. [Source: Application, Appendix 3] Additionally, executed medical director agreement provides two executed joinders that identified Neil Hannigan, MD and Catherine Richardson, MD who are also part of the group practice as physicians who can provide backup services at the proposed facility when necessary.

The executed medical director agreement outlines the roles and responsibilities of Group and Company. Additionally, the agreement also identifies the annual compensation for the medical director. [Source: Application Page 7 and Appendix 3] A review of the medical director's agreement between DaVita and Zheng Ge shows that the agreement outlines the roles and responsibilities of both parties involved. Based on the information reviewed, the department concludes this sub-criterion is met.

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

WAC 246-310 does not contain specific WAC 246-310-230(2) 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 relationships, ancillary and support services should be

for a project of this type and size. Therefore, using its experience and expertise the department

assessed the materials contained in the application.

As a provider of dialysis services in Washington State, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For the proposed DaVita Rainier View Dialysis Center, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site. Additional services 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, Pages 22-23]

DaVita stated because the Rainier View Dialysis Center would be a new facility in Pierce County #5, transfer agreements will be established with a local healthcare provider before the facility becomes operational. To further demonstrate compliance with this sub-criterion, DaVita provided a sample transfer agreement and stated, "Without an operating facility, actual transfer agreement with specifics cannot be executed". [Source: Application Page 22, and Appendix 12]

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

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs. WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2) (a) (ii). 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. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

As stated within this evaluation, DaVita is a provider of dialysis services in approximately 2,010 outpatient dialysis centers located in the United States. In Washington State, DaVita owns or operates 34 kidney dialysis facilities 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. <sup>10</sup>

<sup>&</sup>lt;sup>10</sup> WAC 246-310-230(5).

To comply with this sub-criterion, DaVita provided a contact list of the regulatory agencies responsible for surveying its out-of-state facilities and the District of Columbia. [Source: Application, Appendix 2] In February 2010, the department requested quality of care compliance history from out-of-state licensing and/or surveying entities and the District of Columbia where DaVita or any subsidiaries have health care facilities.

Of the 42 states and entities, the department received responses from 21 states or 50% of the 42 states. The compliance history of the remaining 21 states and the District of Columbia is unknown. Five of the 21 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Iowa that decertified and later reopened, none of the deficiencies is reported to have resulted in fines or enforcement action. All other facilities are reported to be currently in compliance with applicable regulations. [Source: compliance history from state licensing and/or surveying entities] The department concludes that considering the more than 1,642 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 Investigations and Inspections Office has completed 26 compliance surveys for the operational facilities that DaVita either owns or manages. Of the compliance surveys completed, there were minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues are typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [Source: facility survey data provided by the Investigations and Inspections Office]

For medical director services, DaVita provided an executed copy of its medical director agreement between Total Renal Care, Inc., ("Company") and Pacific Nephrology Associates ("Group") and Zheng Ge, MD ("Physician") who is part of Pacific Nephrology Associates. According to two executed joinders to the executed medical director agreement, Neil Hannigan, MD and Catherine Richardson, MD who are also part of the group practice may provide backup services if necessary. The department's review of the compliance history for Dr. Neil Hannigan and Dr. Catherine Richardson revealed no recorded sanctions or license restrictions. Based on the compliance history of DaVita and the two physicians, the department concludes that there is reasonable assurance the proposed DaVita Rainier View Dialysis Center would operate in conformance with state and federal regulations. **This sub-criterion is met**.

<sup>&</sup>lt;sup>11</sup> States that provided responses are: California, Colorado, Connecticut, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nevada, New Mexico, North Dakota, Ohio, Oregon, South Carolina, Tennessee, South Dakota and West Virginia

<sup>&</sup>lt;sup>12</sup> States that did not provide responses are Alabama, Arizona, Arkansas, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Texas, Utah, Virginia and Wisconsin. The department did not send survey to itself. The District of Columbia did not respond to the survey.

<sup>&</sup>lt;sup>13</sup> 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.

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

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

In response to this criterion, DaVita provided a summary of the quality and continuity of care indicators used at its existing facilities. The quality of care program provided by the applicant incorporates all areas of the dialysis program it monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, the applicant provided examples of its quality index data known as 'Empower'.

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, Appendices 12, 17 & 18] Since the patient transfer agreement is a draft, the department would attach a condition to the approval of this project. 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.

For this project, this sub-criterion is addressed in sub-section (3) above and is met

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s project met the cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives</u>, in terms of cost, efficiency, or effectiveness, are not available or practicable.

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

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

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

# Step One

DaVita proposed to establish a new 10-station kidney dialysis facility by relocating existing stations in Pierce County planning area #5 to a new site within the same planning area. The department concludes that the project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

# Step Two

Before submitting this application, DaVita considered the two alternatives summarized below. [Source: Application, Page 24]

# Alternative 1: Do nothing

DaVita stated it considered doing nothing but recognized the lack of patient's access if it did nothing. Therefore, it rejected this option.

# Alternative 2: Establish a new 10-station facility

The applicant stated relocating existing stations within the planning area supports patient's access in the planning area. Therefore, this option is acceptable.

#### **Departments Evaluation**

Given the options considered and given that DaVita is relocating existing stations already counted as dialysis station in the planning area capacity, the department did not identify any other alternative to the ones proposed by the applicant. The department concludes the project is the applicant best available alternative. **This sub-criterion is met.** 

#### Step Three

This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted in Pierce County ESRD planning area #5 during Review Cycle #3. Therefore, this step is not applicable to the project.

# (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.

DaVita proposes to lease the facility from a real estate developer. DaVita states that the scope and methods of the facility will meet Medicare certification and the local authority construction and energy conservation code. The proposed property lease costs were evaluated in the financial feasibility section of this analysis. Within this evaluation, the department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes this sub-criterion is met.

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

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



# 2013 Pierce County 5 ESRD Need Projection Methodology

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	Planning Area Pierce County (5)	6 Year Utilizat					
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	98388	25	33	29	38	42	39
	98430	4	5	5	5	. 6	
	98433	0	0	0	- 0	0	0
	98438	0	2 ,	1	1	2	1
	98439		0	0	0	00	0
	98444	3	3	8	6	5	6
	98445	34	37'	49	58	55	62
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		3	3	7	6	7	15
	98447 98467	0	1	0	0	0.	0
	·	11	11	13	20	19	19
•	98498	23	31	23	30	23	25
	98439	40	46	48	54	55	54
	98580	5	7	5·	6	5	5
	70744	425					
	TOTALS	182 -	211	232	255	251	271
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246-310-284(4)(a)	Rate of Change				-		
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246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
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Station Need for		_	-	[	1		
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# 2013 Pierce County 5 ESRD Need Projection Methodology

