



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

April 14, 2014

CERTIFIED MAIL # 7011 1570 0002 7809 5681

David D. Natali
Regional Operations Director
DaVita HealthCare Partners, Inc.
North Star Division
32275 32nd Avenue South
Federal Way, WA 98001

RE: CN14-21

Dear Mr. Natali:

We have completed review of the Certificate of Need application submitted by DaVita HealthCare Partners, Inc. proposing to establish a 12-station kidney dialysis facility in King 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 12 station dialysis center in Federal Way within King County planning area #5. At project completion, the dialysis center is approved to certify and operate 12 dialysis stations. Services to be provided at DaVita North Federal Way Dialysis Center include in-center hemodialysis with treatment shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. A breakdown of all 12 stations is below:

DaVita North Federal Way Dialysis Center

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	10
Total	12



After the 12 stations are relocated from the 25 station DaVita Federal Way Community Dialysis Center, that facility is approved to certify and operate the remaining 13 stations. A breakdown of the remaining 13 stations is shown below.

DaVita Federal Way Community Dialysis Center

Private Isolation Room	1
Permanent Bed Station	1
Training Station	1
Other In-Center Stations	10
Total	13

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 12 stations from the 25 station DaVita Federal Way Community Dialysis Center no later than 30 days following the opening of the new 12 station dialysis center. The DaVita Federal Way Dialysis Center would be approved to certify and operate 13 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 \$1,724,627

David D. Natali
Regional Operation Director
DaVita HealthCare Partners, Inc.
Certificate of Need Application #14-21
April 14, 2014
Page 3 of 3

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

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 APRIL 14, 2014 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA HEALTHCARE PARTNERS, INC., PROPOSING TO ESTABLISH A TWELVE STATION KIDNEY DIALYSIS FACILITY IN KING 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 2,042 outpatient dialysis centers located in the United States. [Source: Application, Page 1] In Washington State, DaVita owns or operates 34¹ 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 ²
Douglas	Mill Creek Dialysis Center
East Wenatchee Dialysis Center	Marysville Dialysis Center ³
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

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.

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

³ Ibid

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

PROJECT DESCRIPTION

DaVita proposes to relocate 12 dialysis stations from the existing 25 station DaVita Federal Way Community Dialysis Center located at 1015 S. 348th Street within the city of Federal Way. The new 12 station facility would be located at 27320 Pacific Highway South, within the city of Federal Way in the same planning area as DaVita Federal Way Community Dialysis Center⁴. The new 12 station facility would be known as 'DaVita North Federal Way Dialysis Center.' [Source: Application, pages 1 and 8]

Services to be provided at DaVita North Federal Way Dialysis Center include 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 12 station DaVita North Federal Way Dialysis Center is \$1,724,627. Of this amount, approximately \$1,069,738 or 62% is related to leasehold improvements, \$503,292 or 29.2% is related to fixed and moveable equipment \$79,750 or 4.6% is related to professional service fees, the remaining \$71,847 or 4.2% is related to landlord cost. [Source: Application Page 9 and Appendix 7]

If this project is approved, DaVita anticipates the new 12 station facility would become operational by the end of January 2015⁵. 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 11]

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 12 existing stations from the 25 stations Federal Way 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.

⁴ The facility floor plan submitted by DaVita shows that the facility would be built to house 13 stations. One station would not be certified, but would be reserved for future expansion usage.

⁵ For purposes of this evaluation, 2015 will be considered the first full year of operation.

- (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 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)⁶. 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 #4 for year 2013. No other kidney disease treatment center applications were received for King County planning area #5 during Cycle #4. Therefore, the application review was converted to a regular review. A chronological summary of the review activities is below.

⁶ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), (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	October 31, 2013
Application Submitted	November 27, 2013
Department's pre-review activities including screening and responses	November 27, 2013 through December 31, 2013
Beginning of Review	January 9, 2014
End of Public Comment/No Public Hearing Requested or Conducted	February 12, 2014
Rebuttal Comments ⁷	February 28, 2014
Department's Anticipated Decision Date	April 14, 2014
Department's Actual Decision Date	April 14, 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 November 27, 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 August 4, 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

⁷ 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 12 station kidney dialysis center in the city of Federal Way within King County planning area #5 is consistent with applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners, Inc. agree to the following in its entirety.

Project Description:

This certificate approves the establishment of a 12 station dialysis facility in Federal Way within King County planning area #5. At project completion, the dialysis center is approved to certify and operate 12 dialysis stations. Services to be provided at DaVita North Federal Way 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 12 stations is below:

DaVita North Federal Way Dialysis Center

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2. DaVita HealthCare Partners, Inc. must decertify 12 stations from the 25 station DaVita Federal Way Community Dialysis Center no later than 30 days following the opening of the new 12 station dialysis center. The DaVita Federal Way Dialysis Center would be approved to certify and operate 13 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 \$1,724,627

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 new dialysis stations within a planning area.

DaVita's Evaluation

DaVita did not provide a numeric 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 15]

Department Evaluation

Although DaVita is not proposing to add stations to the planning area, the department's projections shows a surplus of 4 dialysis stations in year 2016 (see Appendix A). 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 new stations may only address projected station need in the planning area in which the facility is to be located. This project is not proposing to add new stations to the planning area. The department's review of certification data shows the twelve stations to be relocated are currently Medicare certified and patients are being treated in them. The stations are included in the count of CN approved stations. 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 new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day

of the application submission period is November 1, 2013. [WAC 246-310-282] The quarterly modality report from NRN available at that time was June 2013, which became available on August 4, 2013. Currently DaVita Federal Way Community Dialysis Center is the only facility operational in the planning area. The table below shows the utilization of that facility.

**Table 2
NWRN Facility Utilization Data**

Facility Name	# of Stations	# of Pts.	Pts./Station
DaVita Federal Way Community Dialysis Center	25	115	4.60

As shown above, DaVita Federal Way Community Dialysis Center is not operating at or above the required 4.8 standard. However, 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 existing CN approved stations 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 North Federal Way Dialysis Center would be located in the King 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 North Federal Way Dialysis Center projected utilization in the third year of operation. [Source: Application, Appendix 9]

**Table 3
DaVita North Federal Way Dialysis Center
Third Full Year Projected (2017) Facility Utilization**

Facility Name	#of Stations	# of Pts.	Pts./Station
DaVita North Federal Way Dialysis Center	12	72	6.0

Although DaVita projected that DaVita North Federal Way Dialysis Center would meet this standard in 2017 with all 12 stations operational these stations are not new and therefore this standard does not apply. The department concludes **this sub-criterion is met.**

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

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 its 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 12 stations from an existing 25-station facility and therefore is not competing with another applicant for these stations, if approved 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. **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 January 2015. 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 11] 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 North Federal Way Dialysis Center
Projected Revenue and Expenses for Full Years 2015-2017

	Year -1 2015	Year 2- 2016	Year -3 2017
# of Stations	12	12	12
# of Treatments [1]	8,447	9,781	10,374
# of Patients [2]	64	65	72
Utilization Rate [2]	5.33	5.42	6.00
Net Patient Revenue[1]	\$3,184,670	\$3,761,263	\$4,069,002
Total Operating Expenses [1, 3]	\$2,216,456	\$2,487,209	\$2,739,161
Net Profit or (Loss)[1]	\$968,214	\$1,274,054	\$1,329,841

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

As shown above, DaVita North Federal Way 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 2017. DaVita provided an executed lease agreement between Karl Edmark (“Landlord”) and Total Renal Care, Inc. (“Tenant”)⁸. [Source: Application, Appendix 15]

The department’s review of the executed lease agreement shows that rent costs⁹ identified in the lease are consistent with DaVita’s pro-forma financial projections. DaVita identified Dr. Di Zhao as the medical director for DaVita North Federal Way Dialysis Center and provided a

⁸ Total Renal Care, Inc. is the parent company of DaVita Healthcare Partners, Inc.

⁹ DaVita’s lease agreement identified costs associated with the property common areas and taxes.

copy of an executed medical director agreement. The initial term of the agreement is 5 years and renewal is subject to all parties mutual consent.

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 DaVita North Federal Way Dialysis Center is \$1,724,627. [Source: Application, page 8 and Appendix 7]

**Table 5
DaVita North Federal Way Dialysis Center Capital Cost**

Item	Cost	% of Total
Leasehold improvements	\$1,069,738	62.0%
Fixed and Moveable Equipment	\$503,292	29.2%
Professional Service Fees	\$79,750	4.6%
Landlord Fees	\$71,847	4.2%
Total Project Cost	\$1,724,627	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 North Federal Way 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 North Federal Way 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. 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 payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer 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 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 12 station DaVita North Federal Way Dialysis Center is \$1,724,627. DaVita stated funds needed for the project would be funded from its own reserves. A letter from DaVita's 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 North Federal Way Dialysis Center would be a new facility, DaVita provided a breakdown of all the proposed staff for the first three full calendar years of operation (2015-2017). [Source: Application, page 19] A breakdown of the proposed staffing is summarized in Table 7.

Table 7
DaVita North Federal Way Dialysis Center
Proposed FTE's Year 2015 – 2017

Staff/FTEs	Year 1- 2015	Year 2- 2016 Increase	Year 3- 2017 Increase	Total FTEs
Medical Director	Professional Services Contract			
Administrator	1.0	0.0	0.0	1.0
Registered Nurses	2.4	0.1	0.3	2.8
Patient Care Tech	5.5	0.5	1.0	7.0
Biomedical Tech	0.3	0.0	0.0	0.3
Administrative Assistant	0.8	0.0	0.0	0.8
Social Worker	0.6	0.1	0.1	0.8
Dietician	0.6	0.1	0.1	0.8
Total FTEs	11.2	0.8	1.5	13.5

As shown above, DaVita expects to open the facility with 11.2 FTEs and it would increase staffing as 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, DaVita stated it post job openings nationally and internally and it has an extensive employee traveling program that guarantees it will maintain staffing at its facilities. [Source: Application Pages 19- 20]

Since this project is partial relocation of existing stations within the same planning area, the department also expects some existing staff to move to the new facility since it is unlikely DaVita would need the same staffing level at the current facility with 12 fewer stations.

DaVita identified Di Zhao, 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. Di Zhao is a physician employee of the Group. [Source: Application, Appendix 3] Additionally, the executed medical director agreement provides three executed joinders that identified Yajuan He, MD, Zheng Ge, 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 executed medical director's agreement between DaVita and Pacific Nephrology 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 North Federal Way 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 20 and 21]

DaVita stated because the North Federal Way Dialysis Center would be a new facility in King County planning area #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 21, 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) (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. 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 2,042 outpatient dialysis centers located across 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.¹⁰ 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.¹¹ The compliance history of the remaining 21 states and the District of Columbia is unknown.¹² 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.¹³ 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 2,042 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 as the agent for the Centers for Medicare and Medicaid Services 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 Di Zhao, MD ("Physician") who is part of Pacific Nephrology Associates. According to three executed joinders to the executed medical director agreement, Yajuan He, MD, Zheng Ge, MD and Catherine Richardson, MD who are part of the group practice may provide backup services if necessary. The department's review of the compliance history of all proposed medical directors revealed no recorded sanctions or license restrictions. Based on the compliance history of DaVita and the three physicians, the department concludes that there is reasonable assurance the proposed DaVita North Federal Way Dialysis Center would operate in conformance with state and federal regulations. **This sub-criterion is met.**

¹⁰ WAC 246-310-230(5).

¹¹ 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

¹² 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.

¹³ 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 if this project is approved 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) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

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

If the project met WAC 246-310-210 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 12-station kidney dialysis facility by relocating existing stations in King County planning area #5 to a new site within the same planning area. The department concludes that the project met the applicable 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 only the alternative of do nothing. Below is the review of the alternative and DaVita's rationale for rejecting it. [Source: Application, Page 22]

Do nothing

DaVita stated it considered doing nothing, but recognized this option would not improve patient access within the planning area. Therefore, it rejected this option.

Department Evaluation

DaVita chose to relocate existing stations already counted as station capacity in the planning area. The department did not identify any other alternative that should have been considered. 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 King County ESRD planning area #5 during Review Cycle #4. 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.**