



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

May 18, 2012

Certified Mail 7011 1570 0002 7802 6050

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

RE: CN12-20

Dear Mr. Bosh:

We have completed the review of DaVita, Inc's application proposing to add two stations to its Ellensburg Dialysis Center within Kittitas County. For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided DaVita, Inc. agrees to the following in its entirety.

Project Description:

This project approves the addition of two dialysis stations at DaVita Ellensburg Dialysis Center located at 2101 West Dolarway Road, #1 in Ellensburg, within Kittitas County. At project completion, the dialysis center would certify and operate seven dialysis stations. DaVita Ellensburg Dialysis Center provides services to only hemodialysis patients who dialyze in the chronic setting. The seven-dialysis stations operational at the facility are listed below:

Private Isolation Room	0
Permanent Bed Station	0
Home Training Station	0
Other In-Center Stations	7
Total	7

Condition:

1. DaVita, Inc. agrees with the project description as stated above.

Approved Capital Costs

The approved capital expenditure associated with this project is \$195,760.

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This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any interested or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

Mailing Address:

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

Appeal Option 2:

You or any affected person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:

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

Other Than By Mail

Adjudicative Clerk Office
310 Israel Road SE, Building 6
Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerely,



Steven M. Saxe, FACHE
Director, Health Professions and Facilities

Enclosure

cc: Linda Foss, Department of Health, Investigations and Inspections Office
Karen Stricklett, Department of Health, Customer Service Office

EVALUATION DATED MAY 18, 2012, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA, INC., PROPOSING TO ADD TWO KIDNEY DIALYSIS STATIONS TO THE EXISTING DAVITA ELLENSBURG DIALYSIS CENTER IN KITTITAS COUNTY

APPLICANT DESCRIPTION

DaVita Inc. (DaVita) is a for-profit corporation that currently operates or provides administrative services to approximately 1,642 dialysis facilities located in 43 states and the District of Columbia. DaVita also provides acute inpatient kidney dialysis services in over 720 hospitals throughout the country. [Source: Amended Application, p5] In Washington State, DaVita owns or operates 29 kidney dialysis facilities in 13 separate counties. Below is a listing of the 29 facilities.¹ [source: Application, p5]

Benton	Pacific
Chinook Dialysis Center	Seaview Dialysis Center
Kennewick Dialysis Center	
Clark	Pierce
Battleground Dialysis Center	Graham Dialysis Center
Vancouver Dialysis Center	Lakewood Dialysis Center
	Parkland Dialysis Center
Douglas	Puyallup Dialysis Center
East Wenatchee Dialysis Center	Tacoma Dialysis Center
Franklin	Snohomish
Mid Columbia Kidney Center	Everett Dialysis Center ²
	Mill Creek Dialysis Center
Island	
Whidbey Island Dialysis Center	Spokane
	Downtown Spokane Renal Center
King	North Spokane Renal Center
Bellevue Dialysis Center	Spokane Valley Renal Center
Des Moines Dialysis Center	
Federal Way Dialysis Center	Thurston
Kent Dialysis Center	Olympia Dialysis Center
Olympic View Dialysis Center (management only)	
Westwood Dialysis Center	Yakima
	Mt. Adams Dialysis Center
Kittitas	Union Gap Dialysis Center
Ellensburg Dialysis Center	Yakima Dialysis Center

¹ Battleground Dialysis Center, Des Moines Dialysis Center, East Wenatchee Dialysis Center, and Kennewick Dialysis Center are CN approved but not yet operational.

² Refuge Dialysis, LLC, whose ownership is 80% DaVita and 20% The Everett Clinic, owns this facility.

PROJECT DESCRIPTION

DaVita proposes to add two stations to the existing five stations facility known as ‘DaVita Ellensburg Dialysis Center’ located at 2101 West Dolarway Road, Suite #1 within the city of Ellensburg in Kittitas County. DaVita Ellensburg Dialysis Center provides services to only hemodialysis patients who dialyze in the chronic setting. [source: Application, p9 and Appendices 11 and 16]

The capital expenditure associated with this project is \$195,760. Of that amount, approximately 83.3% is related to leasehold improvements and the remaining 16.7% is related to fixed and moveable equipment. [source: Application, p8]

If this project is approved, DaVita anticipates the two new stations would be operational by the end of September 2012. Under this timeline, calendar year 2013 would be the facility’s first full year of operation with seven dialysis stations, and 2015 would be year three. [source: Application, pp11-12]

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

CRITERIA EVALUATION

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for 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:

- (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 and 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)³. Additionally, DaVita must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.

APPLICATION CHRONOLOGY

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 2011. No other kidney disease treatment center applications were received for Kittitas County ESRD planning area during Cycle #4, therefore; the review was converted to a regular review. A chronological summary of the review activities is shown below.

Action	Dates
Letter of Intent Submitted	October 31, 2011
Application Submitted	November 30, 2011
Department’s pre-review activities including screening and responses	December 1, 2011 through February 21, 2012
Beginning of Review	February 22, 2012
End of Public Comment/No Public Hearing Requested or Conducted	March 27, 2012
Rebuttal Comments Received ⁴	April 10, 2012
Department's Anticipated Decision Date	May 11, 2012
Department's Actual Decision Date	May 18, 2012

³ 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); and WAC 246-310-240(2), (3); WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

⁴ The department did not receive any public comment for this project, as a result, DaVita did not submit any rebuttal documents.

AFFECTED AND INTERESTED 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 and received affected person status.

SOURCE INFORMATION REVIEWED

- DaVita, Inc.’s Certificate of Need application received November 30, 2011
- DaVita, Inc.’s Supplemental information received February 14, 2012
- Years 2005 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 2nd Quarter Data available on August 15, 2011
- Licensing and/or survey data provided by the Department of Health’s Office of Investigation and Inspections
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- Medical Quality Assurance compliance data

CONCLUSION

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

Project Description:

This project approves the addition of two dialysis stations at DaVita Ellensburg Dialysis Center located at 2101 West Dolarway Road, #1 in Ellensburg, within Kittitas County. At project completion, the dialysis center would certify and operate seven dialysis stations. DaVita Ellensburg Dialysis Center provides services to only hemodialysis patients who dialyze in the chronic setting. The seven-dialysis stations operational at the facility are listed below:

Private Isolation Room	0
Permanent Bed Station	0
Home Training Station	0
Other In-Center Stations	7
Total	7

Condition:

1. DaVita, Inc. agrees with the project description as stated above.

Approved Capital Costs

The approved capital expenditure associated with this project is \$195,760.

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

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, Inc.’s project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284.

- (1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

WAC 246-310-284 requires the department to evaluate kidney disease treatment center applications based on the population’s 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.⁵

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

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

⁵ Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

⁶ WAC 246-310-280 defines base year as “the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report.”

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

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

DaVita’s Application of the Numeric Methodology

To determine the type of regression analysis to be used to project station need, DaVita used 2005 through 2010 data for the planning area. Based on that data DaVita used linear regression. The table below shows DaVita’s application of the numeric methodology for Kittitas County ESRD Planning area. [source: Application, pp15-16]

Table 1
Summary of DaVita’s Kittitas County ESRD Planning Area Numeric Methodology

	Year 2011	Year 2012	Year 2013	Year 2014
In-center Patients	14.6	16.4	18.2	20.0
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need (rounded)	5	6	6	7
Minus # CN Approved Stations	5	5	5	5
Net Station Need / (Surplus)	0	1	1	2

As shown in the table above, DaVita projected need for two stations in year 2014, and submitted an application requesting to add two stations to its existing capacity in the planning area.

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning area as described above, the department used linear regression to project need. The number of projected patients (unrounded) was divided by 3.2 to determine the number of new stations needed in the planning area. The net station need for Kittitas County ESRD planning area is two stations. The table below summarizes the department’s application of the numeric methodology for the planning area.

Table 2
Summary of Department's Numeric Methodology
Kittitas County ESRD Planning Area

	Year 2011	Year 2012	Year 2013	Year 2014
In-center Patients	14.60	16.40	18.20	20.00
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need Rounded Up	5	6	6	7
Minus # CN Approved Stations	5	5	5	5
Net Station Need / (Surplus)	0	1	1	2

When comparing the results of Tables 1 and 2 above, both DaVita and the department projected a numeric need for two stations in year 2014. The department's numeric methodology for Kittitas County ESRD planning area is attached to this evaluation as Appendix A.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 3.2 in-center patients per station before new stations can be added. DaVita Ellensburg Dialysis Center is the only dialysis facility located in the planning area. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for this project is November 1, 2011. [WAC 246-310-282] The quarterly modality report from NRN available at that time was June 30, 2011, which became available on August 15, 2011. The table below shows DaVita Ellensburg Dialysis Center utilization as of June 30, 2011.

Table 3
NWRN Facility Utilization

Facility Name	#of Stations	# of Pts	Pts/Station Standard	Pts/Station
DaVita Ellensburg	5	16	3.2	3.20

As shown in the table above, **this standard is met.**

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. DaVita Ellensburg Dialysis Center is located in Kittitas County; therefore, the standard for this criterion is 3.2 in-center patients per approved station. DaVita states that year 2015 would be the third year of operation with seven stations and its year 2015 projected utilization is shown below.

Table 4
DaVita Ellensburg Dialysis Center
Third Full Year Projected (2015) Facility Utilization

Facility Name	#of Stations	# of Pts	Pts/Station
DaVita Ellensburg Dialysis Center	7	23	3.29

As shown above, DaVita Ellensburg Dialysis Center would be operating at 3.29 patients per station by year 3 using their information. [source: Application, p17 and February 14, 2012, supplemental information] **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 residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of Kittitas County ESRD 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.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current Accepting Patients for Treatment Policy used at the dialysis center. The policy outlines the process and guidelines that DaVita uses to admit patients for treatment at the dialysis center. The policy also states that any patient needing treatment will be accepted to any facility without regard to race, creed, color, age, sex, or national origin. [source: Application, Appendix 14]

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. DaVita currently provides services to Medicaid eligible patients at the existing dialysis center. The applicant intends to continue to provide services to Medicaid patients at the DaVita Ellensburg Dialysis Center. A review of the anticipated revenue sources indicates that the facility expects to continue to receive Medicaid reimbursements. [source: Application, p10 and February 14, 2012, supplemental information, p3]

To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination. DaVita currently provides services to Medicare patients at the existing dialysis center. DaVita intends to continue to provide services to Medicare patients at the existing facility. A review of the anticipated revenue sources indicates that it expects to continue to receive Medicare reimbursements. [source: Application, p10 and February 14, 2012, supplemental information, p3]

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 one must use to access charity care at the facility.

DaVita demonstrated its intent to continue to provide charity care to patients receiving treatment at the facility by submitting its current Indigent Care Policy that outlines the process one would use to access this service. DaVita also included a 'charity care' line item as a deduction from revenue within the pro forma income statements documents. [source: February 14, 2012, supplemental Information]

The department concludes that all residents of the planning area would continue to 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 provided the applicant agrees to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita, Inc.'s project has met the financial feasibility criteria in WAC 246-310-220

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

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

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 September 2012. Under this timeline, year 2013 would be the facility's first full calendar year of operation with seven stations. Year 2015 would be the third full year of operation. [source: Application, page 12]

DaVita provided its projected revenue and expense statement for the DaVita Ellensburg Dialysis Center as a seven-station facility. The table below summarizes that information. [source: Supplemental information received February 14, 2012]

Table 5
DaVita Ellensburg Dialysis Center
Projected Revenue and Expenses for Partial Year 2012 and Full Years 2013-2015

	Partial Year 2012	CY 1 2013	CY 2 2014	CY 3 2015
# of Stations	7	7	7	7
# of Treatments [1]	783	2,653	3,067	3,495
# of Patients [2]	17	18	20	23
Utilization Rate [2]	2.43	2.57	2.86	3.29
Net Patient Revenue[1]	\$576,077	\$1,830,247	\$2,129,101	\$2,454,040
Total Operating Expenses [1, 3]	\$220,291	\$667,890	\$741,605	\$855,553
Net Profit or (Loss)[1]	\$355,786	\$1,162,357	\$1,387,496	\$1,598,487

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

As shown above, DaVita Ellensburg Dialysis Center would be operating at a profit in partial year 2012 though the third year of operation.

As an existing facility, DaVita provided an executed lease agreement (first amendment to lease agreement) between Rolmor, LLC as successor to Sherwood Investment, LLC (“Lessor”) and Renal Treatment Centers-West (“Lessee”). [source: Application, Appendix 15]

The department’s review of the executed lease agreement shows that the lease costs identified in the lease are consistent with the pro-forma financial projections.

DaVita provided a copy of its current medical director’s services agreement that identifies the annual compensation for the medical director position. Additionally, DaVita’s pro-forma financial statement identified the annual compensation for the medical director. [source: Application, Appendix 3 and February 14, 2012, supplemental information]

Based on the information, the department concludes that the projected revenue and expenses are reasonable and can be substantiated. **This sub-criterion is met.**

(2) *The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.*

WAC 246-310 does not contain specific 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.

DaVita identified the capital expenditure associated with the addition of two new stations to the DaVita Ellensburg Dialysis Center to be \$195,760, which is broken down in the table below. [source: Application, Appendix 7]

Table 6
DaVita Ellensburg Dialysis Center Capital Cost

Item	Cost	% of Total
Leasehold Improvement	\$163,000	83.3%
Fixed and Moveable Equipment	\$32,760	16.7%
Total Project Cost	\$195,760	100.0%

To further demonstrate compliance with this sub-criterion, DaVita provided the sources of its patient revenue shown in the table below. [source: Application, p10]

Table 7
DaVita Ellensburg Dialysis Center Source of Revenue

Source of Revenue	% of Revenue
Medicare	22.10%
State (Medicaid)	4.30%
Commercial	73.60%
Total	100.00%

The existing DaVita Ellensburg Dialysis Center is expected to have 26% of its revenue from Medicare and Medicaid entitlement programs. These programs are not cost based reimbursement and are not expected to have an unreasonable impact on the charges for services. Based on the department’s review of the application materials, this same conclusion can be made for those with insurance or HMO patients that make up 74% of the project’s revenue. Therefore, the department concludes that this project would probably 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 addition of two stations to DaVita Ellensburg Dialysis Center is \$195,760. DaVita states the project will be funded from its own reserves. A letter from DaVita’s chief operating officer was provided confirming the corporate funding. [source: Application, Appendix 6] A review of DaVita’s audited financial statements shows the funds necessary to finance the project are available. [source: Application, Appendices 6 and 10]

Based on the information provided, the department concludes that the project can be appropriately financed. **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, 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.

As an existing facility, DaVita Ellensburg Dialysis Center currently has 4.1 FTEs. With the additional two stations, DaVita expects to increase to 4.9 FTEs. The facility’s existing and proposed FTEs are shown in the table below.

Table 8

DaVita Ellensburg Dialysis Center Current and proposed FTE’s 2012 – 2017

Staff/FTEs	Partial Year 2012	CY 1-2013 Increase	CY 2-2014 Increase	CY 3-2015 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	0.20	0.00	0.00	0.10	0.30
Registered Nurses	1.00	0.00	0.00	0.20	1.20
Patient Care Tech	2.00	0.00	0.00	0.40	2.40
Biomedical Tech	0.30	0.00	0.00	0.00	0.30
Admin Assistant	0.20	0.00	0.00	0.00	0.20
Social Worker	0.20	0.00	0.00	0.00	0.20
Dietician	0.20	0.00	0.00	0.00	0.20
Number of FTE'S	4.10	0.00	0.10	0.70	4.90

As shown above, DaVita expects to increase FTE’s beginning in year two. DaVita states it does not anticipate any difficulty recruiting staff because it offers competitive wage and benefit package to employees. Additionally, DaVita states that job openings are posted nationally and internally and it has extensive employee travelling program that guarantee it will maintain staffing at its facilities. [source: Application, page 23]

DaVita identified Sajal Kumar, MD as the successor medical director for the existing DaVita Ellensburg Dialysis Center and provided an executed joinder to medical director’s agreement between Total Renal, Inc. (“Company”), and J. Hamilton Licht, P.C., d/b/a Nephrology Associates of Yakima (“Group”), and J. Hamilton Licht, MD, and Sajal Kumar, M.D. (“Physician”). [source: Application, Page 7 and Appendix 3] The joinder medical director agreement outlines the roles and responsibilities of the Company, Group, and Physician.

In addition, the joinder agreement also identifies the annual compensation for the medical director and the applicant's pro-forma financial statement shows the medical director compensation. [source: Application p7 and Appendix 3; February 14, 2012, supplemental information] Based on the information provided the department concludes that sufficient staffing is available or can be recruited. **This sub-criterion is met.**

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

WAC 246-310 does not contain specific WAC 246-310-230(2) 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 its existing Ellensburg Dialysis Center, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services are already 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, p23]

DaVita also provided a copy of its existing Patient Transfer Agreement with Memorial Hospital in Yakima. The agreement outlines the roles and responsibilities of both entities. Nothing in the documents provided suggests that approval of two stations at Ellensburg Dialysis Center would change the agreement. [source: Application, Appendix 12]

Based on the evaluation of supporting documents provided, the department concludes that there is reasonable assurance that DaVita Ellensburg Dialysis Center will continue to have appropriate ancillary and support services with a healthcare provider in Kittitas County ESRD planning area. **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.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,642 outpatient centers located in 43 states (including Washington State), and the District of Columbia. [source: Application, p1] For Washington State, DaVita owns or operates 25 kidney dialysis treatment centers in 12 separate counties. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.⁷ 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, Inc. 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.⁸ The compliance history of the remaining 19 states and the District of Columbia is unknown.⁹

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.¹⁰ 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 2008, the Department of Health's Investigations and Inspections Office has completed 26 compliance surveys for the operational facilities that DaVita either owns or manages.¹¹ Of the compliance surveys completed, there were minor non-compliance issues related to the care and management at the DaVita facilities.

⁷ WAC 246-310-230(5).

⁸ 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

⁹ 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.

¹⁰ 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.

¹¹ As of the writing of this evaluation, DaVita's Battleground Dialysis Center and East Wenatchee Dialysis Centers are not yet operational. The Everett Dialysis Center and Olympic View Dialysis Center are both operational, and managed by DaVita.

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 a copy of its medical director agreement with Sajal Kumar, MD, who is part of the Nephrology Associates of Yakima practice. Two other physicians are part of the practice, and according to the medical director agreement, may provide backup services if necessary. The department's review of the compliance history for Dr. Sajal Kumar, Dr. J Hamilton Licht, and Dr. Karen Harrison revealed no recorded sanctions or license restrictions.

Given the compliance history of DaVita and that of the medical director and nephrology group, the department concludes that there is reasonable assurance the proposed DaVita Ellensburg would continue to operate in conformance with state and federal regulations. **This sub-criterion is met.**

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

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

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program it monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, DaVita also provided examples of its quality index data and its physician, community, and patient services program known as 'Empower'. DaVita also provided a copy of its executed Patient Transfer Agreement with Memorial Hospital in Yakima. [source: Application, p23 and Appendices 12, 17, and 18]

Based on this information, the department concludes the applicant has demonstrated it has, and will continue to have, appropriate relationships with a health care provider in the planning area. **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 considered met.**

D. Cost Containment (WAC 246-310-240) and WAC 246-310-288 (Tie Breakers)

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, Inc.’s project has met the cost containment criteria in WAC 246-310-240

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

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

If the project met WAC 246-310-210 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 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 assess 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’s proposal to add two stations to the existing five-station Ellensburg Dialysis Center has met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two.

Step Two

Before submitting this application, DaVita considered only the alternative of adding a third shift to the dialysis center, but rejected this option because WAC 246-310-284(5) allows Kittitas County to operate at 3.2 patients per station before new stations can be added. Therefore, adding a third patient shift is not desirable at this facility. [source: Application, p25]

Given that the existing facility's current utilization exceeds 3.2 patients per station, and the results of the numeric methodology show a need for two stations in Kittitas County, the department concludes that this project submitted by DaVita is the best available alternative for the planning area. **This sub-criterion is met.**

Step Three

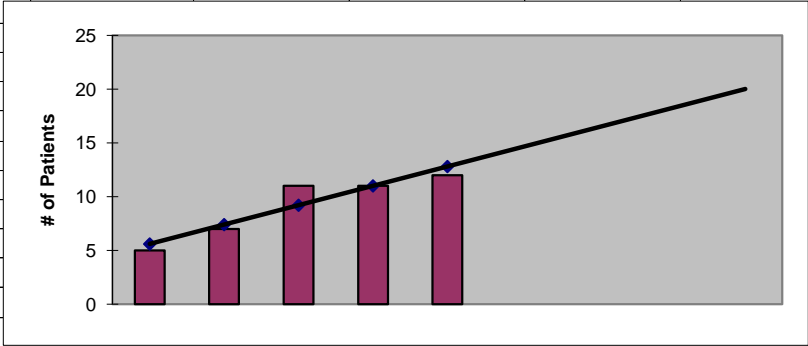
This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted to add dialysis stations in Kittitas County ESRD planning area during the Kidney Disease Treatment Centers Review Cycle #4. This step is not applicable to the project.



**2011
Kittitas County
ESRD Need Projection Methodology**

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Kittitas		2005	2006	2007	2008	2009	2010
Kittitas		6	5	7	11	11	12
TOTALS		6	5	7	11	11	12
246-310-284(4)(a)	Rate of Change		-16.67%	40.00%	57.14%	0.00%	9.09%
	6% Growth or Greater?		FALSE	TRUE	TRUE	FALSE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
				2011	2012	2013	2014
Projected Resident Incenter Patients	from 246-310-284(4)(b)			14.60	16.40	18.20	20.00
Station Need for Patients	Divide Resident Incenter Patients by 3.2			4.5625	5.1250	5.6875	6.2500
	Rounded to next whole number			5	6	6	7
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				5	5	5	5
Results of (4)(c) above			-	5	6	6	7
Net Station Need				0	-1	-1	-2
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
DaVita Ellensburg	5	12	2.40				
Total	5	12					
Source: Northwest Renal Network data 2005-2010							
Most recent year-end data: 2010 year-end data as of 02/16/2011							
Most recent quarterly data as of the 1st day of application submission period: 2nd quarter 2011 as of 08/15/11							

x	y	Linear
2006	5	6
2007	7	7
2008	11	9
2009	11	11
2010	12	13
2011		14.600
2012		16.400
2013		18.200
2014		20.000



SUMMARY OUTPUT

<i>Regression Statistics</i>	
Multiple R	0.938314863
R Square	0.880434783
Adjusted R Square	0.84057971
Standard Error	1.211060142
Observations	5

ANOVA					
	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	32.4	32.4	22.09090909	0.018219855
Residual	3	4.4	1.466666667		
Total	4	36.8			

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>
Intercept	-3605.2	769.0056437	-4.688132044	0.018346156	-6052.519169	-1157.88083	-6052.519169	-1157.88083
X Variable 1	1.8	0.382970843	4.700096711	0.018219855	0.581215855	3.018784145	0.581215855	3.018784145

RESIDUAL OUTPUT

<i>Observation</i>	<i>Predicted Y</i>	<i>Residuals</i>
1	5.6	-0.6
2	7.4	-0.4
3	9.2	1.8
4	11	0
5	12.8	-0.8