

EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF DAVITA, INC. PROPOSING TO ADD THREE DIALYSIS STATIONS TO THE EXISTING FACILITY KNOWN AS ELLENSBURG DIALYSIS CENTER

APPLICANT DESCRIPTION

DaVita, Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,400 outpatient centers located in 43 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in approximately 700 hospitals throughout the country. [source: Application, p5; DaVita website]

In Washington State, DaVita owns or operates a total of 24 kidney dialysis facilities in 12 separate counties. Below is a listing of the DaVita facilities in Washington. [source: CN historical files; DaVita Application, p5]

Clark

Vancouver Dialysis Center

Pacific

Seaview Dialysis Center

Island

Whidbey Island Dialysis Center

Pierce

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

Yakima

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

Benton

Kennewick Dialysis Center
Richland Dialysis Center

Franklin

Mid-Columbia Kidney Center

Kittitas

Ellensburg Dialysis Center

Klickitat

Goldendale Dialysis Center

Thurston

Olympia Dialysis Center

King

Bellevue Dialysis Center
Federal Way Community Dialysis Center
Kent Community Dialysis Center
Olympic View Dialysis Center (Mgmt. only)
Westwood Dialysis Center

Snohomish

Everett Dialysis Center
Mill Creek Dialysis Center

PROJECT DESCRIPTION

This application relates to the Ellensburg Dialysis Center located 2121 West Dolarway in Ellensburg, within Kittitas County. Currently Ellensburg Dialysis Center operates two dialysis stations, and this project proposes to add three dialysis stations, for a facility total of five. [source: Application, cover sheet]

The capital expenditure associated with the addition of three stations is \$118,365, of which approximately 42% is related to leasehold improvements at the site; 40% is related to both fixed and moveable equipment; and the remaining 18% is related to application fees. [source: Application, Appendix 7]

If this project is approved, DaVita anticipates the three additional stations would become operational within four months of approval. Under this timeline, year 2011 would be the facility's first full calendar year of operation and 2013 would be year three. [source: Application, p13]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the increase in the number of dialysis stations at a kidney disease treatment center 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 in how the department is to make its determinations. It states:

“Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

(a) In the use of criteria for making the required determinations, the department shall consider:

- (i) The consistency of the proposed project with service or facility standards contained in this chapter;*
- (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
- (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.”*

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

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

- (i) Nationally recognized standards from professional organizations;*
- (ii) Standards developed by professional organizations in Washington state;*
- (iii) Federal Medicare and Medicaid certification requirements;*
- (iv) State licensing requirements;*
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*

(vi) *The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.*”

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, DaVita, Inc. must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment). Additionally, DaVita must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.¹

CONCURRENT REVIEW CYCLE AND APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #2. No other kidney disease treatment center applications were reviewed for the Kittitas County planning area during Review Cycle #2. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

April 30, 2009	Letter of Intent Submitted
May 29, 2009	Application Submitted
June 1, 2009 through August 16, 2009	Department’s Pre-Review Activities <ul style="list-style-type: none">• screening activities and responses
August 17, 2009	Department Begins Review of the Application <ul style="list-style-type: none">• public comments accepted throughout the review• no public hearing requested or conducted
September 21, 2009	End of Public Comment
October 6, 2009	Rebuttal Documents Received at Department ²
November 20, 2009	Department's Anticipated Decision Date
October 26, 2009	Department's Actual Decision Date

AFFECTED PERSONS

Throughout the review of this project, no entities sought or received affected person status under WAC 246-310-010.

¹ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

² Since no public comment was submitted related to this project; no rebuttal documents were submitted by DaVita.

SOURCE INFORMATION REVIEWED

- DaVita's Certificate of Need application submitted May 29, 2009
- DaVita's supplemental information received August 10, 2009
- Years 2003 through 2008 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2008 Northwest Renal Network 4th Quarter Data
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from DaVita, Inc.'s webpage (davita.com)
- Medical Quality Assurance compliance data

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to add three dialysis stations to the existing two-station facility known as Ellensburg Dialysis Center is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need should be issued.

A. Need (WAC 246-310-210) Need, Kidney Disease Treatment Centers-Methodology (WAC 246-310-284)

Based on the source information reviewed, the department determines that DaVita, Inc. has met the need criteria in WAC 246-310-210(1) and (2) and the applicable kidney disease treatment center standards and methodology in WAC 246-310- 284.

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

WAC 246-310-284 requires the department to evaluate kidney disease treatment centers applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

Kidney Disease Treatment Center Methodology WAC 246-310-284

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.³

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.⁴ 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)]

³ 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]

⁴ WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report." For this project, the base year is 2008.

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

DaVita proposes to add three stations to the existing two station facility located in Kittitas County. Based on the calculation of the annual growth rate in the planning area as described above, linear regression is used to project need. Given that the facility is located in Kittitas County, the number of projected patients is divided by 3.2 to determine the number of stations needed in the planning area.

Table 1 below is a summary of DaVita’s application of the numeric methodology. [source: Application pp18-20]

**Table 1
Summary of DaVita’s Numeric Methodology**

	Year 2009	Year 2010	Year 2011	Year 2012
Incenter Patients	10.7	12.0	13.3	14.6
Patient: Station Conv. Factor	3.2	3.2	3.2	3.2
Total Station Need	3.34	3.75	4.16	4.56
Total Station Need Rounded Up	4	4	5	5
Minus # of CN Approved Stations	2	2	2	2
Net Station Need / (Surplus)	2	2	3	3

As shown in Table 1 above, DaVita projected a need for 3 additional dialysis stations in year 2012.

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project need. Given that the facility is located in Kittitas County, the number of projected patients is divided by 3.2 to determine the number of stations needed in the planning area.

Table 2 on the following page is a summary of the department’s application of the numeric methodology. [source: Appendix A of this evaluation]

**Table 2
Summary of Department's Numeric Methodology**

	Year 2009	Year 2010	Year 2011	Year 2012
Incenter Patients	10.7	12.0	13.3	14.6
Patient: Station Conv. Factor	3.2	3.2	3.2	3.2
Total Station Need	3.34	3.75	4.16	4.56
Total Station Need Rounded Up	4	4	5	5
Minus # of CN Approved Stations	2	2	2	2
Net Station Need / (Surplus)	2	2	3	3

As shown in Table 2, the department also projected a need for 3 additional dialysis stations in year 2012. In summary, DaVita and the department both determined need for 3 additional dialysis stations in year 2012.

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's Ellensburg Dialysis Center is the only facility operating in the Kittitas County 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 is May 1, 2008. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2008, which became available on January 26, 2009. Table 3 below shows the utilization of Ellensburg Dialysis Center as of December 31, 2008.

**Table 3
December 31, 2008 - Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
DaVita's Ellensburg Dialysis Center	2	8	4.0

Table 3 above demonstrates that Ellensburg Dialysis Center meets this capacity requirement.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For the Ellensburg Dialysis Center located in Kittitas County, the requirement is 3.2 in-center patients per approved station. [WAC 246-310-284(6)(a)] DaVita's third full year of operation is year 2013. A summary of the applicant's projected utilization for year 2013 is shown in Table 4 on the following page. [source: August 10, 2009, supplemental information, Attachment 1]

Table 4
Ellensburg Dialysis Center Projected Facility Utilization

Year 3	# of Stations	# of Pts	Pts/Station
2013	5	18	3.60

As shown in Table 4 above, DaVita’s Ellensburg Dialysis Center would meet this standard in year 2013 with all five stations operational.

Based on the above information, the application submitted by DaVita to add three dialysis stations to the existing two station facility located in Kittitas County is supported by the need calculations derived from the historical patient use data. Additionally, DaVita demonstrated that Ellensburg Dialysis Center was operating above the 3.2 patients per station in the most recent NRN data. As a result, three additional stations could be added to the facility. DaVita also provided documentation to demonstrate that Ellensburg Dialysis Center would operate at or above 3.2 patients per station standard with five stations by the end of the third year of operation, or year 2013. 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 health care services to residents of the state of Washington including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the service area would continue to 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 admission and indigent care policies that are used at Ellensburg Dialysis Center. The Admission Policy outlines the process/criteria that DaVita uses to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at DaVita Ellensburg Dialysis Center without regard to race, color, national origin, sex, age, religion, or disability. [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. 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 and Medicaid eligible patients at its existing dialysis centers, including its Ellensburg facility. A review of the anticipated revenue

indicates that the facility expects to continue to receive both Medicare and Medicaid reimbursements. [source: Application, p10]

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 provide charity care to residents by submitting its charity care policy that outlines the process a patient would use to access this service. Further, DaVita included a 'charitable care' line item as a deduction from revenue within the pro forma financial documents. [source: August 10, 2009, supplemental information, Attachment 1]

Based on the above information, the department concludes that all residents will continue to have reasonable access to the health services at Ellensburg Dialysis Center. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that DaVita, Inc. 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.

If this project is approved, DaVita anticipates the three additional stations would become operational within four months of approval, or in early year 2010. Based on this timeline, year 2011 would be Ellensburg Dialysis Center's first full calendar year of operation with five stations and 2013 would be year three. [source: Application p13]

Using the financial information provided in the completed application, Table 5 on the following page illustrates the projected revenue, expenses, and net income for years 2011-2013 for the Ellensburg Dialysis Center. [source: August 10, 2009, supplemental information, Attachment 1]

Table 5
Ellensburg Dialysis Center
Projected Revenue and Expenses for Calendar Years 2011 – 2013

	Year 1 - 2011	Year 2 - 2012	Year 3 - 2013
# of Stations	5	5	5
# of Treatments [1]	2,270	2,572	2,724
# of Patients [2]	16	17	18
Utilization Rate [2]	3.0	3.4	3.6
Net Revenue [1]	\$ 807,634	\$ 994,788	\$ 1,127,223
Total Expense [1,3]	\$ 819,350	\$ 919,928	\$ 1,010,215
Net Profit or (Loss) [1]	(\$ 11,716)	\$ 74,860	\$ 117,008
Net Patient Revenue/Treatment [1]	\$ 355.79	\$ 386.78	\$ 413.81
Total Operating Exp./Treatment [1]	\$ 360.95	\$ 357.67	\$ 370.86
Net Profit (Loss) per Treatment [1]	(\$ 5.16)	\$ 29.11	\$ 42.95

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

As shown in Table 5 above, at the projected volumes identified in the application, Ellensburg Dialysis Center would be operating at a loss in full year 2011 and a profit beginning in the second full year of operation with five stations (2012).

DaVita has been operating the two-station facility in Ellensburg since April 18, 2008. For this project, DaVita provided a copy of its lease agreement between itself and Sherwood Investment, LLC. The lease agreement includes a single-line drawing of the facility’s floor plan and demonstrates that no additional space must be leased to accommodate the three station addition. The lease agreement includes all costs associated with the space, which are substantiated in the pro forma revenue and expense statements. [source: Application, Appendix 15; August 10, 2009, supplemental information, Attachment 1]

Currently, J. Hamilton Licht, MD is the medical director at the Ellensburg facility. DaVita provided a copy of the executed medical director agreement between itself and Dr. Licht. The pro forma revenue and expense statement includes the costs identified in this agreement in the projection years necessary. [source: Application, Appendix 3 and August 10, 2009, supplemental information, Attachment 1]

Based on the information above, the department concludes that the immediate and long-range operating costs of the project can be met. This sub-criterion is met.

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

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact

on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project’s costs with those previously considered by the department.

The capital expenditure associated with the addition of three stations to Ellensburg Dialysis Center is \$118,365. The costs are broken down in Table 6 below. [source: Application, Appendix 7]

Table 6
Ellensburg Dialysis Center Estimated Capital Costs

Item	Total	% of Total
Leasehold Improvements	\$ 50,000	42%
Fixed and Moveable Equipment	\$ 47,034	40%
Certificate of Need Fees	\$ 21,331	18%
Total Estimated Capital Costs	\$ 118,365	100%

DaVita also provided the following statements related to its choice of funding options. [Application, p23]

“Funding from previously allocated operations funds is the least costly approach. Debt financing for this project will not be required since there is sufficient cash on hand. Furthermore, the method of financing would have no impact on the amount charged for each unit of service.”

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 7 below. [source: Application, p24]

Table 7
Ellensburg Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	72%
State (Medicaid)	8%
Insurance/HMO	20%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 80% of the revenue at DaVita’s Ellensburg Dialysis Center. The department concludes that the majority of revenue (80%) is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. The remaining 20% will be derived through other or private insurance reimbursements.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. This sub-criterion is met.

(3) *The project can be appropriately financed.*

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

To demonstrate compliance with this sub-criterion, DaVita provided a letter from the Chief Operating Officer of DaVita demonstrating financial and operational support from the Board of Directors for the additional three stations at Ellensburg Dialysis Center. The letter assured financial support for the proposed dialysis center through cash available through the organizations current holdings. [source: Application, p23 and Appendix 6] Additionally, DaVita provided its most recent audited financial statements for years 2006, 2007, and 2008. A review of DaVita's audited statements shows the funds necessary to finance the project are available. [source: Application, Appendix 10]

Based on the information provided, the department concludes the addition of three dialysis stations to the existing two-station Ellensburg Dialysis Center would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that DaVita, Inc. 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 that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

As an operational facility, Ellensburg Dialysis Center has the majority of the necessary staff already in place. The addition of three stations requires minimal increases in staff. DaVita intends to recruit 1.5 FTEs by the end of full calendar year three (2013). A breakdown of the existing and proposed FTEs is shown in Table 8 on the following page. [source: Application, p25]

**Table 8
Ellensburg Dialysis Center 2009 – 2013 Projected FTEs**

	Year 2009 Current	Year 2010 Partial	Year 2011 Full	Year 2012 Full	Year 2013 Full	Total
Medical Director	Contracted Position					
Administrator	0.20	0.10	0.10	0.10	0.00	0.50
RNs	0.60	0.30	0.10	0.00	0.10	1.10
Patient Care Tech	1.00	0.10	0.10	0.00	0.10	1.30
BioMed Tech	0.20	0.20	0.00	0.00	0.00	0.40
ReUse Tech	0.00	0.00	0.00	0.00	0.00	0.00
Admin Asst	0.00	0.00	0.00	0.10	0.10	0.20
Social Wk	0.20	0.00	0.00	0.00	0.00	0.20
Dietician	0.20	0.00	0.00	0.00	0.00	0.20
FTE Total	2.40	0.70	0.30	0.20	0.30	3.90

As shown in Table 8, the Ellensburg facility currently operates with 2.4 FTEs. The addition of three stations will increase need for FTEs, which DaVita will recruit beginning in year 2010. By the end of year three, Ellensburg Dialysis Center will require 3.9 FTEs to operate with five dialysis stations. DaVita states it expects no difficulty in recruiting staff for facility because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. DaVita states that several existing employees have already expressed interest to increasing their work hours at the center. [source: Application, pp26-27]

DaVita has identified J. Hamilton Licht, MD as the current medical director for Ellensburg Dialysis Center, and Dr. Licht has agreed to continue in that capacity with the additional stations. DaVita provided a copy of the current medical director agreement that outlines the roles and responsibilities of both DaVita and Dr. Licht. [source: Application, Attachment 3]

Based on this information above, the department concludes that adequate staffing for Ellensburg Dialysis Center is available or can be recruited. This sub criterion is met.

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

WAC 246-310 does not contain specific WAC 246-310-230(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.

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing dialysis centers. For 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 on site. Additional services would be 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, p26]

For this Ellensburg facility, DaVita already has patient transfer agreements in place with both hospitals operating in Yakima County—Yakima Memorial Hospital and Yakima Regional Medical Center. A copy of each agreement was provided in the application. The agreements outline the roles and responsibilities for each entity. [source: Application, p26 and Appendix 12]

Based on this information, the department concludes that DaVita currently has appropriate relationships with ancillary and support services in place for its Ellensburg Dialysis Center. The addition of three stations is not expected to change these ancillary and support services or specific agreements. This sub-criterion would be 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 earlier, DaVita, Inc. is a provider of dialysis services in over 1,400 outpatient centers located in 43 states (including Washington State), the District of Columbia, and San Juan Puerto Rico. [source: DaVita website at www.davita.com] Currently within Washington State, DaVita owns and operates 24 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 public⁵. To accomplish this task, in March 2008 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the each of the states, District of Columbia, and San Juan Puerto Rico where DaVita, Inc. or any subsidiaries have health care facilities. Of the 45 entities, the department received responses

⁵ WAC 246-310-230(5).

from 24 states or 60% of the 43 states.⁶ The compliance history of the remaining 19 states and the District of Columbia is unknown.⁷

Ten of the 27 states responding to the survey indicated that minor non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Iowa, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported to have no deficiencies and are currently in compliance with applicable regulations. The Iowa facility chose voluntarily termination in August 2007 due to its inability to remain in compliance with Medicare Conditions for Coverage, rather than undergo the termination process with Medicare. This facility is currently operating as a private ESRD facility.

The department concludes that considering the more than 1,400 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 more than 30 compliance surveys for the operational facilities that DaVita either owns or manages.⁸ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Investigations and Inspections Office]

Compliance history review of the current medical director, J. Hamilton Licht, MD, revealed no recorded sanctions. Given the compliance history of DaVita and that of the current medical director, the department concludes that there is reasonable assurance that the Ellensburg Dialysis Center would continue to operate in compliance with state and federal regulation. 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

⁶ States that provided responses are: Arizona, California, Colorado, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, Washington, and Wisconsin. San Juan Puerto Rico also provided a response.

⁷ States that did not provide responses are: Alabama, Arkansas, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maine, New Mexico, New Jersey, New York, North Carolina, Ohio, South Carolina, South Dakota, Tennessee, and West Virginia. The District of Columbia also did not respond to the survey.

⁸ As of the writing of this evaluation, nine of DaVita's facilities are not yet operational. Those facilities are Everett Dialysis Center, Goldendale Dialysis Center, Kennewick Dialysis Center, Mill Creek Dialysis Center, Olympia Dialysis Center, Parkland Dialysis Center, Richland Dialysis Center, Seaview Dialysis Center, and Whidbey Dialysis Center. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita.

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, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [source: Application, p26 and Appendix 17]

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

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for three additional dialysis stations in the Kittitas County planning area. Within the application, DaVita demonstrated it met the standards to receive approval to establish the needed stations.

Therefore, the department concludes that approval of three additional dialysis stations in the Kittitas County planning area is consistent with the need methodology and would not have the potential of fragmentation of dialysis services within the service 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.
This sub-criterion is addressed in sub-section (3) above and is considered met.

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

Based on the source information reviewed, the department determines that DaVita, Inc. has met the cost containment criteria in WAC 246-310-240.

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

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-

310-210 thru 230. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

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

Step three of this assessment is to apply any service or facility specific criteria (tie-breaker) 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 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

For this project, DaVita's project met the review criteria under WAC 246-310-210, 220, and 230. Additionally, DaVita's project met the dialysis specific review criteria identified in WAC 246-310-284. Therefore, the department moves to step two below.

Step Two

DaVita considered one option before submitting this application. The option is "status quo" or do nothing. DaVita rejected this option because the two-station dialysis center is operating in excess of 100% of a two-patient shift. Doing nothing would mean that the center would have to start operating a third patient shift. DaVita states this option creates a hardship on staff and patients. [source: Application, p28]

The numeric need portion of this evaluation resulted in need for three additional dialysis stations in Kittitas County. The department did not receive any letters of opposition related to this project. Given the only other option to this project is do nothing, taking into account the results of the numeric need methodology, the department concludes that the project described is the best available alternative for the community. This sub-criterion is met.

Step Three

For this project, only DaVita submitted an application to add dialysis station capacity to Kittitas County. As a result, step three is not evaluated under this sub-criterion.

(2) In the case of a project involving construction:

(a) The costs, scope, and methods of construction and energy conservation are reasonable;

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that 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 also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.