

EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF DAVITA, INC. PROPOSING ESTABLISH A FOUR-STATION DIALYSIS CENTER IN THE CITY OF ELLENSBURG WITHIN KITTITAS COUNTY

PROJECT DESCRIPTION

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services through over 1,300 outpatient centers located in 42 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 800 hospitals throughout the country. [source: DaVita website]

For Washington State, DaVita owns or operates a total of eleven kidney dialysis facilities in Franklin, King, Pierce, and Yakima counties. A twelfth facility is approved, but not yet operating, in Clark County. Below is a listing of the eleven DaVita facilities in Washington. [source: CN historical files]

Franklin

Mid-Columbia Kidney Center

King

Bellevue Dialysis Center

Federal Way Community Dialysis Center

Kent Community Dialysis Center

Olympic View Dialysis Center

Westwood Dialysis Center

Pierce

Lakewood Community Dialysis Center

Puyallup Community Dialysis Center

Yakima

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

This application proposes to establish a four-station dialysis facility in Kittitas County, to be known as DaVita Ellensburg Dialysis Center (hereinafter referred to as "EDC"). The new dialysis facility will be located within a newly constructed building located at 2101 West Dolarway, Lot 1, Ellensburg, Washington 98926. It is noted that DaVita provided a copy of the draft lease agreement for the site. The draft agreement identifies all costs associated with the lease. If this project is approved, the department would include a term requiring DaVita to provide a copy of executed lease agreement between itself and Sherwood Investment, LLC (the lessor). [source: December 19, 2006, supplemental information, p1 and Attachment 1]

The capital expenditure associated with the establishment of the four-station facility is \$555,254, of which 37.8% is related to leasehold improvements at the site; 47.5% is related to both fixed and moveable equipment; and the remaining 14.7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p6]

DaVita anticipates that this project would commence immediately after Certificate of Need approval and all four stations would become operational by July 2007. Under this timeline, year 2008 is the facility's first full year of operation. [source: Application, p10]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

CRITERIA EVALUATION

To obtain Certificate of Need approval, DaVita, Inc. 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); 246-310-240 (cost containment); and 246-310-280 (the dialysis station projection methodology and standards).^{1,2}

APPLICATION CHRONOLOGY

October 2, 2006	Letter of Intent Submitted
November 1, 2006	Application Submitted
November 1, 2006 through November 27, 2006	Department's Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses
December 26, 2006	Department Begins Review of the Application
January 30, 2007	End of Public Comment
March 30, 2007	Department's Anticipated Decision Date
March 30, 2007	Department's Actual Decision Date

AFFECTED PERSONS

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

SOURCE INFORMATION REVIEWED

- DaVita's Certificate of Need Application submitted November 1, 2006
- DaVita's supplemental information dated December 15, 2006 and January 3, 2007
- Historical kidney dialysis data obtained from the Northwest Renal Network
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from Center for Medicare and Medicaid (CMS) "Dialysis Facility Compare" website (<http://www.medicare.gov/Dialysis/home.asp>).
- Data obtained from the Internet regarding health care providers
- Data obtained from DaVita, Inc.'s webpage (<http://www.davita.com>)
- Data obtained from Gambro AB's webpage (<http://www.gambro.com>)
- Population data obtained from the Office of Financial Management
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, the application submitted by on behalf of DaVita, Inc. proposing to establish a four-station dialysis center in the city of Ellensburg within Kittitas County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

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).

² New kidney dialysis rules were adopted by the department on January 1, 2007. This application was reviewed for compliance with WAC 246-310-280 as it read at the time this application was declared complete (December 26, 2007). Changes to WAC 246-310-280 through 289 adopted on January 1, 2007 were not considered in this evaluation.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has not met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280.

- (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.

The Department of Health's Certificate of Need Program uses the methodology found in WAC 246-310-280 for projecting numeric need for dialysis stations within a county. Using verified facility utilization information obtained from the Northwest Renal Network for the years 2002 through 2006, the department projects the need for dialysis stations to serve the county.

In recent evaluations, the department has evaluated need by examining both linear and non-linear projections of the data. One measure of the accuracy of a regression equation is the determinant of regression, or R^2 . R^2 is a value that describes the relation of actual data to the expected values based on the regression analysis of that data. In general, the closer an equation's R^2 value is to one, the more reliable a regression equation is perceived to be. The department concludes that each value to be estimated should be evaluated using both linear and non-linear regression methods and the regression equation deemed more reliable should be used to predict that data element. In some cases, this will be the non-linear equation; in others, the data may be better described by a linear equation. For those values with small and widely varying numbers, such as the numbers of patients trained for home hemodialysis and peritoneal dialysis, both methods tend to return regression equations with very small R^2 values, indicating that neither method returns a particularly reliable result.

For this project, the department determined that the more reliable determinant of regression, or R^2 , was linear regression projections for the number of dialyses and the number of patients.

The first step in performing this regression analysis is to determine the service area of the project. WAC 246-310-010 provides the following definition of the ESRD service area:

“End-stage renal dialysis (ESRD) service areas means each individual county, designated by the department as the smallest geographic area for which kidney dialysis station need projections are calculated, or other service area documented by patient origin.”

For this application, the applicant and the department agree that the appropriate ESRD service area is Kittitas County.

The department's projections for Kittitas County are shown in Table I on the following page. [source: Department's methodology based upon Northwest Renal Network facility utilization data-attached to this document as Appendix A.]

**Table I
Department's Dialysis Station Projections
for Kittitas County Based on 2002-2006 Historical Data**

Year	Stations	Existing Capacity	Net Need (Surplus)
2007	1	0	1
2008	2		2
2009	2		2
2010	2		2

As shown in Table I above, the department projects a need for one dialysis station in 2007 and two stations for 2008 through 2010 and 2008, net need for an additional station in year 2009, and two stations by the end of year 2010.

Using the department's methodology as a starting point and patient origin information for years 2001-2005, DaVita provided its dialysis station projections, which are shown in Table II below. [source: Application, p21]

**Table II
DaVita's Dialysis Station Projections
for Kittitas County Based on 2001-2005 Historical Data**

Year	Stations	Existing Capacity	Net Need (Surplus)
2007	2	0	2
2008	2		2
2009	2		2
2010	2		2

As shown in Table II above, DaVita projects a net need of two stations in Kittitas County for years 2007 through 2010. When comparing DaVita's projections in Table II and the department's projections in Table I, the department concludes the difference in net need can be attributed to the Northwest Renal Network historical data used. When this application was submitted, year-end 2006 data was not yet available; therefore, the applicant appropriately used 2001-2005 data. Year-end 2006 data became available on January 20, 2007, and the department should appropriately use 2002-2006 data to evaluate this project.

In summary, using the results shown in Table I above, the department projects a need for one dialysis station in 2007 and two stations for 2008 through 2010 and 2008, net need for an additional station in year 2009, and two stations by the end of year 2010. Based on the methodology shown in Table I, the numeric need for additional stations in the Kittitas County service area does not support approval of the entire project. Approval of the project with only two dialysis stations would be appropriate based on the need projections.

In addition to the projections discussed above, DaVita provided discussion of other factors that it believes should drive the department's examination of need for dialysis stations in Kittitas County. The first major argument submitted by DaVita centers on apparent differences between the observed rates of dialysis for Kittitas County residents and the expected rates of dialysis. DaVita compared the statewide prevalence rates for eighteen different age categories to the Kittitas County population and concluded that the county would be expected to have 23.53 dialysis patients in 2005, as opposed to the twelve (6 in-center, 2 home hemodialysis and 4 home peritoneal dialysis) patients reported by the NWRN.

DaVita also provided an analysis that purported to show, based on 2002 statistics, that the death rates for diabetes (a major cause of kidney failure) in Kittitas County exceed the statewide rates. [source: application, p14 and Appendix 4] The source of DaVita’s Appendix 4 is the department’s Diabetes Prevention and Control program. Because DaVita provided only 2002 data, program staff obtained 2001 and 2003³ data from the Diabetes program’s website. An examination of those data indicates that in 2001 and 2002 both the crude and age-adjusted rates of death for diabetes in Kittitas County exceeded the statewide rates, but in 2003 Kittitas County experienced a lower rate of diabetes-related deaths than the state as a whole. The department also notes that the actual number of diabetes-related deaths in Kittitas County for the three years ranged from 22 to 27 and that the confidence intervals for the Kittitas age-adjusted rates for each of the three years was large enough that the statewide rates fell within them. After examination of the data and consultation with Diabetes program’s epidemiologist, the department concludes that the difference between Kittitas County’s diabetes prevalence and the statewide prevalence for 2001-2003 is not statistically significant.

DaVita provides two other indicators of “extraordinary need” for a new facility in Kittitas County: a high percentage of home dialysis patients and the need for Kittitas County residents to travel to Yakima for treatment. In support of the first of these two arguments, DaVita notes that 6 of the 12 resident dialysis patients in the county at the end of 2005 were receiving home dialysis rather than in-center dialysis. DaVita notes that this 50% home dialysis rate greatly exceeds the statewide rate of 11%. The department concedes that the home dialysis rate for that reporting period was significantly higher than the state as a whole, but notes that, due to the relatively small total number of dialysis patients residing in Kittitas County, that percentage varies greatly. Table III, below, illustrates this variability:

Table III
Kittitas County Dialysis Patients by Modality

Quarter Ending	In-Center Hemodialysis	Home Hemodialysis	Peritoneal Dialysis	Training/Unknown	Total	Kittitas Home Hemodialysis %	State Home %
March 2005	6	2	2	0	10	20%	3%
June 2005	6	2	3	0	11	18%	2%
Sept 2005	7	2	4	0	13	15%	2%
Dec 2005	6	2	4	0	12	17%	2%
March 2006	11	0	4	0	15	0%	2%
June 2006	10	1	2	0	13	8%	2%
Sept 2006	6	1	0	0	7	14%	2%
Dec 2006	5	2	0	0	7	29%	2%

source: Northwest Renal Network

For the two-year period shown above, the rate of home hemodialysis among Kittitas County residents has ranged from a low of 0% to a high of 29%. On average, 14% of the patients in the county are home hemodialysis patients. While this is higher than the statewide average, which has remained between 2% and 3% in the same period, DaVita has provided no evidence that Kittitas County’s home dialysis rate is unacceptable or harmful to the area’s dialysis patients. The department also examined the home hemodialysis and peritoneal

³ Only 2001, 2002, and 2003 reports are available on the internet as of the date of this evaluation.

dialysis rates for fourteen other rural counties similar to Kittitas in either size or population⁴. Of the fifteen total counties examined (Kittitas plus fourteen others), six contain a dialysis facility and nine do not. That examination revealed widely varying rates of both treatment modalities. Eight of the fourteen counties had no home hemodialysis patients, while the remaining seven counties had home hemodialysis rates higher than the statewide rate, ranging from 3% to 10%. All of the fifteen counties had peritoneal dialysis patients, ranging from 2% to 25% of all patients in each county. Kittitas County’s peritoneal dialysis rate for the two-year period was 22%, making it the third highest of the counties examined. The department’s examination of the counties failed to show any clear patterns. Of the fifteen counties, the four with the highest rates of home dialysis do not contain dialysis facilities, but the next three counties do. Of the eight counties reporting no home hemodialysis patients, only three contain dialysis facilities. The home and peritoneal dialysis population characteristics of the counties examined do not reveal any clear distinctions between rural counties that contain dialysis facilities and those that do not. This lack of clear distinctions is further confounded by the fact that the actual numbers of patients in many of these counties is extremely small. In the two years examined, it takes only an average of 1.5 home hemodialysis patients to equal Kittitas County’s 14% home hemodialysis rate. If the two-year average was one patient, that 14% would be reduced to 10%. If the average was two patients, the rate would increase to 17%. In Kittitas County, one patient means a variation of 7%. This is in sharp contrast to more populous counties, where the addition or subtraction of only one patient does not appreciably affect the ratio of home hemodialysis patients to total patients.

Because of the lack of a clear pattern among rural counties dialysis modality rates and the fact that small populations such as Kittitas County’s home and peritoneal dialysis patients are subject to dramatic changes in percentage by small actual changes in the number of patients, the department is unable to reach any conclusions from this examination that support DaVita’s assertion that high home and peritoneal dialysis rates represent a “marker for extraordinary need.”

The department also examined DaVita’s other argument, the need for Kittitas County residents to travel to Yakima for treatment. The department examined the distances from DaVita’s proposed location for EDC to the nearest existing dialysis facilities in Table IV, below:

**Table IV
Distances from Ellensburg to Nearest Dialysis Facilities**

Center	Driving Distance	Driving Time
DaVita Yakima, Yakima	38.3 miles	39 minutes
DaVita Union Gap, Union Gap	44.2 miles	47 Minutes
Central Washington Hospital, Wenatchee	66.3 miles	73 Minutes
DaVita Mt. Adams, Sunnyside	74.9 miles	72 Minutes
FMC Moses Lake, Moses Lake	75.8 miles	73 Minutes
NKC Snoqualmie Ridge, Snoqualmie	82.7 miles	78 Minutes

source: maps.google.com

The two nearest facilities to the proposed location are between 38 and 44 miles away. The department does not have an established standard for travel distances and times in rural

⁴ Adams, Asotin, Chelan, Douglas, Franklin, Grant, Jefferson, Lincoln, Mason, Okanogan, Pacific, Pend Oreille, Stevens and Whitman counties

counties, although State Health Plan documents from the 1980's reflect the standard that all facilities within 90 minute driving time from a proposed facility in this region (central Washington) should be operating at 80% utilization before additional stations could be approved⁵. Another document expressed the standard "An ESRD facility should be located within 90 minutes normal driving time of 90% of the ESRD inpatient population who live in HSAs III and IV."⁶ Each of these documents noted that areas of dense population have shorter expected driving times than areas of less-dense population. If the standards discussed above were to be applied to the six centers listed in Table IV, the conclusion might be reached that the five in-center hemodialysis patients residing in Kittitas County as of December 31, 2006, have six facilities that meet those standards.

In support of its application, DaVita provided the department with 20 letters written in February and March 2006 (9 months prior to application submission). Many of those letters appear to have been written in response to the authors' belief that this project or a similar project in Ellensburg had already been denied by the department. Of those letters, 7 were written by Kittitas County resident dialysis patients or their family members. Of the remaining 13 letters, 9 were written by DaVita Yakima Dialysis employees, and 4 letters were written by DaVita patients that did not reside in Kittitas County. The Kittitas County residents' letters each described the various challenges they experience in reaching their current facility. Two of the patients noted that they live outside Ellensburg, and experience longer travel distances to DaVita Yakima than indicated in Table IV, above. The patients cited long driving distances, difficult winter driving conditions, difficulty obtaining reliable transportation to and from treatment, and the high costs of fuel and vehicle maintenance as barriers to obtaining needed services. The letters from staff members noted that some patients are traveling to Yakima from Cle Elum and Easton (approximately 60 miles and 72 miles, respectively) and discussed the likelihood that long travel distances, particularly during winter, can lead to an increase in the number of missed treatments, resulting in increased risk of hospitalization.

A review of the remaining standards under WAC 246-310-280 follows:

WAC 246-310-280(4) requires that the existing dialysis centers that would stand to lose market share by approval of a project, must be operating at 80% capacity of a 3-patient shift, per non-training station, per year, before additional stations may be added. While there are no dialysis facilities in Kittitas County, DaVita reported that the Kittitas County patients receiving dialysis services in 2006 were all being treated at DaVita's Yakima Dialysis Center (YDC). In 2005, one Kittitas County resident was treated at DaVita's Union Gap Dialysis Center (UGDC), with the remaining patients treated at YDC. For this standard, it is critical to review the most current data available which would reflect the reality of a new facility operating in the service area. For this project, the most current data is the December 2006 quarterly data obtained from the Northwest Renal Network. Table V, on the following page, summarizes the utilization for the two facilities. [source: December 2006 Quarterly Utilization Data]

⁵ 1982 State Health Plan

⁶ 1980 State Health Plan. HSA III was composed of all or most of 8 counties in Central Washington (including Kittitas and Yakima). HSA IV was composed of all or most of the 11 east-most counties in Washington.

**Table V
Yakima County Facility Utilization Data**

Facility/Number of Incenter Stations	June 2006
DaVita Yakima/23 stations	71.0%
DaVita Union Gap/8 stations	87.5%

As shown in Table V above, based on the most recent Northwest Renal Network data, YDC, the facility identified as serving all 2006 Kittitas County dialysis patients, does not meet the standard defined in WAC 245-310-280(4). A review of the remaining quarterly data for 2006 showed that at the facility was below 80% utilization the entire year. This sub-criterion is not met.

The department must also evaluate whether DaVita projects that EDC would be operating at 80% capacity (748.8 dialyses per non-training station) by the end of year three [WAC 246-310-280(5)] as a four-station facility. As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement of this project immediately and all four stations would be operational in July 2007. Under this timeline, year 2008 is the facility's first full year of operation. [source: Application, p10] DaVita provided its projected utilization as a four-station facility to be 61% in year 2008; 81% in year 2009, and 94% in year 2010. Because the applicant's own need projections, prepared consistent with the department's method, showed only a need for two stations, the department asked DaVita to prepare utilization projections based on a two-station facility. DaVita's response projected utilization as a two-station facility to be 79% in 2008 and 95% in 2009 and subsequent years. Based on the projections provided by DaVita, the department concludes it is not reasonable to expect that the proposed four-station facility would be operating at 80% capacity by end of year three, but it is reasonable to expect that the proposed facility would be operating at 80% capacity by the end of year three as a two-station facility. This sub-criterion would be met, subject to approval of only two stations.

- (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.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current admission and indigent care policies that would be used at the new Ellensburg facility. [source: Application, Appendix 14]

The Admission Policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. The document provided outlines the process/criteria that the dialysis center will use to admit patients for treatment. It is intended to ensure that patients will receive appropriate care at the dialysis center. The Admission Policy states that any patient with end stage renal disease needing chronic hemodialysis will be accepted to EDC 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 dialysis services at EDC, 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 to the proposed dialysis center, 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 eleven dialysis centers and intends to maintain this status. A review of the Indigent Care Policy identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. Additionally, DaVita demonstrated its intent to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the pro forma financial documents.

Based on the above information, the department concludes that all residents of the service area would have adequate access to the health services at the proposed 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 the applicant has not met the financial feasibility criteria in WAC 246-310-220.

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

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the four-station facility would be operational in July 2007. Based on this timeline, year 2008 would be EDC's first full year of operation.

For financial review of applications, the department requests data for the first three full years following project completion. Using that financial information provided in the application, Tables VIa and VIb illustrate the projected revenue, expenses, and net income for years 2008-2010 as both a four-station facility as initially proposed and as a two-station facility. [source: Application, Appendix 9]

**Table VIa
Ellensburg Dialysis Center
Projected Revenue and Expenses Full Years 2008 - 2010
4 Station Facility**

	Year One (2008)	Year Two (2009)	Year Three (2010)
# of stations	4	4	4
# of Treatments	2,284	3,020	3,532
# of Patients	15	20	24
% of Occupancy	61.0%	80.7%	94.3%
Net Patient Revenue*	\$ 1,034,750	\$ 1,441,124	\$ 1,768,637
Total Operating Expense	\$ 761,734	\$ 978,948	\$ 1,158,546
Net Profit or (Loss)	\$ 273,016	\$ 462,176	\$ 610,091
Net Patient Revenue/Treatment	\$ 375.59	\$ 379.54	\$ 383.24
Total Operating Exp./Treatment	\$ 276.49	\$ 257.82	\$ 251.04
Net Profit per Treatment	\$ 99.10	\$ 121.72	\$ 132.20

*Includes deductions for charity care and bad debt. All revenue and expense calculations also include home treatments not listed in # of treatments above.

Table VIb
Ellensburg Dialysis Center
Projected Revenue and Expenses Full Years 2008 - 2010
2 Station Facility

	Year One (2008)	Year Two (2009)	Year Three (2010)
# of stations	2	2	2
# of Treatments	1,472	1,778	1,778
# of Patients	10	12	12
% of Occupancy	78.6%	95%	95%
Net Patient Revenue*	\$ 756,412	\$ 822,393	\$ 889,101
Total Operating Expense	\$ 585,852	\$ 624,678	\$ 687,012
Net Profit or (Loss)	\$ 170,560	\$ 197,715	\$ 202,089
Net Patient Revenue/Treatment	\$ 423.05	\$ 367.63	\$ 372.01
Total Operating Exp./Treatment	\$ 327.66	\$ 279.25	\$ 287.45
Net Profit per Treatment	\$ 95.39	\$ 88.38	\$ 84.56

*Includes deductions for charity care and bad debt. All revenue and expense calculations also include home treatments not listed in # of treatments above.

As shown in Table VIa above, at the projected volumes identified in the application, EDC would be operating at a profit in the first three full years of operation as a four-station facility. However, given that the department concluded in the need section of this evaluation that four additional dialysis stations are not needed in the ESRD service area through at least year 2008, the projected number of treatments is likely overstated. Table VIb, however, reflects EDC's projected financial performance as a two-station facility. The department concludes that this project, if limited to two stations can be reasonable expected to meet its immediate and long-term capital and operating costs and 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.

The capital expenditure associated with the establishment of the four-station facility is \$555,254, of which 37.8% is related to leasehold improvements at the site; 47.5% is related to both fixed and moveable equipment; and the remaining 14.7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p7]

To demonstrate compliance with this sub-criterion, DaVita provided the following statements:

“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.” [source: Application, p24]

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 the chart shown on the following page. [source: Application, p25]

Source of Revenue	Percentage 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 EDC. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

However, in the need section of this evaluation, the department concluded that the applicant failed to demonstrate that existing facilities are not available to meet the future need for dialysis services for the residents of Kittitas County. Given that the project is not necessary, the department also concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

(3) The project can be appropriately financed.

As previously stated, the capital expenditure associated with the establishment of the four-station facility is \$555,254, of which 37.8% is related to leasehold improvements at the site; 47.5% is related to both fixed and moveable equipment; and the remaining 14.7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p7] A review of DaVita's historical financial statements shows the funds necessary to finance the project are available.

Based on the information provided, the department concludes the establishment of EDC 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 the applicant has not 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.

To implement this project, DaVita proposes to recruit 4.3 FTEs by the end of full year one (2008), which would increase to a total of 6.60 FTEs by the end of year three (2010). A breakdown of the proposed FTEs is shown in Table VII on the following page. [source: December 15, 2006, screening responses, p2]

**Table VII
Ellensburg Dialysis Center Projected FTEs**

Staff	Year 1 Projected	Year 2 Increase	Year 3 Increase	Total FTEs
Administrator	.20	0.30	0.10	0.60
Medical Director	Professional Services Contract			
RN	1.00	0.30	0.10	1.40
Patient Care Techs	1.40	0.60	0.40	2.40
Biomedical Techs	0.30	0.00	0.10	0.40
Re-Use Tech	0.20	0.10	0.00	0.30
Administrative Assistant	0.40	0.00	0.10	0.50
MSW	0.40	0.00	0.10	0.50
Dietitian	0.40	0.00	0.10	0.50
Total FTE's	4.30	1.30	1.00	6.60

As shown in Table VII above, after the initial recruitment of FTEs, DaVita expects a minimal increase in FTEs for EDC through year 2010. DaVita states it expects no difficulty in recruiting staff for EDC because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. [source: Application, p27]

Based on this information, the department concludes that adequate staffing for EDC 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.

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing eleven dialysis centers. For EDC, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site. Additional services would be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington. [source: Application, p27]

DaVita acknowledges that since this would be a new facility in Kittitas County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [source: Application, p27 and Appendix 12]

Based on this information, the department concludes that DaVita currently has appropriate relationships with ancillary and support services. If this project is approved, the department would include a term requiring DaVita to provide a copy of its executed transfer agreement with a local hospital in Kittitas or Yakima County. Provided that DaVita would agree to the term, 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.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,300 outpatient centers located in 42 states and the District of Columbia. [source: DaVita Webpage] Prior to the October 1, 2005 acquisition of the dialysis operations of Gambro Healthcare US, DaVita operated 665 centers in 37 states and the District of Columbia. Currently within Washington State, DaVita owns and operates eleven kidney dialysis treatment centers. 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 public⁷. To accomplish this task, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the out-of-state facilities where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Besides Washington State, the applicant identified 42 states (including the District of Columbia) where DaVita is currently providing patient services. In January 2007, the department surveyed the 42 entities and received responses from 27 states⁸. Additionally, only Arizona and Iowa had licensing or survey information available via the internet. Therefore, of the 42 states, the department obtained quality of care history for 27 or 64%. The compliance history of the remaining states is unknown⁹

Ten of the 27 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 Delaware, one in New York and one in Texas, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2006 due to several condition-level citations, but was operating in compliance at the time of survey. The New York facility was cited with condition-level deficiencies because it was actually closed and not providing services and was voluntarily de-certified by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005.

The department concludes that considering the 1,300 facilities owned/managed by DaVita, few out-of-state facilities listed above demonstrated substantial non-compliance issues, with only three reported as subject to fines or actually decertified. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, in the most recent 11 years (since January 1996), the Department of Health's Office of Health Care Survey (OHCS) has completed more than 37 compliance surveys for the DaVita facilities in operation.¹⁰

Significant non-compliance issues were discovered in the Kent Dialysis Center and the Olympic View Dialysis Center, whereby both facilities were determined to be out of compliance with the Medicare Conditions of Participation. However, both facilities submitted a plan of corrections, resulting in the correction of the significant issues.

⁷ WAC 246-310-230(5)

⁸ Alabama, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Mississippi, New Hampshire, New York, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin and West Virginia

⁹ Arizona, California, Colorado, District of Columbia, Georgia, Massachusetts, Nebraska, Nevada, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Ohio and South Carolina

¹⁰ DaVita's Vancouver Dialysis Center is not yet operational.

Of the compliance surveys completed in the remaining DaVita facilities, 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. [Office of Health Care Survey Historical Record]

Karen Harrison, MD has agreed to provide medical director services at the proposed dialysis center. DaVita provided a copy of the draft medical director agreement between itself and Dr. Harrison. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation for the medical director responsibilities.¹¹ A review of Dr. Harrison's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Based on DaVita's compliance history and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the EDC would operate in conformance with state and federal regulations. If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed medical director agreement with Karen Harrison, MD. Provided that DaVita would agree to the term, this sub-criterion would be 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.

In response to this criterion, DaVita states:

“The DaVita Quality Improvement Program incorporates all areas of the dialysis program. The program monitors and evaluates all activities related to clinical outcomes, operations management and process flow. Measurable trend analysis focuses on function and processes. Dialysis specific statistical tools (developed by DaVita) are used for measurement, analysis, communication, and feedback. Continuing employment and patient education are integral parts of the program.” [source: Application, page 27]

The above response provided by DaVita does not address how the proposed project will promote continuity of care, not result in unwarranted fragmentation of services for the patients or how the proposed project will have an appropriate relationship with the service area's existing health care system. In order to evaluate this criterion, the department reviewed 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 used the most recent utilization data—December 2006--obtained from the Northwest Renal Network to assist in its evaluation of this sub-criterion. According to that data, the existing dialysis center currently serving Kittitas County's

¹¹ The compensation is identified in the pro forma financials provided in the application.

dialysis patients is operating below the 80% utilization standard required before additional stations may be added. Based on this information, the department must reasonably conclude that the existing facilities would have capacity to serve the patients from Kittitas County. Therefore, the department concludes that approval of this project has the potential of fragmentation of dialysis services in the region, and this sub-criterion is not 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 the applicant has not 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.

Within the application, DaVita provided discussion regarding the following two alternatives to this project. [source: Application, p29]

a) Do Nothing or Status Quo

DaVita states that it believes this application to be consistent with prior applications approved by the department to establish new facilities in service areas without existing dialysis providers. DaVita further contends that if a facility is not established in Kittitas County, "...dialysis patients will continue to leave Kittitas County to receive services and transportation costs for dialysis patients, regardless of payer, will continue at exceedingly high levels." Based on this rationale, DaVita rejected this option.

b) Establish a 6-station center in the county

DaVita provided the following discussion regarding this option:

"Projected station need based on year-end data (2001 through 2006) is for 2 stations. Projected station need based on the most current available mid-year data (2002 through 2006) is for 4 stations. We anticipate that when the department completes its analysis under current rules it will use year-end 2002 through 2006 data which will result in a station need of either 5 stations or 6 stations."

DaVita did not indicate that it had necessarily rejected this alternative, stating:

"The narrative shows that when station need is calculated on a population-based prevalence model, there is a need for six stations. The department has historically not accepted this methodological approach even though it is as accurate as the method used by the department. If the department does accept this approach to identifying need, additional stations could be awarded over the number of stations determined to be needed using the approach that has historically been applied in counties where there are no dialysis facilities."
[source: December 15, 2006, screening responses, p1]

The department recognizes that this project would establish the first dialysis facility in the county. However, as previously concluded in this evaluation, this application fails as a four-

station facility due to insufficient need, and as either a two-station or four-station facility because the facility that stands to lose market share by establishment of EDC (YDC) is operating below 80%. Therefore, on the basis of the information above, the department concludes that establishing a new dialysis facility in Kittitas County is not the best available alternative at this time, and this sub-criterion is not met.

(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 not met.

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

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 not met.