

CERTIFICATE OF NEED EVALUATION OF THE DAVITA, INC. APPLICATION PROPOSING TO ESTABLISH A NEW 15-STATION KIDNEY DIALYSIS CENTER IN EAST WENATCHEE TO SERVE THE RESIDENTS OF DOUGLAS COUNTY.

PROJECT DESCRIPTION

DaVita, Inc. is a for-profit corporation that currently operates or provides administrative services to over 1,300-outpatient dialysis centers and serves about 103,000 dialysis patients and is located in 42 states and the District of Columbia. DaVita, Inc. also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [Source: Application page 4]

In Washington State, DaVita owns or operates a total of fourteen kidney dialysis facilities in six separate counties—Clark, Franklin, King, Kittitas, Pierce, and Yakima. Below is a listing of the Fourteen DaVita facilities located in Washington [Source: CN historical files; & Application, page 4]

Clark

Vancouver Dialysis Center

Franklin

Mid-Columbia Kidney Center

Pierce

Lakewood Community Dialysis Center

Puyallup Community Dialysis Center

Tacoma Dialysis Center

Kittitas

Ellensburg Dialysis Center

Yakima

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

King

Bellevue Dialysis Center

Federal Way Community Dialysis Center

Kent Community Dialysis Center

Olympic View Dialysis Center (management only)

Westwood Dialysis Center

This application proposes to establish a new 15-station kidney dialysis facility in East Wenatchee to be located on the northwest corner of 3rd and Colorado Streets within Douglas County. It will be known as DaVita, Inc. East Wenatchee Dialysis Center. [Source: Application page 1 and Supplemental Information, May 14, 2007]

The capital expenditure associated with the establishment of the 15-station dialysis facility is \$1,592,508, of which approximately 54.3% is related to leasehold improvements at the site; 38.5% is related to both fixed and moveable equipment and the remaining 7.2% is related to architectural, engineering, application, consulting and legal fees. [Source: Application page 7]

DaVita, Inc. anticipates that all 15 stations would become operational within six months of certificate of need approval. Under this timeline, the proposed facility first full calendar year of operation is 2008 and the third full calendar year of operation would be year 2010. [Source: Application, page 10] For ease of reference, the department will refer to the proposed kidney dialysis facility as “DaVita East Wenatchee” and the applicant as “DaVita”

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, each applicant 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 through 286 (the dialysis station projection methodology and standards).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 #1. No other kidney disease treatment center applications were submitted for the Douglas County planning area during Review Cycle #1; therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review

January 30, 2007	Letter of Intent Submitted
February 28, 2007	Application Submitted
March 1, 2007 through May 14, 2007	Department’s Pre-review Activities <ul style="list-style-type: none"> • Screening Activities and Responses
May 22, 2007	Department Begins Review of Application
July 5, 2007	End of Public Comment/No Public Hearing Conducted
July 30, 2007 ²	Rebuttal Documents Received by Department
September 13, 2007	Department’s Anticipated Decision Date
October 29, 2007	Department’s Actual Decision Date

AFFECTED AND INTRESTED PERSONS

Throughout the review of this project, one entity sought and received affected person status under WAC 246-310-010—Central Washington Hospital a dialysis provider located in Wenatchee within Chelan County.

SOURCE INFORMATION REVIEWED

- DaVita’s Certificate of Need Application, received February 28, 2007
- DaVita’s supplemental information received May 14, 2007
- Historical dialysis data obtained from Northwest Renal Network years 2001 through 2006
- Year 2006 Northwest Renal Network 4th Quarter
- Central Washington Hospital public comments received July 5, 2007

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

² The department granted an extension to rebuttal comments due date based on a request by DaVita.

- DaVita's rebuttal comments received July 30, 2007
- Medical Quality Assurance Commission Credentialing Records
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- On-line data obtained from the Douglas County Assessor
- Data obtained from the Washington State Secretary of State Office and webpage
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, DaVita's proposal's to establish a new 15-station kidney dialysis facility in East Wenatchee within Douglas County is not consistent with the application criteria of the Certificate of Need Program. Therefore, a Certificate of Need is denied

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-286.

(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 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology, adopted January 1, 2007, 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. In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last 5 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)]

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

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]

DaVita proposes to establish a 15-station kidney dialysis facility in East Wenatchee within Douglas County. Based on the calculation of the annual growth rate in the planning area as described above, non-linear regression is used to project need. Given that the facility would be located in Douglas County, the number of projected patients is divided by 3.2 to determine the number of stations needed in the planning area. Summarized in Table 1 below, is DaVita's application of the kidney dialysis numeric methodology. [Source: Application pages 15 and 16]

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

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	37.06	45.60	56.11	69.05
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	11.58	14.25	17.53	21.58
Total Station Need Rounded Up	12	15	18	22
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	12	15	18	22

As shown in Table 1 above, DaVita projected need for 22 dialysis stations in year 2010. Based on the results of its methodology, DaVita requested 15 dialysis stations rather than the net result of 22 stations as shown in the table above.

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 also used non-linear regression to project need for the planning area. Given that the facility would be located in Douglas County, the number of projected patients is divided by 3.2 to determine the number of stations needed in the planning area. Table 2 below, is a summary of the department's application of the numeric methodology for Douglas County. [Source: Appendix A attached to this evaluation]

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

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	37.06	45.60	56.11	69.05
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	11.5	14.25	17.53	21.58
Total Station Need Rounded Up	12	15	18	22
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	12	15	18	22

When comparing the results of the two tables above, it is noted that DaVita's projections and the department's projections are exactly the same. In summary, the numeric needs methodology result in a need for 22-stations in Douglas County.

WAC 246-310-284(5) requires that all CN approved stations in the planning area must be operating at 3.2 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period was February 1, 2007. [Source: WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2006 which became available on January 20, 2007. Currently, there are no kidney dialysis centers in Douglas County. Therefore, this criterion is not applicable.

WAC 246-310-284 (6) requires that DaVita East Wenatchee to be operating at 3.2 in-center patients per approved station by the end of year three (2011). DaVita provided the projected third year utilization for the East Wenatchee facility as a 15-station facility. A summary of the projections for year 2011 is shown in Table 3 below. [Source: Application, Appendix 9]

Table 3
Year 2011 DaVita East Wenatchee Projected Utilization

Facility Name	# of Stations	# of Patients	Patients/ Per Stations
DaVita East Wenatchee	15	85	5.66

As shown in Table 3 above, DaVita East Wenatchee projects to be operating above the 3.2 standard by the end of the third year of operation, or year 2011.

WAC 246-310-286 provides standards for planning areas without an existing facility. Given that DaVita proposes to establish a facility in a planning area without an existing facility, this standard applies to the department’s review of the project. The rule requires the department to award the first project proposing to establish a facility in planning areas without an existing facility, provided the project meets applicable review criteria and standards. Douglas County is included in the list of planning areas without an existing provider.⁴

During the review of this application, Central Washington Hospital located in Chelan County offered information indicating that the proposed DaVita East Wenatchee would cause them to lose market share. Comments provided to the department by CWH regarding DaVita’s need projections for Douglas County are summarized below.

Undemonstrated need for dialysis services in East Wenatchee—Douglas County

- The vast majority of the patients to be served by DaVita’s proposed East Wenatchee facility reside within a few miles of CWH’s dialysis facility and that facility has significant excess capacity.
- DaVita has failed to demonstrate that there is an unmet need for dialysis services in Douglas County. [Source: CWH public comments dated: July 5, 2007, page 2]

⁴ Planning areas without an existing provider as of January 1, 2007, are: Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties

CWH also provided a number of comments regarding the Wenatchee (Chelan County) and East Wenatchee (Douglas County) as being one services area of one community. CWH stated “*the vast majority of patients leaving Douglas County to receive dialysis treatments are individuals who reside in East Wenatchee and travel to the CWH facility in Wenatchee (Chelan County)*”. Additionally, CWH stated; “*currently 77% of the patients served at CWH’s dialysis facility reside in the Wenatchee-East Wenatchee area, including 67% of CWH’s Chelan County patients and fully 91% of CWH Douglas County patients*”. [Source: CWH public comments dated: July 5, 2007]

Summarized below is DaVita’s response to the concerns raised by CWH.

DaVita Response

- The department rules under WAC 246-310-284 (1) and (i) and (b) states that applications for new stations may only address projected station need in the planning area in which the facility is to be located and station need projections must be calculated separately for each planning area within the application.
- The department rule plainly requires the program to project need in Douglas County.
- The proposed facility is to be located in Douglas County a planning area that is different from that of CWH. [Source: DaVita, Inc. rebuttal comments dated: July 30, 2007]

The Department Response

Many of the comments submitted by CWH would be appropriate had this application been submitted under the ESRD rules prior to January 1, 2007. However with the adoption of the new rules Chelan and Douglas counties are no longer considered a single planning. The same is true of the Tri-City area of Benton and Franklin counties. WAC 246-310-285 requires that existing providers in the planning area be at that planning area’s respective station utilization. It excludes the utilization of existing stations in neighboring planning areas. The department agrees that DaVita’s proposal to establish a new 15-station dialysis facility in East Wenatchee to serve the residents of Douglas County is reasonable.

Based on the methodology and Douglas County resident’s historical dialysis utilization data, the department concludes that DaVita has demonstrated need for a new 15-station dialysis facility in Douglas County. 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 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 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.

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.

To demonstrate compliance with this sub-criterion DaVita states that, "*Any patient with end stage renal disease needing chronic dialysis will be accepted for treatment at this facility*" [Source: Application, Appendix 14]. DaVita's admission policy prohibits discrimination on the basis of race, color, national origin, sex, age, religion or disability. That policy outlines the eligibility criteria's and stated the income levels at which charity care is provided to prospective recipients. Additionally, the pro-forma income statements provided by DaVita with its application, included charity care expenses at 1% of the total revenue. The department also reviewed the historical financial statements provided by DaVita and those statements contain charity care expenses.

Based on this information, the department concludes that all residents of the service area could reasonably be expected to have adequate access to health services at the East Wenatchee Dialysis facility. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that the applicant did not meet 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 previously in this evaluation, DaVita anticipates commencement of services in May 2008. Based on this timeline, year 2009 would be DaVita's first full calendar year of operation. Summarized in Table 4 below, is DaVita's year one through year four projected financial revenue, expenses, and net income for the DaVita East Wenatchee Dialysis Center as a 15-stations dialysis facility [Source: Application, Appendix 9]

Table 4
East Wenatchee Dialysis Center
Projected Revenue and Expenses Years (1 through 4)

	Partial Year 2008	Full Year 2009	Full Year 2010	Full Year 2011	Full Year 2012
# of Stations	15	15	15	15	15
# of Treatments [1]	6,073	8,473	11,621	13,271	14,172
# of Patients [2]	40	55	75	85	90
Utilization Rate [2]	2.66	3.66	5.00	5.66	6.00
Net Patient Revenue[1]	\$1,408,972	\$3,184,514	\$4,434,947	\$5,508,754	\$6,123,063
Total Operating Expenses [1, 3]	\$1,363,972	\$2,084,143	\$2,747,088	\$3,300,564	\$3,653,053
Net Profit or (Loss)[1]	\$44,236	\$1,100,371	\$1,687,859	\$2,208,190	\$2,470,010
Operating Revenue / Treatment [1]	\$231.88	\$375.84	\$381.63	\$415.10	\$432.05
Operating Exp./ Treatment [1]	\$224.60	\$245.97	\$236.39	\$248.70	\$257.77
Net Profit per Treatment [1]	\$7.28	\$129.87	\$145.24	\$166.39	\$174.29

[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 in Table 4 above, at the projected volumes identified by DaVita, the East Wenatchee facility would be operating the 15-station dialysis center at profit in partial year 2008 through the fourth full calendar of operation in year 2012. DaVita states that the proposed facility will be operated at utilization levels consistent with other facilities.

DaVita provided a draft lease agreement for the site between Total Renal Care, Inc. (Tenant) its parent company and EDG-East Wenatchee, LLC (Landlord). The costs identified in the lease are not consistent with the pro-forma financial projections used to prepare Table 4 above.

When reviewing DaVita's application, it is noted that the lease agreement and the financial information provided in the pro forma revenue and expense statements are inconsistent. The lease agreement identifies a 7,800 square foot facility with an annual lease amount of \$27 per square foot or \$210,600 annually and states *"In the event that the consumer Price Index (CPI) for any lease year during the term shall be greater than the CPI for the preceding lease year, then rent shall be increased for such succeeding lease year to an amount equal the sum of the rent as increased by previous rent adjustments for CPI, payable for the preceding lease year however in no event shall rent be increased by more than three percent (3%)"* [Source: Lease Agreement by and between EDG-East Wenatchee, LLC and Total Renal Care, Inc. Terms and Conditions Article 3 Rent Adjustments, May 1, 2007, page 3]

The pro-forma revenue and expense statement provided show consistently different annual lease/rent amounts than those identified in the lease. Table 5, is a comparison of the amounts.

Table 5
Lease Costs and Pro Forma Comparison

	Lease Amounts	Pro Forma Amounts	Differences
Year 1	\$ 210,600	\$196,000	\$102,400
Year 2	\$ 216,918	\$151,410	\$ 64,254
Year 3	\$ 223,425	\$155,952	\$ 67,978
Year 4	\$230,128	\$160,631	\$ 71,854
Year 5	\$237,032	\$165,450	\$ 75,854
5 yr Total	\$1,118,103	\$829,443	\$288,660

The understatement of lease/rent amounts in the pro forma would result in an understatement of expenses, resulting in an understatement of net loss in year 2008, and an overstatement of net profit in years 2009 through 2012. While this overstatement/understatement issue could be viewed as “conservative pro forma projections,” it is indicative of inconsistencies within the application. In an attempt to fix this problem DaVita submitted a new draft lease as part of its rebuttal.

CWH Comments

The department received comments from CWH regarding the proposed project’s financial feasibility and DaVita’s pro-forma data. CWH outlined several points of concerns regarding the pro forma statement and asserts that the potential magnitude of the concerns should result in the proposed project certificate of need application denial.

DaVita Response

DaVita provided an extensive response to the department. DaVita stated that the continued successful operation of DaVita’s facilities in Washington is compelling proof of the validity and reliability of DaVita’s pro-forma model in demonstrating financial feasibility.

The Department Response

The department reviewed the comments submitted by CWH and concluded that many were projections based on CWH’s experience as a hospital based dialysis facility. These projections may not be applicable to a non-hospital based dialysis facility. Therefore, the department does not agree with all of the concerns. However, the department does agree that expenses as identified by DaVita in the pro-forma’s were not accurate.

During the screening process, the department requested any necessary updates to the proposed facility pro-forma “that reflects all costs associated with the site for the project”. [March 30, 2007 Supplemental Information, #8] DaVita responded that no changes were necessary in the pro-forma other than the correct calendar year headings previously requested in screening. This would indicate that the draft lease submitted in response to supplemental information may continue to be inaccurate in many of the terms being considered for the lease. The inaccuracies in the stated and projected rent are currently the only means to isolate one, of possible additional modifications, that could affect the viability of this project.

A comparison of the pro-forma statement and the stated annual rent plus yearly rent adjustments as stipulated in the lease agreement, would result in an understatement of expenses resulting in an understatement of net loss in year 2008 and an overstatement of net profit in years 2009 through 2012. Further, in an attempt to correct the issue raised by CWH regarding the square footage of the proposed facility, DaVita submitted a new draft lease changing not only the square footage, but also the cost per square. This new draft lease information is not proper rebuttal.

A review of on-line real estate public records kept by the Douglas County Assessor’s Office by the department revealed that the proposed site is not listed as owned by EDG-DaVita East Wenatchee, LLC. Additionally, a public record review of the Washington State Secretary of State’s Office reveals no record of EDG-DaVita East Wenatchee, LLC registered to do business in Washington State. These two factors lead to the department conclusion that DaVita does not have a draft lease that could be reasonably relied on for demonstrating interest in the property.

DaVita identified Fadi Najjar, MD as the Medical Director for the proposed DaVita East Wenatchee Dialysis Center and provided a draft medical director agreement between DaVita and Dr. Najjar. The costs for the medical director services for the 1st year are not consistent in the pro-forma financial information provided in the application. Additionally the draft Medical Director’s agreement has an initial term of one year with the renewal terms stated as “intentionally omitted.” Therefore the department cannot substantiate that the costs included in the pro forma are accurate.

Based on the information presented the department is unable to conclude that the proposed project is financially feasible. This sub-criterion is not 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 costs and charges per dialysis for the proposed facility cannot be compared to recent kidney dialysis proposals submitted to the department. The department is not able to calculate the average cost per dialysis with any certainty due to in-consistent pro-forma data.

The estimated capital expenditure associated with the establishment of the proposed 15-station dialysis facility is \$1,592,508. [Source: Application page 1] Summarized in the Table 6 below, is the capital expenditure.

**Table 6
DaVita East Wenatchee Dialysis Center Capital Cost**

Item	Cost	% of Total
Leasehold Improvements	\$865,000	54.3%
Fixed & Moveable Equipment	\$613,099	38.5%
Architect/Engineering and CN fees	\$114,409	7.2%
Total Project Cost	\$1,592,508	100%

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlement. To demonstrate compliance with this sub-criterion, DaVita provided the sources of its patient revenue shown in the table below. [Source: Application, Page 8]

**Table 7
DaVita's Source of Revenue**

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

As shown in Table 7 above, Medicare and state (Medicaid) entitlements as stated by DaVita are projected to equal 80% of the proposed facility revenue sources that are not cost based reimbursement.

Additional comments provide to the department by CWH regarding the proposed project impact on the costs and charges for health services in Douglas County are summarized below.

- DaVita's proposed project will impact the cost of health care to the public.
- DaVita intends to charge and collect from commercial payors amount higher than CWH. [Source: CWH public comments dated: July 5, 2007]

DaVita Response

- The overwhelming majority of dialysis patients are covered by Medicare and Medicaid and their treatments are paid at fixed rates that will be unaffected by the proposed project. [Source: DaVita July 30, 2007, rebuttal documents]

The Department Response

The department cannot conclude that costs associated with this project will not have unreasonable impact on the remaining 20% because of the inconsistencies in the pro forma. Therefore, the department cannot conclude that the cost of the project will not result in an unreasonable impact on the costs and charges for healthcare services within the service area. This sub-criterion is not met.

(3) The project can be appropriately financed.

The source of financing for the proposed facility is DaVita's cash reserves. A review of DaVita's historical financial statements for years 2004 through 2006, demonstrates that the funds necessary to finance the project are available. [Source: Application Exhibit 10]

DaVita's financial reserves as documented by Exhibit 10 are more than adequate to fund the new 15-station dialysis facility. Based on the information provided the department concludes that the applicant has demonstrated that establishment of the new 15-station East Wenatchee Dialysis Center in Douglas County will not adversely affect DaVita's financial stability. The department concludes that DaVita's application to establish a new 15-station dialysis center in East Wenatchee 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, 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 hire the equivalent of 4.8 new staff during the first partial year of operation and increase the number of new staff to 16.4 by the end of the fourth full year of operation. The proposed project staff increase is summarized in Table 7 below.

**Table 7
East Wenatchee Dialysis Center Proposed FTE's**

Category	Partial Year 2008	Full Year 2009 Increase	Full Year 2010 Increase	Full Year 2011 Increase	Full Year 2012 Increase	Total FTE's
Medical Director	<i>Professional Services Contract</i>					
Administrator	0.9	0.1	0	0	0	1
Registered Nurses	1.1	1.1	0.6	0.4	0.3	3.5
Patient Care Techs	2	2.3	2.2	1.5	0.5	8.5
Biomedical Tech	0.3	0	0	0	0	0.3
Re-Use Techs	0.1	0.1	0.1	0.1	0.1	0.5
Administrative Asst	0	0.5	0.5	0	0	1
Social Worker	0.2	0.2	0.2	0.1	0.1	0.8
Dietician	0.2	0.2	0.2	0.1	0.1	0.8
Number of FTE'S	4.8	4.5	3.8	2.2	1.1	16.4

As shown in Table 7 above DaVita expects to hire 16.4 new FTE's to staff the dialysis center and states that it does not anticipate any difficulty in recruiting the necessary staff to the proposed facility. Additionally, DaVita stated *“The East Wenatchee unit is situated in a location geographically adjacent to an urban area. DaVita offers a competitive wage and benefit package to employees. DaVita post openings nationally and externally and several current employees have expressed interest in working at the proposed facility.”* Furthermore, DaVita stated that it has an extensive employee traveling program that guarantee that DaVita's facilities will continue to have access to appropriate staff necessary for continuity of care”. [Source: Application page 23]

DaVita identified Fadi Najjar, MD as the Medical Director for the proposed DaVita East Wenatchee Dialysis Center and provided a draft medical director agreement between DaVita and Dr. Najjar.

CWH provided the department comments regarding DaVita's structure and process quality of care as summarized below.

- Information contained in DaVita's application raises serious issues as to its ability to hire clinical staff to satisfy this criterion.

- The proposed medical director's arrangement also raises questions about DaVita's ability to meet the structure and process quality of care. [Source: CWH public comments dated: July 5, 2007]

DaVita's Response

- DaVita has experience no difficulty in staffing any new or existing facilities in Washington.
- Staffing from other DaVita facilities have expressed interest in transferring to the East Wenatchee facility. With so many facilities in Washington and elsewhere in United States, DaVita has the flexibility of rapidly addressing unanticipated staffing difficulties
- DaVita's selection of Dr. Fadi Najjar as medial director is based upon the assumption that he would continue practicing at his current location in the Tri-Cities. Any speculations about his performance should take into action the fact that DaVita has never experienced difficulty obtaining full performance from any of its Washington medical directors. [Source: DaVita July 30, 2007, rebuttal documents]

Nothing in the department or Medicare rules requires the Medical Director to live in the same community that the dialysis facility. Therefore, the department has no basis to make this a requirement. A review of the draft Medical Director's agreement identifies an initial term of one year. The renewal terms stated as "intentionally omitted." Therefore the department can only verify that the proposed project has a Medical Director during the first year of operation. Without being able to make this verification through at least the third year of operation, the department cannot conclude the availability of this key staff. This sub-criterion is not 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.

Information provided by DaVita states that 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 upon the commencement of services at the proposed facility. The applicant states that services would be coordinated through DaVita's corporate office in El Segundo, California and support offices in Washington. [Application page 29] To further demonstrate compliance with this sub-criterion, DaVita provided draft transfer agreement. [Application, Appendix 12] If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed transfer agreement with a local hospital in Douglas County.

Prior to providing services at the DaVita East Wenatchee facility DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval.

Based on the evaluation of supporting documents provided, and with agreement to the term above, the department concludes that there is reasonable assurance that the East Wenatchee Dialysis Center will have appropriate ancillary and support services with a local hospital in Douglas County. 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 1,300 outpatient centers located in 42 states (including Washington State) 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 fourteen 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 public⁵. To accomplish this task, in January 2007 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the 42 states and the District of Columbia where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Of the 43 entities, the department received responses from 28 states or 66% of the 42 states.⁶ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁷

Ten of the 28 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. This facility was voluntarily de-certified and closed by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005. No further fines were identified for this facility.

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, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 32 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 Office of Health Care Survey]

⁵ WAC 246-310-230(5).

⁶ Alabama, Arizona, Connecticut, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New York, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

⁷ Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

⁸ DaVita's Ellensburg Dialysis Center and Tacoma Dialysis Center are not yet operational. Olympic View Dialysis Center is owned by Group Health and managed by DaVita.

Compliance history review of the proposed medical director Dr. Fadi Najjar did not reveal any recorded sanctions. DaVita provided a draft medical director agreement with Dr. Najjar. Given the compliance history of DaVita and that of the proposed facility medical director, the department concludes that there is reasonable assurance that DaVita East Wenatchee would be operated in conformance 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.

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its Continuous Quality Improvement Program (CQI). The CQI program incorporates all of DaVita's stated kidney dialysis objectives. The program monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, the DaVita states, "*Continuing employee and patient education are integral parts of the program*". [Source: Application, Appendices 18 and 19] Additionally, DaVita also provided samples of its quality index data and its physician community, and patient services education offered through its quality of care program.

The department also considered DaVita's history of providing care to residents in Washington State and concludes that DaVita has been providing dialysis services to the residents of Washington for several years and has appropriate relationships with healthcare providers in the communities where DaVita's dialysis facilities are located. The department does not expect that the approval of this project would change those relationships. Therefore, the department concludes that the applicant has demonstrated an ability to provide services in a manner appropriate to the health care delivery system and the establishment of a new 15-station dialysis facility in East Wenatchee will not result in an unwarranted fragmentation of service. 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 is addressed in sub-criterion (3) of this evaluation. The department concludes that there is reasonable assurance that the services to be provided will ensure safe and adequate care to the public and in accord with applicable federal and state laws, rules and regulations. This sub-criterion is 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.

To comply with this sub-criterion, DaVita stated that it considered two alternatives to DaVita's alternative and the rationale for rejecting those two alternatives are summarized below.

- Alternative 1: Do nothing maintain the status quo
This alternative was rejected because Douglas County residents are being served by dialysis facilities located in other counties. This alternative was rejected because DaVita states that access to facilities is below acceptable levels.
- Alternative 2: Establish a 22-station center
This alternative was only rejected because according to the applicant, the establishment of a 22-station dialysis facility in Douglas County planning area is a needlessly aggressive strategy. If station needs continues to grow at current rates, a three shift will be considered and additional stations added.

Summarized below are concerns raised by CWH regarding DaVita's ability to comply with the superior alternatives availability sub-criterion.

- DaVita's proposal is not the superior alternative because the establishment of its facility would result in an unnecessary expenditure of over \$1.5 million
- DaVita's proposal would create a surplus of dialysis stations in the Chelan/Douglas Counties area.
- CWH is only 6 miles away and has the capacity to meet needs of Douglas County residents particularly those in East Wenatchee. [Source: CWH public comments dated: July 5, 2007 page 13]

DaVita Response

- CWH criticism ignores the standards imposed by the current rules and rings hollow since CWH has failed to offer a better alternative for Douglas County patients.
- There is not facility in the planning area so tiebreaker do not apply at all
- The existing facility is located in county where need is measured using the 4.8 patients per station standard in such counties, the Program favors facilities that are at least three miles from the existing facility WAC 246-310-288(c)(i).
- CWH acknowledged that the proposed facility would be located six miles from the CWH facility, easily satisfying a broad application of the department policy. [Source: DaVita July 30, 2007, rebuttal documents, page 10]

The Department Response

The department acknowledges CHW's concerns. However, the new rules effective January 1, 2007 result in the department being required to evaluate new projects differently than it did in 2002 when CWH received its CN to expand its capacity. The department cannot conclude however that the current DaVita-East Wenatchee project is the best available alternative. While the department determined that a need was demonstrated, the project as proposed failed to meet financial feasibility and structure and process of care. Therefore, this criterion is not met.

APPENDIX A