

**REVIEW OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON
BEHALF OF DAVITA, INC. PROPOSING TO ESTABLISH A FIVE STATION KIDNEY
DIALYSIS CENTER TO SERVE THE RESIDENTS OF ISLAND COUNTY**

PROJECT DESCRIPTION

DaVita, Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,300 outpatient centers located in 43 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [Application, p4; DaVita website]

In Washington State, DaVita owns or operates a total of twenty-five kidney dialysis facilities in twelve separate counties. Below is a listing of the DaVita facilities in Washington. [CN historical files; DaVita Application, p1]

Clark

Vancouver Dialysis Center

Franklin

Mid-Columbia Kidney Center

Pacific

Seaview Dialysis Center

Kittitas

Ellensburg Dialysis Center

Douglas

East Wenatchee Dialysis Center

Klickitat

Goldendale Dialysis Center

Pierce

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

King

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

Yakima

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

Thurston

Olympia Dialysis Center

Benton

Kennewick Dialysis Center
Richland Dialysis Center

Snohomish

Everett Dialysis Center
Mill Creek Dialysis Center
Tulalip Dialysis Center

This application proposes to establish a new DaVita dialysis facility in Island County. The new facility, to be known as the Whidbey Island Dialysis Center, would have 5 stations and be located at 32650 State Route 20, Bldg. E in the city of Oak Harbor, Washington. The new facility would offer dialysis services to patients residing in the Island County. [Application, p1]

The capital expenditure associated with the establishment of the 5-station facility is \$1,002,246, of which approximately 48% is related to leasehold improvements at the site; 50% is related to

both fixed and moveable equipment; and the remaining 2% is related to application fees. [Application, p7]

Evaluation Breakdown Of ECE	Total	% of Total
Leasehold Improvements	\$ 480,000	48%
Fixed & Moveable Equipment	\$ 505,837	50%
CN Fees	\$ 16,409	2%
Total Estimated Capital Costs	\$ 1,002,246	100.00%

If this project is approved, DaVita anticipates all 5 stations would become operational within eight months of approval. Under this timeline, year 2010 would be the facility’s first full calendar year of operation and 2012 would be year three. [Application, p11]

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 applicable 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). Additionally, DaVita must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.¹

CONCURRENT REVIEW CYCLE AND APPLICATION CHRONOLOGY

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

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

January 31, 2008	Letter of Intent Submitted
February 29, 2008	Application Submitted
March 1, 2008 through June 27, 2008	Department's Pre-Review Activities <ul style="list-style-type: none"> • screening activities and responses
June 28, 2008	Department Begins Review of the Application <ul style="list-style-type: none"> • public comments accepted throughout the review
August 11, 2008	End of Public Comment / Public Hearing Conducted
August 22, 2008	Rebuttal Documents Received at Department
October 10, 2008	Department's Anticipated Decision Date
October 10, 2008	Department's Actual Decision Date

AFFECTED PERSONS

Throughout the review of this project, one entity, Puget Sound Kidney Centers, sought and received affected person status under WAC 246-310-010. PSKC is the current provider of dialysis services in Island County.

SOURCE INFORMATION REVIEWED

- DaVita's Certificate of Need application submitted February 29, 2008
- DaVita's supplemental information dated May 8, 2008
- Public comment received at hearing August 11, 2008
- DaVita's rebuttal comments received August 22, 2008
- Years 2002 through 2007 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2007 Northwest Renal Network 4th Quarter Data
- 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 DaVita, Inc.'s webpage (davita.com)
- Medical Quality Assurance compliance data

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a 5-station dialysis center in Oak Harbor, within Island County is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is approved with the terms cited below.

The total approved costs associated with this project are \$1,002,246.

Terms

1. Prior to the project commencement, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located at 32650

State Route 20, Bldg. E in the city of Oak Harbor, Washington. The executed lease agreement shall be consistent with the draft agreement provided within the application.

2. Prior to providing services DaVita, Inc. must provide to the department for review and approval an executed copy of the Medical Director's agreement. The executed medical director agreement shall be consistent with the draft agreement provided within the application consistent with the draft agreement provided within the application.
3. Prior to providing services at the Whidbey Island Dialysis Center, DaVita, Inc. will provide an executed copy of a Patient Transfer Agreement for the department's review and approval.

A. Need (WAC 246-310-210)

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

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

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.²

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 five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

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

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)]

² 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's Application of the Numeric Methodology

DaVita proposes to establish a 5-station dialysis center in Oak Harbor in Island County. Based on the calculation of the annual growth rate in the planning area as described above, linear regression is used to project need. Given that the facility would be located in Island County, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area.

Table 1 below is a summary of DaVita's application of the numeric methodology. [Application, p18-20]

Table 1
Summary of DaVita's Numeric Methodology

	Year 2008	Year 2009	Year 2010	Year 2011
Incenter Patients	37.0	41.4	45.8	50.2
Patient: Station Conv. Factor	4.8	4.8	4.8	4.8
Total Station Need	7.71	8.62	9.54	10.46
Total Station Need Rounded Up	8	9	10	11
Minus # of CN Approved Stations	6	6	6	6
Net Station Need / (Surplus)	2	3	4	5

As shown in Table 1 above, DaVita projected a need for 5 dialysis stations in year 2011.

Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project need. Given that the facility would be located in Island County, the number of projected patients is divided by 4.8 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. [Appendix A of this evaluation]

Table 2
Summary of Department's Numeric Methodology

	Year 2008	Year 2009	Year 2010	Year 2011
Resident Incenter Patients	37.00	41.40	45.80	50.20
Patient: Station Conv. Factor	4.8	4.8	4.8	4.8
Total Station Need	7.7083	8.6250	9.5417	10.4583
Total Station Need Rounded Up	8	9	10	11
Minus # of CN Approved Stations	6	6	6	6
Net Station Need / (Surplus)	2	3	4	5

As shown in Table 2, the department also projected a need for 5 dialysis stations in year 2011. In summary, the net station need for Island County is calculated to equal 5 stations.

As shown above, Island County currently has 6 stations operating within the planning area. WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period is February 1, 2008. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2007, which became available on January 21, 2008. All 6 stations are at one location - Puget Sound Kidney Center's Whidbey Island facility. Table 3 below shows the December 31, 2007, utilization of the PSKC facility and demonstrates that this capacity requirement is met.

**Table 3
December 31, 2007 - Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
PSKC Whidbey Island	6	31	5.17

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For Island County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] DaVita's proposed dialysis stations are to be located within Island County; as a result, the applicant's must demonstrate compliance with this criterion using the 4.8 in-center patients per station. Further, DaVita's third full year of operation is year 2012. A summary of the applicant's projected utilization for year 2012 is shown in Table 4 below and demonstrates that DaVita's projections meet this standard. [Application, p16]

**Table 4
Projected Facility Utilization**

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita Whidbey Island	2012	5	28 ³	5.60

Based on the above information, the application submitted by DaVita, Inc. to establish a 5-station dialysis center in Island County is supported by the need calculations derived from the historical patient use data. Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. This sub-criterion is met.

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

DaVita is currently a provider health care services to residents of the State of Washington including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the service area would continue to have access to an applicant's proposed services, the department requires applicants to provide a copy of

³ DaVita cites a patient count of 36 for 2012 on p9 & 16 of the application, but calculates the 2012 Pro Forma with a patient count of 28. The department used the figure cited in the financial calculations as the projected patient count in the third year of the Whidbey Island facility

its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current admission and indigent care policies that would also be used at the new Whidbey Island facility. The Admission policy outlines the process/criteria that DaVita Whidbey Island will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at DaVita Whidbey Island without regard to race, color, national origin, sex, age, religion, or disability. [Application, Appendix 14; May 8, 2008 Screening Responses, Attachment 4]

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

DaVita currently provides services to Medicare and Medicaid eligible patients at its existing dialysis centers. It intends to also provide services to Medicare and Medicaid at the proposed facility. A review of the anticipated revenue indicates that the facility expects to continue to receive both Medicare and Medicaid reimbursements. [Application, p22]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

DaVita demonstrated its intent to provide charity care to residents by submitting its charity care policy that outlines the process a patient would use to access this service. Further, DaVita included a 'charitable care' line item as a deduction from revenue within the pro forma financial documents. [Application, Appendix 14; May 8, 2008 Screening Responses, Attachment 5]

Based on the above information, the department concludes that all residents of the service area would have reasonable access to the health services at the proposed Whidbey Island Dialysis Center. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that DaVita, Inc. has met the financial feasibility criteria in WAC 246-310-220.

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

If this project is approved, DaVita anticipates commencement immediately and DaVita Whidbey Island would be operational within eight months of approval. Based on this timeline, year 2010 would be DaVita Whidbey Island’s first full calendar year of operation and 2012 would be year three. [Application, p11]

Using the financial information provided in the completed application, Table 5 below illustrates the projected revenue, expenses, and net income for fiscal years 2010-2012 for the Whidbey Island Dialysis Center. [May 8, 2008 Screening Responses, Appendix 5]

Table 5
Whidbey Island Dialysis Center
Projected Revenue and Expenses Calendar Years 2010 – 2012

	Year 1 - 2010	Year 2 - 2011	Year 3 - 2012
# of Stations	5	5	5
# of Treatments [1]	2,696	3,744	4,193
# of Patients [2]	18	25	28
Utilization Rate [2]	3.60	5.00	5.60
Net Revenue [1]	\$ 1,297,878	\$ 1,850,187	\$ 2,174,440
Total Expense [1,3]	\$ 1,019,710	\$ 1,302,919	\$ 1,551,138
Net Profit or (Loss) [1]	\$ 278,168	\$ 547,268	\$ 623,302
Net Patient Revenue/Treatment [1]	\$ 392.35	\$ 396.95	\$ 401.48
Total Operating Exp./Treatment [1]	\$ 308.26	\$ 279.54	\$ 286.40
Net Profit (Loss) per Treatment [1]	\$ 84.09	\$ 117.41	\$ 115.09

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

As shown in Table 5 above, at the projected volumes identified in the application, DaVita Whidbey Island would be operating at a profit in the first full year of service (2010).

DaVita has selected a site for the Whidbey Island facility that is located in a commercial area within the City of Oak Harbor. The draft lease that is provided in the application outlines the annual rent and terms to retain the space, with available extensions, through 2034. DaVita also supplied documents from the City of Oak Harbor that confirms the location is zoned to allow for permitting of state licensed medical services. [Application, Appendix 15; May 8, 2008 Screening Responses, Attachment 2]

DaVita has identified Dr. Fadi Najjar as the intended Medical Director for the new Whidbey Island facility. The applicant supplied a draft contract that indicates Dr. Najjar’s compensation for service in this capacity. The pro forma has included the costs outlined in this agreement in the projection years necessary. [Application, Attachment 3; May 8, 2008 Screening Responses, Attachment 5]

Based on the above information, if this project is approved, the department would attach a term requiring DaVita to provide to the department a copy of the executed Lease Agreement.

The executed Lease Agreement must be consistent with the draft agreement provided in the application. Further, the executed agreement must be provided to the department before commencement of the project. With acceptance of this term, this sub-criterion would be 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 5-station facility is \$1,002,246, of which approximately 48% is related to leasehold improvements at the site; 50% is related to both fixed and moveable equipment; and the remaining 2% is related to application fees. [Application, p7]

Table 6
DaVita’s Whidbey Island Estimated Capital Costs

Evaluation Breakdown Of ECE	Total	% of Total
Leasehold Improvements	\$ 480,000	48%
Fixed & Moveable Equipment	\$ 505,837	50%
CN Fees	\$ 16,409	2%
Total Estimated Capital Costs	\$ 1,002,246	100.00%

To further demonstrate compliance with this sub-criterion, DaVita stated, “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.” [Application, p21]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 7 below. [Application, p22]

Table 7
DaVita’s Whidbey Island Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	58%
State (Medicaid)	7%
Insurance/HMO	35%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 65% of the revenue at DaVita’s Whidbey Island Dialysis Center. The department concludes that the majority of revenue (65%) is dependent upon entitlement sources that are not cost based

reimbursement and are not expected to have an unreasonable impact on charges for services. The remaining 35% will be derived through other or private insurance reimbursements.

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

(3) The project can be appropriately financed.

To demonstrate compliance with this sub-criterion, DaVita provided a letter from the Chief Operating Officer of DaVita demonstrating financial and operational support from the Board of Directors for the establishment of additional Washington locations. The letter assured financial support for the proposed dialysis center through cash available through the organizations current holdings. [Application, p21 & Appendix 6] Additionally, DaVita provided its most recent historical financial statements for years 2004 through 2006. A review of DaVita’s historical financial statements shows the funds necessary to finance the project are available. [Public Comment; Application, Appendix 10]

Based on the information provided, the department concludes the establishment of a 5-station facility in Whidbey Island would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that DaVita, Inc. has met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

To staff its proposed 5-station facility, DaVita intends to recruit 2.90 FTEs in partial year 2009, which would increase to a total of 6.5 FTEs by the end of full calendar year three (2012). A breakdown of the proposed FTEs is shown below. [Application p23]

**Table 8
Whidbey Island Dialysis Center 2008 – 2011 Projected FTEs**

	2009 Partial Year	2010 Year 1	2011 Year 2	2012 Year 3	Total
Medical Director	Contracted Position				
Administrator	0.20	0.30	0.10	0.20	0.80
RNs	1.10	0.30	0.40	0.40	2.20
Patient Care Tech	1.00	0.50	0.10	0.40	2.00
BioMed Tech	0.30	0.00	0.00	0.00	0.30
ReUse Tech	0.10	0.10	0.00	0.20	0.40
Admin Asst	0.00	0.00	0.00	0.10	0.10
Social Wk	0.10	0.10	0.10	0.10	0.40
Dietician	0.10	0.10	0.10	0.00	0.30
FTE Total	2.90	1.40	0.80	1.40	6.50

As shown in Table 8, the facility will be operating with 4.4 FTE's by the end of the first full year to serve the projected 18 patients [Table 5 above]. DaVita expects a steady increase in staff for DaVita Whidbey Island to account for the increases in patient totals through 2012. DaVita states it expects no difficulty in recruiting staff for DaVita Whidbey Island because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. DaVita states that several employees have already expressed interest in working at its proposed Whidbey Island facility. [Application, p24]

DaVita has identified Dr. Fadi Najjar as the intended Medical Director for the new Whidbey Island facility. The applicant supplied a draft contract that indicates Dr. Najjar's service in this capacity. The agreement outlines the roles of both DaVita and Dr. Najjar in relation to the medical director responsibilities. If this project is approved, the department will include a term requiring DaVita to provide a copy of the executed medical director agreement with Fadi Najjar, MD prior to commencement of services consistent with the draft agreement provided within the application. [Application, Attachment 3]

Based on this information, and acceptance of the term described, the department concludes that adequate staffing for DaVita Whidbey Island is available or can be recruited. This sub criterion is met.

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

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing dialysis centers. For DaVita Whidbey Island, 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; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [Application, p24]

DaVita acknowledges that since this would be a new facility in Island County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [Application, p24; 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 the executed transfer agreement with a local hospital in Island 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 43 states (including Washington State) and the District of Columbia. [DaVita website] Currently within Washington State, DaVita owns and operates twenty-five 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 public⁴. 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 states and the District of Columbia where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Of the 43 states, the department received responses from 28 states or 66% of the 43 states.⁵ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁶

Ten of the 28 states responding to the survey indicated that 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. A single facility in both Delaware and New York were voluntarily decertified 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 applicant also reported that a facility in Memphis, purchased as part of an acquisition, has been decertified due to a record of performance deficiencies. [Application, Appendix 4]

These locations represent a nominal portion of the over 1,300 facilities owned and operated by DaVita. And, while the department did not receive responses from all states where DaVita operates, it did obtain a 66% return rate. The noted non-responsive locations equate to 0.23% of DaVita's total facilities. Therefore, the department concludes the out-of-state compliance surveys are an acceptable measure.

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.⁷ 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. [Facility survey data provided by the Office of Health Care Survey]

⁴ WAC 246-310-230(5).

⁵ 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.

⁶ Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

⁷ Olympic View Dialysis Center is owned by Group Health and managed by DaVita.

Fadi Najjar, 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. Najjar. The agreement outlines the roles and responsibilities of both DaVita & Dr. Najjar, the compensation and the initial 10 year term. A review of the compliance history of Dr. Najjar has shown that his credentials are up to date and reveal no recorded sanctions. [Medical Quality Assurance Commission compliance data] As stated above, if this project were approved, the department would include a term requiring DaVita to provide a copy of the executed medical director agreement consistent with the draft agreement provided within the application.

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 DaVita Whidbey Island facility would operate in conformance with state and federal regulations. With the acceptance of the term cited above, 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 quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [Application, p24; Appendices 17 & 18]

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

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 5 additional dialysis stations in the Island County planning area. Within the application, DaVita demonstrated it met the standards to receive approval to establish the needed stations.

Therefore, the department concludes that approval of 5 new dialysis stations in Island County planning area is consistent with the need methodology and would not have the potential of fragmentation of dialysis services within the service area. This sub-criterion is met.

- (5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This sub-criterion is addressed in sub-section (3) above and is considered met.

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

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

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

Before submitting this application, DaVita considered three options, one of which (Alternative #1) was chosen and became the focus of this application. The alternatives and DaVita's rationale for rejecting the two not chosen are summarized below.

Alternative #2: Establish a robust, 5-station at the Whidbey Island site in the Island County planning area with full services.

DaVita states that it evaluated the option of including a permanent bed station in the proposed 5 station facility. The applicant determined that the inclusion of a permanent bed station, in a location equipped to meet only the projected need, would reduce the utilization of the overall facility. [Application, p27]

Alternative #3: Pursue joint ventures and shared services in developing an Island County planning area project.

DaVita considered the existing Puget Sound Kidney Center 5-station facility and concluded what is needed was improved access and choice. With DaVita's practice of supporting the needs of their facilities with regional support programs, there is no need for DaVita to look outside their organization for joint or shared services. [Application, p27]

The option of "do nothing" was not considered. Because additional stations are projected as needed, the department concludes this option is not be the best option for Island County residents. The department is unaware of any regulation that limits the use of a bed station in such a way that would impact the facility's dialysis capacity. Therefore the department does not agree with the applicant's reasoning for rejecting Alternative #2. However, the department concludes the establishment of a 5-station facility in Island County is the best available alternative because the application meets the other applicable review requirements and there is a projected station need. This criterion is 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 met.

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

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.

APPENDIX A