

CERTIFICATE OF NEED EVALUATION OF THE DAVITA, INC. APPLICATION PROPOSING TO ESTABLISH A NEW 9-STATION KIDNEY DIALYSIS CENTER IN MARSYVILLE TO SERVE THE RESIDENTS OF SNOHOMISH 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. [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 9-station kidney dialysis facility in Marysville to be located on the Southwest corner of 116th and Smokey Point Boulevard within Snohomish County. It will be known as DaVita, Inc. Tulalip Dialysis Center. [Source: DaVita supplemental information, dated: May 11, 2007, page 1]

The capital expenditure associated with the establishment of the 9-station dialysis center is \$1,337,202, of which approximately 54.4% is related to leasehold improvements at the site; 37.1% is related to both fixed and moveable equipment and the remaining 8.5% is related to architectural, engineering, application, consulting and legal fees. [Source: Application page 7]

DaVita, Inc. anticipates that all 9 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 Tulalip” 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

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 Snohomish County Planning Area 1 during Review Cycle #1; therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review

January 31, 2007	Letter of Intent Submitted
February 28, 2007	Application Submitted
March 1, 2007 through May 11, 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 27, 2007	End of Public Comment/Public Hearing
August 13, 2007	Rebuttal Documents Received at the Department
September 27, 2007	Department's Anticipated Decision Date
October 26, 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— Puget Sound Kidney Center (PSKC) a dialysis provider located in Smokey Point within Snohomish County.

SOURCE INFORMATION REVIEWED

- DaVita's Certificate of Need Application received February 28, 2007
- DaVita's supplemental information received May 11, 2007
- Historical dialysis data obtained from Northwest Renal Network years 2001 through 2006
- Year 2006 Northwest Renal Network 4th Quarter
- Comments received at the public hearing on July 27, 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.

- PSKC rebuttal comments received August 13, 2007
- DaVita, Inc. rebuttal comments received August 13, 2007
- Medical Quality Assurance Commission Credentialing Records
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Snohomish County online Government Information & Services Real Property Information
- Data obtained from 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 9-station kidney dialysis facility in the city of Marysville within Snohomish County planning area 1, 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 246-310-284.

- (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, 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.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 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.

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]

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

DaVita’s Application of the Numeric Methodology

DaVita proposes to establish the 9-station kidney dialysis facility in Marysville to serve the residents of Snohomish County Planning Area 1. 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 Snohomish County, the number of projected patients is divided by 4.8 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 page 17]

Table 1
Summary of DaVita’s Snohomish County planning area 1
Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	98.6	109.2	119.8	130.4
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	20.542	22.750	24.958	27.167
Total Station Need Rounded Up	21	23	25	28
Minus # CN Approved Stations	18	18	18	18
Net Station Need / (Surplus)	3	5	7	10

As shown in Table 1 above, DaVita projected need for 10 dialysis station in Snohomish County Planning Area 1 in year 2010. Based on the results of the methodology, DaVita requested 9 dialysis stations.

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 linear regression to project need for the planning areas. Given that the facility would be located in Snohomish County Planning Area 1, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. Summarized in Table 2 below, is the department’s application of the numeric methodology. [Source: Appendix A attached to this evaluation]

Table 2
Summary of the Department's Snohomish County Planning Area 1
Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	98.6	109.2	119.8	130.4
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	20.542	22.750	24.958	27.167
Total Station Need Rounded Up	21	23	25	28
Minus # CN Approved Stations	18	18	18	18
Net Station Need / (Surplus)	3	5	7	10

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 10-stations in Snohomish County Planning Area 1.

WAC 246-310-284(5) requires that all CN approved stations in the planning area must 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 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, PSKC kidney dialysis center is the only dialysis provider operational in Snohomish County Planning Area 1 and according to data available to the department, PSKC is currently operating at 5.67 utilization rate. This criterion is met.

WAC 246-310-286 requires DaVita Tulalip to be operating at 4.8 in-center patients per approved station by the end of year three (2011). DaVita provided the projected third year utilization for the DaVita Tulalip facility as a 9-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 Tulalip Projected Utilization

Facility Name	# of Stations	# of Patients	Patients/ Per Stations
DaVita Tulalip	9	50	5.67

As shown in Table 3 above, DaVita Tulalip projects to be operating above the 4.8 standard by the end of the third year of operation, or year 2011.

Based on DaVita's projection with all 9-station operational, the facility would be operating at over 4.8 patients per in-center station by the third year of operation or year 2011. The department concludes that DaVita's proposal to establish a new 9-station dialysis facility in Marysville to serve the residents of Snohomish County Planning Area 1 met this criterion. Based on the methodology and Snohomish County Planning Area 1

resident's historical dialysis utilization data, DaVita has demonstrated need for a new 9-station dialysis facility in Marysville, within Snohomish County planning area 1. 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.

Summarized below are comments provided to the department by PSKC regarding DaVita's ability to provide charity care to all residents of the service area.

- DaVita's application has no provision for charity care, it allows time payment and does not explain what happens if a patient is unable to pay for services and cannot afford monthly payments. [Source: PSKC public comment dated: July 27, 2007]

Summarized below are the responses by DaVita to the concerns raised by PSKC

- Appendix 14 attached to DaVita's application is a complete operating copy of the indigent care policy which document access is never denied due to indigence or inability to pay for services at DaVita's facilities.
- DaVita's operating financial pro-forma includes a line item showing that funds budgeted to provide charity care is consistent with the indigent care policy. [Source: DaVita, Inc. rebuttal comment dated: August 13, 2007 page 2]

The Department Response

Based upon source information reviewed and DaVita's responses to the comments made by PSKC the department concludes that DaVita pro-forma submitted to the department shows charity care and demonstrates that all residents of the service areas could reasonably be expected to have adequate access to healthcare services at the DaVita Tulalip 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 operations. Summarized in Table 3 below, is DaVita's year one through year four projected financial revenue, expenses, and net income for the DaVita Tulalip Dialysis Center as a 9-station dialysis facility [Source: Application, Appendix 9]

**Table 4
 DaVita Tulalip 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	9	9	9	9	9
# of Treatments [1]	3,078	5,478	7,128	8,029	8,781
# of Patients [2]	20	35	45	50	54
Utilization Rate [2]	2.22	3.89	5.00	5.56	6.00
Net Patient Revenue[1]	\$845,882	\$1,789,368	\$2,689,240	\$3,294,031	\$3,756,749
Total Operating Expenses [1, 3]	\$947,217	\$1,323,174	\$1,737,668	\$1,989,654	\$2,219,328
Net Profit or (Loss)[1]	(\$101,335)	\$466,194	\$951,572	\$1,304,377	\$1,537,421
Operating Revenue / Treatment [1]	\$274.82	\$326.65	\$377.28	\$410.27	\$427.83
Operating Exp./ Treatment [1]	\$307.74	\$241.54	\$243.78	\$247.81	\$252.74
Net Profit per Treatment [1]	(\$32.92)	\$85.10	\$133.50	\$162.46	\$175.08

[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 above, the DaVita Tulalip facility would be operating the 9-station dialysis center at a loss in partial year 2008 and

to a profit in years 2009 through 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-DaVita Marysville, 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 5,500 square feet facility with an annual lease amount of \$31 per square foot or \$170,5000 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-DaVita Marysville, LLC and Total Renal Care, Inc. Terms and Conditions Article 3 Rent Adjustments, May 11, 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	\$170,500	\$170,133	\$367
Year 2	\$175,615	\$131,428	\$44,187
Year 3	\$180,883	\$135,371	\$45,512
Year 4	\$186,309	\$139,432	\$46,877
Year 5	\$191,899	\$143,615	\$48,284
5 yr Total	\$905,206	\$719,979	\$185,227

The overstatement of lease/rent amounts in the pro forma would result in an overstatement of expenses, resulting in an overstatement of net loss in year 2008, and an understatement of net profit in years 2009 through 2012. While this overstatement could be viewed as a “conservative pro forma projections,” it is indicative of inconsistencies within the application.

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.

During the review of this application, PSKC provided comments to the department regarding the proposed new facility. PSKC states that DaVita “*does not have an interest in the site, and the information provided regarding the proposed Marysville’s site is speculative at best*”. [Source: PSKC rebuttal comments dated: August 13, 2007 page1]

Summarized below is DaVita’s response to the concern raised by PSKC.

- After correctly identifying the site DaVita has proposed and having reviewed the draft lease submitted for the site, PSKC makes two highly technical and irrelevant complaints. PSKC complains that a wholly-owned DaVita subsidiary, not DaVita, Inc. appears as lessee.
- EDG-DaVita Marysville, LLC the proposed facility lessor and the lessee Total Renal Care, Inc. are both wholly-owned DaVita, Inc. subsidiaries.
- The proposed site landlord warrants the proper use of the property per the lease agreement submitted to the department on May 11, 2007 as attachment 2.
- The lessor EDG-DaVita Marysville, LLC is a developer with a contract to purchase the property from the current owners. [Source: DaVita, Inc. rebuttal comments dated: August 13, 2007, page1]

The Department Response

After reviewing comments by PSKC and DaVita’s responses, the department does not agree with DaVita that the comments are “highly technical and irrelevant.” The department does agree with DaVita that a draft lease agreement was submitted as supplemental information during the application review. However, the draft lease agreement annual rent amount does not correspond with lease/rent amounts in the pro forma statement provided to the department. 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 overstatement of expenses resulting in an overstatement of net loss in year 2008 and an understatement of net profit in years 2009 through 2012. A public record review of the Washington State Secretary of State’s Office reveals no record of EDG-DaVita Marysville, LLC registered to do business in Washington State. Additionally, a review of the Snohomish County On-line Government Information Services by the department revealed that the proposed site is not owned by EDG-DaVita Marysville, LLC. These two factors lead to the department’s conclusion that DaVita does not have a draft lease that could be reasonably relied on for demonstrating interest in the proposed site.

DaVita identified Fadi Najjar, MD as the Medical Director for the proposed DaVita Tulalip Dialysis Center and provided a draft medical director agreement between DaVita and Dr. Najjar. The draft Medical Director’s agreement identifies the term of the agreement and role and responsibilities of both parties. However, the draft does not identify the compensation to be paid to the Medical Director. The costs for the medical director services included in the pro-forma statements cannot be substantiated based on the draft Medical Director’s agreement provided in the application.

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 9-station dialysis facility is \$1,339,661. [Source: Application page 1] Summarized in Table 6 below, is the capital expenditure.

**Table 6
DaVita Tulalip Dialysis Center Capital Cost**

Item	Cost	% of Total
Leasehold Improvements	\$727,000	54.4%
Fixed & Moveable Equipment	\$495,703	37.1%
Architect/Engineering and CN fees	\$114,500	8.5%
Total Project Cost	\$1,337,203	100%

The department recognizes that the majority of reimbursements for dialysis services are thorough Medicare ESRD entitlement. To further, demonstrate compliance with this sub-criterion, DaVita provided the sources of its patient revenue shown in the table 7 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, 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. 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 9-station dialysis facility. Based on the information provided, the department concludes that DaVita has demonstrated that establishment of the new 9-station Tulalip Dialysis Center in Snohomish County Planning Area 1 will not adversely affect DaVita’s financial stability. The department concludes that DaVita’s application to establish a new 9-station dialysis center in Marysville to serve the residents of Snohomish County Planning Area 1 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 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 2.20 new staff during the first partial year of operation and thereafter, increase the number of new staff to 7.10 by the end of the fourth full year of operation. The proposed project staff increase is summarized in Table 8 below.

**Table 8
Tulalip 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	0.2	0.8	-	-	-	1
Registered Nurses	1.1	0.6	0.5	0.1	0.1	2.4
Patient care Tech	1.2	1.2	1.1	0.8	0.7	5
Biomedical Tech	0.2	-	-	-	-	0.2
Re-Use Tech	0.2	-	0.1	-	-	0.3
Administrative Asst	-	0.2	0.3	-	0.1	0.5
Social Worker	0.2	0.1	0.1	-	0.1	0.5
Dietician	0.2	0.1	0.1	-	-	0.5
Number of FTE'S	3.3	3.0	2.2	0.9	1.0	10.4

As shown in Table 8 above, DaVita expects to hire 10.4 total FTE’s by the 4 year of operation to staff the Tulalip dialysis center and states that it does not anticipate any difficulty in recruiting the necessary staff to the proposed facility. Additionally, DaVita states that “DaVita offers a competitive wage and benefit package to employees by posting openings nationally and externally and several current employees have expressed interest in working at the DaVita Tulalip facility”. Furthermore, DaVita also 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 24]

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

PSKC provided the department comments regarding DaVita's structure and process quality of care and those comments are summarized below.

- The project will not promote continuity of care and DaVita's volume of applications around the state shows determined efforts to take over the dialysis business.
- The proposed facility medical director lives in a different city and PSKC is not sure if he has patients admitting privileges at local Snohomish County hospitals.
- DaVita fails to identify a referring physician in support of its application. [Source: PSKC public comment dated: July 27, 2007]

Below are a summary of DaVita's responses to PSKC comments.

- DaVita currently owns or operates 14 dialysis facilities throughout the State of Washington and each of those facilities promotes continuity of care and has appropriate relationships with existing healthcare systems in their area operational areas.
- DaVita does not know any incumbent provider in Washington that has suffered unreasonable patient's losses to a new DaVita facility.
- A speaker at the public hearing on July 27, 2007 representing Marysville Care Center supported DaVita's application
- PSKC is currently operating in excess of 4.8 patients per station. [Source: DaVita, Inc. rebuttal comment dated: August 13, 2007 page 2]

The Department Response

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. DaVita's response that a speaker at the public hearing representing Marysville Care Center supported DaVita's application submitted to address PSKS's comment regarding physician support is not creditable. Marysville Care Center is a nursing home and may have residents requiring dialysis living there, however the nursing home is not a referring physician. However, nothing in the department or Medicare rules require an applicant to document physician support to receive approval.

Therefore, the department does not agree that the issues raised by PSKC should result in a fail under this sub-criterion.

Base on information provided by DaVita, the department concludes that staffing is expected to be available for recruitment by the applicant when the dialysis center commences services in May 2008. 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.

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 24]

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 Snohomish County.

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

Below is a summary of comment received from PSKC.

- DaVita has no signed transfer agreement and no established relationship with a local healthcare provider. [Source: PSKC public comment dated: July 27, 2007]

The responses below were provided to the department by DaVita regarding the concern raised above by PSKC.

- As addressed in DaVita's application and screening responses DaVita will initiate the application process for transfer agreements following issuance of a CN.
- The Program recently has approved DaVita's applications subject to a condition that prior to providing services at a new facility, DaVita provide to the department an executed copy of the patient transfer agreement.
- DaVita has experience no difficulty obtaining the appropriate patients transfer agreement prior to providing services at a new facility. [Source: DaVita, Inc. rebuttal comment dated: August 13, 2007 page 4]

The Department Response

The department concludes that rebuttal comments provided by DaVita are reasonable and consistent with previous information in applications submitted by DaVita. Therefore, the department does not agree that the issues raised by PSKC should result in a fail under this sub-criterion.

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 Tulalip Dialysis facility will have appropriate ancillary and support services with a healthcare provider in Snohomish County. This sub-criterion is met provided DaVita agrees to the term identified above. .

- (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 public³. 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.⁴ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁵

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 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 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.⁶ 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

³ WAC 246-310-230(5).

⁴ 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.

⁵ Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

⁶ 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.

submitted and implemented acceptable plans of correction. [Source: facility survey data provided by the Office of Health Care Survey]

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. The agreement outlines the roles and responsibilities of the medical director. Given the compliance history of DaVita and that of the proposed facility medical director, the department concludes that there is reasonable assurance that DaVita Tulalip 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 9-station dialysis facility in Marysville 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 there is substantial stations need in Snohomish County Planning Area 1. The current facility serving Snohomish County Planning Area 1 Puget Sound Kidney Center-Smokey Point facility exceeds 4.8 patients per station as of December 31, 2006 quarterly report, therefore this alternative was rejected.
- Alternative 2: Establish 6-stations in Planning area 3
This alternative was rejected because as at third quarter 2006, Snohomish County Planning Area 3 shows net stations need of 6-stations and the utilization of the existing Puget Sound Kidney Center South exceed 4.8 patients per station. However, the existing facility station utilization dropped in the fourth quarter of 2006 to below 4.8 patients per stations threshold as required by the dialysis rules.

Summarized below are comments received from PSKC.

- DaVita application fails to identify all of the alternatives that are available and must be considered.
- DaVita fails to considers PSKC alternative proposal of adding 12-additional station to its existing PSKC-Smokey Point facility.[Source: PSKC public comment dated: July 27, 2007]

Below are DaVita's responses to PSKC comments.

- At the time DaVita filed its application for this project, expansion at PSKC-Smokey Point was not a possible alternative.
- PSKC had not filed a letter of intent for expansion for the PSKC-Smokey Point facility. [Source: DaVita, Inc. rebuttal comment dated: August 13, 2007 page 4]

The Department Response

The department acknowledges DaVita's responses to PSKC concerns, but disagrees with DaVita that this is the best available alternative and concludes that the applicant has not demonstrated that the establishment of a new 9-station dialysis facility in Snohomish County Planning Area 1 is the best available alternative.

The department cannot conclude that the current DaVita Marysville project is the best available alternative. While the department determined that a need was demonstrated, the project as proposed failed to meet financial feasibility. Therefore, this criterion is not met.

APPENDIX A