

CERTIFICATE OF NEED EVALUATION OF THE DAVITA, INC. APPLICATION PROPOSING TO ESTABLISH A NEW 10-STATION KIDNEY DIALYSIS CENTER IN LONG BEACH TO SERVE THE RESIDENTS OF PACIFIC COUNTY.

PROJECT DESCRIPTION

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,300 outpatient centers located in 42 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [Source: DaVita 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 in Washington. [Source: CN historical files; & Application, Page 1]

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

DaVita's application proposes to establish a new 10-station dialysis facility in Pacific County. The facility to be known as DaVita Seaview Dialysis Center would have 10-stations and be located at the intersections of Pacific Highway and South 18th Street SW, Long Beach, Washington 98631. The proposed facility cite is also known as Pacific County tax lot number 73026076001, Block 76, Lots 3, 4, 7 and 8. [Source: August 14, 2007, Supplemental Information, Page 1 and Draft Lease Agreement Attachment 1] The proposed DaVita Seaview Dialysis Center would serve the residents of Pacific County.

The capital expenditure associated with the establishment of the 10-station dialysis center is \$1,333,858, of which approximately 52% is related to leasehold improvements at the site; 40% is related to both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [Source: Application, Page 6]

If this project is approved, DaVita anticipates all 10-stations would become operational by the end of October 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [Source: DaVita Application, Page 10]

For ease of reference, the department will refer to the proposed kidney dialysis facility as “DaVita Seaview” 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 #2. No other kidney disease treatment center applications were submitted for Pacific County during Review Cycle #2; therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

April 30, 2007	Letter of Intent Submitted
May 31, 2007	Application Submitted
June 4, 2007 through November 26, 2007 ²	Department’s Pre-review Activities <ul style="list-style-type: none">• Screening Activities and Responses
December 5, 2007	Department Begins Review of Application
January 9, 2008	End of Public Comment/Public Hearing
January 21, 2008	Rebuttal Documents Received at the Department
March 6, 2008	Department’s Anticipated Decision Date
March 3, 2008	Department’s Actual Decision Date

AFFECTED AND INTRESTED PERSONS

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

SOURCE INFORMATION REVIEWED

- DaVita’s Certificate of Need Application received May 31, 2007
- DaVita’s supplemental information received August 14, 2007
- DaVita’s supplemental information received September 25, 2007
- DaVita’s supplemental information received November 21, 2007
- Historical dialysis data obtained from Northwest Renal Network years 2001 through 2006

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 Department conducted a third screening.

- Year 2006 Northwest Renal Network 4th Quarter
- Public comments received by the department January 9, 2008
- DaVita, Inc. rebuttal comments received January 22, 2008
- Medical Quality Assurance Commission Credentialing Records
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Pacific County Assessor's on-line 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, the application submitted DaVita, Inc. proposing to establish a new 10-station dialysis center in Seaview within Pacific County is consistent with the applicable criteria. Provided that DaVita, Inc. agrees to the terms identified below, a Certificate of Need would be issued for the establishment of the 10-station Seaview Dialysis Center to be located in Long Beach within Pacific County. The approved capital expenditure associated with the establishment of the Seaview Dialysis Center is \$1,333,858.

Terms

1. 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 agreement shall be consistent with the draft agreement provided within the application.
2. Prior to providing services at the Seaview Dialysis Center, DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval.
3. Prior to commencing this project, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located at the Southeast Corner of Pacific Highway and 18th Street Southwest, Long Beach, WA 98631 Tax Lot #73026076001.

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.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)]

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’s Application of the Numeric Methodology

DaVita proposes to establish the 10-station kidney dialysis facility in Seaview to serve the residents of Pacific 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 Pacific 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 page 16]

Table 1
Summary of DaVita’s Pacific County Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	23.7	25.6	27.5	29.4
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	7.41	8.00	8.59	9.19
Total Station Need Rounded Up	8	8	9	10
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	8	8	9	10

As shown in Table 1 above, DaVita projected need for 10 dialysis station in Pacific County in year 2010. Based on the results of the methodology, DaVita requested 10 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 Pacific 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 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 Pacific County Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	23.7	25.6	27.5	29.4
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	7.406	8	8.593	9.187
Total Station Need Rounded Up	8	8	9	10
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	8	8	9	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 Pacific 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 May 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, Pacific County does not have a dialysis facility. This criterion is met.

WAC 246-310-286 requires DaVita Seaview 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 DaVita Seaview facility as a 10-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 Seaview Projected Utilization**

Facility Name	# of Stations	# of Patients	Patients/ Per Stations
DaVita Seaview	10	37	3.70

As shown in Table 3 above, DaVita Seaview projects to be operating above the 3.2 standard by the end of the third year of operation, or year 2011. During the review of this application, the department received comments regarding the proposed project. Public comments provided to the department by Fresenius Medical Care (FMC) states that DaVita overstated projected patient volume and assumed that it will achieve 100% market share in Pacific County by the end of year 2012. [Source: FMC public comments dated January 9, 2008]

DaVita’s Response

DaVita states that FMC comments are baseless and relies upon an erroneous need projection, ignores the unmet need for home dialysis training and after hours (5.00 p.m.) treatments that providers in adjacent counties fail to serve. Further, DaVita states that its application includes a higher projected volume beyond 2010 because its dialysis comparison research shows that the closest facility in which most Pacific County patients dialyzed, is a FMC facility in Oregon that does not have an after hour (5.00 p.m.) opening. DaVita anticipates that once the proposed facility is operational, patient’s from the non-after hours opening facility will be attracted to the proposed DaVita Seaview. Additionally, DaVita states that WAC 246-310-286 allows the program to consider in migration of patients from Oregon when it projects utilization in the Pacific County services area. [Source: DaVita, Inc. rebuttal comments dated January 22, 2008]

Department Response

The department notes that DaVita used the appropriate ESRD methodology under WAC 246-310-284 to project that 10-stations are needed in Pacific County. The department disagrees with DaVita’s assertions that WAC 246-310-286 allows the program to consider that patient’s volumes from Astoria, Oregon could be used to project future patients volume. This WAC allows the applicant to supplement NRN data to project station need. The department does agree that under circumstances patients outside the immediate planning area may use a facility. We also acknowledge that DaVita’s patient projections are optimistic, but not necessarily unrealistic.

Further as shown in Table 3, based on DaVita's projection's with all 10-station operational, the proposed facility would be operating at over 3.2 patients per in-center station by the third year of operation or year 2011. Therefore, the department concludes that DaVita's proposal to establish a new 10-station dialysis facility in Seaview to serve the residents of Pacific County met this criterion.

Based on the methodology and Pacific County resident's historical dialysis utilization data, DaVita has demonstrated need for a new 10-station dialysis facility in Seaview within Pacific 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 upon source information reviewed, department concludes that all residents of the service areas could reasonably be expected to have adequate access to healthcare services at the DaVita Seaview 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 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 October 2008. Based on this timeline, year 2009 would be DaVita’s first full calendar year of operations. Summarized in Table 4 below, is DaVita’s year one through year four projected financial revenue, expenses, and net income for the DaVita Seaview Dialysis Center as a 10-station dialysis facility [Source: Application, Appendix 9]

**Table 4
 DaVita Seaview 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	10	10	10	10	10
# of Treatments [1]	2,587	4,708	5,771	6,682	7,441
# of Patients [2]	16	28	33	37	40
Utilization Rate [2]	1.60	2.80	3.30	3.70	4.00
Net Patient Revenue[1]	\$639,899	\$1,324,999	\$1,875,157	\$2,239,201	\$2,557,719
Total Operating Expenses [1, 3]	\$942,161	\$1,286,529	\$1,637,102	\$1,906,727	\$2,130,494
Net Profit or (Loss)[1]	(\$302,262)	\$38,470	\$238,055	\$332,474	\$427,225
Operating Revenue / Treatment [1]	\$247.35	\$281.44	\$324.93	\$335.11	\$343.73
Operating Exp./ Treatment [1]	\$364.19	\$273.26	\$283.68	\$285.35	\$286.32
Net Profit per Treatment [1]	(\$116.84)	\$8.17	\$41.25	\$49.76	\$57.41

[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 above in Table 4, at the projected volumes identified, the DaVita Seaview facility would be operating the 10-station dialysis center at a loss in partial year 2008 and a profit in years 2009 through 2012. DaVita states that the proposed facility will be operated at utilization levels consistent with other facilities. In order to clarify that DaVita has site control, it provided a draft lease agreement between EDG-DV Seaview, LLC (Tenant) and Total Renal Care, Inc. its parent company as the Landlord. Rent costs data identified in the draft lease are consistent with the pro-forma financial projections used to prepare Table 4 above.

During the review of this application, Fresenius Medical Care Holdings, Inc. the parent company of Renal Care Group Northwest, Inc. provided comments to the department regarding the proposed project. Those comments are summarized below.

- DaVita’s projected volume of 40 HD patients for Pacific County in 2012 is fully 21% greater than the 33 patients produced under the methodology.
- DaVita assumed a payer mix and revenue steam that is not consistent with Fresenius experience in Pacific County. [Source: Fresenius public comments received January 9, 2008]

DaVita Patient's Volume Projections Response

Challenges of DaVita patient's volume by FMC are baseless because it has no base under WAC 246-310-284. DaVita is committed to supporting patients who choose to dialyze in a home setting. At this time, Pacific County patients have no local alternative for home dialysis training program. For year end 2006, 13% of all dialysis patients were home dialysis patients thus applying the state average, DaVita expects that Pacific County would generate at least 4 to 5 home dialysis patients. Adding to the count, Grays Harbor an adjacent planning area does not provide a home training program and DaVita expects to draw potential home dialysis patients from that planning area. Under this estimate, DaVita believes that its estimate of 5-9 home patients is reasonable. DaVita provided a new pro-forma to address directly the patient's volume issues raised by FMC. The revised pro-forma provided in rebuttal relies on FMC's assumptions about patient volume and it still demonstrates the project is financially feasible.

DaVita Payer Mix Projections Response

DaVita previously explained its payer mix and the reason for the 20% insurance/HMO change to 35%. As previously explained, the change reflects a difference in categorizing revenue, not from any change in actual revenue source. DaVita uses data obtained from its 10-K filing with the Security Exchange Commission showing its company wide performance. Previous applications used data from 10-Ks and internal company report for the years 2005 and earlier. DaVita Seaview application uses data from year 2006, 10-K which became available earlier this year. The difference involves the categorization of Medicare and Medicaid assigned HMO patients. DaVita serves a category of patients who have assigned their Medicare and Medicaid benefits to an HMO and is reimbursed by the HMO's.

The 2006, 10-K characterizes the revenue as commercial/HMO and DaVita has carried that approach into recent applications. The revenue associated with this category is 12% Medicare and 3% Medicaid qualified enrollees and the combine total of the two categories explains the difference from previous applications. DaVita is not able to predict with accuracy the actual payer mix it will experience at a new facility and it relies on a company-wide performance data as a starting point for estimating future payer mix for new facilities. [Source: DaVita, Inc. rebuttal comments January 22, 2008, pages 4-5]

The Department Response

The department notes that the only reasonable method available in which an applicant can verify its patient's volume assumption is to refer to the applicant's company-wide performance data regarding payer-mix. The department concludes that DaVita's responses are reasonable regarding its market share expectations and agrees with the assertions that it cannot predict with accuracy the actual payer mix it will experience in a new facility. The department would expect DaVita to rely on its company-wide performance data as a starting point for estimating future payer mix for its new facilities.

If approved, the Department would include a term that DaVita provide for review and approval an executed lease agreement contract which includes the relevant terms as identified in the draft agreement.

Term

- *Prior to commencing this project, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located at the Southeast Corner of Pacific Highway and 18th Street Southwest, Long Beach, WA 98631 Tax Lot #73026076001.*

Based on the information presented the department concludes that the proposed project is financially feasible. This sub-criterion is met.

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

The estimated capital expenditure associated with the establishment of the 10-station dialysis facility is \$1,333,858. [Source: Application page 1] Summarized in Table 5 below, is the capital expenditure.

**Table 5
DaVita Seaview Dialysis Center Capital Cost**

Item	Cost	% of Total
Leasehold Improvements	\$692,500	51.92%
Fixed & Moveable Equipment	\$526,949	39.51%
Architect/Engineering and CN fees	\$114,409	8.58%
Total Project Cost	\$1,337,858	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 6 below. [Source: Application, Page 21]

**Table 6
DaVita's Source of Revenue**

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

As shown in Table 6, Medicare and state (Medicaid) entitlements as stated by DaVita are projected to equal 65% of the proposed facility revenue sources that are not cost based reimbursement. The department concludes that costs associated with this project will not have

unreasonable impact on the remaining 35%. Therefore, the department concludes 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 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 10-station dialysis facility. Based on the information provided, the department concludes that DaVita has demonstrated that establishment of the new 10-station Seaview Dialysis Center in Pacific County will not adversely affect DaVita’s financial stability. The department concludes that DaVita’s application to establish a new 10-station dialysis center in Seaview to serve the residents of Pacific County 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 3.10 new staff during the first partial year of operation and thereafter, increase the number of new staff to 9.50 by the end of the fourth full year of operation. The proposed project staff increase is summarized in Table 7 below.

**Table 7
Seaview 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	0.80	-	-	-	1.00
Registered Nurses	1.10	0.10	0.40	0.30	0.10	2.00
Patient care Tech	1.00	1.40	-	0.40	0.40	3.20
Biomedical Tech	0.20	-	0.60	-	-	0.80
Re-Use Tech	0.20	0.10	-	0.10	0.10	0.50
Administrative Asst	-	-	-	0.30	0.30	0.60
Social Worker	0.20	0.10	0.40	0.10	0.00	0.80
Dietician	0.20	0.10	0.10	0.10	-	0.10
Number of FTE'S	3.10	2.60	1.60	1.30	0.90	9.50

As shown in Table 7 above, after the initial recruitment of FTEs, DaVita expects a steady increase in FTEs for its Seaview Dialysis Center through year 2012. DaVita states it expects no difficulty in recruiting staff for the new facility because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. In addition, DaVita states that several employees have already expressed interest in working at its proposed facility. [Source: Application, Page 23]

DaVita identified Catherine Richardson, MD as the Medical Director for the proposed Seaview Dialysis Center and provided a draft medical director's agreement between Pacific Nephrology Associates, PS (the "Group"), Dr. Richardson and DaVita. The draft medical director agreement outlines the roles and responsibilities of the Group and Dr. Richardson. Additionally, the draft agreement also identifies the annual compensation for the medical director. [Source: DaVita Application, Page 5 and Appendix 3]

If approved, the Department would include a term that DaVita provide for review and approval an executed medical director contract which includes the relevant terms and compensation as identified in the draft agreement prior to project completion.

Term

- *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 agreements shall be consistent with the draft agreement provided within the application.*

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 October 2008. This sub-criterion is met provided DaVita agrees to the term identified above.

- (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 Pacific County.

Term

- *Prior to providing services at the DaVita Seaview Dialysis 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 Seaview Dialysis facility will have appropriate ancillary and support services with a healthcare provider in Pacific 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 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 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.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 significant non-compliance deficiencies were cited at DaVita facilities in the past three years. Of those states responding, with the exception of a single facility each in Delaware, New York and 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 was scheduled for decertification in 2006 due to several non-compliance citations, but was operating in compliance at the time of the survey. The New York facility was cited with non-compliance condition-level deficiencies and was voluntarily de-certified and closed by DaVita.

In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005 and no further fines were identified for this facility. During the 2007 ESRD Cycle 3 application submission period⁷, DaVita disclosed to the department that one of its facilities in Tennessee was de-certified due to some significant non-compliance citations and closed by the authorities of that state in June 2007. The department reviewed the circumstance leading to the closure of this facility and determines that DaVita will implore safeguards within its operations to prevent future occurrences of significant non-compliances happening at its facilities. Further, 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 four reported as subject to fines or actually decertified. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

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 ESRD Cycle 3, 2007, application submission period last working day of August 2007.

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]

Compliance history review of the proposed medical director Dr. Catherine Richardson did not reveal any recorded sanctions. DaVita provided a draft medical director agreement with Dr. Richardson. 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 Seaview 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 10-station dialysis facility in Seaview, within Pacific County 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.

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.

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

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

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

To comply with this sub-criterion, DaVita stated that it considered two alternatives to the project and rejected one alternative. Summarized below are the two alternatives considered.

- Alternative 1: Do nothing maintain the status quo

This alternative was rejected because there is substantial stations need in Pacific County. Currently Pacific County does not have a provider and there is need for 10-stations which means that patients currently must travel outside the county to seek treatment. The establishment of facility in the county eliminates the need for patients to travel outside for treatment.

- Alternative 2: Establish 10-station center in Seaview

This alternative was chosen because it improves access with the use of a 2-shift model and provides patients choice of provider and eliminates the need for patients to travel outside for treatment. Adding 10-stations is consistent with the need for stations in the county and it promotes the efficient use of capital and improves labor availability.

Based on the information presented, the department agrees that this is the best available alternative and concludes that the applicant has demonstrated that the establishment of a new 10-station dialysis facility in Seaview within Pacific County is the best available alternative. 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