

**REVIEW OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON
BEHALF OF DAVITA, INC. PROPOSING TO ESTABLISH A TWENTY-ONE
STATION KIDNEY DIALYSIS CENTER TO SERVE THE RESIDENTS OF PIERCE
COUNTY PLANNING AREA #5**

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. [Application, p4]

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 thirteen DaVita facilities located in Washington. [CN historical files; & Application, p4]

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

King

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

Yakima Dialysis Center

This application proposes to establish a new DaVita dialysis facility in Pierce County. The new facility, to be known as the DaVita Parkland Dialysis Center, would have 21 stations and be located at an unspecified address on the Southwest corner of 138th St and Pacific Avenue South in the city of Tacoma, Washington. The new facility would offer dialysis services to patients residing in the Pierce County planning area #5. [July 25, 2007, supplemental information, p1 & Attachment 2]

The capital expenditure associated with the establishment of the 21 station facility is \$1,867,462, of which approximately 56% is related to leasehold improvements at the site; 38% is related to both fixed and moveable equipment; and the remaining 6% is related to architect, engineering, application, consulting, and legal fees. [Application, p7]

Evaluation Breakdown Of ECE	Total	% of Total
Leasehold Improvements	\$ 1,037,500	56%
Fixed & Moveable Equipment	\$ 715,553	38%
Professional Fees	\$ 98,000	5%
CN Fees	\$ 16,409	1%
Total Estimated Capital Costs	\$ 1,867,462	100.00%

If this project is approved, DaVita anticipates all 21 stations would become operational within eight months of approval. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [Application, p12]

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 Pierce County planning area #5 during Review Cycle #1. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

January 30, 2007	Letter of Intent Submitted
February 28, 2007	Application Submitted
March 1, 2007 through April 5, 2007	Department's Pre-Review Activities <ul style="list-style-type: none"> • 1st screening activities and responses
April 6, 2007 through June 15, 2007	Superior Court Judge "stayed" this application while a hearing was conducted related to a competing application submitted by

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.

June 16, 2007 through July 31, 2007	Franciscan Health System. The Superior Court hearing concluded on June 15, 2007, and the “stay” was lifted.
August 1, 2007	Department Resumes Pre-Review Activities <ul style="list-style-type: none"> • 1st screening activities and responses
September 4, 2007	Department Begins Review of the Application <ul style="list-style-type: none"> • public comments accepted throughout the review
October 10, 2007 ²	End of Public Comment/No Public Hearing Conducted
November 26, 2007	Rebuttal Documents Received at Department
November 26, 2007	Department's Anticipated Decision Date
	Department's Actual Decision Date

AFFECTED PERSONS

Throughout the review of this project, one entity sought and received affected person status under WAC 246-310-010—Franciscan Health System’s (FHS), a dialysis provider located in Tacoma, within Pierce County.

SOURCE INFORMATION REVIEWED

- DaVita’s Certificate of Need application submitted February 28, 2007
- DaVita’s supplemental information dated July 25, 2007
- Franciscan Health System public comments received September 5, 2007
- DaVita’s rebuttal comments received October 10, 2007
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2006 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)
- Certificate of Need historical files
- Medical Quality Assurance compliance data
- Data obtained from the Washington Secretary of State website
- Data obtained from the Pierce County Assessor website

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a 21 station dialysis center in Parkland, within Pierce County planning area #5 is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

² On September, 11, 2007, the timeline was adjusted to allow for 10 days per rule to respond after reports indicated a lost mail package that was mailed to DaVita containing the over 800 pages of public comment submitted on behalf of Franciscan Health System. On September 12, 2007, the department granted DaVita’s request for an additional extension to the recalculated 10 day deadline to respond to comment.

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, 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 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)]

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 a 21 station dialysis center in Parkland to serve patients in Pierce County planning area #5. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was used to project need. Given that the facility would be located in Pierce County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [DaVita Application, p17-19]

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning areas as described above, the department also used linear regression to project need for Pierce County planning area #5. The department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5) as required by rule.

Based on the numeric methodology, Tables 1 below depict a summary of the projected net need provided by the applicant and the department’s projected net need for Pierce County planning area #5. DaVita divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

**Table 1
Pierce #5 Numeric Methodology Summary of Projected Net Station Need**

	4.8 in-center patients per station			
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
DaVita	41.92	21	20.92	21
DOH	41.9167	21	20.9167	21

When comparing the results of the two tables above, it is noted that DaVita’s projections and the department’s projections are the same. In summary, the numeric needs methodology result in a need for 21 in-center stations in Pierce County Planning Area #5.

As shown in Table 1 above, currently Pierce County Planning Area #5 has 21 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, 2007. [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. All 21 stations are at one facility—DaVita’s Lakewood Dialysis Center. Table 2 below shows the December 31, 2006, utilization of the Lakewood Dialysis Center and demonstrates that this capacity requirement is met.

Table 2

December 31, 2006-Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
DaVita Lakewood Dialysis Center	21	125	5.95

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 Pierce 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 Pierce County planning area #5; 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 2011. A summary of the applicant’s projected utilization for year 2011 is shown in Table 3 below. [DaVita Application, p15 & Appendix 9]

**Table 3
Year 2011 Projected Facility Utilization**

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita Parkland Dialysis Center	2011	21	116 ⁴	5.52

As shown in Table 3 above, DaVita’s projections meet this standard.

Based on the above information, the application submitted by DaVita, Inc. proposes to establish a 21-station dialysis center in Pierce County planning area #5. 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 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.

⁴ DaVita cites a patient count of 120 for 2011 on p9 &17 of the application, but calculates the 2011 Pro Forma with a patient count of 116. The department used the figure cited in the financial calculations as the projected patient count in the third year of the Parkland facility

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 provided a copy of its current admission and indigent care policies that would also be used at the new Parkland facility. The Admission policy outlines the process/criteria that DaVita Parkland 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 Parkland without regard to race, color, national origin, sex, age, religion, or disability. [Application, Appendix 14]

DaVita currently provides services to Medicare and Medicaid eligible patients at its existing fourteen dialysis centers and intends to maintain this status. A review of the Admission and Charity Care policies provided for DaVita Parkland identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. [Application, Appendix 14]

Additionally, 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 'charity care' line item as a deduction from revenue within the pro forma financial documents. [Application, Appendices 9 & 14; July 25, 2007, supplemental information, Attachment 4]

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 Parkland 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 not met the financial feasibility criteria in WAC 246-310-220.

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

If this project is approved, DaVita anticipates commencement immediately and DaVita Parkland would be operational within eight months of approval. Based on this timeline, year 2009 would be DaVita Parkland's first full calendar year of operation and 2011 would be year three. [Application, p12]

Using the financial information provided in the application, Table 4 below illustrates the projected revenue, expenses, and net income for fiscal years 2009-2011 for the Parkland Dialysis Center. [DaVita Application, p10]

Table 4
Parkland Dialysis Center
Projected Revenue and Expenses Calendar Years 2009 – 2011

	Year 1 - 2009	Year 2 - 2010	Year 3 - 2011
# of Stations	21	21	21
# of Treatments ^[1]	11,831	15,725	17,372
# of Patients ^[2]	79	105	116
Utilization Rate ^[2]	3.76	5.00	5.52
Net Revenue ^[1]	\$ 3,993,718	\$ 4,348,029	\$ 5,273,032
Total Expense ^[1,3]	\$ 2,750,413	\$ 3,706,392	\$ 4,394,665
Net Profit or (Loss) ^[1]	\$ 1,243,305	\$ 641,637	\$ 878,367
Net Patient Revenue/Treatment ^[1]	\$ 337.56	\$ 276.50	\$ 303.54
Total Operating Exp./Treatment ^[1]	\$ 232.48	\$ 235.70	\$ 252.97
Net Profit (Loss) per Treatment ^[1]	\$ 105.09	\$ 40.80	\$ 50.56

[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 4 above, at the projected volumes identified in the application, DaVita Parkland would be operating at a profit in the first full year of service (2009). The profit per treatment shows a notable reduction in the following years, but would continue to operate at a profit through 2011 as a 21 station facility.

As previously stated, Franciscan Health Systems provided comments with an extensive review of this project. [FHS Public Comment, p1-20] The comments focus on two separate issues and are summarized below.

- 1) DaVita’s draft lease issues regarding site and ownership; and
- 2) DaVita’s pro forma information provided in the application.

1. DaVita’s Draft Lease

- DaVita submitted an incomplete application from the onset. When the application was submitted on February 28, 2007, DaVita did not identify a site for the dialysis center or provide complete documentation that it has sufficient interest in a site.
- The lessor of the property identified in the draft lease, EDG-Parkland, LLC. is not currently registered to conduct business in Washington State.
- The lessor of the property identified in the draft lease is different than the current owner of the property based on the Pierce County Assessor website.

As a result, FHS asserts that DaVita does not demonstrate that it has either a clear legal title for the propose site or, in the case of a lease agreement, site control as required in Certificate of Need guidelines.

2. Pro forma Financial

- DaVita believes that it is not required to fully allocate corporate or regional overhead expenses to its pro forma financials.
- DaVita believes that it is not required to follow Generally Accepted Accounting Principles [despite the fact that they have warranted in their Securities and Exchange Commission filings that they do so].
- Considerable and unjustifiable increases in revenues are attributable to “Other” revenue sources. What the other items consist of is unspecified and are attributed to produce an inordinate amount of the revenues.
- FHS also provides comments regarding DaVita’s identification of the following line items within DaVita’s pro forma financial documents—depreciation, bad debt, repairs/maintenance and revenue per treatment.

DaVita’s responses to the comments raised by Franciscan Health System are also summarized below. [DaVita’s October 10, 2007 rebuttal documents, p1-16]

DaVita’s Draft Lease Agreement Rebuttal

- The lease costs identified in the draft lease agreement and the pro forma financial documents “readily compare and confirm” the information submitted with the July 25, 2007 screening responses. [p1]
- The department does not require applicants to demonstrate legally binding site control during the application process—for good reason. Binding site control requires executed legal agreements that are costly to obtain. The agreements would take valuable commercial properties off the market for an indefinite period of time while the Program evaluates the applications and parties exhaust appeals. Rather than needlessly impose such substantial costs on all applicants, the department has elected to allow applicants to provide draft leases that provide all relevant costs and terms related to facility cost and operation.
- DaVita has properly identified the parties to the lease as its subsidiary Total Renal Care, and one individual. As is typical with DaVita’s past and pending applications, it has a contractual relationship with the lessor to build and equip the facility to-suit and lease the completed facility to DaVita. The lessor makes appropriate arrangements with the landowner, typically either to purchase or lease the site if the application is successful. DaVita states, “The more burdensome approach FHS purports to advocate would require applicants and third parties to prepare complex and binding legal documents that would detail legal relationships from the record title holder to the independent developer and DaVita”. They continue, “Instead the department has asked for a draft lease that shows lease costs and other material terms”. [p5]

Pro forma Financial Information Rebuttal

- FHS falsely contends that DaVita has not fully allocated general overhead in its pro forma. FHS also asserts that DaVita has allocated its G&A expenses in the pro forma but has reported the expenses at a lower rate than reported on a company-wide basis in the DaVita 2006 10-K. The pro forma shows [the following] values for general

and administrative expenses. [DaVita provided a table with corporate and division G&A broken down for years 1 through 5, p9]

- DaVita can internally decide to protect a small, new facility from actually paying a full share of G&A if warranted to maintain appropriate cash flow attributable to the facility. The comfortable operating margin projected for the Parkland facility makes such consideration irrelevant.
- There is an important difference between GAAP financial reports and company pro forma estimates, such as DaVita's CN pro formas. The December 2005 stakeholder report to the Department of Health rejected the notion of pursuing greater standardization in CN pro formas, potentially including standardized depreciation schedules.
- DaVita CN pro forma is a product of a larger and highly-complex decision-support financial model for DaVita's internal use. The model used a 29-year or 40-year schedule for improvements and a 7-year schedule for equipment. In response to criticisms by FHS and others, DaVita has evaluated this aspect of the model and future pro formas will use shorter schedules for leasehold improvements (10 years rather than 29 years). [DaVita provided revised computations for its leasehold depreciation and a comparison of depreciation costs for 10 years when compared to 29 years.]
- FHS erroneously criticizes the pro forma statements when it compares revenue ratios that are separate and unrelated. In addition, the rate of 17% of the total is based upon corporate experience in estimating gross revenue projections.
- Regarding bad debt, repairs and maintenance, and revenue per treatment, DaVita provided detailed responses and also provided a pro forma document to demonstrate that, in aggregate, none of the comments raised by Franciscan Health System would "undercut" the financial feasibility of the Parkland project.

Department Response

After reviewing the information provided by both Franciscan Health System and DaVita, the department provides the following evaluation.

Site Control

After reviewing the comments provided by Franciscan Health System and the responses provided by DaVita, the department concludes that the draft lease agreement provided by DaVita does not demonstrate appropriate control of the site as required under CN application guidelines.

Preliminary research showed that, according to the Pierce County Assessor, the property cited in Exhibit A of the draft lease is commercial property registered to PSNB Parkland 138th and is listed as a Key Bank location. No building is currently attributed to this parcel. [Pierce County Assessor website]

The landlord/lessor identified as a Washington limited liability company in the draft lease agreement is EDG-DV Parkland. [DaVita July 25, 2007 screening responses, Attachment 2 & Exhibit

E] According to the records available from the Washington Secretary of State, EDG-DV Parkland is not listed as a registered entity.

DaVita states that, “[EDG-DV Parkland] is a developer that will have a contract to purchase the property from the property owner...and will lease the space to DaVita”. [DaVita July 25, 2007 screening responses, p5] DaVita argues that EDG Development, LLC is duly registered with the Washington Secretary of State, though not cited as a party in of the agreements submitted, and will be responsible for instigating the simple process to form the Parkland corporation.

DaVita has missed the aim of a draft lease agreement. Once a draft agreement is submitted, the department expects the agreement to be between the applicant (DaVita or its subsidiary— Total Renal Care) and the owner of the property. DaVita did not provide any documentation to demonstrate that EDG-DV Parkland has legal control of the property to enter into a lease agreement with Total Renal Care. An entity that has no ownership or identified control of property cannot reasonably enter into any agreement—draft or executed— committing to the use for that property. Further, the draft submitted is with an organization which does not currently exist. As such, the draft submitted has no value in establishing any site control, for either party, in the proposed site.

Not stated in the issues addressed above, but necessary to consider, is that there is no indication that the timeline for beginning services can reasonably be met based on the number of actions required for the building of a new facility with a developer that does not currently have any agreement to utilize the property. As stated prior to this discussion, the Department is unable to conclude that DaVita has any controlling interest in the site.

Pro forma Statements

After reviewing the comments provided by Franciscan Health System and the responses provided by DaVita, the department concludes that many of the comments/concerns were based on Franciscan Health System’s experience as a hospital-based dialysis facility. These comments/concerns may not be applicable to a non-hospital based dialysis facility. Therefore, the department does not agree with all of the concerns cited.

Confirmation of costs recorded in the draft lease versus the Pro Forma was also reviewed in relation to issues outlined above. DaVita provided a breakout in the rebuttal documents that compares the rent reported in both the Pro Forma and lease. Calculations represented correctly identify the disparity to equal to less than 1% of total expenses. [p3] The department reconstituted the table from DaVita’s rebuttal comments in Table 5 below.

**Table 5
Department comparison of Pro Forma and Draft Lease Rent**

	2008	2009	2010	2011	2012
ProForma	\$ 260,667	\$ 201,365	\$ 207,406	\$ 213,628	\$ 220,037
Lease*	\$ 215,050	\$ 221,502	\$ 228,147	\$ 234,991	\$ 242,040
Difference	\$ (45,617)	\$ 20,137	\$ 20,741	\$ 21,363	\$ 22,003
% Total	0.89%	0.73%	0.56%	0.49%	0.46%

Expenses					
% Lease differs from Pro Forma	-17%	13%	15%	17%	19%

* allows for 3% annual increase outlined in draft lease

The 2008 Pro Forma expenses have been increased to \$260,667 to correctly correspond to the costs submitted in Appendix 9 of the DaVita application and resubmitted in rebuttal. Table 6 also includes a calculation showing the percent change in the rent expenses, as a line item of the total expenses, in relation to the lease terms. The total costs over the five years, according to DaVita's Pro Forma, equals \$1,103,103. This understates the rent by \$38,627 when compared to what the lease indicates would be paid over the same 5 year period.

During the screening process, the department requested any necessary updates to the proposed facilities Pro Forma that "reflects all costs associated with the identified site". [July 25, 2007 Screening Question, #9] DaVita responded that no changes were necessary.

As a result, DaVita did not provide a valid draft lease for the site as required under Certificate of Need guidelines. Further, rent costs identified in the lease cannot be substantiated in the project's pro formas, therefore, the proposed Parkland facility cannot be fully evaluated on its long-range capital and operating costs. 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 capital expenditure associated with the expansion of the Parkland facility is \$1,867,462 of which 56% is related to construction, 38% for both fixed and moveable equipment; and the remaining 6% is related to architect, engineering, application, consulting, and legal fees. [Application, p7]

Table 6
DaVita's Parkland Estimated Capital Costs

Item	Total	% of Total
Leasehold Improvements	\$ 1,037,500	56%
Fixed & Moveable Equipment	\$ 715,553	38%
Professional Fees	\$ 98,000	5%
CN Fees	\$ 16,409	1%
Total Estimated Capital Costs	\$ 1,867,462	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, p23]

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, p24]

Table 7
DaVita's Parkland Dialysis Center
Sources and Percentages of Revenue

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

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 80% of the revenue at DaVita's Parkland Dialysis Center. The department concludes that the majority of revenue (80%) 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 20% will be derived through other or private insurance reimbursements. 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 and the reported lease costs. The department is unable to conclude the average cost per dialysis is reasonable or accurate.

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 not 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 for the establishment of DaVita Parkland. The letter assured financial support for the proposed dialysis center at a capital cost of \$1,867,462. [Application, p9 & Appendix 6] Additionally, DaVita provided its most recent historical financial statements for years 2003 through 2005. [Application, Appendix 10] A review of DaVita's historical financial statements shows the funds necessary to finance the project are available.

Based on the information provided, the department concludes the establishment of an 21 station facility in Parkland 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 not met the structure and process (quality) of care criteria in WAC 246-310-230.

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

To staff its proposed 21 station facility, DaVita intends to recruit 9.20 FTEs in partial year 2008, which would increase to a total of more than 24 FTEs by the end of full calendar year three (2011). A breakdown of the proposed FTEs is shown in Table 8 below. [Application p25]

**Table 8
Parkland Dialysis Center 2008 – 2011 Projected FTEs**

Staff/FTEs	2008 Partial	2009 Increase	2010 Increase	2011 Increase	Total
Medical Director	Contracted Position				
Administrator	1.00	0.00	0.00	0.00	1.00
RN	2.10	1.10	1.10	0.60	4.90
Patient Care Techs	3.80	2.30	2.80	2.00	12.00
Biomedical Techs	0.50	0.00	0.00	0.00	0.50
Re-Use Techs	0.80	0.20	0.20	0.30	1.50
Administrative Assistant	0.20	0.40	0.40	0.50	1.50
Social Worker	0.40	0.30	0.30	0.00	1.50
Dietitian	0.40	0.30	0.30	0.00	1.50
FTE Total	9.20	4.60	5.10	3.40	24.40

As shown in Table 8 above, after the initial recruitment of FTEs, DaVita expects a steady increase in staff for DaVita Parkland through year 2010 and a minimal increase in year 2011. DaVita states it expects no difficulty in recruiting staff for DaVita Parkland 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 Parkland facility. [Application, p26]

DaVita has identified Dr. Catherine Richardson as the intended Medical Director for the new Parkland facility. The applicant supplied a draft contract that indicates Dr. Richardson's service in this capacity. The agreement outlines the roles of both DaVita and Dr. Richardson in relation to the medical director responsibilities. [DaVita June 25, 2007 screening responses, Attachment 3, p4]

Based on this information, the department concludes that adequate staffing for DaVita Parkland 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 fourteen dialysis centers. For DaVita Parkland, 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, p26]

DaVita acknowledges that since this would be a new facility in Pierce County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [Application, p26; 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 Pierce County. Provided that DaVita would agree to the term, this sub-criterion would be met.

- (3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,300 outpatient centers located in 42 states (including Washington State) and the District of Columbia. [source: DaVita Webpage] Prior to the October 1, 2005, acquisition of the dialysis operations of Gambro Healthcare US, DaVita operated 665 centers in 37 states and the District of Columbia. Currently within Washington State, DaVita owns and operates fourteen kidney dialysis treatment centers. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public⁵. To accomplish this task, in January 2007 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the 42 states and the District of Columbia where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Of the 43 entities, the department received responses from 28 states or 66% of the 42 states.⁶ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁷

Ten of the 28 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Delaware, one in New York and one in Texas, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2006 due to several condition-level citations, but was operating in compliance at the time of survey. The New York facility was cited with

⁵ WAC 246-310-230(5).

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

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

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

As stated earlier, DaVita owns or manages 1,300 facilities. While the department did not receive responses from all states where DaVita operates, it did have 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 acceptable.

For Washington State, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 32 compliance surveys for the operational facilities that DaVita either owns or manages.⁸ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Office of Health Care Survey]

Catherine Richardson, 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. Richardson. The agreement outlines the roles and responsibilities of both DaVita & Dr. Richardson, the compensation and the required renewal of each one (1) year term. A review of the compliance history of Dr. Richardson has shown that her credentials are up to date and reveal no recorded sanctions. [Medical Quality Assurance Commission compliance data] If this project were approved, the department would include a term requiring DaVita to provide a copy of the executed medical director agreement with Catherine Richardson, MD. A condition would be that the term of service, cited in the executed medical director agreement, extend to a minimum of 3 years to correlate to the period projected in the application's pro forma.

Based on DaVita's compliance history, the compliance history of the proposed medical director, and DaVita's agreement to the term and condition associated with the medical director, the department concludes that there is reasonable assurance that the DaVita Parkland facility would operate in conformance with state and federal regulations. 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

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.

patient services education offered through its quality of care program. [Application, p26; 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 considered 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 21 additional dialysis stations in Pierce County planning area #5. However, as stated in the financial feasibility portion of this evaluation, demonstrated site control and financial inconsistencies prevent an accurate evaluation of the proposed facility's lease costs and forecasted viability. In the long-term, this may lead to the unnecessary opening and closing of a facility, leading to a loss of service.

Therefore, the department concludes that approval of an additional dialysis center in Pierce County planning area #5 would have the potential of future fragmentation of dialysis services within the service area, and this sub-criterion is not met.

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

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

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

Based on the source information reviewed, the department determines that DaVita, Inc. 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.*

Before submitting this application, DaVita considered two alternatives to this application. The alternatives and DaVita's rationale for rejecting them are summarized below.

Alternative #1: Do not build a new dialysis center in Pierce Planning Area 5

DaVita states that delays and on-going litigation have caused substantial delays for any operator serving Pierce County patients. Additionally, DaVita considered the need projects for 2010 and determined that this option "would run counter to the orderly and predictable development of health resources". [Application, P28]

Alternative #2: Establish a Parkland facility that is smaller than 21 stations

DaVita considered the Department's tie-breaking criteria in combination with an additional CN application submitted separately to expand a facility in Lakewood. It was determined

that an application for the establishment of a new facility, that would score higher in the possible application of the tie-breaker criteria, would be a better alternative.

Based on DaVita's discussion of the two options above, both options were rejected before submitting this project.

In determining the best available alternative the department considered its findings on the other applicable review criteria. The department cannot conclude that the current DaVita Parkland project is the best available alternative. While the department determined that a need was demonstrated, the project as proposed failed to meet financial feasibility and structure and process of care criteria. Therefore, this criterion is not met.

(2) *In the case of a project involving construction:*

(a) *The costs, scope, and methods of construction and energy conservation are reasonable;*

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is 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