

**EVALUATION OF TWO CERTIFICATE OF NEED APPLICATIONS SUBMITTED BY
DAVITA, INC PROPOSING TO ADD DIALYSIS STATIONS IN BENTON COUNTY:**

- **A TEN-STATION DIALYSIS CENTER IN THE CITY OF KENNEWICK**
- **A NINETEEN-STATION DIALYSIS CENTER IN THE CITY OF RICHLAND**

PROJECT DESCRIPTIONS

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, 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 fourteen DaVita facilities located in Washington. [source: 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

King

Bellevue Dialysis Center

Federal Way Community Dialysis Center

Kent Community Dialysis Center

Olympic View Dialysis Center (management only)

Westwood Dialysis Center

Yakima

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

DaVita submitted two Certificate of Need applications to add dialysis station capacity in Benton County--one facility in Kennewick and one in Richland. For reader ease, the department will refer to the Kennewick project as "DaVita-Kennewick" and the Richland project as "DaVita-Richland." Each application will be evaluated separately within this document.

DaVita-Kennewick

This application proposes to establish a ten-station dialysis facility at 3208 West 19th Avenue in the city of Kennewick. [source: July 10, 2007, supplemental information, p1]

The capital expenditure associated with the establishment of the 10-station facility is \$1,371,182, of which approximately 53% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 7]

If this project is approved, DaVita anticipates all 10 stations would become operational by the end of September 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [source: Application, p10]

DaVita-Richland

This application proposes to establish a 19-station dialysis facility on the southeast corner of Wellsian Way and Aaron Drive in the city of Richland. [source: July 10, 2007, supplemental information, p1]

The capital expenditure associated with the establishment of the 19-station facility is \$1,714,689, of which approximately 54% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 7]

If this project is approved, DaVita anticipates all 19 stations would become operational by the end of September 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [source: Application, p10]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both of DaVita's projects are 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 DaVita application 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 288.¹

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted these projects under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1. A chronologic summary of the review is shown below.

Action	DaVita-Kennewick	DaVita-Richland
Letter of Intent Submitted	January 31, 2007	January 31, 2007
Application Submitted	February 28, 2007	February 28, 2007
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" these two applications while a hearing was conducted related to a competing application submitted by Fresenius Medical Care. The Superior Court hearing concluded on June 15, 2007, and the "stay" was lifted.	

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); and WAC 246-310-287.

APPLICATION CHRONOLOGY (continued)

June 16, 2007 through July 9, 2007	Department Resumes Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses
July 9, 2007	Department Begins Review of the Application <ul style="list-style-type: none">• public comments accepted throughout the review
September 14, 2007	End of Public Comment/No Public Hearing Conducted
October 15, 2007	Rebuttal Documents Received at Department
November 29, 2007	Department's Anticipated Decision Date
November 29, 2007	Department's Actual Decision Date

CONCURRENT REVIEW AND AFFECTED PERSONS

The concurrent review process promotes the expressed public policy goal of RCW 70.38 that the development or expansion of health care facilities are accomplished in a planned, orderly fashion and without unnecessary duplication. For dialysis projects, concurrent review allows the department to review dialysis applications proposing to serve the same planning area [as defined in WAC 246-310-280(9)] simultaneously to reach a decision that serves the best interests of the planning area's residents.

In the case of the two projects submitted by DaVita, the department will issue one single evaluation regarding whether both, any, or none of the projects should be issued a Certificate of Need.

For each application, one entity sought and received affected person status under WAC 246-310-010—Fresenius Medical Care, owner and operator of Tri-Cities Kidney Center, a 13-station dialysis center currently operating in Benton County.

SOURCE INFORMATION REVIEWED

DaVita-Kennewick

- DaVita, Inc.'s Kennewick Certificate of Need application submitted February 28, 2007
- DaVita, Inc.'s Kennewick supplemental information dated July 9, 2007
- Fresenius Medical Care's comments dated September 14, 2007
- DaVita, Inc.'s rebuttal comments received October 15, 2007

DaVita-Richland

- DaVita, Inc.'s Richland Certificate of Need application submitted February 28, 2007
- DaVita, Inc.'s Richland supplemental information dated July 9, 2007
- Fresenius Medical Care's comments dated September 14, 2007
- DaVita, Inc.'s rebuttal comments received October 15, 2007

For Both Projects

- 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
- Data obtained from the Washington Secretary of State website
- Benton County Assessor Office website
- Medical Quality Assurance compliance data

CONCLUSIONS

DaVita-Kennewick

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a ten-station dialysis center in the city of Kennewick within Benton County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

DaVita-Richland

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a nineteen-station dialysis center in the city of Richland within Benton County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that both DaVita projects have met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280.

- (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 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)]

DaVita's Application of the Numeric Methodology

Consistent with WAC 246-310-280(9), DaVita applied the numeric methodology to the Benton County planning area using linear regression. Given both facilities would be located

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]

in Benton County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: DaVita-Kennewick Application, pp15-18; DaVita-Richland Application, pp15-18]

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 Benton County. 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).

Based on the numeric methodology, Table 1 below depicts a summary of the projected net need provided by DaVita and the department for Benton County. The department’s numeric methodology for Benton County is attached to this evaluation as Appendix A.

**Table 1
Benton County 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	41.46	13	28.46	29.00
DOH	41.458	13	28.458	29.00

When comparing the results of the two methodologies shown in Table 1 above, it is noted that the Benton County results are the same for DaVita and the department. In summary, the net station need for Benton County is 29 stations as shown in Table 1 above. [source: Department’s methodology, Appendix A attached to this evaluation]

As shown in Table 1 above, currently Benton County has 13 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 13 stations are at one facility— Fresenius Medical Care’s Tri-Cities Kidney Center located in Kennewick. Table 2 below shows the December 31, 2006, utilization of Tri-Cities Kidney 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
Tri-Cities Kidney Center	13	87	6.69

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 Benton County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] Both of DaVita’s projects propose to be located within Benton

County, as a result, DaVita must demonstrate compliance with this criterion using the 4.8 in-center patient per station for each project. A summary of each project's utilization for year 2011 is shown below.

DaVita-Kennewick

DaVita proposes its third full year of operation would be 2011. Table 3 below is a summary of DaVita-Kennewick's projections for its proposed 10 station dialysis center. [source: July 10, 2007, supplemental information, Attachment 5]

**Table 3
Year 2011 Projected Facility Utilization**

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita-Kennewick	2011	10	55	5.50

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

DaVita-Richland

For its Richland project, DaVita proposes its third full year of operation would be 2011. Table 4 below is a summary of DaVita-Richland's projections for its proposed 19 station dialysis center. [source: July 10, 2007, supplemental information, Attachment 5]

**Table 4
Year 2011 Projected Facility Utilization**

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita-Richland	2011	19	110	5.80

As shown in Table 4 above, DaVita Richland's projections meet this standard.

Based on the above information and standards, the department's conclusion regarding this sub-criterion follows.

DaVita-Kennewick

DaVita proposes to establish a 10-station dialysis center in Kennewick, within Benton County. 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.

DaVita-Richland

DaVita proposes to establish a 19-station dialysis center in Richland, within Benton County. 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.

As previously stated, DaVita currently provides dialysis services to residents of specific service areas within 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.

DaVita-Kennewick and DaVita-Richland

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 Kennewick and Richland facilities. The Admission policy outlines the process/criteria that the new facility 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 the dialysis center without regard to race, color, national origin, sex, age, religion, or disability. [source: DaVita-Kennewick, Appendix 14; DaVita-Richland, 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 the both proposed Benton County facilities identify the proposed financial resources as including both Medicare and Medicaid revenues. [source: DaVita-Kennewick, Appendix 14; DaVita-Richland, 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 for both DaVita-Kennewick and DaVita-Richland. [source: DaVita-Kennewick, Application, Appendix 14 and July 9, 2007, supplemental information, Attachment 5; DaVita-Richland, Application, Appendix 14 and July 9, 2007, supplemental information, Attachment 5]

Based on the above information, the department concludes that all residents of the service area would have reasonable access to the health services at the proposed DaVita –Kennewick and DaVita Richland dialysis centers. This sub-criterion is met for both projects.

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.’s Kennewick project has not met the financial feasibility criteria in WAC 246-310-220; and
- DaVita, Inc.’s Richland project 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.

DaVita-Kennewick

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the 10-station facility would be operational by the end of September 2008. Based on this timeline, year 2009 would be DaVita-Kennewick’s first full calendar year of operation and 2011 would be year three. [source: Application, p10]

Using the financial information provided in the application, Table 5 below illustrates the projected revenues, expenses, and net income for years 2008-2011 for DaVita-Kennewick. [source: July 10, 2007, supplemental information, Attachment 5]

**Table 5
DaVita-Kennewick
Projected Revenues and Expenses Calendar Years 2008 - 2011**

	Partial Year 2008	Full Year 1 2009	Full Year 2 2010	Full Year 3 2011
# of Stations	10	10	10	10
# of Treatments ^[1]	3,827	6,226	7,877	8,778
# of Patients ^[2]	25	40	50	55
Utilization Rate ^[2]	2.50	4.00	5.00	5.50
Net Revenue ^[1]	\$ 1,288,936	\$ 1,944,745	\$ 2,002,165	\$ 2,378,902
Total Expense ^[1,3]	\$ 1,253,106	\$ 1,479,948	\$ 1,908,583	\$ 2,213,459
Net Profit or (Loss) ^[1]	\$ 35,830	\$ 464,797	\$ 93,582	\$ 165,443
Net Patient Revenue/Treatment ^[1]	\$ 344.27	\$ 324.67	\$ 267.38	\$ 288.81
Total Operating Exp./Treatment ^[1]	\$ 334.70	\$ 247.07	\$ 254.89	\$ 268.72
Net Profit (Loss) per Treatment ^[1]	\$ 9.57	\$ 77.60	\$ 12.50	\$ 20.09

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

As shown in Table 5 above, at the projected volumes identified in the application, DaVita anticipates that its Kennewick facility would be operating at a profit in years 2008 through 2011 as a 10-station facility. The department also notes the DaVita anticipates a large profit in the first full year of operation (year 2009), which reduces significantly in years two and three.

Public comment submitted by Fresenius Medical Care focused on the two issues summarized below. [source: FMC public comments, pp4-8, Attachment 1]

- 1) DaVita’s draft lease agreement, including the site for the project; and
- 2) DaVita’s pro forma information provided in the application.

DaVita's Draft Lease Agreement, including the site for the dialysis center

- DaVita submitted an incomplete letter of intent and application by not identifying the site for the project. The letter of intent stated DaVita would establish a dialysis center “located in Kennewick, Washington,” identifying no specific site. The application submitted on February 28, 2007, stated “Address TBD.”
- Within its July 9, 2007, supplemental information, DaVita identified its site to be 3208 West 19th Avenue in Kennewick, and submitted a draft lease agreement for the site. DaVita did not provide complete documentation that it has sufficient interest in the site.
- The lessor (owner) of the property identified in the draft lease is different than the current owner of the property based on the Benton County Assessor website. As a result, DaVita does not demonstrate that it has either a clear legal title for the proposed site or, in the case of a lease agreement, site control as required in Certificate of Need guidelines.

Pro forma Financial Information provided in the application

- DaVita's line item percentages of increases and decreases are inconsistent with projected increases and decreases in other line items. For example, volumes are projected to increase 63% between partial year 1 (2008) and full year 1 (2009), however, line items for rent, utilities, repairs and maintenance, and “other revenue” either increase or decrease at different percentages.
- DaVita provides no explanation for why its “EBIT” [earnings before income taxes] drops by 80% between full year 1 (2009) and full year 2 (2010), while its patient treatments increase 27%. Then, EBIT increases by 77% between years 3 (2011) and 4 (2012), while patient volumes increase by 11%.

DaVita's responses to the comments raised by Fresenius Medical Care are summarized below.
[source: DaVita's October 15, 2007, rebuttal documents, pp1-10, Exhibit 1]

DaVita's Draft Lease Agreement, including the site for the dialysis center

- DaVita's LOI identified the ESRD service area for the project; DaVita's provided a draft lease agreement and address for the proposed site of the dialysis center within its screening responses as requested by the department.
- The department allows draft lease agreements; DaVita provided its draft lease for the site.
- The draft lease identifies EDG-DV Kennewick, LLC as having “a contractual right to purchase such land” and “full power and authority to execute this lease.” Commercial property development, such as construction of a new dialysis facility, can occur in a variety of ways. Not all of the ways involve a prior acquisition or title transfer to the developer or facility owner. In this instance, the lessor—EDG-DV Kennewick, LLC—has a binding option on a contract to purchase the property from the property owner and will lease the space to DaVita. Benton County records do not show the lessor/developer's interest.
- EDG Development is duly registered with the Washington Secretary of State [copy of document provided as Exhibit 1]. Developers commonly establish single-purpose LLCs for individual projects. The fact that EDG Development may not have formed its project-specific LLC [EDG-DV Kennewick, LLC] at the time of FMC's inquiry is

meaningless. An LLC can be formed in one day with the submission of a single document and \$175 fee to the Secretary of State.

Pro forma Financial Information provided in the application

- DaVita’s pro forma is a product of a larger and highly-complex decision-supported 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 FMC, 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.]
- Regarding estimates for volumes and revenues, FMC’s comments assume that revenue in a new facility should vary in a linear relationship to volume. The pro forma is based on DaVita’s actual experience with new facilities. The difference in the volume increase and revenue increase is based on two factors: 1) volume increases include home patient volume increases that are significantly greater than 63%; and 2) revenue per home volume is greater than revenue per chronic treatment, which compounds the increase in overall volume. Items included in “other revenue” are EPO and ancillary items, including peritoneal dialysis that is independent of the in-center dialysis revenue.
- Regarding rent, utility, repairs and maintenance expenses in year one (2008) and year two (2009), year one includes four months of start-up expenses that are not included in subsequent years. This is a one-time expense.
- DaVita accurately projects EBIT. FMC expects DaVita to explain its changes in EBIT values. EBIT values are calculated from many other values set forth in DaVita’s pro forma and are influenced by dozens of variables. In general, DaVita’s pro forma is based upon experience and EBIT does not vary in a linear relationship with volume, as FMC implies. FMC’s comparison of EBIT values to treatment volumes is simplistic and meaningless in the context of DaVita’s complex pro forma.

Department Response

After reviewing the information provided by both Fresenius Medical Care and DaVita, the department provides the following evaluation.

DaVita’s Draft Lease Agreement, including the site for the dialysis center

After reviewing the comments provided by Fresenius Medical Care 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.

Page 1 of the draft lease agreement identifies the landlord (lessor) as EDG-DV Kennewick, LLC, “a Washington Limited Liability Company.” The Washington Secretary of State website does not identify EDG-DV as an existing LLC. Page 2 of the draft lease agreement states that the lessor [EDG-DV Kennewick, LLC] has the contract right to purchase the premises, which confirms that the lessor does not have appropriate control of the site. According to the Benton County website, the property is commercial property owned by Columbia River Bank. DaVita asserts that the developer—EDG Development, LLC—will establish a single purpose LLC—to develop the property, and the fact that it has not yet been formed is meaningless, since it can be formed in one day. Further, DaVita asserts that the department has allowed draft lease agreements in the past, and has not indicated that

draft agreements are no longer acceptable. DaVita has missed the point 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. If the owner of the property is not included in the draft agreement, the agreement is not a draft. One who has no ownership or legal control of property cannot legally enter into any agreement—draft or executed—for that property. The department considers the entities [landlord and tenant] entering into a draft lease agreement essential to the agreement. Without either of those two entities identified in the draft agreement, the agreement does not qualify as a draft. It is simply an informational document with no binding information. DaVita did not provide any documentation to demonstrate that EDG Development, LLC or EDG-DV Kennewick, LLC has legal control of the property to enter into a lease agreement—draft or otherwise—with Total Renal Care.

Another concern, not noted by Fresenius Medical Care, is the inconsistency between the lease costs in the draft agreement and the pro forma lease rent expense line item. The amount identified in the rent expense line item cannot be computed using basic information provided in the lease agreement. [source: DaVita's July 9, 2007, supplemental information, Attachment 2, pp3] This inconsistency would indicate that the draft lease submitted in response to screening may not be accurate in many terms being considered for the lease.

Pro forma Financial Information provided in the application

After reviewing the comments provided by Fresenius Medical Care and the responses provided by DaVita, the department concludes that concerns regarding depreciation, volume/revenue relationships, and the four months of start-up expenses in year one (2008) were appropriately addressed by DaVita.

However, the concern raised by Fresenius Medical Care regarding the EBIT or annual net profit or loss shown in Table 5 was also noted by the department. To evaluate this concern, the department compared DaVita's pro forma financial statement for DaVita Kennewick with past DaVita projects.³ In past projects, DaVita's pro forma anticipates a steady increase in net profits for the first three full calendar years of operation, rather than a profit spike in full year one, followed by a significant decline in full year two as shown in Table 5. Even a closer review of DaVita's pro formas for its Kennewick project does not reveal whether the inconsistency is the profit spike in year 2009 or the substantial decrease in profits for years 2010 and 2011.

In summary, DaVita did not provide a valid draft lease for the site as required under Certificate of Need guidelines. Further, the lease costs identified in the lease agreement cannot be substantiated in the project's pro formas. Finally, DaVita's pro formas raise questions that are not addressed by DaVita in its application materials. As a result, the DaVita-Kennewick project cannot be fully evaluated on its long-range capital and operating costs. Therefore, this sub criterion is not met.

³ DaVita projects used for comparison are CN Applications #07-24-Tacoma, #07-20-Clallam; #07-30-DesMoines; 07-32-Graham, and #07-51-Federal Way.

DaVita-Richland

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the 19-station facility would be operational by the end of September 2008. Based on this timeline, year 2009 would be DaVita-Richland's first full calendar year of operation and 2011 would be year three. [source: Application, p10]

Using the financial information provided in the application, Table 6 below illustrates the projected revenues, expenses, and net income for years 2008-2011 for DaVita-Richland. [source: July 10, 2007, supplemental information, Attachment 5]

Table 6
DaVita-Richland
Projected Revenues and Expenses Calendar Years 2008 - 2011

	Partial Year 2008	Full Year 1 2009	Full Year 2 2010	Full Year 3 2011
# of Stations	19	19	19	19
# of Treatments ^[1]	7,045	10,346	15,144	17,697
# of Patients ^[2]	45	65	95	110
Utilization Rate ^[2]	2.36	3.42	5.00	5.78
Net Revenue ^[1]	\$ 1,665,896	\$ 3,305,672	\$ 3,604,687	\$ 4,661,012
Total Expense ^[1,3]	\$ 1,638,693	\$ 2,229,782	\$ 3,044,733	\$ 3,747,544
Net Profit or (Loss) ^[1]	\$ 27,203	\$ 1,075,890	\$ 559,954	\$ 913,468
Net Patient Revenue/Treatment ^[1]	\$ 247.20	\$ 339.60	\$ 253.37	\$ 282.93
Total Operating Exp./Treatment ^[1]	\$ 243.17	\$ 229.07	\$ 214.01	\$ 227.48
Net Profit (Loss) per Treatment ^[1]	\$ 4.04	\$ 110.53	\$ 39.36	\$ 55.45

[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 6 above, at the projected volumes identified in the application, DaVita anticipates that its Richland facility would be operating at a profit in years 2008 through 2011 as a 19-station facility. The rent/lease costs identified in the draft lease agreement are substantiated within the pro forma financial information provided in the application.

However, similar to DaVita's Kennewick project, the department also notes the DaVita anticipates a much larger profit in the first full year of operation (year 2009), which reduces significantly in years two and three for the Richland facility.

Public comment submitted by Fresenius Medical Care focused on the two issues summarized below. [source: FMC public comments, pp5-8, Attachment 1]

- 1) DaVita's draft lease agreement, including the site for the project; and
- 2) DaVita's pro forma information provided in the application.

DaVita's Draft Lease Agreement, including the site for the dialysis center

- DaVita submitted an incomplete letter of intent and application by not identifying the site for the project. The letter of intent stated DaVita would establish a dialysis center

- “located in Richland, Washington,”* identifying no specific site. The application submitted on February 28, 2007, stated *“Richland Dialysis Center Address TBD.”*
- Within its July 9, 2007, supplemental information, DaVita identified its site to be *“___ Aaron Drive,”* and submitted a draft lease agreement for the site. No legal description is provided in the draft agreement. An approximate site description of the general location states *“the southeast corner of Wellsian Way and Aaron Drive, Richland, Washington.”* DaVita did not provide complete documentation to demonstrate it has a site.

Pro forma Financial Information provided in the application

- DaVita’s line item percentages of increases and decreases are inconsistent with projected increases and decreases in other line items. For example, volumes are projected to increase 47% between partial year 1 (2008) and full year 1 (2009), however, line items for rent, utilities, repairs and maintenance, and “other revenue” either increase or decrease at different percentages.
- DaVita provides no explanation for why its “EBIT” [earnings before income taxes] drops by 48% between full year 1 (2009) and full year 2 (2010), while its patient treatments increase 46%. Then, EBIT increases by 63% between years 3 (2011) and 4 (2012), while patient volumes increase by 17%.

DaVita’s responses to the comments raised by Fresenius Medical Care are summarized below.
[source: DaVita’s October 15, 2007, rebuttal documents, pp1-10]

DaVita’s Draft Lease Agreement, including the site for the dialysis center

- DaVita’s LOI identified the ESRD service area for the project; DaVita provided a draft lease agreement and the address is as accurate as the Richland address records allow. In addition, DaVita provided the nearest intersection.
- The department allows draft lease agreements; DaVita provided its draft lease for the site.
- The draft lease identifies Bush Living Trust (lessor) and Total Renal Care. Bush Living Trust is identified in the Benton County property records as the legal owner of the site.

Pro forma Financial Information provided in the application

- DaVita’s 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 FMC, 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.]
- Regarding estimates for volumes and revenues, FMC’s comments assume that revenue in a new facility should vary in a linear relationship to volume. The pro forma is based on DaVita’s actual experience with new facilities. The difference in the volume increase and revenue increase is based on two factors: 1) volume increases include home patient volume increases that are significantly greater than 47%; and 2) revenue per home volume is greater than revenue per chronic treatment, which compounds the increase in overall volume. Items included in “other revenue”

- are EPO and ancillary items, including peritoneal dialysis that is independent of the in-center dialysis revenue.
- Regarding rent, utility, repairs and maintenance and water expenses in year one (2008) and year two (2009), year one includes four months of start-up expenses that are not included in subsequent years. This is a one-time expense.
 - DaVita accurately projects EBIT. FMC expects DaVita to explain its changes in EBIT values. EBIT values are calculated from many other values set forth in DaVita's pro forma and are influenced by dozens of variables. In general, DaVita's pro forma is based upon experience and EBIT does not vary in a linear relationship with volume, as FMC implies. FMC's comparison of EBIT values to treatment volumes is simplistic and meaningless in the context of DaVita's complex pro forma.

Department Response

After reviewing the information provided by both Fresenius Medical Care and DaVita, the department provides the following evaluation.

DaVita's Draft Lease Agreement, including the site for the dialysis center

After reviewing the comments provided by Fresenius Medical Care and the responses provided by DaVita, the department concludes that the draft lease agreement provided by DaVita does not demonstrate appropriate control of a specific site as required under CN application guidelines.

Application guidelines require that the applicant supply documentation regarding the use of the proposed site for dialysis services and that the applicant has sufficient interest in the proposed location. [source: ESRD Application, Questions O & P] DaVita provided a copy of a draft lease agreement between the tenant, Total Renal Care, Inc (DaVita's parent corporation), and the landlord, Bush Living Trust. The draft lease agreement provided a legal description of the site to be " Aaron Drive, Richland Washington."

To address the claims presented in comment and addressed in rebuttal, the department initially worked to confirm the address cited in both the screening responses and the DaVita's draft lease submitted in response to screening questions. The specific address for the site is not provided. The department then worked to confirm a site using the information provided in Exhibit A of the draft agreement. While Exhibit A requires a legal description, the information provided in the exhibit is not a legal description or property site number.

"Although exact address will not be assigned until building permits have been issued, the approximate address is 1300 Aaron Drive, Richland, WA, 99352, located at the southeast corner of Aaron Drive and Wellsian Way on the south side of Aaron Drive."

The Benton County Assessor website shows Bush Trustees as the owners of several properties located on Aaron Drive. The draft lease agreement does not identify a specific site, or address, or legal description, or suite/unit #.

The department concludes that because the draft lease agreement provided by DaVita does not identify a specific site, or address, or legal description, or suite/unit #, the site can be only approximated. Since Certificates of Need are site specific, an approximate site is insufficient for the issuance of a Certificate of Need.

Pro forma Financial Information provided in the application

After reviewing the comments provided by Fresenius Medical Care and the responses provided by DaVita, the department concludes that concerns regarding depreciation, volume/revenue relationships, and the four months of start-up expenses in year one (2008) were appropriately addressed by DaVita.

However, the concern raised by Fresenius Medical Care regarding the EBIT or annual net profit or loss shown in Table 6 was also noted by the department. To evaluate this concern, the department compared DaVita's pro forma financial statement for DaVita Richland with past DaVita projects.⁴ In past projects, DaVita's pro forma anticipates a steady increase in net profits for its first three full years of operation, rather than a profit spike in full year one and then a significant decline in full year two as shown in Table 6. Even with a closer review of DaVita's pro formas for its Richland project, the department is unable to determine whether the inconsistency is the profit spike in year 2009 or the substantial decrease in profits for years 2010 and 2011. The department also notes that both of DaVita's Benton County projects show this inconsistency.

In summary, DaVita did not provide a valid draft lease for the site as required under Certificate of Need guidelines. Further, DaVita's pro formas raise questions that are not addressed in the application materials. As a result, the DaVita-Richland project cannot be fully evaluated on its long-range capital and operating costs. Therefore, 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.

DaVita-Kennewick

The capital expenditure associated with the establishment of the 10-station facility is \$1,371,182, of which approximately 53% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 7]

To demonstrate compliance with this sub-criterion, DaVita provided the following statements:

"...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." [source: Application, p21]

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

⁴ DaVita projects used for comparison are CN Applications #07-24-Tacoma, #07-20-Clallam; #07-30-DesMoines; 07-32-Graham, and #07-51-Federal Way.

Table 7
DaVita-Kennewick
Sources and Percentages of Revenue

Source of Revenue	Percentage 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-Kennewick. 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 cannot conclude that the costs of this project would probably not result in an unreasonable impact to the costs and charges for health care facilities. This sub-criterion is not met.

DaVita-Richland

The capital expenditure associated with the establishment of the 19-station facility is \$1,714,689, of which approximately 54% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 7]

To demonstrate compliance with this sub-criterion, DaVita provided the following statements:

“...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.” [source: Application, p21]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 8 on the following. [source: Application, p22]

Table 8
DaVita-Richland
Sources and Percentages of Revenue

Source of Revenue	Percentage 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-Richland. 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. The department is unable to conclude the average cost per dialysis is reasonable or accurate.

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

(3) The project can be appropriately financed.

DaVita-Kennewick.

As previously stated, the capital expenditure associated with the establishment of the 10-station facility is \$1,371,182, of which approximately 53% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: Application, Appendix 7] A review of DaVita’s historical financial statements shows the funds necessary to finance the project are available. [Application, Appendix 10]

Based on the information provided, the department concludes the establishment of a 10-station dialysis center in Kennewick, within Benton County would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met

DaVita-Richland

The capital expenditure associated with the establishment of the 19-station facility is \$1,714,689, of which approximately 54% 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, Appendix 7] A review of DaVita’s historical financial statements shows the funds necessary to finance the project are available. [Application, Appendix 10]

Based on the information provided, the department concludes the establishment of a 19-station dialysis center in Richland, within Benton County 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.'s Kennewick project has not met the structure and process (quality) of care criteria in WAC 246-310-230; and
- DaVita, Inc.'s Richland project 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.

DaVita-Kennewick

To staff its proposed 10-station facility in Kennewick, DaVita intends to recruit 5.00 FTEs in partial year 2008, which would increase to a total of 11.30 FTEs by the end of full calendar year three (2011). A breakdown of the proposed FTEs is shown in Table 9 below. [source: Application, p22]

Table 9
DaVita-Kennewick 2008 – 2011 Projected FTEs

Staff/FTEs	2008 Partial Year	2009 Increase	2010 Increase	2011 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	0.60	0.40	0.00	0.00	1.00
RN	1.10	0.60	0.60	0.60	2.90
Patient Care Techs	2.20	0.80	1.20	0.30	4.50
Biomedical Techs	0.30	0.00	0.00	0.00	0.30
Re-Use Techs	0.20	0.10	0.20	0.10	0.60
Administrative Assistant	0.00	0.30	0.30	0.20	0.80
MSW	0.30	0.10	0.10	0.10	0.60
Dietitian	0.30	0.10	0.10	0.10	0.60
Total FTE's	5.00	2.40	2.50	1.40	11.30

As shown in Table 9 above, after the initial recruitment of FTEs, DaVita expects a steady increase in FTEs for its Kennewick dialysis facility through year 2011. 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, p23]

DaVita also provided a copy of the draft medical director agreement for services at its Kennewick facility. The medical director costs are substantiated within DaVita-Kennewick's pro forma financial information.

Based on this information, the department concludes that adequate staffing for DaVita-Kennewick is available or can be recruited. This sub criterion is met.

DaVita-Richland

To staff its proposed 19-station facility in Richland, DaVita intends to recruit 6.70 FTEs in partial year 2008, which would increase to a total of 19.10 FTEs by the end of full calendar year three (2011). A breakdown of the proposed FTEs is shown in Table 10 on the following page. [source: Application, p23]

Table 10
DaVita-Richland 2008 – 2011 Projected FTEs

Staff/FTEs	2008 Partial Year	2009 Increase	2010 Increase	2011 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	1.00	0.00	0.00	0.00	1.00
RN	2.10	0.60	1.10	0.40	4.20
Patient Care Techs	2.30	2.90	2.30	2.00	9.50
Biomedical Techs	0.40	0.00	0.00	0.00	0.40
Re-Use Techs	0.30	0.10	0.20	0.40	1.00
Administrative Assistant	0.00	0.80	0.20	0.20	1.20
MSW	0.30	0.30	0.20	0.10	0.90
Dietitian	0.30	0.30	0.20	0.10	0.90
Total FTE's	6.70	5.00	4.20	3.20	19.10

As shown in Table 10 above, after the initial recruitment of FTEs, DaVita expects a steady increase in FTEs for its Richland dialysis facility through year 2011. 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, p24]

DaVita also provided a copy of the draft medical director agreement for services at its Richland facility. The medical director costs are substantiated within DaVita-Richland's pro forma financial information.

Based on this information, the department concludes that adequate staffing for DaVita-Richland 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.

DaVita-Kennewick

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing fourteen dialysis centers. For a new facility in Kennewick, within Benton County, 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. [source: Application, p24]

DaVita acknowledges that since this would be a new facility in Benton County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [source: Application, p23 and 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 hospital in Benton County. Provided that DaVita would agree to the term, this sub-criterion would be met.

DaVita-Richland

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing fourteen dialysis centers. For a new facility in Richland within Benton County, 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. [source: Application, p24]

DaVita acknowledges that since this would be a new facility in Benton County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [source: Application, p24 and 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 hospital in Benton 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.*

DaVita-Kennewick and DaVita-Richland

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

⁵ WAC 246-310-230(5).

from 28 states or 66% of the 42 states.⁶ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁷

Ten of the 28 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Delaware, one in New York and one in Texas, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2006 due to several condition-level citations, but was operating in compliance at the time of survey. The New York facility was cited with condition-level deficiencies. This facility was voluntarily de-certified and closed by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005. No further fines were identified for this facility.

The department concludes that considering the 1,300 facilities owned/managed by DaVita, few out-of-state facilities listed above demonstrated substantial non-compliance issues, with only three reported as subject to fines or actually decertified. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

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

Wassim Khawandi, MD has agreed to provide medical director services at both of the new Benton County dialysis centers. For each facility, DaVita provided a copy of the draft medical director agreement between itself and Dr. Khawandi. The agreement outlines the roles and responsibilities of both DaVita and the proposed medical director. A review of the compliance history of Dr. Khawandi has shown that his credentials are up to date and reveal no recorded sanctions. [source: compliance history provided by Medical Quality Assurance Commission] If either project, or both projects, were approved, the department would attach a term to the approval requiring DaVita to submit a copy of the executed medical director agreement for department review and approval.

Based on DaVita's compliance history and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the new dialysis centers in Benton County would be operated in conformance with state and federal regulations. Provided that DaVita would agree to the term regarding the medical director agreement, this sub-criterion would be met for both projects.

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

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

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

- (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.

DaVita-Kennewick and DaVita-Richland

In response to this criterion for both projects, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [source: DaVita-Kennewick Application, p23, Appendices 17 & 18; DaVita-Richland Application, p24, Appendices 17 & 18]

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

Additionally, the department must consider 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 29 additional dialysis stations in Benton County. Within its two applications, DaVita proposes to establish a 10 station dialysis center in Kennewick and a 19-station center in Richland. However, as stated in the financial feasibility portion of this evaluation, inconsistencies prevent an accurate evaluation of the both facilities forecasted viability. In the long-term this may lead to the unnecessary opening and closing of a facility, resulting in a loss of service. Therefore, the department concludes that approval of DaVita's additional dialysis station capacity in Benton County would have the potential of fragmentation of dialysis services within the service area, and this sub-criterion is not met for either application.

- (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.

For both projects, 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.'s Kennewick project has not met the cost containment criteria in WAC 246-310-240; and
- DaVita, Inc.'s Richland project 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.

DaVita-Kennewick and DaVita-Richland

Within the two applications, DaVita provided discussion regarding two alternatives to both projects. [source: DaVita-Kennewick Application, p25; DaVita-Richland Application, p26]

- Do not establish a center in Kennewick or Richland

DaVita states that current utilization of the existing facility in Benton County (Tri-Cities Kidney Center) exceeds 100% utilization indicating a need for additional current capacity within the Benton County services area.

- Establish a 29 station center in Richland

Regarding this alternative, DaVita acknowledges that one 29-station facility in Richland would address the need in Benton County. However, DaVita states that with the geographic dispersion of patients in the county, 29 stations are too many for the Richland center alone, with no stations in Kennewick.

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

The department recognizes that the numeric need methodology identifies a 2010 need for 29 stations in Benton County. Approval of both DaVita projects would meet the dialysis station numeric need.

In determining the best available alternative, the department considered its findings on the other applicable review criteria. Neither project submitted by DaVita met all other review criteria—both projects failed to meet the review criteria of Financial Feasibility and Structure and Process of Care. Base on these factors, the department concludes that both DaVita projects are not the best available alternative. This sub-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;

DaVita-Kennewick and DaVita-Richland

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 not 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.

DaVita-Kennewick and DaVita-Richland

As stated in the project description portion of this evaluation, this project involve 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 not met.

E. Kidney Disease Treatment Centers—Tie-breakers (WAC 246-310-288)

This criterion is applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. Once the department evaluates the applications for compliance with the other applicable review criterion, only then can it determine if this criterion is to be applied.

To determine if this criterion applies to the two applications under review, the department considered its findings on the other review criteria.

DaVita-Kennewick

The department previously concluded that the DaVita application did not meet all the applicable review criteria. As a result, this tie-breaker criterion is not applicable.

DaVita-Richland

The department previously concluded that the DaVita application did not meet all the applicable review criteria. As a result, this tie-breaker criterion is not applicable.