

## **EXECUTIVE SUMMARY**

### **EVALUATIONS OF THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN SNOHOMISH COUNTY PLANNING AREA #3:**

- **FRESENIUS / QUALICENTERS PROPOSING TO ESTABLISH A NINE-STATION DIALYSIS CENTER IN THE CITY OF MILL CREEK**
- **DAVITA, INC. PROPOSING ESTABLISH A NINE-STATION DIALYSIS CENTER IN THE CITY OF BOTHELL**

### **BRIEF PROJECT DESCRIPTIONS**

#### **QualiCenters Inland Northwest**

This application proposes to establish a 9-station facility to be located at 15906 Mill Creek Blvd. in Mill Creek. The new dialysis center would be known as QualiCenters South Snohomish<sup>1</sup> and would serve the residents of Snohomish County planning area #3.

The capital expenditure associated with the establishment of the 9-station facility is \$851,689. If this project is approved, QualiCenters anticipates all 9 stations would become operational by the end of November 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation. [QualiCenters Application, p1]

#### **DaVita, Inc.**

This application proposes to establish a 9-station facility to be located at 18001 Bothell Everett Highway in Bothell. The new dialysis center would be known as the DaVita Mill Creek Dialysis Center would serve the residents of Snohomish County planning area #3.

The capital expenditure associated with the establishment of the 9-station facility is \$1,251,403. If this project is approved, DaVita anticipates all 9 stations would become operational by the end of November 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation. [DaVita Amended Application, p1 & 8]

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

Both projects are subject to Certificate of Need review. Both the QualiCenters and DaVita, Inc. projects propose 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).

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<sup>1</sup> QualiCenters lists two separate potential names for the new facility (App., p.1 & Exhibit 1). For purposes of constancy, the center will be referred to as QualiCenters South Snohomish

## **CONCLUSIONS**

### **QualiCenters Inland Northwest**

For the reasons stated in this evaluation, the application submitted on behalf of QualiCenters proposing to establish a 9-station dialysis center in the city of Mill Creek within Snohomish County planning area #3 is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

### **DaVita, Inc.**

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a 9-station dialysis center in the city of Bothell within Snohomish County planning area #3 is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is approved.

The total approved costs associated with this project are \$1,251,403.

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APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN  
SNOHOMISH COUNTY PLANNING AREA #3:**

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**PROJECT DESCRIPTIONS**

**QualiCenters Inland Northwest**

Fresenius Medical Care Holdings, Inc. is the parent corporation of the following five subsidiaries:

QualiCenters Inc.	Pacific Northwest Renal Services
Inland Northwest Renal Care Group, LLC	Renal Care Group, Inc.
National Medical Care, Inc.	

Under the four of the five subsidiaries listed above, Fresenius Medical Care Holdings, Inc. (Fresenius) operates dialysis centers in 45 states, the District of Columbia, and Puerto Rico.<sup>2</sup> [CN historical files; QualiCenters Application, Pages 1-2]

In Washington State, Fresenius or one of its subsidiaries owns, operates, or manages fifteen kidney dialysis facilities in twelve separate counties. Below is a listing of the fifteen facilities in Washington.<sup>3</sup> [CN historical files; QualiCenters Application, pp2-4 & Exhibit #1]

**Benton County**

Columbia Basin Dialysis Center

**Clark County**

Fresenius Fort Vancouver Dialysis Facility  
Fresenius Salmon Creek Dialysis Facility

**Grant County**

Fresenius Moses Lake Dialysis Facility

**Gray Harbor County**

Fresenius Aberdeen Dialysis Facility

**Spokane County**

Fresenius Northpointe Dialysis Facility  
Fresenius Spokane Kidney Center  
Fresenius Valley Dialysis Facility

**Cowlitz County**

QualiCenters Longview

**Stevens County**

Colville Dialysis Center

**Lewis County**

Fresenius Chehalis Facility

**Mason County**

Fresenius Shelton Dialysis Facility

**Okanogan County**

Fresenius Omak Dialysis Facility

**Thurston County**

Fresenius Lacey Dialysis Facility

**Walla Walla County**

QualiCenters Walla Walla

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<sup>2</sup> The National Medical Care, Inc. subsidiary does not operate any dialysis facilities.

<sup>3</sup> Two facilities—Colville Dialysis Center and QualiCenters Kelso—were recently approved by the department and are not yet operational.

This application, submitted on behalf of QualiCenters, Inc., (QualiCenters), proposes to establish a nine station dialysis facility to be known as the QualiCenters South Snohomish dialysis facility, to serve the patients residing in Snohomish County planning area #3.

The estimated capital expenditure for the establishment of the South Snohomish facility is \$851,689. If this project is approved, QualiCenters anticipates that all approved stations would be available for patient use by November 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation. [QualiCenters Application, p.7]

<b>Breakdown of QualiCenters Costs</b>	<b>Total</b>	<b>% of Total</b>
Construction	\$ 562,036	66%
Fixed & Moveable Equipment	\$ 220,766	26%
Taxes	\$ 68,887	8%
<b>Total Estimated Capital Costs</b>	<b>\$ 851,689</b>	<b>100.00%</b>

**DaVita Inc.**

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. [DaVita Amended Application, p4]

In Washington State, DaVita owns or operates a total of sixteen kidney dialysis facilities in eight separate counties. Below is a listing of the sixteen DaVita facilities located in Washington. [CN historical files; & DaVita Amended Application, p4]

**Clark**

Vancouver Dialysis Center

**Franklin**

Mid-Columbia Kidney Center

**Pacific**

Seaview Dialysis Center

**Kittitas**

Ellensburg Dialysis Center

**Pierce**

Lakewood Community Dialysis Center

Puyallup Community Dialysis Center

Tacoma Dialysis Center

**King**

Bellevue Dialysis Center

Federal Way Community Dialysis Center

Kent Community Dialysis Center

Olympic View Dialysis Center (Mgmt. only)

Westwood Dialysis Center

**Yakima**

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

**Thurston**

Olympia Dialysis Center

This application proposes to establish a dialysis facility in Snohomish County planning area #3. The new facility, to be known as the DaVita Mill Creek Dialysis Center, would have 9 stations and be located at 18001 Bothell Everett Highway and would serve the residents of Snohomish County planning areas #3. [DaVita November 30, 2007 supplemental information, p 1]

The capital expenditure associated with the establishment of the 9-station facility is \$1,251,403. If this project is approved, DaVita anticipates that all approved stations would

be available for patient use by November 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation. [DaVita Amended Application, p8 & 10]

<b>Breakdown of DaVita, Inc. Costs</b>	<b>Total</b>	<b>% of Total</b>
Leasehold Improvements	\$ 657,500	53%
Fixed & Moveable Equipment	\$ 483,143	39%
Professional Fees	\$ 93,000	7%
CN Fees	\$ 17,760	1%
<b>Total Estimated Capital Costs</b>	<b>\$ 1,251,403</b>	<b>100.00%</b>

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

Both projects are subject to Certificate of Need review. Both the QualiCenters and DaVita, Inc. projects propose the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

### **CRITERIA EVALUATION**

To obtain Certificate of Need approval, each applicant must demonstrate compliance with the 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, each must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 288.<sup>4</sup>

### **APPLICATION CHRONOLOGY**

As directed under WAC 246-310-282(1) the department accepted these projects under the Kidney Disease Treatment Centers-Concurrent Review Cycle #3. A chronologic summary of the review is shown below.

<b>Action</b>	<b>QualiCenters</b>	<b>DaVita</b>
Letter of Intent Submitted	July 31, 2007	July 31, 2007
Application Submitted	August 31, 2007	August 31, 2007
DaVita Amendment Received	n/a	September 29, 2007
Final Amendment Period	September 30 through October 15, 2007	
Department's pre-review Activities including screening and responses	October 16, 2007 through December 6, 2007	
Beginning of Review	December 7, 2007	
End of Public Comment	February 5, 2008	
Rebuttal Comments Received	March 6, 2008	
Department's Anticipated Decision Date	April 21, 2008	
Department's Actual Decision Date	April 21, 2008	

<sup>4</sup> 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 and 287.

## **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 is 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 these projects submitted by QualiCenters and DaVita, the department will issue one single evaluation regarding whether both, any or none of the projects should be issued a Certificate of Need.

## **SOURCE INFORMATION REVIEWED**

- DaVita, Inc.'s Certificate of Need application submitted August 31, 2007
- QualiCenters' Certificate of Need application submitted August 31, 2007
- DaVita, Inc.'s Certificate of Need Amended application submitted September 28, 2007
- DaVita, Inc.'s supplemental information dated November 30, 2007
- QualiCenters' supplemental information dated November 30, 2007
- Public comment received during the course of the review
- DaVita, Inc.'s rebuttal comments received March 7, 2008
- DaVita, Inc.'s supplemental rebuttal comments received March 12, 2008
- QualiCenters' rebuttal comments received March 12, 2008
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2007 Northwest Renal Network 2<sup>nd</sup> 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 ([www.davita.com](http://www.davita.com))
- Data obtained from QualiCenters' webpage ([www.fmcna.com](http://www.fmcna.com))
- Data obtained from the Washington Secretary of State offices and webpage
- Data obtained from the Snohomish County Assessor webpage
- Certificate of Need historical files

## **CONCLUSIONS**

### **QualiCenters Inland Northwest**

For the reasons stated in this evaluation, the application submitted on behalf of QualiCenters proposing to establish a 9-station dialysis center in the city of Mill Creek within Snohomish County planning area #3 is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

### **DaVita, Inc.**

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a 9-station dialysis center in the city of Bothell within Snohomish

County planning area #3 is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is approved.

The total approved costs associated with this project are \$1,251,403.

**A. Need (WAC 246-310-210)**

Based on the source information reviewed, in relation to WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280, the department determines that:

- QualiCenters Inland Northwest's project has not met the need criteria detailed in WAC 246-310-284(6); and
- DaVita, Inc.'s project has met the need criteria in WAC 246-310-210 and 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.<sup>5</sup>

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.

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<sup>5</sup> Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

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

QualiCenters Inland Northwest’s Application of the Numeric Methodology

QualiCenters proposes to establish a 9-station dialysis center in Mill Creek to serve patients in Snohomish County planning area #3. 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 Snohomish County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [QualiCenters Application, p16-18]

DaVita’s Application of the Numeric Methodology

DaVita proposes to establish a 9-station dialysis center in Bothell to serve patients in Snohomish County planning area #3. 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 Snohomish County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [DaVita Amended Application, p16-19]

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 Snohomish County planning area #3. 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 shows a summary of the projected net need provided by each applicant and the department for Snohomish County planning area #3. Both DaVita and QualiCenters 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  
Snohomish County #3 Numeric Methodology Summary of Projected Net Station Need**

	<b>4.8 in-center patients per station</b>			
	<b>2010 Projected # of stations</b>	<b>Minus Current # of stations</b>	<b>2010 Net Need</b>	<b>2010 Net Need (Rounded)</b>
<b>QualiCenters</b>	36.00	27	9.00	9
<b>DaVita</b>	35.33	27	8.33	9
<b>DOH</b>	35.33	27	8.33	9

When comparing the applicants’ and department’s results shown in Tables 1 above, it shows that the projections of both applicants match the department’s figures. As a result, the net station need for Snohomish planning area #3 is determined to be nine (9).

As shown in Table 1 above, currently Snohomish County planning area #3 has 27 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 August 1, 2007. [WAC 246-310-282] The quarterly modality report from NRN available at that time was June 30, 2007, which became available on July 27, 2007. All 27 stations are at one facility - Puget Sound Kidney Centers - South in Mountlake Terrace. Table 2 below shows the June 30, 2007, utilization of PSKC's South facility and demonstrates that this capacity requirement is met.

**Table 2  
December 31, 2006-Facility Utilization Data**

<b>Facility Name</b>	<b># of Stations</b>	<b># of Pts</b>	<b>Pts/Station</b>
Puget Sound Kidney Centers - South	27	132	4.89

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 Snohomish County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] Both DaVita and QualiCenters propose dialysis stations to be located within Snohomish County planning area #3, as a result, both applicant's must demonstrate compliance with this criterion using the 4.8 in-center patient per station. Further, both QualiCenters' and DaVita's third full year of operation is year 2011. A summary of both applicants' projected utilization for year 2011 is shown in Table 3 below.

**Table 3  
Year 2011 Projected Facility Utilization**

<b>Facility Name</b>	<b>Year 3</b>	<b># of Stations</b>	<b># of Pts</b>	<b>Pts/Station</b>
QualiCenters South Snohomish	2011	9	37 <sup>6 7</sup>	4.11
DaVita Mill Creek Dialysis Center	2011	9	49 <sup>8</sup>	5.44

As shown in Table 3 above, the DaVita's projections meet this standard. In contrast, based upon pro forma financial figures, QualiCenters is not projecting to be providing service to a sufficient number of patients. As a result, QualiCenters does not meet this standard. [QualiCenters Application, p8 & Exhibit 7]

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

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<sup>6</sup> On the final day of public comment, QualiCenters submitted a position paper comparing the two applications. Within the discussion on issues related to the draft lease, QualiCenters submitted a third version of the proposed facilities pro forma income statement and balance sheet [p3]. The new pro forma income statement, as stated, corrected errors in the income statement previously supplied in response to screening. Noted changes include the total revenue and profitability in each of the three full years. The Department has determined that this submission constitutes an inappropriate amendment to the application and will not be considered in this review. WAC 246-310-010(50) and 246-310-170

<sup>7</sup> QualiCenters cites a patient count of 46 for 2011 on p8 of the application, but calculates the 2011 Pro Forma with a patient count of 37. The department used the figure cited in the financial calculations as the projected patient count in the third year of the South Snohomish facility.

<sup>8</sup> DaVita cites a patient count of 53 for 2011 on p9 & 17 of the application, but calculates the 2011 Pro Forma with a patient count of 49. The department used the figure cited in the financial calculations as the projected patient count in the third year of the Mill Creek facility.

### QualiCenters Inland Northwest

QualiCenters proposes to establish a 9-station dialysis center in Snohomish County planning area #3. Based on the above standards and criteria, the project is not consistent with applicable criteria of the Certificate of Need Program. This sub-criterion is not met for QualiCenters' application.

### DaVita, Inc.

DaVita proposes to establish a 9-station dialysis center in Snohomish County planning area #3. 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 for DaVita's application.

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

### QualiCenters Inland Northwest

To demonstrate compliance with this sub-criterion, QualiCenters provided a copy of its current Admission and Indigence policies that would also be used at the new South Snohomish facility. The documents outline the process/criteria that the dialysis center uses to admit patients for treatment. It is intended to ensure that patients will receive appropriate care at the dialysis center. The Admission criteria states that any patient with end stage renal disease needing treatment will be accepted to a QualiCenters' facility without regard to race, creed, color, age, sex handicap, disability, national origin, social status, or ability to pay. [QualiCenters Application, Exhibit 5 & 6]

### DaVita, Inc.

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 Mill Creek facility. The Admission policy outlines the process/criteria that Mill Creek 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 Mill Creek without regard to race, color, national origin, sex, age, religion, or disability. [DaVita Amended Application, Appendix 14]

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.

### QualiCenters Inland Northwest

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

DaVita, Inc.

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

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.

QualiCenters Inland Northwest

QualiCenters demonstrated its intent to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the Pro Forma income statements documents. [QualiCenters' November 30, 2008 Supplemental Information, Attachment 4]

DaVita, Inc.

DaVita demonstrated its intent to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the Pro Forma income statements documents [DaVita Amended Application, Appendix 9]

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

QualiCenters Inland Northwest

The department concludes that all residents of the service area would have adequate access to the health services at the proposed South Snohomish facility. This sub-criterion is met.

DaVita, Inc.

The department concludes that all residents of the service area would have adequate access to the health services at the proposed Mill Creek Dialysis Center. This sub-criterion is met.

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

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

- QualiCenters Inland Northwest's project has met the financial feasibility criteria in WAC 246-310-220; and
- DaVita, Inc.'s project has met the financial feasibility criteria in WAC 246-310-220;

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

QualiCenters Inland Northwest

QualiCenters anticipates commencement of services for this facility to be in November of 2008. Based on this timeline and the projected release of this evaluation, 2009 would be QualiCenters' first full year of operation for the South Snohomish facility.

For financial review of applications, the department requests data for the first three full years following project completion. Using the financial information provided as part of the completed application, Table 4 below illustrates the projected revenue, expenses, and net income in years 2009-2011 for the South Snohomish. [QualiCenters November 30, 2007 Supplemental Information, p6]

**Table 4**  
**Proposed South Snohomish Dialysis Center**  
**Projected Revenue and Expenses**

	<b>Year 1 - 2009</b>	<b>Year 2 - 2010</b>	<b>Year 3 - 2011</b>
# of Stations	9	9	9
# of Treatments [1]	3,528	5,544	6,169
# of Patients [2]	30	36	37
Utilization Rate [2]	3.33	4.00	4.11
Net Revenue [1]	\$ 1,099,218	\$ 1,727,342	\$ 1,922,059
Total Expense [1,3]	\$ 1,117,935	\$ 1,545,017	\$ 1,682,685
Net Profit or (Loss) [1]	(\$ 18,717)	\$ 182,325	\$ 239,374
Net Patient Revenue/Treatment [1]	\$ 311.57	\$ 311.57	\$ 311.57
Total Operating Exp./Treatment [1]	\$ 316.88	\$ 278.68	\$ 272.76
Net Profit (Loss) per Treatment [1]	(\$ 5.31)	\$ 32.89	\$ 38.80

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

As shown in Table 4, at the projected volumes identified in the application, the South Snohomish would be operating at a profit as a 9-station facility beginning the second year following through the third completed year of the project.

Although, as previously stated, QualiCenters submitted a third version of the proposed facility's pro forma as part of public comment. For purposes of this review, the Department relied upon the pro forma income/expense statement submitted in response to screening questions, rather than the untimely version provided in public comment. The screening version allowed the applicant to update of a number of related income and expense totals and produces a projected profit, though it also projects an inadequate utilization rate of 4.11.

QualiCenters has selected a site for the South Snohomish facility that is located in the city of Mill Creek. The draft lease provided in the application outlines the terms and the annual rent for the space through 2018. QualiCenters also supplied confirmation from the planning department of the City of Mill Creek that identifies the location as being zoned for professional use and that a dialysis facility would be permitted at the site. In addition, line drawings for the proposed facility allow for the necessary stations. [QualiCenters November 30, 2007 Supplemental Information, Attachment 1 &2]

Based on the above information, though projecting a utilization rate below the utilization standard for the proposed facility, the department concludes that QualiCenters' projected revenues are reasonable and this sub-criterion is met.

DaVita, Inc.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the nine station facility would be operational no later than January 1, 2009. Based on this timeline, year 2009 would be Mill Creek's first full year of operation.

Using the financial information provided in the application, Table 5 below illustrates the projected revenue, expenses, and net income for years 2009-2011 for the Mill Creek Kidney Center. [DaVita Amended Application, Appendix 9]

**Table 5  
Proposed Expansion of the Mill Creek Dialysis Center  
Projected Revenue and Expenses**

	<b>Year 1 - 2009</b>	<b>Year 2 - 2010</b>	<b>Year 3 - 2011</b>
# of Stations	9	9	9
# of Treatments [1]	4,792	6,739	7,338
# of Patients [2]	32	45	49
Utilization Rate [2]	3.56	5.00	5.44
Net Revenue [1]	\$ 1,467,817	\$ 2,174,529	\$ 2,684,012
Total Expense [1,3]	\$ 1,437,137	\$ 1,936,277	\$ 2,320,320
Net Profit or (Loss) [1]	\$ 30,680	\$ 238,252	\$ 363,692
Net Patient Revenue/Treatment [1]	\$ 287.92	\$ 302.10	\$ 337.61
Total Operating Exp./Treatment [1]	\$ 281.90	\$ 269.00	\$ 291.86
Net Profit (Loss) per Treatment [1]	\$ 6.02	\$ 33.10	\$ 45.75

[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, Mill Creek would be operating at a profit in the first three full years of operation as a 9-station facility.

DaVita has selected a site for the Mill Creek facility that is located between the cities of Mill Creek and Bothell. The draft lease provided in the application outlines the terms and the annual rent for the space through 2018. DaVita also supplied supportive zoning information for the short plat located within Snohomish County that identifies the location as being zoned for use that would include a dialysis facility. In addition, preliminary line drawings for the proposed facility allow for the necessary stations. [DaVita Amended Application, Attachment 16; DaVita November 30, 2007 Supplemental Information, Attachment 1 & 2; DaVita March 7, 2007 Rebuttal Comments, Exhibit A & 1]

Based on the above information, the department concludes that DaVita's project revenues are reasonable and this sub-criterion is met.

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

QualiCenters Inland Northwest

The capital expenditure associated with the establishment of the South Snohomish facility is \$851,689 of which 66% is related to construction, 26% for both fixed and moveable equipment; and the remaining 8% is related taxes and construction reserves. The capital cost breakdown is reprinted below. [QualiCenters Application, p28]

<b>Breakdown of QualiCenters Costs</b>	<b>Total</b>	<b>% of Total</b>
Construction	\$ 562,036	66%
Fixed & Moveable Equipment	\$ 220,766	26%
Taxes	\$ 68,887	8%
<b>Total Estimated Capital Costs</b>	<b>\$ 851,689</b>	<b>100.00%</b>

In comment submitted at the public hearing, DaVita states, “Neither the original nor the revised pro forma balance sheets identified the CN application fee as part of the project capital expenditures”. DaVita contends that when the fee of \$16,409 is added to what DaVita calculates to be the correct estimated capital costs (addressed below), the total difference in the capital expenditure in the application and the LOI submitted “exceeds 16 percent”. [DaVita’s February 5, 2008 Public Hearing comments, p4]

In response, QualiCenters points to the definition of capital expenditures in WAC 246-310-280(2) which states:

"Capital expenditures," as defined by Generally Accepted Accounting Principles (GAAP), are expenditures made to acquire tangible long-lived assets. Long-lived assets represent property and equipment used in a company's operations that have an estimated useful life greater than one year. Acquired long-lived assets are recorded at acquisition cost and include all costs incurred necessary to bring the asset to working order.

QualiCenters continues that a state review fee typically, and in most instances, does not meet this definition and are correctly excluded from the totals. They continue in describing how the fees are treated as regional overhead costs which are allocated under “G&A” in the pro forma. [QualiCenters’ Rebuttal Statement, p2]

During public comment, DaVita also submitted a letter commenting upon the balance statements submitted as part of the QualiCenters application. The concern expressed was that QualiCenters was understating the capital expenditure of the proposed South Snohomish facility. The basis of the issue were the depreciation values used and noted differences between the application’s tally of estimated capital expenditures and the property assets reported on the pro forma balance sheet for the proposed facility. DaVita believes that the result, once this inaccuracy is corrected to show the actual capital costs as they would be in relation to the balance sheet figures, was an increase in capital expenditures in excess of 12%. Thus, the application should be returned as instructed under WAC 246-310-080(6) for a significant change from the letter of intent. [DaVita January 25, 2008 Public Comment letter, p1]

In response, QualiCenters acknowledged that there were errors in the calculated assets used in the balance sheet submitted, as part of the application, incorrectly calculated the value of related capital items. The result is an overstated Property, Plant and Equipment figure. QualiCenters continues to point out that the accuracy or omission of a balance sheet has not prejudiced a review since the implementation of the new ESRD rules implemented in January of 2007. In fact, this point is addressed by DaVita in their rebuttal response which states, “A project-specific balance sheet for a single new facility owned by a multi-facility company, such as DaVita or FMC, is a largely hypothetical and meaningless document”. [QualiCenters Rebuttal Statement, p4; DaVita March 7, 2008 Rebuttal Statement, p7]

The Department, in this particular review, concurs with both applicants. A balance sheet is generally a statement of the financial position of a business at a particular point in time. The Department will not prejudice the QualiCenters application by holding it to a different standard of review than DaVita’s or any other multi-facility organization. In addition, the Department will not prejudice DaVita’s application for not providing any pro forma balance sheet.

For further review, the department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, QualiCenters also provided the sources of patient revenue shown in Table 6 below. [QualiCenters Application, p29]

**Table 6**  
**Anticipated Revenue Sources - QualiCenters**

<b>Source of Revenue</b>	<b>% of Revenue</b>
Medicare	73
State (Medicaid)	5
Other Insurance	22
<b>Total</b>	<b>100 %</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 78% of the revenue at QualiCenters’ new facility. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis treatment for the proposed project was compared to those of recent kidney dialysis proposals and the average cost per dialysis is reasonable.

Based on the information provided, the department concludes that the reported costs of QualiCenters’ proposed project are acceptable and would probably not result in an unreasonable impact to the costs and charges for health care facilities. This sub-criterion is met.

DaVita, Inc.

The capital expenditure associated with the establishment of the twenty-station Mill Creek facility is \$1,251,403, and of that amount, 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. As a practice, DaVita has

included program fees as a portion (1%) of the totals. The capital cost breakdown is reprinted below. [DaVita November 30, 2007 Supplemental Information, Attachment 3]

<b>Breakdown of DaVita, Inc. Costs</b>	<b>Total</b>	<b>% of Total</b>
Leasehold Improvements	\$ 657,500	53%
Fixed & Moveable Equipment	\$ 483,143	39%
Professional Fees	\$ 93,000	7%
CN Fees <sup>9</sup>	\$ 17,760	1%
<b>Total Estimated Capital Costs</b>	<b>\$ 1,251,403</b>	<b>100.00%</b>

In comment submitted at the public hearing, QualiCenters asserts that DaVita themselves are inaccurately calculating depreciation schedules. In this instance, QualiCenters claims that DaVita improperly depreciates items over an 11.7 year period of time. In response, DaVita states, “We have not reported any ‘average depreciable life’ because the number is meaningless and not related to any program requirement”. DaVita continues, “Apparently, FMC has attempted to calculate DaVita’s ‘average depreciable life’ but fails to tell how it did so...”. DaVita punctuates their response by noting their adherence in the practice of reflecting depreciation costs as an expense in the pro forma income statement. [QualiCenters Public Hearing comments, p3; DaVita’s Public Hearing comments, p8]

As addressed above, depreciation schedules are subject to differing, self-prescribed definitions. As such, the Department is accepting the pro forma income statement submitted with the original application as a good faith estimate of the accounting forecast of the Mill Creek facility.

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. [DaVita Amended Application, p23]

**Table 7  
Anticipated Revenue Sources - DaVita**

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

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 65% of the revenue at the Mill Creek facility. DaVita cites an internal evaluation of the corporate SEC filings to determine a more accurate allocation for the revenues it reported on a company-wide basis. The results are described as patients assigning their Medicare and Medicaid benefits to a Health Maintenance Organization (HMO) for service. In Washington State, DaVita has a contract with Group Health Cooperative to provide service to patients such as these. Though these reimbursements tend to follow the rates negotiated under

<sup>9</sup> Includes the initial application fee of \$16,409 and the amendment fee of \$1,351

Medicaid and Medicare contracts, there is justification for separating them from the other revenue categories. DaVita speculates that the HMO revenue will account for approximately 15% of the reported 35%. [DaVita November 30, 2007 Supplemental Information, p2]

The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis treatment for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

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

(3) *The project can be appropriately financed.*

QualiCenters Inland Northwest

As previously stated, the capital expenditure associated with the establishment of QualiCenters' 9-station facility is \$851,689. QualiCenters proposes that funding will be provided from current reserves from the parent company. This statement is supported with a letter confirming the commitment of corporate funding. The financial health of the organization indicates that there would be sufficient resources to support the proposed project. Review of the financial position of Fresenius Medical Care shows the funds necessary to finance the project is available. [QualiCenters Application, Appendix 1; QualiCenters November 30, 2007 Supplemental Information, Attachment 6]

Based on the information provided, the department concludes the expansion of the South Snohomish facility would not adversely affect the financial stability of QualiCenters as a whole. This sub-criterion is met

DaVita, Inc.

As previously stated, the capital expenditure associated with the establishment of DaVita's 9-station facility is \$1,251,403. This statement is supported with a letter confirming the commitment of corporate funding. DaVita states that the project will be funded from DaVita's capital expenditure budget. A review of DaVita's consolidated financial statements shows the funds necessary to finance the project are available. [DaVita Amended Application, Appendix 6 & 10]

Based on the information provided, the department concludes the establishment of the Mill Creek facility 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:

- QualiCenters Inland Northwest's project has met the structure and process (quality) of care criteria in WAC 246-310-230; and
- DaVita, Inc.'s project has met the structure and process (quality) of care criteria in WAC 246-310-230;

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

QualiCenters Inland Northwest

To staff its 9-station facility, QualiCenters proposes to initially recruit 2.9 FTEs and add an additional 2.0 FTEs in year one (2009). By the end of year three (2011) a total to 8.10 FTEs will support the facility. A breakdown of the proposed FTEs is shown in Table 8 below. [QualiCenters Application, p30]

**Table 8  
South Snohomish Dialysis Center Projected FTEs**

<b>FTEs</b>	<b>Partial Yr 2008</b>	<b>Full Year 1 2009</b>	<b>Full Year 2 2010</b>	<b>Full Year 3 2011</b>
Medical Director	Contract Position			
Nurse Mgr	0.25	0.50	0.50	0.70
Outpatient RN	0.75	1.50	1.50	2.00
Patient Care Tech	1.00	2.00	2.00	4.00
Equipment Tech	0.40	0.40	0.40	0.60
Social Wk	0.25	0.25	0.25	0.40
Dietician	0.25	0.25	0.25	0.40
Secretary	0.00	0.00	0.00	0.00
<b>FTE Total</b>	<b>2.90</b>	<b>4.90</b>	<b>4.90</b>	<b>8.10</b>

As shown above, the additional FTEs are targeted to add registered nurses and dialysis technicians. QualiCenters believes that the geographic location of this new facility will allow for the necessary applicant pool to fill these positions. [QualiCenters Application, p31]

DaVita provided comment and rebuttal on the issue of whether QualiCenters had projected adequate staffing for the proposed facility. DaVita states, “the adequacy of facility staffing is at the heart of patient care concerns and merits the Program’s close scrutiny”. Further, DaVita asserts that the proposed facility’s core staffing and related cost projections are materially inaccurate and prevent the program from making a meaningful evaluation of the QualiCenters application.

In support of the position, DaVita cites RCW 18.135.060(2) that, in part, allows for trained dialysis technicians to perform many of the tasks required for treatment in dialysis facilities. The citation outlines that a licensed registered nurse is required to be physically present and immediately available to supervise the care provided by the trained technicians. DaVita also cites Medicare rules regarding the definition of a full-time nurse and that they be on-duty any time patients are undergoing treatment. DaVita asserts that since the partial year (2008 in Table 8) does not account for the minimum amount of supervision necessary to operate the facility, the application cannot be adequately evaluated under this criterion.

In summary, DaVita does not believe that QualiCenters has planned for enough supervisory coverage to legally operate at the level outlined in the QualiCenters application. [DaVita March 7, 2008 Rebuttal Statement, p2-5]

In rebuttal, QualiCenters provided information that outlined their plans for determining their staffing needs. QualiCenters states, “that during much of the first two years of operation, we will not have a large enough number of patients to warrant operating 18 shifts per week”. The plan outlined includes establishing a set cycle of days (M/W/F or T/TR/S) where patients may schedule for treatments after 5 p.m. as proposed in the application. QualiCenters intends to expand the treatment times to the remaining days of the week when volumes warrant. [QualiCenters March 12, 2008 Rebuttal Comments, p9]

The Department consulted with survey staff responsible for determining whether a facility meets Medicare certification standards. Based upon the review of all the information and in consultation with survey staff the department concludes that the planning would allow for the required coverage. Further, in recent surveys, there is no indication that any of the QualiCenters or Fresenius facilities have been cited for non-compliance to either the Washington or Medicare staffing requirements. [Compliance survey data provided by Office of Health Care Survey (OHCS)]

QualiCenters has identified Dr. Seth Thaler as the Medical Director for the proposed facility. The applicant supplied a draft contract that indicates Dr. Thaler’s intended service in this capacity. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation limits for the medical director responsibilities. [QualiCenters Supplemental Information, Attachment 5]

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

DaVita, Inc.

To staff its 9-station facility, DaVita proposes to recruit 3.5 FTEs in year one (2009), which would increase to a total of 8.9 FTEs by the end of year three (2011). A breakdown of the proposed FTEs is shown in Table 9 below. [DaVita Amended Application, p23]

**Table 9  
Mill Creek Dialysis Center Projected FTEs**

<b>FTEs</b>	<b>Year 1 2009</b>	<b>Increase Year 2 2010</b>	<b>Increase Year 3 2011</b>	<b>TOTAL</b>
Medical Director	Contract Position			
Administrator	0.20	0.80	0.00	1.00
RNs	0.60	0.80	0.40	1.80
Patient Care Tech	1.80	0.70	1.50	4.00
Biomed Tech	0.30	0.00	0.00	0.30
Re-Use Tech	0.20	0.10	0.10	0.40
Admin Asst	0.00	0.00	0.60	0.60
Social Wk	0.20	0.10	0.10	0.40
Dietician	0.20	0.10	0.10	0.40
<b>FTE Total</b>	<b>3.50</b>	<b>2.60</b>	<b>2.80</b>	<b>8.90</b>

As shown in Table 9 above, after the initial recruitment of FTEs, DaVita expects a steady increase in FTEs for Mill Creek through year 2011. The applicant continued the forecast through 2013, but 77% of the necessary staff are expected to be hired by the third year of

operation. DaVita states it expects no difficulty in recruiting staff for Mill Creek 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 Mill Creek facility. [DaVita Amended Application, p24]

DaVita has identified Dr. Fadi Najjar as the contracted Medical Director for the Mill Creek facility. The applicant supplied a draft contract that indicates Dr. Najjar's service in this capacity. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation limits for the medical director responsibilities. [DaVita Supplemental Information, Attachment 4]

Based on this information, the department concludes that adequate staffing for the Mill Creek facility 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.*

#### QualiCenters Inland Northwest

Documentation provided in the application confirms that QualiCenters, and their parent Fresenius Medical Care, maintains appropriate relationships with ancillary and support services for its existing dialysis centers. For this project, the applicant cites that they currently have relationships with Virginia Mason, the University of Washington Medical Center, and Swedish Hospital to address its current patients needs. The applicant plans to provide social services and dietary support in center. Other ancillary services such as pharmacy, laboratory, and radiology will be secured well before the opening. A preliminary listing of potential providers in the area indicates that the services are available for contracting through existing organizations and businesses. [QualiCenters Application, p31]

QualiCenters acknowledges that since this would be a new facility in Snohomish County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, QualiCenters provided an example of a draft transfer agreement. [QualiCenters Application, Exhibit 8]

Based on this information, the department concludes that QualiCenters will have appropriate relationships with ancillary and support services. If this project is approved, the department would include a term requiring QualiCenters to provide a copy of the executed transfer agreement with a local hospital in Snohomish County. Provided that QualiCenters would agree to the term, this sub-criterion would be met.

#### DaVita, Inc.

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing dialysis centers. For a new facility in Snohomish County planning area #3, 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. [DaVita Amended Application, p25]

DaVita acknowledges that since this would be a new facility in Snohomish County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided an example of a draft transfer agreement. [DaVita Amended Application, p25 and Appendix 12]

Based on this information, the department concludes that DaVita will have 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 Snohomish 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.

QualiCenters Inland Northwest

As stated earlier, QualiCenters is currently a provider of dialysis services in three facilities within Washington State and is a part of Fresenius Medical Care. Fresenius operates approximately 2,100 dialysis clinics worldwide, of which 1,500 are located in North America. [FMC website] Currently within Washington State, Fresenius or it’s subsidiaries, owns and operates an additional 12 kidney dialysis treatment centers.

The department’s survey of other states revealed minor non-compliance issues typical of a dialysis facility, related to the care, medical records, and management at the FMC facilities. In summary, in those states that license and/or survey dialysis facilities, FMC submitted plans of correction and implemented the required corrections when these non-compliance issues were identified. [Licensing and/or survey data provided by out of state health care survey programs]

The Department also reviewed Washington State compliance surveys, in the most recent 6 years (since January 2001), recorded in the Department of Health’s Office of Health Care Survey (OHCS). As stated in the project description portion of this evaluation, Fresenius, through its subsidiaries RCGNW and QualiCenters, owns and/or operates the following fourteen kidney dialysis treatment facilities in Washington State:

<b>Facility Name</b>	<b>City/County Location</b>	<b># of stations</b>
Fresenius – Aberdeen	Aberdeen, Grays Harbor County	16
Fresenius – Chehalis	Chehalis, Lewis County	12
Fresenius - Ft. Vancouver	Vancouver, Clark County	24
Fresenius – Lacey	Lacey, Thurston County	25
Fresenius - Moses Lake	Moses Lake, Grant County	20
Fresenius - Northpointe	Spokane, Spokane County	24
Fresenius – Omak	Omak, Okanogan County	15
Fresenius - Salmon Creek	Vancouver, Clark County	16
Fresenius - Colville	Colville, Stevens County	6
Fresenius – Shelton	Shelton, Mason County	6

<b>Facility Name</b>	<b>City/County Location</b>	<b># of stations</b>
Fresenius – Spokane	Spokane, Spokane County	27
Fresenius – Valley	Spokane Valley, Spokane County	20
QualiCenters Columbia Basin	Kennewick, Benton County	13
QualiCenters Longview	Longview, Cowlitz County	6
QualiCenters Walla Walla	Walla Walla, Walla Walla County	12

The Fresenius-owned or operated facilities in Washington have collectively been surveyed 25<sup>10</sup> times in the last six years. Ten of those surveys revealed no deficiencies. The Omak facility was surveyed in 2007 and revealed three patient care issues that were corrected. A previous survey of Ft. Vancouver also revealed potentially hazardous conditions that were promptly corrected by the applicant. The remaining 13 revealed minor non-compliance issues and the facilities submitted plans of corrections for the non-compliance issues within the allowable response time. [Compliance survey data provided by Office of Health Care Survey (OHCS)]

Seth Thaler, MD has agreed to provide medical director services at the proposed dialysis center. QualiCenters provided a copy of the draft medical director agreement between itself and Dr. Thaler. The agreement outlines the roles and responsibilities of both entities and the length of the term. A review of the compliance history of Dr. Thaler has shown that his credentials are up to date and reveal no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of QualiCenters and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the dialysis center would continue to operate in conformance with state and federal regulation. This sub-criterion is met.

DaVita, Inc.

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. [DaVita website] 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 sixteen 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 public<sup>11</sup>. 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

<sup>10</sup> Omak, 2007 (three issues out of compliance – all met with acceptable corrective actions), 2004, 2001; Ft. Vancouver, 2006 (condition-level deficiency regarding water quality testing – acceptable plan of corrections submitted. Follow-up surveys indicate facility in substantial compliance) 2003, no def; QualiCenters Walla Walla, 2006, 2003, no def; Aberdeen, 2006 no def; Lacey 2001, 2000, 2004; Shelton, 2006 no def; Moses Lake, 2006 no def; Salmon Creek 2006, 2003, no def; Spokane Kidney Center 2005, 2004, 2002; Spokane Valley 2005, 2002, 2001; Northpointe 2005, 2002 no def; Chehalis 2002, 2005

<sup>11</sup> WAC 246-310-230(5).

42 entities.<sup>12</sup> The compliance history of the remaining 13 states and the District of Columbia is unknown.<sup>13</sup>

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 because it was actually closed and not providing services and was voluntarily de-certified by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005, and no further fines were identified for this facility.

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.<sup>14</sup> Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [Facility survey data provided by the Office of Health Care Survey]

Fadi Najjar, MD has agreed to provide medical director services at the proposed dialysis center. DaVita provided a copy of the draft medical director agreement between itself and Dr. Najjar. The agreement outlines the roles and responsibilities of both entities and the automatic renewal of the term. A review of the compliance history of Dr. Najjar has shown that her credentials are up to date and reveal no recorded sanctions. [Medical Quality Assurance Commission compliance data]

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 center would be operated 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.*

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<sup>12</sup> 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.

<sup>13</sup> Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

<sup>14</sup> 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.

### QualiCenters Inland Northwest

In response to this criterion, QualiCenters states, “The South Snohomish [facility] will be the first unit in the Puget Sound area”. QualiCenters continues, “We are confident that we will be able to identify partners that will assist in the provisions of high quality and seamless care delivery to our patients”. [QualiCenters Application, p32]

The department also considered QualiCenters’ 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 many years and has been appropriately participating in relationships with community facilities, such as Virginia Mason and the Swedish Medical Center, to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that these same types of relationships would not be developed for this project. [Office of Health Care Survey Historical Record]

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 9 additional dialysis stations in the Snohomish County planning area #3. QualiCenters has not provided the information necessary to establish that they will be at the minimum utilization to serve this need in the pro forma forecast, but the need methodology was correctly calculated.

Therefore, the department concludes that approval of 9 additional dialysis stations in Snohomish County planning area #3 is consistent with the need methodology and would not have the potential of fragmentation of dialysis services within the service area. This sub-criterion is met.

### DaVita, Inc

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [DaVita Amended Application, p25, Appendix 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 these same types of relationships would not be developed for this project. [CN historical files]

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 9 additional dialysis stations in the Snohomish County planning area #3. Within the application, DaVita demonstrated it met the standards to receive approval to add the needed stations.

Therefore, the department concludes that approval of 9 additional dialysis stations in Snohomish County planning area #3 is consistent with the need methodology and would not have the potential of fragmentation of dialysis services within the service area. This sub-criterion is met.

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

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:

- QualiCenters Inland Northwest's project has not met the cost containment criteria in WAC 246-310-240; and
- DaVita, Inc.'s project has met the cost containment criteria in WAC 246-310-240;

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

##### QualiCenters Inland Northwest

The only alternative to this project considered by QualiCenters is 'do nothing' or develop a new unit to match need. QualiCenters rejected this option by stating, "we knew that we had the quality and the development expertise needed to establish a unit and offer a care environment that serves to benefit the local dialysis community". [QualiCenters Application, p34]

Further, Table 2 of this evaluation shows that the only existing provider in the planning area was operating at 4.89 patients per station as of June 30, 2007. This patient per station utilization is greater than the utilization standard of 4.8 patients per station, which also demonstrates that do-nothing is not a viable option.

##### DaVita, Inc.

Within the application, DaVita provided discussion regarding the following two alternatives to this project. [Application, p26]

- Establish a 9-station Mill Creek center  
DaVita considered a minimally functional facility for the planning area. Pointing to the need for isolation and permanent bed capabilities, coupled with on-site training for all dialysis modalities, as part of a complete service facility, this alternative was rejected.
- Pursue Joint Ventures and Shared Services within the planning area  
DaVita considered the existing 27 station facility operated by PSKC, but believed that what was needed in the service area is improved access and choice that only a separate location can provide. Therefore, this alternative was rejected.

Based on DaVita's discussion of the two options above, both options were rejected before submitting this project for a robust, full service 9-station facility.

In determining the best available alternative the department considered its findings on the other applicable review criteria. The DaVita project met all other review criteria. The QualiCenters project, however, failed to meet the review criteria of Need and Structure and Process of Care. Based on these factors, the department concludes the DaVita application is the best available alternative.

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

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

QualiCenters Inland Northwest

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.

DaVita, Inc.

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.

QualiCenters Inland Northwest

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.

DaVita, Inc.

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.

**E. 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 this criterion applies to the two applications under review, the department considered its findings on the other review criteria. The department previously concluded that the DaVita application met all the applicable review criteria. Further, the department previously concluded that the QualiCenters application failed to meet need, structure and process of care, and cost containment. Because QualiCenters' application failed to meet three of the four required universal review criteria, this criterion is not applicable.

# Appendix A