

## **EXECUTIVE SUMMARY**

### **EVALUATION OF THE TWO CERTIFICATE OF NEED APPLICATIONS SUBMITTED BY DAVITA, INC. AND PUGET SOUND KIDNEY CENTERS (PSKC) PROPOSING TO ADD NEW DIALYSIS STATIONS IN SNOHOMISH COUNTY PLANNING AREA 1.**

- **DAVITA, INC. IS PROPOSING THE ESTABLISHMENT OF A NEW 10-STATION DIALYSIS CENTER IN THE CITY OF MARYSVILLE TO SERVE THE RESIDENTS OF SNOHOMISH COUNTY PLANNING AREA 1.**
- **PUGET SOUND KIDNEY CENTERS (PSKC) IS PROPOSING TO ADD 10-STATIONS TO THE EXISTING CAPACITY IN SNOHOMISH COUNTY PLANNING AREA 1.**

### **BRIEF PROJECT DESCRIPTIONS**

#### **DaVita Inc.**

This project proposes to establish a new 10-station facility in Snohomish County Planning Area one to be known as Tulalip Dialysis Center and it would be located on the southwest corner of 116<sup>th</sup> Street and Smokey Point Boulevard within the city of Marysville. The proposed facility site is also known as Snohomish County Tax Lot APN#30050900300700. [Source: DaVita Application, Page 1 and February 29, 2008, Supplemental Information, Page 1]

The capital expenditure associated with the establishment of the 10-station facility is \$1,332,552. [Source: Application, Page 7] If this project is approved, DaVita anticipates all 10-stations would become operational by the end of October 2009. Under this timeline, year 2010 would be the facility's first full calendar year of operation and 2012 would be year three. [Source: DaVita Application, Page 11]

#### **Puget Sound Kidney Dialysis Centers (PSKC).**

This project proposes to add 10-stations to the existing capacity located at 18828 Smokey Point Boulevard in the City of Arlington within Snohomish County Planning Area 1. The capital expenditure associated with the addition of 10-stations to the existing capacity is \$154,000. [Source: Application, Page 1] If this project is approved, PSKC anticipates the added capacity would become operational immediately upon CN approval. As stated by PSKC, the Smokey Point facility would be operating a total of 28-stations by the end of year 2008 and year 2009 would be the facility's first full calendar year of operation and year 2011 would be year three. [Source: Application, Page 7]

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

### **DaVita**

DaVita project is subject to Certificate of Need review as the establishment of a new healthcare facility falls under the provisions of Revised Code of Washington (RCW) 70.38.105(4) (a) and Washington Administrative Code (WAC) 246-310-020(1) (a).

### **PSKC**

PSKC project is subject to Certificate of Need review as the increase in the number of dialysis stations at an existing kidney disease treatment center falls under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

## **CONCLUSIONS**

### **DaVita Inc.**

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a new 10-station dialysis center in the City of Marysville within Snohomish County Planning Area 1, to serve the residents of the planning area is consistent with applicable criteria.

If approved, the Department would include terms that DaVita provide for review and approval of the items listed below. Provided that DaVita agrees to the terms identified below, a Certificate of Need would be issued for the establishment of the 10-station DaVita Tulalip Dialysis Center to be located in the city of Marysville within Snohomish County Planning Area 1. The approved capital expenditure associated with the establishment of the dialysis center is \$1,332,552.

### **Terms**

1. Prior to providing services DaVita, Inc. must provide to the department for review and approval an executed copy of the Medical Director's agreement. The executed agreement shall be consistent with the draft agreement provided within the application.
2. Prior to providing services at the DaVita Tulalip Dialysis Center, DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval.
3. Prior to the project commencement, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located on the southwest corner of 116<sup>th</sup> Street and Smokey Point Boulevard within the city of Marysville, WA 98271. The proposed site is also known as Snohomish County Tax Lot APN #30050900300700.

### **Puget Sound Kidney Centers**

For the reasons stated in this evaluation, the application submitted on behalf of Puget Sound Kidney Centers proposing to expand the existing 18-station Smokey Point Kidney Dialysis Center by 10-station's met all the applicable criteria in WAC 246-310-210 through 240 resulting in the department using tie-breaker criteria in WAC 243-310-288. Using the tie-breaker's criteria, the department determined that PSKC's application is not the best available alternative and a Certificate of Need is denied.

**EVALUATION OF THE TWO CERTIFICATE OF NEED APPLICATIONS SUBMITTED BY DAVITA, INC. AND PUGET SOUND KIDNEY CENTERS (PSKC) PROPOSING TO ADD NEW DIALYSIS STATIONS IN SNOHOMISH COUNTY PLANNING AREA 1.**

- **DAVITA, INC. IS PROPOSING THE ESTABLISHMENT OF A NEW 10-STATION DIALYSIS CENTER IN THE CITY OF MARYSVILLE TO SERVE THE RESIDENTS OF SNOHOMISH COUNTY PLANNING AREA 1.**
- **PUGET SOUND KIDNEY CENTERS (PSKC) IS PROPOSING TO ADD 10-STATIONS TO THE EXISTING CAPACITY IN SNOHOMISH COUNTY PLANNING AREA 1.**

**PROJECT DESCRIPTIONS**

**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. [Source: DaVita Application, Page 4]

In Washington State, DaVita owns or operates a total of twenty three kidney dialysis facilities in eleven separate counties Benton, Clark, Franklin, Pacific, Pierce, King, Kittitas, Klickitat, Snohomish, Thurston and Yakima. Below is a listing of the twenty-three DaVita facilities in Washington. [Source: CN historical files; & Application, Page 1]

**Benton**

Richland Dialysis Center (new facility)<sup>1\*</sup>  
Kennewick Dialysis Center (new facility)\*

**Clark**

Vancouver Dialysis Center

**Franklin**

Mid-Columbia Kidney Center

**Pacific**

Seaview Dialysis Center

**Pierce**

Lakewood Community Dialysis Center  
Puyallup Community Dialysis Center  
Tacoma Dialysis Center  
Parkland Dialysis Center (new facility)\*  
Graham Dialysis Center

**King**

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

**Kittitas**

Ellensburg Dialysis Center  
DaVita Mill Creek Dialysis Center

**Klickitat**

DaVita Goldendale Dialysis Center\*

**Snohomish**

Everett Dialysis Center (new facility)\*

**Thurston**

Olympia Dialysis Center

**Yakima**

Mt. Adams Kidney Center  
Union Gap Dialysis Center  
Yakima Dialysis Center

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<sup>1</sup> Recently approved facilities not yet operational

This project proposes to establish a new 10-station facility in Snohomish County Planning Area one to be known as Tulalip Dialysis Center and it would be located on the southwest corner of 116<sup>th</sup> Street and Smokey Point Boulevard within the city of Marysville. The proposed facility site is also known as Snohomish County Tax Lot APN#30050900300700. [Source: DaVita Application, Page 1 and February 29, 2008, Supplemental Information, Page 1]

The capital expenditure associated with the establishment of the 10-station facility is \$1,332,552, of which approximately 54.2 % is related to leasehold improvements at the site; 37.4 % is related to both fixed and moveable equipment; and the remaining 8.4 % is related to architectural, engineering, application, consulting, and legal fees. [Source: Application, Page 7] If this project is approved, DaVita anticipates all 10-stations would become operational by the end of October 2009. Under this timeline, year 2010 would be the facility's first full calendar year of operation and 2012 would be year three. [Source: DaVita Application, Page 11]

Puget Sound Kidney Centers

PSKC is a not-for-profit kidney dialysis provider established in 1980 as a community based provider in northern Snohomish County. Currently, PSKC operates owns or operates four dialysis centers and an acute mobile dialysis services facility. Listed below are the facilities own or operated by PSKC in Washington State. [Source: CN historical files]

<b>Facility Name, City and Location</b>	<b># of Stations</b>
Puget Sound Kidney Centers—Dahl Annex	Mobile dialysis services
Puget Sound Kidney Center Everett—Snohomish County	37
Puget Sound Kidney Center—South Mountlake Terrace—Snohomish County	27
Puget Sound Kidney Center—Smokey Point Arlington—Snohomish County	18
Puget Sound Kidney Center—Whidbey Island Coupeville—Island County	6

PSKC application proposes to add 10-stations to the existing capacity located at 18828 Smokey Point Boulevard in the City of Arlington within Snohomish County Planning Area 1. The capital expenditure associated with the 10-station addition to the existing capacity is \$154,000 which is related to fixed and moveable equipment. [Source: Application, Exhibit 8] PSKC anticipates the Smokey Point facility would be operating a total of 28-stations by the end of year 2008 and year 2009 would be the facility's first full calendar year of operation and year 2011 would be year three. [Source: Application, Page 7]

**APPLICABILITY OF CERTIFICATE OF NEED LAW**

DaVita

DaVita project is subject to Certificate of Need review as the establishment of a new healthcare facility falls under the provisions of Revised Code of Washington (RCW) 70.38.105(4) (a) and Washington Administrative Code (WAC) 246-310-020(1) (a).

PSKC

PSKC project is subject to Certificate of Need review as the increase in the number of dialysis stations at an existing kidney disease treatment center falls under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

## **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 applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 288<sup>2</sup>

## **APPLICATION CHRONOLOGY**

As directed under WAC 246-310-282(1) the department accepted both applications under the Kidney Disease Treatment Centers-Concurrent Review Cycle #4. A chronological summary of the review is shown below.

<b>Action</b>	<b>DaVita</b>	<b>PSKC</b>
Letter of Intent Submitted	October 31, 2007	October 26, 2007
Application Submitted	November 30, 2007	November 29, 2007
Department's Pre-Review Activities including Screenings and Responses	December 4, 2007 through February 29, 2008	
Beginning of Review	March 17, 2008	
End of Public Comment	May 16, 2008	
Rebuttal Comments Received	June 16, 2008	
Department's Anticipated Decision Date	July 31, 2008	
Department's Actual Decision Date	July 31, 2008	

## **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 this projects, concurrent review allows the department to review dialysis applications proposing to serve the same planning area or an adjacent planning area where there is no existing facility as defined in WAC 246-310-280(9) and WAC 246-310-284 (a) to simultaneously reach a decision that serves the best interests of the planning area's residents.

In the case of the applications submitted by DaVita and PSKC, the department will issue one single evaluation regarding whether both, any or none of the applicants should be issued a Certificate of Need. For each application, the other competing applicant sought and received affected person status under WAC 246-310-010. No other entity sought or received affected person status relating to the two projects.

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<sup>2</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); and WAC 246-310-287.

## **SOURCE INFORMATION REVIEWED**

- DaVita, Inc. Certificate of Need application submitted November 30, 2007
- PSKC Certificate of Need application submitted November 29, 2007
- DaVita, Inc. supplemental information dated February 28, 2008
- PSKC supplemental information dated February 27, 2008
- DaVita, Inc. public comments received on May 14, 2008<sup>3</sup>
- PSKC rebuttal comments received June 12, 2008<sup>4</sup>
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2007 Northwest Renal Network 4<sup>th</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
- Certificate of Need historical files
- Medical Quality Assurance compliance data

## **CONCLUSIONS**

### **DaVita Inc.**

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a new 10-station dialysis center in the City of Marysville within Snohomish County Planning Area 1, to serve the residents of the planning area is consistent with applicable criteria.

If approved, the Department would include terms that DaVita provide for review and approval of the items listed below. Provided that DaVita agrees to the terms identified below, a Certificate of Need would be issued for the establishment of the 10-station DaVita Tulalip Dialysis Center to be located in the city of Marysville within Snohomish County Planning Area 1. The approved capital expenditure associated with the establishment of the dialysis center is \$1,332,552.

### **Terms**

1. Prior to providing services DaVita, Inc. must provide to the department for review and approval an executed copy of the Medical Director's agreement. The executed agreements shall be consistent with the draft agreement provided within the application.
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3. Prior to the project commencement, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located on the southwest corner of 116<sup>th</sup> Street and Smokey Point Boulevard within the city of Marysville, WA 98271. The proposed site is also known as Snohomish County Tax Lot APN #30050900300700.

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<sup>3</sup> PSKC did not provide public comments

<sup>4</sup> DaVita, Inc. did not provide rebuttal comments

## Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Puget Sound Kidney Centers proposing to expand the existing 18-station Smokey Point Kidney Dialysis Center by 10-station's met all the applicable criteria in WAC 246-310-210 through 240 resulting in the department using tie-breaker criteria in WAC 243-310-288. Using the tie-breaker's criteria, the department determined that PSKC's application is not the best available alternative and a Certificate of Need is denied.

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

Based on the source information reviewed, the department determines that both applicants 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.<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)]

DaVita’s Application of the Numeric Methodology

DaVita proposes to establish a 10-station kidney dialysis facility in the City of Marysville serve patients in Snohomish County Planning Area 1. Consistent with WAC 246-310-280 (9), DaVita applied the numeric methodology for the planning area using linear regression. 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. [Source: Application Pages 17 and 18]

PSKC Application of the Numeric Methodology

PSKC proposes to add 10-stations to the existing Puget Sound kidney dialysis Centers in City of Arlington to serve patients in Snohomish County Planning Area 1. Consistent with WAC 246-310-280 (9), PSKC applied the numeric methodology for the planning area using linear regression. Given that the facility would be located in Snohomish County Planning Area 1, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application Page 13]

The Department Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning area the department also used linear regression to project need. For Snohomish County, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. [Source: Appendix A attached to this evaluation]

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

**Table 1  
Summary of Snohomish County Numeric Methodology**

	4.8 in-center patients per station			
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
<b>DaVita</b>	27.17	18	9.17	10
<b>PSKC</b>	27.08	18	9.08	10
<b>DOH</b>	27.08	18	9.08	10

When comparing both applicant and the department’s projection results shown in Table 1 above, it is noted that the results of both DaVita and PSKC projections matches the department’s projections.

WAC 246-310-284(5) requires that all CN approved stations in the planning area must be operating at 4.8 in-center patients per station before new stations can be added. Currently PSKC—Smokey Point is the only dialysis facility operating in Snohomish County Planning Area 1. That facility was operating at 5.67 patients per in-center station based on the required NWRN data. Therefore, this sub-criterion is met.

WAC 246-310-284(6) requires new in-center dialysis stations to 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 Planning Area 1, the requirement is 4.8 in-center patients per approved station. Both DaVita and PSKC propose dialysis stations to be added within Snohomish County Planning Area 1, as a result; both applicants must demonstrate compliance with this criterion using the 4.8 in-center patient per station. For DaVita the third full year of operation is year 2012 and for PSKC the third full year of operation is year 2011. A summary of both DaVita's and PSKC's projected utilization for year 2011 and 2012 is shown in Table 2.

**Table 2  
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>
DaVita Tulalip Dialysis Center	2012	10	60	6.0
Puget Sound Kidney Dialysis Center	2011	28	140	5.0

As shown in Table 2 above, both DaVita's and PSKC's projections meet this standard. [Source: DaVita Application, Appendix 9 and PSKC Supplemental Information, Exhibit 3]

Based on the information contained in Table 1, the department's conclusions regarding both projects are as follows.

DaVita

DaVita proposes to establish a 10-station dialysis center in Marysville to serve the residents of Snohomish County Planning Area 1. Based on the above standard and criteria, DaVita's project is consistent with applicable criteria of the Certificate of Need Program. This sub-criterion is met.

PSKC

PSKC proposes to add 10-stations to existing capacity at the Smokey Point Dialysis Center in Arlington within Snohomish County Planning Area 1. As noted in Table 1, the department's numeric methodology shows a need for 10-stations in Snohomish County Planning Area 1. Based on the standards and criteria, this 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, both applicants currently provide 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 areas 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

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 proposed DaVita Tulalip Dialysis Center. The Admission Policy outlines the process and criteria the new facility would use to admit patients for treatment and ensures that patients 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: Application, Appendix 14]

A review of the Admission and Charity Care policies for the proposed DaVita Tulalip Dialysis Center identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. [Source: Application, Appendix 14]

Additionally, DaVita demonstrated its intent to provide charity care to the residents in the planning areas by submitting its charity care policy that outlines the process a patient would use to access service. Further, DaVita's pro-forma financial statement included a charity care line item as a deduction from revenue within the pro-forma. [Source: Application, Appendix 9] Based on the above information, the department concludes that all residents of the service areas would have reasonable access to health services at the proposed DaVita Tulalip Dialysis Center. This sub-criterion is met.

#### PSKC

To comply with this criterion, PSKC provided a copy of its patient Admission Policy for Puget Sound Kidney Centers. The Admission Policy outlines the process and criteria that the proposed facility would use to admit patients for treatment and ensures that patients receive appropriate care at the facility. [Source: Application, Exhibits 14] The Admission Policy states that any patient with end stage renal disease needing dialysis are accepted for treatment at the facility without regard to race, color, national origin, sex, age, religion, or disability.

The applicant stated Medicaid recipients will have access to its facility. A review of its financial statement show revenue from Medicaid is expected. The Puget Sound Kidney Center—Smokey Point facility is currently providing dialysis services as a Medicare certified facility and a review of its financial statement shows revenue from Medicare.

To demonstrate that charity care would be available to the residents of the planning area, PSKC provided a copy of its Community Service Statement for the Puget Sound Kidney Centers that is currently being used at the existing PSKC—Smokey Point facility. The Community Service Statement provided by PSKC indicated that charity care is available to the residents of the planning area. Additionally, PSKC pro-forma income statement included a charity care line item

as a deduction from revenue within its pro-forma income statement. [Source: Supplemental Information February 27, 2008, Exhibit 3]

Based on the above information, the department concludes that all residents of the service area would continue to have reasonable access to health services at the existing PSKC—Smokey Point facility. This sub-criterion is met.

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

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

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

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates all 10-station would become operational by the end of October 2009. Under this timeline, year 2010 would be the proposed DaVita Tulalip Dialysis Center first full calendar year of operation and 2012 would be year three. [Source: DaVita Application, Page11] Summarized in Table 3, is DaVita's year one through year four projected financial revenue, expenses, and net income for the DaVita Tulalip Dialysis Center as a 10-station dialysis facility. [Source: Application, Appendix 9]

**Table 3**  
**DaVita Tulalip Dialysis Center**  
**Projected Revenue and Expenses Years (1 through 4)**

	<b>Partial Year 2009</b>	<b>Full Year 2010</b>	<b>Full Year 2011</b>	<b>Full Year 2012</b>	<b>Full Year 2013</b>
# of Stations	10	10	10	10	10
# of Treatments [1]	3,954	5,691	7,488	8,237	8,986
# of Patients [2]	24	38	50	55	60
Utilization Rate [2]	2.40	3.80	5.00	5.50	6.00
Net Patient Revenue[1]	\$1,412,068	\$2,435,076	\$3,352,851	\$3,830,417	\$4,319,055
Total Operating Expenses [1, 3]	\$1,326,957	\$1,688,516	\$2,114,515	\$2,398,960	\$2,674,716
Net Profit or (Loss)[1]	\$85,111	\$746,560	\$1,238,336	\$1,431,457	\$1,644,339
Operating Revenue / Treatment [1]	\$384.03	\$410.84	\$425.65	\$436.37	\$446.18
Operating Exp./ Treatment [1]	\$360.88	\$284.89	\$268.44	\$273.29	\$276.31
Net Profit per Treatment [1]	\$23.15	\$125.96	\$157.21	\$163.07	\$169.87

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

As shown in Table 3, at the projected volumes identified, the DaVita Tulalip facility would be operating the 10-station dialysis center at a profit in partial years 2009 through the forth full years of operations or year 2013. DaVita states that the proposed facility will be operated at utilization levels consistent with other facilities. To show that it has site control, DaVita provided a draft lease agreement and a letter from EDG-Development, LLC a property developer. The letter dated November 29, 2007, states, "This letter will confirm the intention of EDG-Development, LLC to transfer to its wholly-owned subsidiary EDG-DV Marysville, LLC all of its rights, title and interest in the property described in the draft lease between EDG-DV Marysville, LLC and Total Renal Care, Inc." [Source: Application, Appendix 15]

A review of the draft lease agreement between EDG-DV Marysville, LLC (Tenant) and Total Renal Care, Inc. (Landlord) shows that rent costs identified in the draft lease are consistent with the pro-forma financial projections used to prepare the information in Table 3 above.

Further, the department noted that the provided agreement stipulates, “3 periods of 45 days each beginning when buyer removes contingencies under the due diligence period” referred to as the “final regulatory compliance period” and a “30 days extension after end of the final regulatory compliance” referred to as the “closing date”. [Source: February 29, 2008, Supplemental information, Attachment 2]

Further, the department notes that the Real Estate Purchase and Sale Agreement states that it may be amended or modified only by a written instrument executed by the seller and buyer. As at the time of this review, the department has not been notified by DaVita or EDG-Development, LLC that the agreement have been amended or modified. Therefore, the department considers the purchase and sales agreement submitted by DaVita to be valid as intended by both the buyer and sellers.

During the review of this application, PSKC did not provide any comments during the first 30 days of the public comment period. However, the department noted that PSKC provided comments during rebuttal period. The department considers the comments provided by PSKC during rebuttal comment period as inappropriate rebuttal comments and would not address those comments. Summarized below, are the inappropriate rebuttal comments provided by PSKC regarding DaVita’s site control.

#### DaVita does not have site control

- DaVita’s previous application was denied because it lacked site control and yet again, DaVita has identified the same property and PSKC believes that this application is also flawed.
- The department asked about EDG-DV Marysville, LLC since it did not show up on the Secretary of State records. DaVita acknowledge that the entity did not exist until long after review had begun by providing a certificate of formation dated February 14, 2008.
- The draft lease agreement is between two other parties EDG-DV Marysville, LCC and Total Renal Care, Inc. The statement of intent to convey interest in the property to EDG-DV Maryville at later date is dishonest.
- The terms of the purchase and sales agreement provided by DaVita has expired and the closing date has passed. EDG Development has not actually acquired or transferred any rights to this day and has no rights in the property to transfer to EDG-DV Marysville, LLC.
- DaVita application understates expenses and overstates financial performance. DaVita’s projected numbers in both the original and the pro-forma submission in response to screening questions shows unexplained discrepancies [Source: PSKC rebuttal comment received June 12, 2008]

#### The Department Response

As stated before, the department noted that the comments provided by PSKC above are not proper rebuttal comments. However, the department’s review of DaVita’s application to ascertain site control revealed that the Real Estate Purchase and Sales Agreement provided as supplemental information shows that its was signed by both EDG-Development, LLC referred to as the (buyer)

and the individual property owners referred to as the (sellers). Further review of DaVita’s application also shows that it provided a letter from EDG-Development, LLC which was received by the department on February 29, 2008. Additionally, the department’s record indicates that formal review of both projects began on March 17, 2008. In addition, the department’s review of the pro-forma income statement provided by DaVita did not show any inconsistency.

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

**Term**

- *Prior to the project commencement, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located on the southwest corner of 116<sup>th</sup> Street and Smokey Point Boulevard within the city of Marysville, WA 98271. The proposed site is also known as Snohomish County Tax Lot APN #30050900300700.*

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

**PSKC**

If this project is approved, PSKC anticipates the added capacity would become operational immediately upon CN approval. As stated by PSKC, the Smokey Point facility would be operating a total of 28-stations by the end of year 2008 and year 2009 would be the facility’s first full calendar year of operation and year 2011 would be year three. [Source: Application, Page 7] Summarized in Table 4, is PSKC year one through year three projected financial revenue, expenses, and net income for the PSKC—Smokey Point Dialysis Center as a 28-station dialysis facility. [Source: February 27, 2008; Supplemental Information, Exhibit 3]

**Table 4  
PSKC—Smokey Point Dialysis Center  
Projected Revenue and Expenses Years (1 through 3)**

	<b>Partial Year 2008</b>	<b>Full Year 2009</b>	<b>Full Year 2010</b>	<b>Full Year 2011</b>
# of Stations	28	28	28	28
# of Treatments [1]	9,919	18,564	20,280	21,761
# of Patients [2]	109	119	130	140
Utilization Rate [2]	3.89	4.25	4.64	5.00
Net Patient Revenue[1]	\$2,602,882	\$4,871,451	\$5,321,754	\$5,710,388
Total Operating Expenses [1, 3]	\$2,575,694	\$4,791,521	\$5,198,965	\$5,561,999
Net Profit or (Loss)[1]	\$27,188	\$79,930	\$122,789	\$148,389
Operating Revenue / Treatment [1]	\$262.41	\$262.41	\$262.41	\$262.41
Operating Exp./ Treatment [1]	\$259.67	\$258.11	\$256.36	\$255.59
Net Profit per Treatment [1]	\$2.74	\$4.31	\$6.05	\$6.82

[1] Includes both in-center and home dialysis patients; [2] in-center patients only; [3] includes interest, charity care.

As shown in Table 4 above, at the projected volumes identified by PSKC the Smokey Point facility would be operating the 28-station dialysis center at a profit starting from the first year of expansion to the end of the third years of operation.

When reviewing PSKC's application, the department noted that the executed medical director agreement between Puget Sound Kidney Center's referred to as the (Centers) and the Kidney and Arthritis Clinic, P.C referred to as the (Clinic) states, "*The Centers shall pay the Clinic a fee for administrative and technical advisory services, commencing January 1, 2008, the fee will be \$5,000 per month (\$60,000 annually)*" while the pro-forma income statement provided stated medical director services fees as \$23,300 for partial year 2008 and for the three full years of operations, the fees is \$40,000. [Source: Supplemental Information received February 27, 2008, Exhibit 1] The department received comments from DaVita regarding PSKC's financial feasibility. Summarized below are the comments provided by DaVita.

#### PSKC medical director's costs cannot be reconciled

- The medical director's agreement included with PSKC's response to screening questions includes no references to an expanded Smokey Point facility. The agreement specifies annual medical director's compensation of \$60,000 through 2010 for all four existing PSKC dialysis centers.
- PSKC's revised pro-forma for the expanded Smokey Point facility indicates that medical director compensation would be \$40,000 per year for that facility alone. If accurate, then a total of \$20,000 would remain under the agreement for medical director a service at PSKC's three other facilities.
- We doubt that PSKC's medical director has agreed to serve Smokey Point for \$40,000 and the other three PSKC facilities for only \$20,000. A more likely, but unverifiable explanation is that PSKC has submitted a medical director agreement that does not cover the Smokey Point expansion.
- Adding to the uncertainty about its medical director arrangement at Smokey Point, the consolidated pro-forma PSKC submitted with the application shows overall medical director expenses at \$130,000 per year more than double the \$60,000 amount actually substantiated in the medical director agreement. [Source: Public comments received May 14, 2008]

#### The Department Response

The department disagrees with DaVita assertions that PSKC's medical director costs are inconsistent. The department notes that the medical director agreement between the Centers and the Clinic states that for all PSKC's facilities, the annual medical director's cost would be \$60,000. Because the agreement between the Centers and the Clinic stipulates that the Clinic would be paid \$60,000 annually for providing medical director services and since PSKC did not provide any other documentation regarding medical director cost, the department assumes that the Smokey Point pro-forma income statement provided represents a portion of all the allocated medical directors cost for all Puget Sound kidney facilities. Further, the department would also disagree with DaVita's other assertions that uncertainty exists with PSKC's medical director arrangement at the Smokey Point facility because a consolidated pro-forma shows a different medical director expense. It's the department's understanding that the consolidated expenses statement represents all of PSKC's facilities revenues and expenses. Therefore, the department concludes that the medical director costs are consistent with the pro-forma financial projections used to prepare the information in Table 4.

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

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

DaVita Inc.

The costs and charges per dialysis for the proposed DaVita Tulalip Dialysis Center can be compared to recent kidney dialysis proposals submitted to the department. The estimated capital expenditure associated with the establishment of 10-station dialysis facility is \$1,332,552. [Source: Application pages 1 and 7] Summarized in Table 5 below, is the capital expenditure.

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

<b>Item</b>	<b>Cost</b>	<b>% of Total</b>
Leasehold Improvements	\$720,000	54.2%
Fixed & Moveable Equipment	\$498,143	37.4%
Architect/Engineering and CN fees	\$114,409	8.4%
<b>Total Project Cost</b>	<b>\$1,332,552</b>	<b>100%</b>

The department recognizes that the majority of reimbursements for dialysis services are thorough Medicare ESRD entitlement. To further, demonstrate compliance with this sub-criterion, DaVita provided the sources of its patient revenue shown in the table 6. [Source: Application, Page 9]

**Table 6  
DaVita Tulalip Dialysis Center Revenue and Payor Source**

<b>Source of Revenue</b>	<b>% of Revenue</b>	<b>% of Patients per Payor</b>
Medicare	58%	78%
Medicaid /State	7%	9%
Insurance / HMO	35%	13%
<b>Total</b>	<b>100%</b>	<b>100%</b>

As shown in Table 6 above, Medicare and state (Medicaid) entitlements as stated by DaVita are projected to equal 65% of revenue and 87% patients per payor source. The projected Medicare and Medicaid revenue sources are not cost based reimbursement. The department concludes that costs associated with this project will not have an unreasonable impact on the remaining 35% of revenue and 13% of patients per payor source.

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

PSKC

PSKC identified the capital expenditure associated with the expansion of the existing 18-stations facility to a 28-stations dialysis center to be \$154,000. [Source: Application, Page 1] Summarized in the table below is PSKC capital expenditure.

**Table 7**  
**PSKC—Smokey Point Capital Cost**

<b>Item</b>	<b>Cost</b>	<b>% of Total</b>
Fixed & Moveable Equipment	\$153,571	100%
<b>Total Project Cost</b>	<b>\$153,571</b>	

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, PSKC also provided the sources of its patient revenue shown in Table 8 below. [Source: Application, Page 6]

**Table 8**  
**PSKC Source of Revenue**

<b>Source of Revenue</b>	<b>% of Revenue</b>
Medicare	73%
State (Medicaid)	9%
Other	18%
<b>Total</b>	<b>100%</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 82% of the revenue at the Smokey Point facility. The department concludes that the majority of the projected revenue at the Smokey Point facility is dependent upon entitlement sources that are not cost based reimbursement and are therefore, not expected to have an unreasonable impact on charges for services. The department concludes that costs associated with this project will not have an unreasonable impact on the remaining 18% of revenue. This sub-criterion is met.

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

DaVita Inc.

The source of financing for the proposed DaVita Tulalip Dialysis Center is the facility parent company cash reserves. A review of DaVita’s historical financial statements for years 2004 through 2006, demonstrates that the funds necessary to finance the project are available. [Source: Application, Exhibit 10]

DaVita’s financial reserves as documented by Exhibit 10 are more than adequate to fund the new 10-station dialysis facility. Based on the information provided, the department concludes that DaVita has demonstrated that the establishment of a new dialysis center in Snohomish County Planning Area1 will not adversely affect DaVita’s financial stability. Further, the department concludes that DaVita’s application proposing to establish a new facility in Marysville to serve the residents of Snohomish County Planning Area 1 can be appropriately financed. This sub-criterion is met.

PSKC

PSKC source of financing for the expansion of the Smokey Point Center is the applicant’s parent company cash reserves. The department received documentation from PSKC board stating that the necessary funds needed to finance the Smokey Point facility are available. [Source: Application Exhibit 17] The department concludes that PSKC application proposing to expand the existing Smokey Point facility in Snohomish County Planning Area 1, to serve the residents of the planning area can be appropriately financed. This sub-criterion is met.

**C. Structure and Process (Quality) of Care (WAC 246-310-230)**

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

- DaVita, Inc.’s project has met the structure and process (quality) of care criteria in WAC 246-310-230; and
- PSKC 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.*

DaVita Inc.

To implement this project DaVita proposes to hire the equivalent of 3.9 new staff during the first partial year of operation and thereafter, increase the number of new staff to 11.8 by the end of the fourth full year of operation. The proposed project staff increase is summarized in Table 9 below.

**Table 9**  
**DaVita Goldendale Dialysis Center Proposed FTE’s 2008 – 2012**

<b>Category</b>	<b>Partial Year 2008</b>	<b>Year 1. 2009 Increase</b>	<b>Year 2. 2010 Increase</b>	<b>Year 3. 2011 Increase</b>	<b>Year 4. 2012 Increase</b>	<b>Total FTE’s</b>
Medical Director	<i>professional services contract</i>					
Administrator	0.5	0.5	0.00	0.00	0.00	1.00
Registered Nurses	1.1	0.6	0.50	0.10	0.60	2.90
Patient care Tech	0.20	1.50	1.00	1.00	0.00	5.00
Biomedical Tech	0.20	0.00	0.00	0.00	0.00	0.20
Re-Use Tech	0.00	0.00	0.10	0.00	0.00	0.30
Administrative Asst	-	0.30	0.20	0.30	0.20	1.00
Social Worker	0.20	0.10	0.10	0.20	0.10	0.70
Dietician	0.00	0.10	0.10	0.20	0.10	0.70
Number of FTE’S	<b>3.90</b>	<b>3.10</b>	<b>2.00</b>	<b>1.80</b>	<b>1.00</b>	<b>11.80</b>

As shown in Table 9 above, after the initial recruitment of FTE’s, DaVita expects a steady increase in FTE’s for thee proposed DaVita Tulalip Dialysis Center through year 2012. DaVita states it expects no difficulty in recruiting staff for the new facility because several employees have expressed interest in working at the proposed facility. The applicant also states that it has an extensive employee traveling program guaranteeing that all the appropriate staff would be available to staff its facilities. Further, DaVita asserted that it advertises and post employment opportunity announcements internally and nationally. [Source: Application, Page 25]

DaVita identified Fadi Najjar, MD (“Physician”) as the medical director for the proposed DaVita Tulalip Dialysis Center and provided a draft medical director’s agreement between Total Renal Care referred to as the (“Company”). The draft medical director agreement outlines the roles and responsibilities of the Physician and the Company. Additionally, the draft agreement also identifies the annual compensation for the medical director. [Source: Application Exhibit 3 and Supplemental Information received February 29, 2008, Attachment 4]

The department reviewed Dr. Najjar’s compliance history and that review did not reveal any recorded sanctions. The medical director’s agreement provided outlines the roles and responsibilities of both parties involved. If approved, the Department would include a term that DaVita provide for review and approval an executed medical director contract which includes the relevant terms and compensation as identified in the draft agreement prior to project completion.

**Term**

- *Prior to providing services DaVita, Inc. must provide to the department for review and approval an executed copy of the Medical Director’s agreement. The executed agreements shall be consistent with the draft agreement provided within the application.*

Base on information provided by DaVita, the department concludes that staffing is expected to be available for recruitment by the applicant when the dialysis center commences services in October 2009. This sub-criterion is met provided DaVita agrees to the term identified above.

**PSKC**

PSKC currently employs 6 registered nurses and 23.5 ancillary staff at the Smokey Point facility. For the expansion, PSKC proposes to hire 16 new staff to the 28-station dialysis center. By the fourth year of the facility expansion or by year 2012, PSKC would be operating the 28-station facility with a total of 45.5 FTE’s. The proposed FTE breakdown is shown in Table 10 below. [Source: Supplemental Information received February 27, 2008, Page 2]

**Table 10  
PSKC-Smokey Point Current and Proposed FTE’s 2009 – 2012**

<b>Category</b>	<b>Current FTE</b>	<b>Partial 2008</b>	<b>Year 1 2009 Increase</b>	<b>Year 2 2010 Increase</b>	<b>Year 3 2011 Increase</b>	<b>Year 4 2012 Increase</b>
Medical Director	Professional Services Contract					
Administrator	0.5	0.00	0.00	0.00	0.00	0.00
Unit Clerk	1.00	0.00	0.00	0.00	0.00	0.00
Registered Nurse	6.00	2.00	0.00	0.00	0.00	2.00
Patient Care Tech	15.0	4.00	0.00	0.00	0.00	4.00
Bio-Medical Tech	1.00	1.00	0.00	0.00	0.00	0.00
Re-Use Tech	4.00	1.00	0.00	0.00	0.00	1.00
Administrative Sec	1.00	0.00	0.00	0.00	0.00	0.00
Dietician	1.00	0.50	0.00	0.00	0.00	0.50
<b>Total FTE’s</b>	<b>29.5</b>	<b>8.50</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>7.50</b>

As shown in Table 10 above, PSKC expects a steady increase in FTE’s to the Smokey Point facility through year 2012. The applicant states, “PSKC experience no problems in recruiting, training and retaining highly qualified providers of health care and will not experience a problem in this regard in the future”. [Source: Application, Page 17]

PSKC identified the Kidney and Arthritis Clinic, P.S (“the Clinic”) as the medical consultant for the Smokey Point facility and provided an executed medical director’s agreement between the Puget Sound Kidney Centers (the “Centers”) and the Clinic. The executed medical director agreement provided outlined the roles and responsibilities of both the Clinic and the Centers. [Source: Supplemental Information, Exhibit 1]

Base on information provided by PSKC, the department concludes that staffing is expected to be available for recruitment by the applicant. 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, Inc.

Information provided by DaVita states that ancillary and support services such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site upon the commencement of services at the proposed facility. The applicant states that services would be coordinated through DaVita’s corporate office in El Segundo, California and support offices in Washington. [Source: Application, Page 25] To further demonstrate compliance with this sub-criterion, DaVita provided draft transfer agreement. [Application, Appendix 12]

If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed transfer agreement with a local healthcare provider.

### **Term**

- *Prior to providing services at the DaVita Tulalip Dialysis Center, DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department’s review and approval.*

Based on this information and with agreement to the term above, the department concludes that DaVita currently has appropriate relationships with ancillary and support services. This sub-criterion would be met.

### **PSKC**

The Smokey Point facility currently provides ancillary services. Additionally, PSKC—Evert and PSKC—South two facilities own by the applicant and located in Snohomish County also provide the following ancillary service social services, nursing services, nutrition services, administration, patient financial counseling, information systems, patient education, plant operations, staff education, material management, and technical services on a daily basis or as needed. [Source: Application, Page 18]

The department concludes that PSKC currently has appropriate relationships with ancillary and support services, and approval of this project is not expected to negatively affect existing relationships. This sub-criterion is 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, 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. [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 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>6</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 42 states.<sup>7</sup> The compliance history of the remaining 13 states and the District of Columbia is unknown.<sup>8</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. 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.<sup>9</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. [Source: facility survey data provided by the Office of Health Care Survey]

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<sup>6</sup> WAC 246-310-230(5).

<sup>7</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>8</sup> Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

<sup>9</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.

Compliance history review of the proposed medical director Dr. Fadi Najjar did not reveal any recorded sanctions. DaVita provided a draft medical director agreement with Dr. Najjar. The agreement outlines the roles and responsibilities of the medical director. Given the compliance history of DaVita and that of the proposed facility medical director, the department concludes that there is reasonable assurance that the proposed DaVita Tulalip Dialysis Center would be operated in conformance with state and federal regulation. This sub-criterion is met.

### PSKC

As stated in the project description portion of this evaluation, PSKC was established in 1980 and owns or operates four dialysis facilities in Washington State - three in Snohomish County and one in Island County. 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>10</sup>. To accomplish this task, the department reviewed PSKC's quality of care compliance history for all four facilities.

In the most recent 10 years, the Department of Health's Office of Health Care Survey (OHCS) has completed twelve compliance surveys for the PSKC facilities in operation.<sup>11</sup> Of the compliance surveys completed, all revealed minor non-compliance issues related to care and management. These non-compliance issues are typical of a dialysis facility and PSKC submitted and implemented acceptable plans of correction. [Office of Health Care Survey]

PSKC identified Alan Haakenstad, MD as the medical director for the Smokey Point facility and according to the terms of the agreement between the Centers and the Clinic, Dr. Haakenstad was also identified as the medical director for the other four facilities owned by PSKC. A compliance history review of Dr. Haakenstad credential with the Department of Health Medical Quality Assurance Commission reveals no recorded sanctions. [Source: Licensing and compliance history data provided by DOH-Medical Quality Assurance Commission]

Based on PSKC's compliance history and the compliance history of Dr. Haakenstad the department concludes that there is reasonable assurance that the Smokey Point facility would continue to operate in conformance with state and federal regulations. This sub-criterion is met.

- (4) *The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.*

### 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. [Source: Application, Page 25, Appendices 17]

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<sup>10</sup> WAC 246-310-230(5)

<sup>11</sup> PSKC-Everett: surveys completed 1997, 2000, 2003, & 2007; PSKC-South: surveys completed 1997, 2001, 2004, & 2007; PSKC-Smokey Point: initial survey completed 2005, 2007; PSKC-WI: initial survey completed 2005, 2006

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 by the department shows a need for 10 new dialysis stations in Snohomish County Planning Area 1. Within its application, DaVita proposes to establish 10-station dialysis center in the city of Marysville within Snohomish County Planning Area 1. Therefore, the department concludes that the approval of DaVita's application for 10-stations in Marysville to serve the residents of Snohomish County Planning Area 1 would not cause fragmentation of dialysis services. Based on this information, the department concludes that approval of this project would promote continuity in the provision of healthcare for the planning areas and would not result in an unwarranted fragmentation of services. This sub-criterion is met.

#### PSKC

To demonstrate that this project will continue to promote continuity of care, PSKC states, "*The majority of patients treated at Smokey Point resides near the center and are followed by physicians whose practice is reasonably near to their homes and/or the treatment facility. This improves the likelihood that their physicians will see patients at appropriate intervals and that overall quality and continuity of care will be maximized.*" [Source: Application, Page 18]

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 by the department shows need for ten new stations in Snohomish County Planning Area one.

Based on the above information, the department concludes that there is reasonable assurance that the Smokey Point facility will continue to promote continuity of care in the planning area. Further, PSKC's relationships with existing health care providers in the planning area will continue and not result in an unwarranted fragmentation of services. 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:

- DaVita, Inc.'s application has met the cost containment criteria in WAC 246-310-240; and
- PSKC's application 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.*

#### DaVita, Inc.

To comply with this sub-criterion, DaVita stated that it considered two alternatives besides the project. Summarized and listed below are the alternatives considered by DaVita.

- Do not establish a center in Tulalip.
- Collaborate in developing a 10 station center in Snohomish County Planning Area 1.

Alternative 1: Do not add new stations

There is substantial station need in Snohomish County. Since there is high demand in Snohomish County Planning Area 1 and the Puget Sound Kidney Center—Smokey Point facility exceeds 4.8 patients per station as of the October 31, 2007 quarterly report, this alternative was rejected. [Source: Application pages 27]

Alternative 2: Collaborate in developing a 10-station center in Tulalip

The analysis shows that a 10-station facility is needed in Snohomish County Planning Area one. Since the existing provider submitted an application for 10-station expansion and another provider submitted an application for a new 10-station facility, there are no alternatives that would provide both choice and sufficient capacity to provide isolation capability and a permanent bed station. For the reason stated, the two alternatives were rejected and the decision to establish a new 10-station facility was accepted. [Source: Application pages 26 and 27]

Base on the alternatives considered and rejected by DaVita the department concludes that the proposed DaVita Tulalip project is their best available alternative. Therefore, this criterion is met.

PSKC

PSKC did not discuss alternatives to the proposed project in its application, but states, “It will use existing cash reserves to pay for this expansion”. [Source: Application page 19]

In determining the best available alternative, the department considered its findings on the other applicable review criteria and concludes that PSKC’s application has met all other review criteria. Base on these factors, the department concludes that PSKC’s application proposing to expand the Smokey Point facility is their best available alternative. Therefore, this criterion is met.

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

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

DaVita, Inc.

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

PSKC

This project does not involve construction because this is an existing facility. 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.

DaVita, Inc.

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

## PSKC

This project does not involve construction because this is an existing facility. 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 whether this criterion applies to the two applications under review, the department considered its findings on the other review criteria. Upon completion of that review, the department concluded that both DaVita, Inc. and Puget Sound Kidney Centers application's meet the applicable standards outlined in WAC 246-310-210 through 240 and that tie-breakers are necessary.

The department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.

During the review of both applications, the department received public comments from DaVita stating that PSKC's application did not show tie-breakers criteria. Summarized below is the comment provided by DaVita.

### PSKC non-application of tie-breakers criteria

- PSKC 10-station proposal meet the projected need for 2010. However, the DaVita project addresses a number of other patient care needs that are not addressed by the PSKC application and screening responses. The DaVita project improves patient's access by establishing a new facility more than 3 miles from the existing PSKC—Smokey Point Center. DaVita commits to provide a permanent bed station, an isolation station, training services and after 5:00 p.m. shift. [Source: DaVita's public comments received May 14, 2008]

### The Department Response

After reviewing the comments provided by DaVita, the department agrees with the assertions that PSKC did not provide any information within its application to show or demonstrates how its application satisfies tie-breakers criteria. However, the department noted that PSKC provided tie-breakers criteria documentation as rebuttal comment. The department concludes that since PSKC tie-breakers documentation was provided as rebuttal comment, it would not consider the tie-breakers documentation provided as proper rebuttal comments and will evaluate the award of tie-breaker criteria based on the application material.

(1) *The department will award one point per tie-breaker to any applicant that meets a tie-breaker criterion in this subsection.*

(a) *Training services (1 point):*

(i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or

(ii) The applicant is an existing provider in the planning area that offers training services in any of its existing facilities within thirty-five miles of the proposed new facility and either intends to offer training services at the new facility or through those existing facilities; or

(iii) The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and

(iv) Northwest Renal Network's most recent year-end facility survey must document the provision of these training services by the applicant.

DaVita

DaVita states it would provide training and support for home hemodialysis and peritoneal treatments as part of the services at the proposed DaVita Tulalip Dialysis Center. The departments review of NRN year-end data for 2006 shows that this is currently being practiced at DaVita's facilities in Washington. The department expects that if approved, the proposed DaVita Tulalip Dialysis Center would provide home hemodialysis and peritoneal treatments. A point is awarded. [Source: Application Page 8 and Appendix 11]

PSKC

The department was able to determine from PSKC's historical financial statement. [Source: Application, Forecasted Statement of Operations and Changes in net Asset Exhibit 6] that the Puget Sound Kidney Centers provides home training. The department noted that PSKC provided tie-breaker information with rebuttal comments. The department does not consider this information as proper rebuttal because it was provided inappropriately. However, the department concludes that home training is provided at the Smokey Point facility therefore, would consider that PSKC met this tie-breaker criterion. A point is awarded.

	Tie-Breaker Point Distribution	
	DaVita	PSKC
1(a) – Training Services	1	1
Total	1	1

(b) *Private room(s) for isolating patients needing dialysis (1 point).*

DaVita

DaVita also provided information to verify that if approved, the proposed DaVita Tulalip Dialysis Center would also have patients isolation room.[Source: Application, page 8 and Appendix 16] A point is awarded.

PSKC

PSKC did not show within its application or provide any information within its application the location of private room for isolating patients need dialysis. The department noted that PSKC provided rebuttal comments claiming this service, but the department did not accept this information as proper rebuttal. No point is awarded.

	Tie-Breaker Point Distribution	
	DaVita	PSKC
1(b) – Private Isolation Room	1	0
Cumulative Total	2	1

(c) *Permanent bed stations at the facility (1 point).*

DaVita

DaVita states, “The Tulalip Dialysis Center will provide 10 chronic stations and hemodialysis patients requiring dialysis in a permanent bed station would be served”. [Source: Application, Page 8 and Appendix 16] A point is awarded.

PSKC

PSKC did not show within its application nor provide any information within its application the provision of a Permanente bed location. No point is awarded.

	Tie-Breaker Point Distribution	
	DaVita	PSKC
1(c) – Permanent Bed	1	0
Cumulative Total	3	1

(d) *Evening shift (1 point): The applicant currently offers, or as part of its application proposes to offer at the facility a dialysis shift that begins after 5:00 p.m.*

DaVita

DaVita states that hemodialysis patients requiring shifts beginning after 5:00 p.m. would be served at the proposed DaVita Tulalip Dialysis Center. A point is awarded. [Source: Application, Page 8]

PSKC

PSKC did not show within its application nor provide any information within its application the provision of dialysis shifts occurring after 5.00 p.m. No point is awarded.

	Tie-Breaker Point Distribution	
	DaVita	PSKC
1(d) – Evening Shift.	1	0
Cumulative Total	4	1

(e) *Meeting the projected need (1 point): Each application that proposes the number of stations that most closely approximates the projected need.*

DaVita

DaVita’s need projection also matches the Department’s calculations for an additional 10-stations needed in Snohomish County Planning Area one by the year 2012. DaVita’s project proposes to add 10- stations to the planning area. A point is awarded.

PSKC

Central’s need projections matched the department’s calculations for 10-stations needed in Snohomish County Planning Area One by the year 2012. PSKC’s project proposes to add 10-stations in Snohomish County Planning area one. A point is awarded.

	Tie-Breaker Point Distribution	
	DaVita	PSKC
1(e) – Meets Need	1	1
Cumulative Total	5	2

(2) Only one applicant may be awarded a point for each of the following four tie-breaker criteria:  
(a) Economies of scale (1 point): Compared to the other applications, an applicant demonstrates its proposal has the lowest capital expenditure per new station.

DaVita

DaVita also proposes to establish a new 10-station dialysis facility in Tulalip within Snohomish County planning area one for a total cost of \$1,332,552. The department calculated that of the \$1,332,552 projected by DaVita it would spend the sum of \$133,255 per station. Compared to PSKC’s cost per station below, DaVita cost per station is more. No point is awarded.

PSKC

PSKC proposes to expand its existing Smokey Point facility by an additional 10-station for a total cost of \$154,000. The department calculated that of the \$154,000 projected by PSKC it would cost the sum of \$15,400 per station. Compared to DaVita’s cost per station above, PSKC’s cost per station is less. A point is awarded.

	Tie-Breaker Point Distribution	
	DaVita	PSKC
2(a) – Economy of Scale	0	1
Cumulative Total	5	3

(b) Historical provider (1 point):

- (i) The applicant was the first to establish a facility within a planning area; and
- (ii) The application to expand the existing facility is being submitted within five years of the opening of its facility; or
- (iii) The application is to build an additional new facility within five years of the opening of its first facility.

DaVita

DaVita is not currently providing dialysis services in Snohomish County planning area one. Therefore, DaVita’s proposal does not qualify for this point. No point is awarded. [Source: CN Historical files]

PSKC

Currently, PSKC Smokey Point is the only provider located in the planning area. This facility has been operational at the planning area for longer than the time allowed for this tie-breaker point. No point is awarded. [Source: CN Historical files]

	Tie-Breaker Point Distribution	
	DaVita	PSKC
2(b) – Historical Provider	0	0
Cumulative Total	5	3

*(c) Patient geographical access (1 point): The application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of them. The department will award the point for the facility located farthest away from existing facilities within the planning area provided:*

- (i) The facility is at least three miles away from the next closest existing facility in planning areas that qualify for 4.8 patients per station; or
- (ii) The facility is at least eight miles from the next closest existing facility in planning areas that qualify for 3.2 patients per station.

DaVita

DaVita’s proposed project would be located more than three miles away from the existing PSKC-Smokey Point facility therefore, DaVita projects qualifies for geographical access tie-breaker criteria. A point is awarded.

PSKC

PSKC’s application is proposing to expand its existing Smokey Point facility by an additional 10-station. Therefore, the proposed expansion does not qualify for patient geographical access. No point is awarded.

	Tie-Breaker Point Distribution	
	DaVita	PSKC
2(c) – Geographical Access	1	0
Cumulative Total	6	3

*(d) Provider choice (1 point):*

- (i) The applicant does not currently have a facility located within the planning area;
- (ii) The department will consider a planning area as having one provider when a single provider has multiple facilities in the same planning area;
- (iii) If there are already two unrelated providers located in the same planning area, no point will be awarded.

DaVita

DaVita is proposing to establishment a new facility in Snohomish County planning area one. The planning area currently has only one provider. DaVita’s application would provide choice for the planning area and therefore, qualifies for this tie-breaker criterion, because it’s a new provider proposing to serve the planning area. Therefore, this tie-breaker criterion is applicable. A point is awarded

PSKC

PSKC is proposing to expand its existing Smokey Point facility by an additional 10-station. PSKC’s application does not qualify for this tie-breaker criterion, because it’s an existing provider. No point is awarded

	Tie-Breaker Point Distribution	
	DaVita	PSKC
2(d) – Provider Choice	1	0
<b>Cumulative Total</b>	<b>7</b>	<b>3</b>

At the completion of tie-breaker point allocations, DaVita, Inc. application accumulated a total of seven (7) points, while Puget Sound Kidney Dialysis’ Centers proposal to expand its current Smokey Point facility accumulated a total of three (3) points. Due to the results of the points awarded outlined in this section, the department has determined that DaVita’s project is the application accumulating the most number of points and is the first application to be considered in the allocation of station to meet the projected need. Since the proposed DaVita, Inc. project, accounts for all 10-stations projected in Snohomish County Planning Area One, therefore; are no stations remaining to be award to Puget Sound Kidney Dialysis Centers as the application earning the lowest point total.

Table 11  
WAC 246-310-288 – Tie-Breaker Summary Table

	Tie-Breaker Point’s Distribution	
	DaVita	PSKC
1(a) – Training Svc.	1	1
1(b) – Private Room	1	0
1(c) – Permanent Bed	1	0
1(d) – Evening Shift.	1	0
1(e) – Meets Need	1	1
2(a) – Economy of Scale	0	1
2(b) – Historical Provider	0	0
2(c) – Geographical Access	1	0
2(d) – Provider Choice	1	0
<b>Cumulative Total</b>	<b>7</b>	<b>3</b>

# **APPENDIX A**