STATE OF WASHINGTON DEPARTMENT OF HEALTH

July 20, 2012

CERTIFIED MAIL # 7011 1570 0002 7802 6210

Harold Kelly, President and CEO Puget Sound Kidney Centers 1005 Pacific Avenue Everett, Washington 98201

Re: CN #12-11

Dear Mr. Kelly:

We have completed review of the Certificate of Need application submitted by Puget Sound Kidney Centers proposing to establish a 9 station dialysis center in Skagit County. For the reasons stated in this evaluation, the application submitted is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Kidney Centers agrees to the following in its entirety.

Project Description:

Establish a 9-station facility providing hemodialysis, peritoneal dialysis, home and peritoneal training, shifts after 5:00 p.m., backup hemodialysis for home dialysis patients, and visitor hemodialysis for dialysis patients. At project completion, the Anacortes Dialysis Center would be approved to certify and operate a total of 9 dialysis stations. The stations are listed below.

Home Training	1
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
Total	9

Conditions:

- 1. Puget Sound Kidney Centers agrees with the project description above.
- 2. Prior to providing services, Puget Sound Kidney Centers must provide an updated copy of the executed transfer agreements that includes the new Anacortes facility.

Approved Costs:

The approved capital expenditure associated with this project is \$4,053,082.

Harold Kelly, President and CEO Puget Sound Kidney Centers July 20, 2012 Page 2 of 2

You have two options, either accept or reject the above in its entirety. If you accept the above in its entirety, your application will be approved and a Certificate of Need sent to you. If you reject any provision of the above, you must identify that provision, and your application will be denied because approval would not be consistent with applicable Certificate of Need review criteria. Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail: Department of Health Certificate of Need Program 111 Israel Road SE Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerely,

Steven M. Saxe, FACHE

Director, Health Professions and Facilities

cc: Department of Health, Investigations and Inspections Office

EXECUTIVE SUMMARY

EVALUATION DATED JULY 20, 2012 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO SKAGIT COUNTY:

- PUGET SOUND KIDNEY CENTERS PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN SKAGIT COUNTY
- DAVITA, INC. PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN SKAGIT COUNTY

BRIEF PROJECT DESCRIPTIONS

Puget Sound Kidney Centers

Puget Sound Kidney Centers proposes to establish a new 9-station facility to be located at 803 31st Street in Anacortes, Washington. The new dialysis center would be known as PSKC - Anacortes and would serve the residents of Skagit County. [source: PSKC Application, p2]

The capital expenditure associated with the establishment of the 9-station facility is \$4,055,071¹. If this project is approved, PSKC anticipates all 9 stations would be certified and operational before the end of 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation. [source: PSKC Application, p12, PSKC Supplemental Information, p9]

DaVita, Inc.

DaVita proposes to establish a 9-station facility to be located at 145 Cascade Place, Suite 100 in Burlington, Washington. The new dialysis center would be known as the Burlington Dialysis Center and would serve the residents of Skagit County. [source: DaVita Application, p8]

The capital expenditure associated with the establishment of the 9-station facility is \$1,505,575². If this project is approved, DaVita anticipates all 9 stations would be certified and operational by the end of 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation. [source: DaVita Application, Table 1 & p12, DaVita Supplemental Information, 3]

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

¹ As the land owner, PSKC's figures do not include any separate landlord costs in the project capital costs.

² A difference of \$3,000 appears in the calculation of the leasehold improvements between Table 1 and Appendix 7 of the DaVita application. Responses to screening questions identify Table 1 as the accurate projected costs and will be cited as the capital costs for this project.

CONCLUSIONS

Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers proposing additional dialysis capacity within Skagit County is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Kidney Centers agrees to the following in its entirety:

Project Description:

Establish a 9-station facility providing hemodialysis, peritoneal dialysis, home and peritoneal training, shifts after 5:00 p.m., backup hemodialysis for home dialysis patients, and visitor hemodialysis for dialysis patients. At project completion, the Anacortes Dialysis Center would be approved to certify and operate a total of 9 dialysis stations. The stations are listed below.

Home Training	1
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
Total	9

Conditions:

- 1. Puget Sound Kidney Centers agrees with the project description above.
- 2. Prior to providing services, Puget Sound Kidney Centers must provide an updated copy of the executed transfer agreements that includes the new Anacortes facility.

Approved Costs:

The approved capital expenditure associated with this project is \$4,053,082.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a 9-station dialysis center in Burlington within Skagit County is not consistent the applicable criteria of the Certificate of Need Program and is denied.

EVALUATION DATED XXXX OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO SKAGIT COUNTY:

- PUGET SOUND KIDNEY CENTERS PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN SKAGIT COUNTY
- DAVITA, INC. PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN SKAGIT COUNTY

APPLICANT DESCRIPTIONS

Puget Sound Kidney Centers

Puget Sound Kidney Centers (PSKC) is a not-for-profit corporation established in 1980 to serve dialysis patients. Currently, PSKC owns and operates four dialysis facilities in Washington State and an acute mobile dialysis unit that services the area hospitals. The four PSKC facilities are listed below. [source: PSKC Application, p4]

Snohomish

Puget Sound Kidney Center - Everett Puget Sound Kidney Center-South Puget Sound Kidney Center-Smokey Point

Island

Puget Sound Kidney Center-Whidbey Island

DaVita, Inc.

DaVita Inc. (DaVita) is a for-profit corporation that currently operates or provides administrative services to approximately 1,642 dialysis facilities located in 43 states and the District of Columbia. DaVita also provides acute inpatient kidney dialysis services in over 720 hospitals throughout the country. In Washington State, DaVita owns or operates 30 kidney dialysis facilities in 14 separate counties. Below is a listing of the 30 facilities.³ [source: source: CN historical files & Application, p5]

Benton	Pacific
Chinook Dialysis Center	Seaview Dialysis Center

Kennewick Dialysis Center

Chelan Pierce
Grahan

ChelanGraham Dialysis CenterDaVita Dialysis CenterLakewood Dialysis CenterParkland Dialysis CenterClarkPuyallup Dialysis Center

Vancouver Dialysis Center Tacoma Dialysis Center

Douglas Snohomish

East Wenatchee Dialysis Center Everett Dialysis Center⁵

³ Des Moines Dialysis Center, East Wenatchee Dialysis Center, Kennewick Dialysis Center, and Zillah Dialysis Center are CN approved but not yet operational.

⁴ DaVita recently purchased the dialysis center previously owned by Central Washington Hospital. The new name of the dialysis center is unknown as of the writing of this evaluation.

⁵ Refuge Dialysis, LLC, whose ownership is 80% DaVita and 20% The Everett Clinic, owns this facility.

Franklin

Mid Columbia Kidney Center

Island

Whidbey Island Dialysis Center

King

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

Kittitas

Ellensburg Dialysis Center

Mill Creek Dialysis Center

Spokane

Downtown Spokane Renal Center North Spokane Renal Center Spokane Valley Renal Center

Thurston

Olympia Dialysis Center

Yakima

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

PROJECT DESCRIPTIONS

Puget Sound Kidney Centers

This application proposes to establish a new 9-station facility to be located at 803 31st Street in Anacortes, Washington. The new dialysis center has been referred to as PSKC - Anacortes and would serve the residents of Skagit County. [source: PSKC Application, p2]

Services expected to be provided at the Anacortes facility include in-center hemodialysis, home and peritoneal dialysis training, backup hemodialysis for home dialysis patients, and visitor hemodialysis for dialysis patients. The facility would include a permanent bed station, an isolation station, and a shift beginning after 5pm. [source: PSKC Application, p9]

The capital expenditure associated with the establishment of the 9-station facility is \$4,055,071. Of that amount, 70% is related to land and construction; 14% for equipment; and the remaining 16% is related to applicable fees, permits, and taxes. [source: PSKC Supplemental Information, p9]

If this project is approved, PSKC anticipates all 9 stations would become operational before the end of 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation. [source: PSKC Application, p12]

DaVita, Inc.

DaVita proposes to establish a 9-station facility to be located at 145 Cascade Place, Suite 100 in Burlington, Washington. The new dialysis center would be known as the DaVita Burlington Dialysis Center and would serve the residents of Skagit County. [source: DaVita Application, p8]

Services expected to be provided at DaVita Burlington include in-center hemodialysis, home and peritoneal dialysis training, backup hemodialysis for home dialysis patients, and visitor hemodialysis for dialysis patients. The facility would include a permanent bed station, an isolation station, and a shift beginning after 5pm. [source: DaVita Application, p9]

The capital expenditure associated with the establishment of the 9-station facility is \$1,505,575. Of that amount 58% is related to leasehold improvements; 29% for fixed/moveable equipment; and the remaining 13% is related to professional fees and taxes. [source: DaVita Application, Table 1]

If this project is approved, DaVita anticipates all 9 stations would become operational by the end of 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation. [source: DaVita Application, p12]

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

CRITERIA EVALUATION

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for the application. WAC 246-310-200(2) provides additional direction in how the department is to make its determinations. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

- (a) In the use of criteria for making the required determinations, the department shall consider:
 - (i) The consistency of the proposed project with service or facility standards contained in this chapter;
 - (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and
 - (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."

In the event the WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

"The department may consider any of the following in its use of criteria for making the required determinations:

- (i) Nationally recognized standards from professional organizations;
- (ii) Standards developed by professional organizations in Washington state;
- (iii) Federal Medicare and Medicaid certification requirements;
- (iv) State licensing requirements;
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application."

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, an 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); and 246-310-240 (cost containment). Additionally, the applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this project under the year 2011 Kidney Disease Treatment Centers-Concurrent Review Cycle #4. Below is a chronologic summary of the projects.

Action	PSKC	DaVita
Letter of Intent Submitted	October 31, 2011	October 31, 2011
Application Submitted	November 30, 2011	November 30, 2011
Department's pre-review Activities including	December 1, 2011	December 1, 2011
screening and responses	through February 15,	through February 15,
screening and responses	2012	2012
Beginning of Review		
 public comments accepted throughout review 	February 16, 2012	February 16, 2012
 no public hearing conducted 		
End of Public Comment	April 16, 2012	April 16, 2012
Department's Anticipated Decision Date	June 29, 2012	June 29, 2012
Department's Actual Decision Date	July 20, 2012	July 20, 2012

CONCURRENT REVIEW AND AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person as:

- "...an "interested person" who:
 - (a) Is located or resides in the applicant's health service area;
 - (b) Testified at a public hearing or submitted written evidence; and
 - (c) Requested in writing to be informed of the department's decision."

Under concurrent review, each applicant is an affected person for the other application. Throughout the review of this project, one other entity sought or received affected person status under WAC 246-310-010(2).

• Skagit Valley Hospital – An acute care hospital located in Skagit County that also provides outpatient dialysis services.

⁶ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(3), and WAC 246-310-287, 288, and 289.

SOURCE INFORMATION REVIEWED

- Puget Sound Kidney Centers Certificate of Need application submitted November 30, 2011
- DaVita, Inc. Burlington Certificate of Need application submitted November 30, 2011
- Puget Sound Kidney Centers Supplemental Information submitted January 31, 2012
- DaVita, Inc. Burlington Supplemental Information submitted January 31, 2012
- Public comment received during the review
- Puget Sound Kidney Centers rebuttal comments submitted May 16, 2012
- DaVita, Inc. rebuttal comments submitted May 16, 2012
- Years 2005 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 2nd Quarter Data⁷
- Licensing and survey data provided by the Department of Health's Investigations and Inspections Office
- Department of Health / Health Systems Quality Assurance Provider Credential Information
- Certificate of Need historical files

CONCLUSIONS

Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Puget Sound Kidney Centers proposing additional dialysis capacity within Skagit County is sufficient to pass the applicable criteria of the Certificate of Need Program, provided Puget Sound Kidney Centers agrees to the following in its entirety:

<u>Project Description:</u>

Establish a 9-station facility providing hemodialysis, peritoneal dialysis, home and peritoneal training, shifts after 5:00 p.m., backup hemodialysis for home dialysis patients, and visitor hemodialysis for dialysis patients. At project completion, the Anacortes Dialysis Center would be approved to certify and operate a total of 9 dialysis stations. The stations are listed below.

Home Training	1
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
Total	9

Conditions:

Conditions

3. Puget Sound Kidney Centers agrees with the project description above.

4. Prior to providing services, Puget Sound Kidney Centers must provide an updated copy of the executed transfer agreements that includes the new Anacortes facility.

Approved Costs:

The approved capital expenditure associated with this project is \$4,053,082.

⁷ Modality reports for 2011 3rd quarter utilization did not become available until after the application submission period.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a 9-station dialysis center in Burlington within Skagit County is not consistent the applicable criteria of the Certificate of Need Program and is denied.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes:

- Puget Sound Kidney Center's Anacortes project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284; and
- DaVita's Burlington project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need. WAC 246-310-284 requires the department to evaluate kidney disease treatment centers applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1)

Kidney Disease Treatment Center Methodology WAC 246-310-284

criteria is also identified in WAC 246-310-284(5) and (6).

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology 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 (NRN).⁸

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. 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. [source: WAC 246-310-284(4)(a)]

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. [source: WAC 246-310-284(4)(b) and (c)]

WAC 246-310-284(5) identifies that for all planning areas <u>except</u> 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

⁸ 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]

⁹ WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report." For these projects, the base year is 2010.

determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

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

Puget Sound Kidney Centers' Application of the Numeric Methodology

PSKC proposes to establish a 9-station center in Anacortes, within Skagit County. Based on the calculation of the annual growth rate in the planning area as described above, PSKC used a linear regression to project need. Given that the facility would be located in the Skagit County Planning Area, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: PSKC Application, p19]

DaVita, Inc.'s Application of the Numeric Methodology

DaVita proposes a 9-station facility in Burlington, also within Skagit County. Based on the calculation of the annual growth rate in the planning area as described above, DaVita used the same linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: DaVita Application, p16]

Department's Application of the Numeric Methodology

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

The table below provides a summary of the projected net need established by the applicants and the department for the Skagit County Planning Area.

Table 1
Skagit County Planning Area Numeric Methodology Summaries of Projected Net Station Need

	4.8 in-center patients per station			
	2014 Projected # of stations	2014 Net Need		
PSKC	36	27	9	
DaVita	36	27	9	
		•		
DOH	36	27	9	

When comparing the applicants' and Department's results shown above, it shows that the projections of each of the applicants match the Department's figures. As a result, the net station need for Skagit County Planning Area is nine.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 incenter 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 for these projects is November 1, 2011. The quarterly modality report from NRN available at that time was June 30, 2011. For the Skagit County planning area, there are 27 stations located in a single facility owned and operated by Skagit Valley Hospital in Mount Vernon. The table below shows the utilization of the Skagit Valley Dialysis Center. [source: WAC 246-310-282]

Table 2
June 30, 2011 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
Skagit Valley Dialysis Center	27	130	4.81

The data demonstrates that the current facility satisfies the minimum utilization requirement. **This sub-criterion is met.**

WAC 246-310-284(6)

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 the Skagit County Planning Area, the requirement is 4.8 in-center patients per approved station. As a result, the applicants must demonstrate compliance with this criterion using the 4.8 in-center patient per station. [source: WAC 246-310-284(6)(a)]

Puget Sound Kidney Centers

PSKC anticipates all 9 stations would become operational by the spring of 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation and 2016 would be year three. A summary of the applicant's projected utilization for the third year of operation is shown below. [source: PSKC Supplemental Information, p2]

Table 3
PSKC - Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
PSKC-Anacortes	2016	9	45	5.00

As shown above, PSKC's Anacortes facility is expected to exceed the minimum standard. DaVita expressed doubt in PSKC's ability to achieve these forecasted patient counts due to the location of the proposed facility. By choosing Anacortes, DaVita believes that it is too remote from the available population centers and that the historical use rates in the surrounding zip codes are insufficient to obtain the projected utilization.

In rebuttal, PSKC disputes this conclusion. When the region surrounding the proposed facility is reviewed, PSKC identifies 14 to 18 patients in the immediate area; with upwards of 22 in the extended catch area. PSKC also notes that current numbers may also be deflated due to lack of more local access. Letters of support for the PSKC proposal also indicate that local health care

providers do not believe the location will be detrimental. [source: DaVita Public Comment, p3; PSKC rebuttal, p3, Public Comment]

Based on the above standards and criteria, and information provided in rebuttal and public comment, the project is consistent with applicable criteria of the Certificate of Need Program. **This sub-criterion is met**.

DaVita, Inc.

DaVita anticipates all of the proposed stations would become operational by the end of 2013. Under this timeline, year 2014 would be each facility's first full calendar year of operation and 2016 would be year three. A summary of the applicant's projected utilization for the third year of operation is shown below. [source: DaVita Application, p15]

Table 4
DaVita - Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita-Burlington	2016	9	44	4.89

As shown above, the proposed DaVita project is expected to exceed this standard. Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. **This sub-criterion is met**.

(2) <u>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.</u>

Puget Sound Kidney Centers

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of the Skagit County Planning Area would 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 demonstrate compliance with this sub-criterion, PSKC provided a copy of its current Community Service Statement Policy that is currently used within its facilities. The policy serves as both the admission and charity care policy that the PSKC facility will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to age, race, color, ethnicity, sex or sexual orientation, religious or political beliefs, medical disease, disorder or disability, or on the basis of income or payment resources. [source: PSKC Application, Exhibit 9]

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.

PSKC currently provides services to Medicaid eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed facility. A review of the anticipated revenue indicates that the new facility expects to receive Medicaid reimbursements. [source: PSKC Application, p30; PSKC Supplemental Information, Attachment 3]

PSKC currently provides services to Medicare eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed facility. A review of the anticipated revenues indicates that the new facility also expects to receive Medicare reimbursements. [source: PSKC Application, p30; PSKC Supplemental Information, Attachment 3]

PSKC demonstrated its intent to provide charity care to Skagit County residents by submitting the Community Service Statement Policy currently used within its facilities. It describes the agreement to accept patients regardless of income or payment resources for required treatments. PSKC also included a 'charity' line item as a deduction from revenue within the pro forma income statements for its facility. [source: PSKC Supplemental Information, Attachment 3; PSKC Application, Exhibit 9]

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

DaVita, Inc.

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of the Skagit County Planning Area would 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 demonstrate compliance with this sub-criterion, DaVita provided a copy of its current policy for 'Accepting Patients for Treatment' that is currently used in its facilities. The policy outlines the process/criteria that the DaVita facilities will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facilities without regard to race, color, nation origin, sex, age, religion, or disability. [source: DaVita 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.

DaVita currently provides services to Medicaid eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the anticipated revenue indicates that the new facility expects to receive Medicaid reimbursements. [source: DaVita Application, p21; DaVita Supplemental Information; Exhibit B]

DaVita currently provides services to Medicare eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the

anticipated revenues indicates that the new facility also expects to receive Medicare reimbursements. [source: DaVita Application, p21; DaVita Supplemental Information; Exhibit B]

DaVita demonstrated its intent to provide charity care to Skagit County residents by submitting the 'Indigent Care Policy' currently used within its facilities. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. DaVita also included a 'charity' line item as a deduction from revenue within the pro forma income statements for its facility. [source: DaVita Application, Appendix 14; DaVita Supplemental Information; Exhibit B]

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

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

Based on the source information reviewed, the department concludes:

- Puget Sound Kidney Center's Anacortes project has met the financial feasibility criteria in WAC 246-310-220; and
- DaVita's Burlington 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.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

Puget Sound Kidney Centers

PSKC anticipates the Anacortes facility will become operational by the end of 2013. Based on this timeline, calendar year (CY) 2014 would be the facility's first full year of operation. Using the financial information provided as part of the application, the table below illustrates the projected revenue, expenses, and net income for CY 2014 through 2016 for the Anacortes facility. [source: PSKC Supplemental Information, Attachment 3]

Table 5
PSKC-Skagit County
Projected Revenue and Expenses Calendar Years 2014 - 2016¹⁰

	2014	2015	2016
# of Stations	9	9	9
# of Treatments [1]	4,144	5,624	6,727
# of Patients [2]	28	38	45
Utilization Rate [2]	3.11	4.22	5.00
Net Revenue [1]	\$ 1,227,340	\$ 1,682,933	\$ 2,042,839
Total Expense [1,3]	\$ 1,357,205	\$ 1,704,520	\$ 1,957,952
Net Profit or (Loss) [1]	\$ (129,865)	\$ (21,587)	\$ 84,887

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

As shown above, at the projected volumes identified in the application, PSKC anticipates that the 9-station facility would be operating at a loss through year two and a profit in year three.

The site PSKC selected for its Anacortes facility is located on plots of land currently owned by the applicant. PSKC provided the Skagit County assessor documents to demonstrate site ownership. A letter from the city of Anacortes also confirms that the zoning for the area allows for the operation of the proposed facility.

PSKC operates using a Facility and Corporate Medical Director model. Under this model, each PSKC facility has a facility-specific medical director. Additionally, PSKC contracts with a corporate medical director who acts as a liaison between PSKC's President/CEO and the facility specific medical directors. The corporate medical director also works with the facility-specific medical directors to advise and provide clinical and administrative expertise. Mark Gunning, M.D. is to provide medical director coverage for the proposed facility and Alan Haakenstad, M.D. to provide corporate medical director coverage. The agreements identify the terms and compensation to provide coverage within the dialysis facility and on a corporate level. The medical director service costs are accounted for in the pro forma documents. [source: PSKC Application, Exhibit 2; PSKC Supplemental Information, Attachment 3]

During the review of this project, DaVita submitted comments related to the depreciation expenses reported by PSKC. DaVita states, "PSKC projects a marginal third year profit by underreporting its depreciation expense". A comparison of PSKC's depreciation approach with past applications reveals that PSKC calculates a lower expense. ¹¹ DaVita concludes that, at a minimum, PSKC should explain and justify how it calculates depreciation expenses. [source: DaVita Comment, p5]

In rebuttal, PSKC provided responses to DaVita's method. PSKC notes that DaVita makes an 'erroneous comparison' when they assert that the depreciation on a leased facility is the same as a newly constructed and owned facility. PSKC acknowledges that this approach is different than DaVita's, but is not incorrect. PSKC notes that DaVita fails to acknowledge that the accounting

¹⁰ Whole numbers may not add due to rounding.

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¹¹ DaVita compared PSKC's depreciation expenses with 11 past applications. Eight were DaVita's own projects, and one each was submitted by Northwest Kidney Centers, Central Washington Hospital, and Fresenius Medical Care.

rules for depreciation differ for a building that is owned (PSKC's project) than one that is leased (DaVita's project). [source: PSKC rebuttal, p7]

After reviewing the issues and PSKC's rationale and explanation of its deprecation approach, the department concludes it is reasonable.

Based on the above information, the department concludes that PSKC's projected revenues and expenses are reasonable and can be substantiated. **This sub-criterion is met**.

DaVita, Inc.

DaVita anticipates the Burlington facility will become operational in calendar year (CY) 2013. Based on this timeline, CY2014 would be the facility's first full year of operation. Using the financial information provided as part of the application, the table below illustrates the projected revenue, expenses, and net income for CY 2014 through 2016 for the Burlington facility. [source: DaVita Supplemental Information, Exhibit B]

Table 6
DaVita-Burlington
Projected Revenue and Expenses Calendar Years 2014 - 2016¹²

	2014	2015	2016
# of Stations	9	9	9
# of Treatments [1]	3,145	4,942	6,589
# of Patients [2]	21	33	44
Utilization Rate [2]	2.33	3.67	4.89
Net Revenue [1]	\$ 902,566	\$ 1,897,163	\$ 2,732,563
Total Expense [1,3]	\$ 1,186,217	\$ 1,801,016	\$ 2,384,980
Net Profit or (Loss) [1]	\$ (283,651)	\$ 96,147	\$ 347,583

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

As shown above, at the projected volumes identified in the application, DaVita anticipates that the 9-station Burlington facility would be operating at a profit in each of the forecast years.

DaVita selected a site for its new facility located at 145 Cascade Place, Suite 100 in Burlington, Washington. The executed lease provided in the application outlines the terms and the annual rent for the space for 10 years following commencement of the lease. The annual lease costs are substantiated in the pro forma financial documents used to prepare the summary above. [source: DaVita Application, Appendix 15]

Additionally, DaVita provided a copy of a draft Medical Director Agreement expected to be used between itself and Cha-Jen Kuan and the North Sound Kidney Physicians. The medical director service costs are also substantiated in the pro forma documents. If approved, a condition would be included requiring DaVita to provide an executed copy of the medical director agreement consistent with this draft that was presented in the application. [source: DaVita Application, Appendix 3]

¹² Whole numbers may not add due to rounding.

Based on the above information, the department concludes that DaVita's projected revenues and expenses are reasonable and can be substantiated. **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.

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

Puget Sound Kidney Centers

The capital expenditure associated with the establishment of PSKC's proposed Anacortes facility is \$4,055,071, of which 71% is related to site preparation and construction; 14% for moveable equipment; and the remaining 15% is related to fees, permits, and taxes. The capital cost breakdown is shown below. [source: PSKC Supplemental Information, p9]

Table 7
Estimated Capitals Costs of Proposed PSKC Skagit County

Item	Cost	% of Total
Construction/Site Preparation	\$ 2,868,160	71%
Moveable Equipment	\$ 560,606	14%
Professional Fees	\$ 265,500	7%
Permits / Sales Tax	\$ 360,805	8%
Total Estimated Capital Costs	\$ 4,055,071	100%

PSKC intends to finance the project entirely from a combination of available board reserves and debt financing. A review of the financial statement provided in the application indicates that PSKC had sufficient cash assets and board approval to fund the project. Additional details are considered in the sub-section below. [source: PSKC Application, p29 & Exhibit 11]

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 patient revenue shown below. [source: PSKC Application, p11]

Table 8
PSKC-Skagit County
Sources and Percentages of Revenue

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Source of Revenue	% of Revenue		
Medicare	75%		
Medicaid	3%		
Commercial	19%		
Other	3%		
Total	100%		

As shown above, the Medicare and Medicaid entitlements are projected to be 78% of the revenue at the facility. The department concludes that since the majority of revenue is dependent upon

entitlement sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining revenue will be derived through other or private insurance reimbursements.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. **This subcriterion is met**.

DaVita, Inc.

The capital expenditure associated with the establishment of DaVita's proposed Burlington facility is \$1,505,575, of which 58% is related to leasehold improvements; 29% for both fixed and moveable equipment; 5% for professional fees and the remaining 7% is landlord costs. The capital cost breakdown is shown below. [source: DaVita Application, p8; DaVita Supplemental Information, p2]

Table 9
Estimated Capitals Costs of Proposed DaVita – Burlington

Item	Cost	% of Total
Leasehold Improvements	\$ 878,750	58%
Fixed & Moveable Equipment	\$ 438,825	29%
Professional Fees	\$ 81,000	5%
Landlord Costs	\$ 107,000	7%
Total Estimated Capital Costs	\$ 1,505,575	100%

DaVita's portion of the capital expenditure is \$1,398,575 and intends to finance the project entirely from available board reserves. A review of the financial statement provided in the application indicates that DaVita had sufficient cash assets to fund the project. The application also includes a letter of Operational and Financial commitment from DaVita's Chief Operations Officer. [source: DaVita Application, Appendix 6]

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 below. [source: DaVita Application, p10]

Table 10
DaVita – Burlington
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	61%
Medicaid	9%
Insurance / HMO	30%
Total	100%

As shown above, the Medicare and Medicaid entitlements are projected to equal approximately 70% of the revenue at the facility. The department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining revenue will be derived through other or private insurance reimbursements.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. **This subcriterion is met**.

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

Puget Sound Kidney Centers

As previously stated, the capital expenditure associated with the establishment of PSKC's 9-station facility is \$4,055,071. PSKC states that the project will be funded primarily from PSKC's existing cash reserves. If necessary, PSKC will debt finance up to \$1,000,000 of the project. A review of PSKC's statements of financial position show the funds necessary to finance the entire project are available. Since PSKC may opt to debt finance a portion of the costs, PSKC included interest costs within its proforma revenue and expense statements. [source: PSKC Application, p29 & Exhibit 10; PSKC Supplemental Information, Attachment 3]

During the review of this project, DaVita submitted comments related to PSKC's future debt liability as a result of the costs associated with this project. DaVita states, that as a result of commitments to the Whidbey Island facility and the construction proposed for this Anacortes location, "PSKC proposes to spend a total of 7.6 million in the next year for two projects, using cash reserves and up to \$2 million in debt financing". DaVita concludes that the PSKC balance sheets do not have enough cash reserves to fund both projects without putting its entire organization on a 'financial knife edge'. [source: DaVita Comment, p8]

In rebuttal, PSKC provided responses to DaVita's assertions about their financial position. PSKC notes that DaVita makes an 'erroneous conclusion' and that their holdings and projected financial ratios do not fall to the level cited in DaVita's analysis. According to the assets and liabilities reported in PSKCs audited 2010 statements, PSKC had \$11,745,184 in assets. With 2010 liabilities reported to be \$2,106,739, the financial ratio was 5.6. As PSKC notes, DaVita develops their projected ratio using 2010 assets against 2012-2013 liabilities to produce an unfavorable financial ratio. PSKC contends that their year over year financial positions have increased and that forecasts of the organizations standings would produce the assets necessary for both of these planned projects and would produce a much more favorable ratio. [source: PSKC rebuttal, p8; DaVita comment, p8]

Department's Review

A review of the audited financials provided by PSKC do show continued growth in the current assets of the organization. Figures from 2007 through 2010 show double digit growth in each year with an average of 16% over the 3 year period provided. Independent of rebuttal information, forecasts based solely upon average historical growth would serve to notably improve PSKCs financial ratios and are more appropriate than comparing future liabilities against past assets.

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of PSKC 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 \$1,505,575. DaVita's portion of the costs is \$1,398,575. DaVita states that the project will be funded from DaVita's available board reserves. A review of DaVita's statements of financial position show the funds necessary to finance the project are available. [source: DaVita Application, p20 & Appendix 6]

Based on the information provided, the department concludes that approval of this project 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 concludes:

- Puget Sound Kidney Center's Anacortes project has met the Structure and Process of Care criteria in WAC 246-310-230; and
- DaVita's Burlington project has met the Structure and Process of Care criteria in WAC 246-310-230

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

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

Puget Sound Kidney Centers

To staff its proposed 9-station facility, PSKC intends to have 5.5 FTEs in partial year one and increase the FTEs to 11.8 by the end of full calendar year 2016 A breakdown of the proposed FTEs is shown on the following page. [source: PSKC Application, p31]

Table 11 PSKC 2013 – 2016 Projected Total FTEs

	2013 2014 2015 2016						
Staff/FTEs	Total	Total	Total	Total			
Medical Director		Professional Se	rvices Contrac	t			
Direct Care Manager	0.35	0.35	0.35	0.35			
RNs	1.00	2.00	2.50	3.00			
Dialysis Tech	2.00	3.00	4.50	4.50			
Biomed Tech	0.20	0.20	0.20	0.20			
Reuse Tech	0.80	0.80	1.60	1.60			
Stock/Lab Tech	0.2	0.2	0.4	0.4			
Computer Tech	0.1	0.1	0.1	0.1			
Social Wk	0.10	0.20	0.30	0.30			
Dietician	0.20	0.30	0.40	0.50			
Secretary	0.10	0.10	0.10	0.10			
Clerk	0.45	0.45	0.75	0.75			
Total FTE's	5.50	7.70	11.20	11.80			

After the initial recruitment of 5.5 FTEs in 2013, PSKC plans for annual increases. PSKC states that it does not anticipate any difficulty in recruiting staff. PSKC states that a quality workplace with training and educations resources supports this assertion and that "PSKC's goal is to grow its own staff, and PSKC's training, education and flexible human resources policies have allowed PSKC to succeed with its strategy in the past". [source: PSKC Application, p32]

PSKC models its medical director coverage to include both a facility and a corporate medical director. PSKC identified Mark Gunning, M.D. to provide medical director coverage for the proposed facility and provided a copy of the executed medical director's agreement. The agreement outlines the roles and responsibilities of the clinic doctors and the PSKC facility. PSKC also identified Alan Haakenstad, M.D. to provide corporate medical director coverage and provided a copy of the executed corporate medical director's agreement. The agreements identify the terms and annual compensation for the medical director services. [source: PSKC Application, Exhibit 2]

Based on the information reviewed, the department concludes adequate staffing for the 9-station facility is available or can be recruited. **This sub-criterion is met.**

DaVita, Inc.

To staff its proposed 9-station Burlington facility, DaVita intends to hire 6.7 FTEs in full year one (2014) and increase the FTEs steadily through full calendar year three (2016) and beyond. Breakdowns of the incremental increases are shown on the following page. [source: DaVita Supplemental Information, Exhibit C]

Table 12 DaVita, Inc. 2014 – 2017 Projected Incremental FTEs

Staff/FTEs	2014 Addition	2015 Addition	2016 Addition	2017 Addition	Total			
Medical Director	114411011	Professional Services Contract						
Administrator	1.00	0.00	0.00	0.00	1.00			
RNs	2.00	1.10	1.00	0.30	4.40			
Patient Care Tech	1.70	1.00	1.30	0.80	4.80			
Biomedical Tech	0.50	0.00	0.00	0.00	0.50			
Admin Assistant	0.50	0.50	0.00	0.00	1.00			
Social Work	0.50	0.00	0.30	0.20	1.00			
Dietician	0.50	0.00	0.30	0.20	1.00			
Total FTE's	6.70	2.60	2.90	1.50	13.70			

After the initial recruitment in 2013, DaVita expects to add to the FTE totals in each of the following years. DaVita states that it does not anticipate any difficulty in recruiting staff for the Burlington facility due to its location and past success in attracting qualified health personnel. Further, DaVita states that this is aided by their wage and benefit package and that "DaVita has an extensive employee-traveling program guaranteeing all appropriate staff". [source: DaVita Application, p22]

DaVita identified North Sound Kidney Physicians and Chia-Jen (C.J.) Kuan, M.D. as the medical director for the proposed facility and provided a copy of the draft medical director's agreement. The agreement outlines the roles and responsibilities of both DaVita and Dr. Kuan and identifies the term and annual compensation for the medical director services. If this project is approved, the department would attach a condition to the approval requiring DaVita to provide a copy of the executed medical director agreement for review. [source: Application, Appendix 3]

Based on the information reviewed, the department concludes adequate staffing for the 9-station 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.

WAC 246-310 does not contain specific WAC 246-310-230(2) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

Puget Sound Kidney Centers

Information provided in the application indicates that PSKC currently maintains the relationships with the necessary facilities for hospital care and support services for its existing dialysis centers. According to the applicant, ancillary and support services, such as; social services, nutrition services, patient and staff education, financial counseling, material management, administration,

and technical services would be provided through staff located at the proposed Anacortes facility. [source: PSKC Application, p32]

A copy of executed transfer agreements with three separate hospitals in the county outlines the responsibilities and expectations for the transfer of all PSKC patients to the hospital for care that the attending physician determines to be necessary. If approved, a condition will be added to require PSKC to supply updated or amended agreements to include the new facility in Anacortes, prior to providing services.

Based on this information, the department concludes that PSKC is likely to extend their current relationships with ancillary and support services to include the proposed facility. If this project is approved, the department would include a condition requiring PSKC to provide an updated copy of the executed transfer agreements that includes the Anacortes facility. With the condition, this subcriterion is met.

DaVita, Inc.

Information provided in the application confirms that DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For its proposed Burlington facility, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site. Additional services would be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: DaVita Application, p22]

DaVita acknowledges that since this would be a new facility in Skagit 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. [source: DaVita Application, p25 & Appendix 12]

Based on this information, the department concludes DaVita currently has access to the necessary ancillary and support services that could support the proposed facility. If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed transfer agreement with a local hospital that is consistent with the example presented in the application. With the condition, 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.
WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

Puget Sound Kidney Centers

As stated earlier, PSKC is currently a provider of dialysis services within Washington State. 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.¹³

Since January 2008, the department of Health's Investigations and Inspections Office (IIO) has completed seven compliance surveys for the PSKC facilities in operation. 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. [source: Compliance history provided by IIO facility files]

For medical director services, PSKC identified both a facility and a corporate medical director. PSKC identified Mark Gunning, M.D. to provide medical director coverage for the proposed facility and Alan Haakenstad, M.D. to provide corporate medical director coverage. A review of the compliance history of the doctor's identified revealed no recorded sanctions. [source: Health Systems Quality Assurance Provider Credential Information; PSKC Application, Exhibit 2]

Given the compliance history of PSKC and the associated medical directors, the department concludes that there is reasonable assurance that the PSKC facility would operate in compliance with state and federal regulations. **This sub-criterion is met.**

DaVita, Inc.

As previously stated, DaVita provides dialysis services in over 1,642 outpatient centers located in 43 states and the District of Columbia. For Washington State, DaVita owns or operates 30 kidney dialysis treatment centers in 14 separate counties. 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.¹⁴ To comply with this sub-criterion, DaVita provided a contact list of the regulatory agencies responsible for surveying its out-of-state facilities and the District of Columbia. [source: Application, Appendix 2]

In February 2010, the department requested quality of care compliance history from out-of-state licensing and/or surveying entities and the District of Columbia where DaVita, Inc. or any subsidiaries have health care facilities. Of the 42 states and entities, the department received responses from 21 states or 50% of the 42 states.¹⁵ The compliance history of the remaining 19 states and the District of Columbia is unknown.¹⁶

Five of the 21 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 Iowa that decertified and later re-opened as a private ESRD facility,

¹⁴ WAC 246-310-230(5).

¹³ WAC 246-310-230(5).

¹⁵ States that provided responses are: California, Colorado, Connecticut, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nevada, New Mexico, North Dakota, Ohio, Oregon, South Carolina, Tennessee, South Dakota and West Virginia

¹⁶ States that did not provide responses are Alabama, Arizona, Arkansas, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Texas, Utah, Virginia and Wisconsin. The department did not send survey to itself. The District of Columbia did not respond to the survey.

none of the deficiencies are reported to have resulted in fines or enforcement action. ¹⁷ All other facilities comply with applicable regulations. [source: Compliance history from state licensing and/or surveying entities]

The department concludes that considering the more than 1,642 facilities owned/managed by DaVita, one out-of-state facility listed above demonstrated substantial non-compliance issues; therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2008, the Department of Health's Investigations and Inspections Office has completed more than 30 compliance surveys for the operational facilities that DaVita either owns or manages. 18 Of the compliance surveys completed, there were some minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues are typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: DOH Investigations and Inspections Office records]

For medical director services, DaVita provided a copy of its draft agreement with North Sound Kidney Physicians and C.J. Kuan, M.D. Under the contract, Dr. Kuan is designated as medical director for the Burlington facility. A review of the compliance history for Dr. Kuan revealed no recorded sanctions. [source: Health Systems Quality Assurance Provider Credential Information; DaVita Application, Exhibit 3]

Given the compliance history of DaVita and that of the proposed medical director, the department concludes that there is reasonable assurance that the Burlington facility would operate in compliance 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.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Puget Sound Kidney Centers

The department considered PSKC'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: PSKC Application, p33; CN historical files]

¹⁷ The Iowa facility chose voluntarily termination in August 2007 due to its inability to remain in compliance with Medicare Conditions for Coverage rather than undergo the termination process with Medicare. This facility is currently operating as a private ESRD facility.

As of the writing of this evaluation, four facilities are CN approved but not yet operational: Des Moines Dialysis Center, East Wenatchee Dialysis Center, Kennewick Dialysis Center, and Zillah Dialysis Center. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita. Everett Dialysis Center is co-owned by DaVita and the Everett Clinic.

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 dialysis stations in the Skagit County Planning Area. This project proposes to establish a 9-station facility in Skagit County.

Approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **This sub-criterion is met**.

DaVita, Inc.

The department 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: DaVita Application, p22; 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 dialysis stations in the Skagit County Planning Area. This project proposes to establish a 9-station facility in Skagit County.

Approval of this project would promote continuity in the provision of health care for the planning area, and would 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.

Puget Sound Kidney Centers

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

DaVita, Inc.

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

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

Based on the source information reviewed, the department concludes:

- Puget Sound Kidney Center's Anacortes project has met the Cost Containment criteria in WAC 246-310-240(1) and (2); and
- DaVita's Burlington project has not met the Cost Containment criteria in WAC 246-310-240(1) and (2)
- (1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.</u> To determine if a proposed project is the best alternative, the department takes a multi-step approach. <u>Step one</u> determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met WAC 246-310-210 through 230 criteria, the department would move to <u>step two</u> in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific (tie-breaker) criteria contained in WAC 246-310. The tie-breaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

Both proposed projects meet the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

Puget Sound Kidney Centers

Within the application, PSKC the alternative of 'do nothing'. PSKC states it rejected this alternative because of increased volumes at the Skagit Valley facility and a need methodology indicating that there is emerging need in the planning area. [source: PSKC Application, p35]

DaVita, Inc.

Within the application, DaVita identified three options before submitting this application. A summary of each is below. [source: DaVita Application, p24]

Option 1 - Establish a 9-station facility in Burlington

DaVita states it accepted this option because Burlington is the best location to serve the greatest density of patients. DaVita was also able to identify a site that provided a low capital expenditure per station

Option 2 - Establish a 9-station facility in Sedro Woolley

Sedro Woolley is located in the eastern portion of the county and DaVita states it considered this alternative because Sedro Woolley would also improve geographical access to patients. However, DaVita determined that Burlington was the superior choice.

Option 3 - Establish a 4 or 9-station facility in Anacortes

DaVita states that this option was rejected when the DaVita determined the projected utilization would only generate need to support 2 to 3 stations. With program requirements to establish a minimum of a 4-station facility for planning areas of this size, DaVita rejected this alternative.

Both applicants outlined varied options for consideration and rejected each of them for a 9-station facility. Each selected the preferred alternative in their respective cities.

Step Three

WAC 246-310-288 identifies specific tie-breaker criteria that must be applied if two or more applications meet <u>all</u> applicable review criteria and there is not enough station need projected for all applications to be approved. These tie-breakers provide an un-biased method of determining which project is the best alternative. Under the tie-break criteria, 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.

Below is an evaluation of the tie-breaker criteria under WAC 246-310-288(1) and (2).

WAC 246-310-288(1)

- (1) The department will award one point per tie-breaker to any applicant that meets a tie-breaker criteria 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.
 - (b) Private room(s) for isolating patients needing dialysis (1 point).
 - (c) Permanent bed stations at the facility (1 point).
 - (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.
 - (e) Meeting the projected need (1 point): Each application that proposes the number of stations that most closely approximates the projected need.

Puget Sound Kidney Center

A total of five points is possible. Table 13 on the following page shows the distribution of tie-breaker points under this sub-criterion for PSKC.

Table 13 WAC 246-310-288(1) PSKC Tie-Breaker Review

WAC 246-310-288(1)	Point	Source
(a)(iii) Training services	1	Application, p9
(b) Private room(s) for isolating patients	1	Screening, p9 & 56
(c) Permanent bed stations at the facility	1	Screening, p9 & 56
(d) Evening shift	1	Application, p25
(e) Meeting the projected need	1	Application, p19
Total Points	5	

DaVita

A total of five points is possible. Table 14 shows the distribution of tie-breaker points under this sub-criterion for DaVita.

Table 14 WAC 246-310-288(1) DaVita Tie-Breaker Review

WAC 246-310-288(1)	Point	Source
(a)(iii) Training services	1	Application, p9
(b) Private room(s) for isolating patients	1	Application, p9; Screening, Exh. A
(c) Permanent bed stations at the facility	1	Application, p9; Screening, Exh. A
(d) Evening shift	1	Application, p9
(e) Meeting the projected need	1	Application, p17
Total Points	5	

PSKC expressed doubts regarding DaVita's qualification for the permanent bed station point. PSKC notes that no hospital bed is listed in the equipment list supplied in the application, therefore, no credit for a permanent bed station should be awarded. DaVita responded to this claim by describing their intent to purchase and use a fully reclining patient chair. This type of equipment is capable of providing a supine position for anyone requiring such accommodation and DaVita states, "Our equipment list shows two oversized fully-reclining chairs and our line drawing shows adequate space for the clearly indicated permanent bed station". On the basis of this information, DaVita was awarded the bed station point. [source: PSKC comment, p6; DaVita Supplemental Information, p5; DaVita Rebuttal, p4]

Under WAC 246-310-288(1) where each applicant could receive a maximum of 5 points, both PSKC and DaVita received the maximum number of points.

WAC 246-310-288(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.
 - (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.
- (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.
- (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.

Only one applicant may receive a point for each of the four tie-breaker criteria under this section. Table 15 below shows the distribution of tie-breaker points under this sub-criterion for PSKC.

Table 15 WAC 246-310-288(2) PSKC Tie-Breaker Review

WAC 246-310-288(2)	Point	Source
(a) Economies of Scale	0	Screening, p9 [\$450,563 per station]
(b) Historical Provider	0	
(c) Patient Geographical Access	1	MapQuest Mileage Estimates
(d) Provider Choice	1	Program Memorandum ¹⁹
Total Points	2	

Table 16 below shows the distribution of tie-breaker points under this sub-criterion for DaVita.

Table 16 WAC 246-310-288(2) DaVita Tie-Breaker Review

WAC 246-310-288(2)	Point	Source
(a) Economies of Scale	1	Application, p8 [\$167,286 per station]
(b) Historical Provider	0	
(c) Patient Geographical Access	0	MapQuest Mileage Estimates
(d) Provider Choice	0	Program Memorandum
Total Points	1	

¹⁹ This tie-breaker is written very literally and will be evaluated as is written. Considerations used to determine a tie-breaker of this sub-criterion (if necessary) is the applicant that was awarded a point under (c) above. If a tie still exists, the point will be awarded to the applicant that proposed to be the furthest away from the existing providers of the applicants that qualify.

Table 17 below shows the total accumulation of tie-breaker points for both PSKC and DaVita.

Table 17 WAC 246-310-288 – Tie-Breaker Summary Table

	Tie-Breaker Point Distribution		
	PSKC	DaVita	
1(a)(iii) – Training services	1	1	
1(b) – Private Room	1	1	
1(c) – Permanent Bed Station	1	1	
1(d) – Evening Shift	1	1	
1(e) – Meets Need	1	1	
2(a) – Economies of Scale	0	1	
2(b) – Historical Provider	0	0	
2(c) – Geographical Access	1	0	
2(d) – Provider Choice	1	0	
Cumulative Total	7	6	

At the completion of the tie-breaker point allocations, PSKC accumulated a total of seven (7) points and DaVita accumulated a total of six (6) points. Due to the results outlined in this section, the department concludes that PSKC's project is the application accumulating the largest number of points and is the first application to be considered in the allocation of stations to meet the projected need.

Since the PSKC project accounts for all 9 of the station need projected for the planning area, there are no stations remaining to award to DaVita as the application earning the next highest point total.

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

Puget Sound Kidney Centers

Based on the results of the tie-breaker criteria above, PSKC's project meets this sub-criterion. **This project is approved**.

DaVita, Inc.

Based on the results of the tie-breaker criteria above, DaVita's project does not meet this sub-criterion. **This project is denied**.

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

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

WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable. However, the department, through its experience knows that construction projects are usually built to exceed these minimum standards. Therefore, the department considered information in the applications that addressed the reasonableness of their construction projects that exceeded the minimum standards.

Puget Sound Kidney Centers

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). **This sub-criterion is met.**

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). **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.

Puget Sound Kidney Centers

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). **This sub-criterion is met**.

DaVita, Inc.

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). **This sub-criterion is met**.

Appendix A



2011 Skagit County ESRD Need Projection Methodology

	Planning Area	6 Year Utiliz	ation Data -	Resident Ince	enter Patients	S	
	Skagit	2005	2006	2007	2008	2009	2010
	Skagit	81	73	77	85	109	120
	TOTALS	81	73	77	85	109	120
246-310-284(4)(a)	Rate of Change		-9.88%	5.48%	10.39%	28.24%	10.09%
(/ (/	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
(/(/				2011	2012	2013	2014
Projected Resident Incenter Patients	from 246-310-284(4)(b)			130.60	143.20	155.80	168.40
Station Need for Patients	Divide Resident Incenter	Patients by	4.8	27.2083	29.8333	32.4583	35.0833
	Rounded to next whole n	umber		28	30	33	36
246-310-284(4)(d)	subtract (4)(c) from approv	ved stations					
Existing CN Approved S				27	27	27	27
Results of (4)(c) above			•	28	30	33	36
Net Station Need				-1	-3	-6	-9
Negative number indicates ne	eed for stations						
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization	(Patients pe	r Station)		
Skagit Valley	27	130	4.81				
Total	27	130					
Source: Northwest Renal							
SOURCE, INDITINGSER CHIME	INCLIVIOIN UALA ZUUD-ZU IU	I					



2011 Skagit County ESRD Need Projection Methodology

