



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

July 11, 2012

CERTIFIED MAIL # 7010 2780 0003 6529 7625

Jason Bosh, Regional Operations Director
DaVita, Inc. – North Star, Region 1
1301 A Street, #400
Tacoma, Washington 98402

Re: CN #12-05

Dear Mr. Bosh:

We have completed review of the Certificate of Need submitted by DaVita, Inc. proposing to relocate the existing Whidbey Island Dialysis Center within Island County and add three dialysis stations.¹ For the reasons stated in this evaluation, the application to relocate and add stations is not consistent with the Certificate of Need review criteria. However, the relocation portion of the application is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

DaVita, Inc. is approved to relocate Whidbey Island Dialysis Center, in its entirety, to a different building at the same address. The address of the new site is 32650 State Route 20, Building D, Suite 101, in Oak Harbor.

Once relocated, Whidbey Island Dialysis Center would certify and operate five dialysis stations. The facility will provide the following services: in-center hemodialysis, backup hemodialysis for home dialysis patients, visitor hemodialysis, and an isolation station. The stations are listed below.

| | |
|--------------------------|----------|
| Private Isolation Room | 1 |
| Other In-Center Stations | 4 |
| Total | 5 |

Condition:

1. DaVita, Inc. agrees with the project description stated above.

¹ The relocation portion of this project does not meet the exemption requirements of WAC 246-310-289. Therefore, prior Certificate of Need approval is required to relocate the facility.

Jason Bosh, Regional Operations Director
DaVita, Inc. – North Star, Region 1
July 11, 2012
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Approved Costs:

The approved capital expenditure associated with the relocation of Whidbey Island Dialysis Center is \$1,366,139. This amount represents the total capital expenditure of \$1,446,139 minus the landlord's project costs of \$80,000.

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:

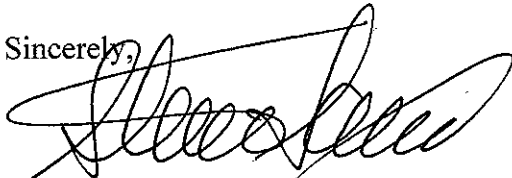
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

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

Enclosure

EXECUTIVE SUMMARY

EVALUATION DATED JULY 11, 2012, FOR TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY TO ISLAND COUNTY:

- **PUGET SOUND KIDNEY CENTERS PROPOSING TO ADD THREE STATIONS TO PSKC-WHIDBEY ISLAND**
- **DAVITA, INC. PROPOSING TO RELOCATE WHIDBEY ISLAND DIALYSIS CENTER AND ADD THREE STATIONS**

BRIEF PROJECT DESCRIPTIONS

Puget Sound Kidney Centers

Puget Sound Kidney Centers is a private, not-for-profit corporation, incorporated in the state of Washington that provides dialysis services through its facilities located in Snohomish and Island counties. Puget Sound Kidney Centers proposes to add three dialysis stations to its existing Whidbey Island dialysis facility located in the city of Oak Harbor, within Island County. At project completion, the dialysis center would be certified for and operating a total of 9 dialysis stations.

The capital expenditure associated with the addition of three stations is \$294,375. If this project is approved, Puget Sound Kidney Centers anticipates the addition of three stations would occur by the end of year 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation with 9 stations and 2015 would be year three. [source: Application, p1, 3, & 11]

DaVita, Inc.

DaVita, Inc is a publicly held, for-profit corporation, incorporated in the state of Washington that provides dialysis services through its facilities across the nation. For this project, DaVita, Inc. proposes to both relocate its existing dialysis center in Island County and add 3 stations to the new facility. At project completion, the facility would be certified for and operating 8 stations at the new site of 2650 State Route 20, Building D, #101 in Oak Harbor, within Island County.

The capital expenditure associated with the relocation and station addition is \$1,514,133. If this project is approved, DaVita, Inc. anticipates the relocation and station addition would be complete by the end of year 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation at the new site with 8 dialysis stations and 2015 would be year three. [source: Application, p4, p8, and p11]

DaVita, Inc. also submitted information in the application to allow the program to review the relocation of the dialysis center without the addition of stations. If only the relocation was approved, the facility would continue to be certified for and operating 5 stations at the new site of 2650 State Route 20, Building D, #101 in Oak Harbor, within Island County.

The capital expenditure associated with only the relocation is \$1,446,139. If this project is approved, DaVita, Inc. anticipates the relocation would be complete by the end of year 2012. Under this timeline, 2013 would be the 5-station facility's first full calendar year of operation at the new site and 2015 would be year three. [source: Application, p4 and p11; November 30, 2011, supplemental information, p3]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Puget Sound Kidney Centers’ project is subject to Certificate of Need review as an increase in dialysis station capacity at an existing center under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

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

CONCLUSIONS

Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers proposing to add three dialysis stations to the existing PSKC-Whidbey Island facility 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:

Puget Sound Kidney Centers is approved to add three dialysis stations to PSKC Whidbey Island located at 430 Southeast Midway Boulevard, in Oak Harbor, within Island County. At project completion, the facility is approved to certify and operate a nine-station facility. The facility will provide the following services: hemodialysis, peritoneal dialysis, shifts after 5:00 p.m., and home hemo and peritoneal training and support for dialysis patients. The stations are listed below.

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

Conditions:

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

Approved Costs:

The approved capital expenditure associated with the station addition is \$294,375.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to relocate Whidbey Island Dialysis Center and add three stations is not consistent with the Certificate of Need review criteria. However, DaVita, Inc.'s relocation of Whidbey Island Dialysis Center is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

DaVita, Inc. is approved to relocate Whidbey Island Dialysis Center, in its entirety, to a different building at the same address. The address of the new site is 32650 State Route 20, Building D, Suite 101, in Oak Harbor.

Once relocated, Whidbey Island Dialysis Center would certify and operate five dialysis stations. The facility will provide the following services: incenter hemodialysis, backup hemodialysis for home dialysis patients, visitor hemodialysis, and an isolation station. The stations are listed below.

| | |
|--------------------------|----------|
| Private Isolation Room | 1 |
| Other In-Center Stations | 4 |
| Total | 5 |

Conditions:

1. DaVita, Inc. agrees with the project description above.

Approved Costs:

The approved capital expenditure associated with the relocation of Whidbey Island Dialysis Center is \$1,366,139. This amount represents the total capital expenditure of \$1,446,139 minus the landlord's project costs of \$80,000.

EVALUATION DATED JULY 11, 2012, FOR TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY TO ISLAND COUNTY:

- **PUGET SOUND KIDNEY CENTERS PROPOSING TO ADD THREE STATIONS TO PSKC-WHIDBEY ISLAND**
- **DAVITA, INC. PROPOSING TO RELOCATE WHIDBEY ISLAND DIALYSIS CENTER AND ADD THREE STATIONS**

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 - three in Snohomish County and one in Island County. The four PSKC facilities are listed below.

Snohomish

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

Island

- Puget Sound Kidney Center-Whidbey Island

In addition to the four dialysis centers listed above, PSKC also has an acute mobile dialysis division housed in Everett. PSKC contracts with local hospitals to provide dialysis services to hospital inpatients. [source: Application, p2; CN historical files]

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. [source: Application, p5] In Washington State, DaVita owns or operates 30 kidney dialysis facilities in 14 separate counties. Below is a listing of the 30 facilities.¹ [source: CN historical files & Amended Application, pp5-6]

| | |
|-------------------------------------|--------------------------|
| Benton | Pacific |
| Chinook Dialysis Center | Seaview Dialysis Center |
| Kennewick Dialysis Center | |
| | Pierce |
| Chelan | Graham Dialysis Center |
| DaVita Dialysis Center ² | Lakewood Dialysis Center |
| | Parkland Dialysis Center |
| Clark | Puyallup Dialysis Center |
| Vancouver Dialysis Center | Tacoma Dialysis Center |

¹ Des Moines Dialysis Center, East Wenatchee Dialysis Center, Kennewick Dialysis Center, and Zillah Dialysis Center are CN approved but not yet operational.

² 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.

| | |
|--|--------------------------------------|
| | |
| Douglas | Snohomish |
| East Wenatchee Dialysis Center | Everett Dialysis Center ³ |
| | Mill Creek Dialysis Center |
| Franklin | |
| Mid Columbia Kidney Center | Spokane |
| | Downtown Spokane Renal Center |
| Island | North Spokane Renal Center |
| Whidbey Island Dialysis Center | Spokane Valley Renal Center |
| | |
| King | Thurston |
| Bellevue Dialysis Center | Olympia Dialysis Center |
| Des Moines Dialysis Center | |
| Federal Way Dialysis Center | Yakima |
| Kent Dialysis Center | Mt. Adams Dialysis Center |
| Olympic View Dialysis Center (management only) | Union Gap Dialysis Center |
| Westwood Dialysis Center | Yakima Dialysis Center |
| | Zillah Dialysis Center |
| Kittitas | |
| Ellensburg Dialysis Center | |

Washington Administrative Code 246-310-289

WAC 246-310-289 provides guidance related to the relocation of existing dialysis centers. It states, in its entirety:

- (1) *When an entire facility proposes to relocate to another planning area, a new health care facility is considered to be established under WAC [246-310-020\(1\)](#)*
- (2) *When an existing facility proposes to relocate a portion of its stations to either another planning area or within the same planning area, a new health care facility is considered to be established under WAC [246-310-020\(1\)](#).*
- (3) *When an entire facility proposes to relocate within the same planning area, a new health care facility is not considered to be established under WAC [246-310-020\(1\)](#) if:*
 - (a) *The existing facility ceases operation;*
 - (b) *No new stations are added to the replacement facility;*
 - (c) *There is no break in service between the closure of the existing facility and the operation of the replacement facility;*
 - (d) *The existing facility has been in operation for at least five years at its present location; and*
 - (e) *The existing facility has not been purchased, sold or leased within the past five years.*

During the review of these two projects, each applicant submitted arguments related to this topic, which are addressed below.

Puget Sound Kidney Centers

On May 25, 2004, PSKC was issued CN #1284 approving the establishment of the 4-station dialysis center at 430 Southeast Midway Boulevard in Oak Harbor, within Island County. On April 10, 2006,

³ Refuge Dialysis, LLC, whose ownership is 80% DaVita and 20% The Everett Clinic, owns this facility.

PSKC was issued CN #1327 approving the addition of 2 stations to the facility, for a total of 6. The facility has been operating at this site for approximately seven years. [source: CN historical files]

On March 21, 2011, PSKC submitted an exemption request for the relocation of PSKC-Whidbey Island. PSKC proposed to relocate the 6-station center to a newly constructed building at the same site. Once the new facility was operational, the former facility would be demolished to allow for parking. According to documentation obtained from the postmaster, the address of the new site would remain at 430 Southeast Midway Boulevard in Oak Harbor. [source: PSKC Exemption Application]

On April 26, 2011, the Certificate of Need Program issued the exemption to PSKC under WAC 246-310-289(3). At this time, the relocation project is expected to be complete by the end of September 2012. [source: DOR #11-26 and March 2012 progress report submitted April 4, 2012]

Within its public comments, DaVita argues that PSKC did not properly submit an exemption request, and therefore, is not entitled to the exemption for the relocation. DaVita also asserts that PSKC should have included all costs associated with the relocation and the additional stations. Since PSKC did not include those costs, DaVita reasons that the PSKC application should be denied. [source: February 14 2012, public comments]

Department's Review

The department reviewed the historical information related to the establishment of PSKC-Whidbey Island. In addition, the department reviewed the exemption application submitted by PSKC for the relocation and concluded that PSKC was properly issued an exemption for relocation of the facility.

PSKC's newly constructed building could ultimately house 12 dialysis stations and on-site support services. Within this application, PSKC provided three separate cost breakdowns:

- the construction of the entire building, including the relocation of the 6-station facility;
- the equipment needed to add the 3 stations proposed in this application; and
- costs for the 3 station addition, with allocated construction costs.

[source: Application, p26]

For PSKC, the department considered the capital expenditure to be the costs for the 3 station addition, with allocated construction costs.

DaVita, Inc.

On October 17, 2008, DaVita was issued CN #1386 approving the establishment of the 5-station dialysis center at 32650 State Route 20, Building E in Oak Harbor, within Island County. The facility is known as Whidbey Island Dialysis Center (WIDC) and has been operating at this site since mid year 2010, or for approximately 2 years. [source: CN historical files]

With this application, DaVita proposes to relocate the 5-station facility to a different building at the same address, and add 3 more stations. The address of the new site is 32650 State Route 20, Building D, Suite 101, in Oak Harbor. DaVita also provided information to allow the program to review the relocation of the dialysis center without the addition of stations.

Within its public comments, PSKC argues that DaVita's project should have included the costs associated with operating a center for two years, and then relocating to a new site. PSKC identifies

these costs at over \$1,000,000. Since DaVita did not include a line item for these costs, PSKC asserts that the DaVita's application should be denied. [source: February 14, 2012, public comments]

Department's Review

DaVita appropriately does not assert that its relocation should qualify for an exemption under WAC 246-310-289(3). As a result, DaVita included the costs to relocate the existing center and the costs for the additional stations. DaVita also identified the costs to relocate the center without additional stations. WAC 246-310-280(2) defines '*capital expenditures*' for dialysis projects. DaVita identified the costs for this project consistent with the definition. The costs to establish the five-station center at the current site were properly reviewed during the review of that application in 2008. Including the costs of the 2008 project with this relocation and station addition project is inappropriate.

For DaVita's project, the department considered the capital expenditure for the project to be the costs for the relocation and the addition of stations. This cost is identified at \$1,514,133. For the relocation only, DaVita identified those costs to be \$1,446,139.

PROJECT DESCRIPTIONS

Puget Sound Kidney Centers

This application proposes to add 3 stations to PSKC-Whidbey Island, for a total of 9 stations. [source: Application, p1 & p5] As a 6-station facility, PSKC currently offers incenter hemodialysis, backup hemodialysis for home dialysis patients, and visitor hemodialysis. With the additional 3 stations, PSKC would expand its services at PSKC-Whidbey Island to include home training, a dedicated bed station, and an isolation station. [source: Application, p3 & 7]

PSKC's newly constructed building could ultimately house 12 dialysis stations and on-site support services. For this project, the department considers the capital expenditure to be the costs for the 3 station addition, with allocated construction costs, which is \$294,375. Of that amount, 73.8% is the construction costs allocated to the 3 station addition; 25.5% is related to equipment; and the remaining 0.7% is related to taxes. [source: Application, p26]

If this project is approved, PSKC anticipates the 3 additional stations would become operational by the end of year 2012. Under this timeline, 2013 would be the 9-station facility's first full calendar year of operation and 2015 would be year three. [source: Application, p11]

DaVita, Inc.

With this application, DaVita proposes to relocate the 5-station facility to a different building at the same address, and add 3 more stations. The address of the new site is 32650 State Route 20, Building D, Suite 101, in Oak Harbor. If this project is approved, WIDC would be operating 8 stations at the new site. [source: Application, p4 and p8]

As a 5-station facility, WIDC currently offers incenter hemodialysis, backup hemodialysis for home dialysis patients, visitor hemodialysis, and an isolation station. [source: Application #08-40, p8] With the additional 3 stations, DaVita would continue to provide the services described above. [source: Application, p9]

DaVita identified a capital expenditure for its project of \$1,514,133. Of that amount 74.3% is leasehold improvements, 15.4% for fixed/moveable equipment; 5.3% is landlord's portion of costs;

and the remaining 5.0% is related to professional fees. [source: November 30, 2011, supplemental information, p5]

If this project is approved, DaVita anticipates the relocation and the station addition would be complete and the resulting 8-station facility would be become operational by the end of year 2012. Under this timeline, 2013 would be the 8-station facility's first full calendar year of operation 2015 would be year three. [source: Application, p12]

For the relocation only, DaVita would be operating 5 stations at the new site. DaVita would continue to provide incenter hemodialysis, backup hemodialysis for home dialysis patients, visitor hemodialysis, and an isolation station. [source: Application #08-40, p8]

DaVita identified a capital expenditure for the relocation only to be \$1,446,139. Of that amount 77.8% is leasehold improvements, 11.0% for fixed/moveable equipment; 5.5% is landlord's portion of costs; and the remaining 5.7% is related to professional fees. [source: November 30, 2011, supplemental information, p3]

If just the relocation project is approved, DaVita anticipates the relocation would be complete by the end of year 2012. Under this timeline, 2013 would be the 5-station facility's first full calendar year of operation and 2015 would be year three at the new site. [source: Application, p12]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Puget Sound Kidney Centers' project is subject to Certificate of Need review as an increase in dialysis stations capacity at an existing center under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

DaVita's Whidbey Island Dialysis Center has been in operation with five-stations since year 2010. For this project, WAC 246-310-289(3) provides the following guidance:

When an entire facility proposes to relocate within the same planning area, a new health care facility is not considered to be established under WAC [246-310-020\(1\)](#) if:

- (a) The existing facility ceases operation;*
- (b) No new stations are added to the replacement facility;*
- (c) There is no break in service between the closure of the existing facility and the operation of the replacement facility;*
- (d) The existing facility has been in operation for at least five years at its present location; and*
- (e) The existing facility has not been purchased, sold or leased within the past five years.*

Since Whidbey Island Dialysis Center has been operating at its current site for less than five years, DaVita, Inc.'s project is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

CRITERIA EVALUATION

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 284.⁴

⁴ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-286, and WAC 246-310-287.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1), the department accepted both projects under the year 2011 Kidney Disease Treatment Centers-Concurrent Review Cycle #3. A chronologic summary of both projects is shown below.

| Action | PSKC | DaVita |
|--|--|-----------------|
| Letter of Intent Submitted | July 29, 2011 | July 29, 2011 |
| Application Submitted | August 31, 2011 | August 31, 2011 |
| Amendment Application Submitted | September 30, 2011 | None |
| Department's pre-review activities including screening and responses | September 1, 2011, through December 15, 2011 | |
| Beginning of Review • public comments accepted throughout review • no public hearing conducted | December 16, 2011 | |
| End of Public Comment | February 14, 2012 | |
| Rebuttal Documents Received | March 15 2012 | |
| Department's Anticipated Decision Date | April 30, 2012 | |
| Decision Date with 30 day Extension | May 30, 2012 | |
| Department's Actual Decision Date | July 11, 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, no other entities sought or received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Puget Sound Kidney Centers Amended Certificate of Need application received September 30, 2011
- DaVita, Inc. Certificate of Need application received August 31, 2011
- Puget Sound Kidney Centers supplemental information received November 30, 2011
- DaVita, Inc. supplemental information received November 30, 2011
- Puget Sound Kidney Centers public comment received February 14, 2012
- DaVita, Inc. public comments received February 14, 2012
- Puget Sound Kidney Centers rebuttal comments received March 15, 2012
- DaVita rebuttal comments received March 15, 2012
- Years 2005 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network

SOURCE INFORMATION REVIEWED (continued)

- Year 2011 Northwest Renal Network 1st Quarter Data as of May 16, 2011
- DOR #11-26 issued to Puget Sound Kidney Centers for the relocation of PSKC-Whidbey Island
- Quarterly progress reports related to DOR #11-26 referenced above
- Licensing and survey data provided by the Department of Health’s Investigations and Inspections Office
- Provider credential status provided by the Department of Health’s Health Systems Quality Assurance on-line search
- Certificate of Need historical files

CONCLUSIONS

Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers’ proposing to add three dialysis station to the existing PSKC-Whidbey Island facility 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:

Puget Sound Kidney Centers is approved to add three dialysis stations to PSKC Whidbey Island located at 430 Southeast Midway Boulevard, in Oak Harbor, within Island County. At project completion, the facility is approved to certify and operate a nine-station facility. The facility will provide the following services: hemodialysis, peritoneal dialysis, shifts after 5:00 p.m., and home hemo and peritoneal training and support for dialysis patients. The stations are listed below.

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

Conditions:

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

Approved Costs:

The approved capital expenditure associated with the three-station addition is \$294,375.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to relocate Whidbey Island Dialysis Center and add three stations is not consistent with the Certificate of Need review criteria. However, DaVita, Inc.'s relocation of Whidbey Island Dialysis Center is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

DaVita, Inc. is approved to relocate Whidbey Island Dialysis Center, in its entirety, to a different building at the same address. The address of the new site is 32650 State Route 20, Building D, Suite 101, in Oak Harbor.

Once relocated, Whidbey Island Dialysis Center would certify and operate five dialysis stations. The facility will provide the following services: incenter hemodialysis, backup hemodialysis for home dialysis patients, visitor hemodialysis, and an isolation station. The stations are listed below.

| | |
|--------------------------|----------|
| Private Isolation Room | 1 |
| Other In-Center Stations | 4 |
| Total | 5 |

Conditions:

1. DaVita, Inc. agrees with the project description above.

Approved Costs:

The approved capital expenditure associated with the relocation of Whidbey Island Dialysis Center is \$1,366,139. This amount represents the total capital expenditure of \$1,446,139 minus the landlord's project costs of \$80,000.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes:

- Puget Sound Kidney Centers' 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, provided the applicant agrees to the conditions identified in the 'conclusion' section of this evaluation; and
- DaVita, Inc.'s 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, provided the applicant agrees to the conditions identified in the 'conclusion' section of this evaluation.

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

Kidney Disease Treatment Center Methodology WAC 246-310-284

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.⁵

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.⁶ 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,

⁵ 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]

⁶ 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.

Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

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

WAC 246-310-280(9) identifies the ESRD planning areas for the state. Both PSKC and DaVita propose to add dialysis station capacity to Island County, which is one planning area in its entirety.

Puget Sound Kidney Centers’ Application of the Numeric Methodology

PSKC proposes to add 3 stations to its existing 6-station dialysis center in Oak Harbor. Based on the calculation of the annual growth rate in the planning area as described above, PSKC used a linear regression to project need. For Island County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. PSKC’s numeric methodology projected a need for 3 stations in Island County for year 2014. [source: Application, pp15-17]

DaVita, Inc.’s Application of the Numeric Methodology

DaVita proposes to relocate its 5-station dialysis center in Oak Harbor and add 3 stations. 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. DaVita’s numeric methodology projected a need for 3 stations in Island County for year 2014. [source: Application, pp16-17]

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 Island County. 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 shows a summary of the projected net need provided by both applicants and the department for the planning area.

**Table 1
Island County Planning Area
Numeric Methodology Summary**

| | 4.8 in-center patients per station | | |
|---------------|--|--|----------------------|
| | 2014 Projected # of stations (rounded up) | Minus Current # of stations | 2014 Net Need |
| PSKC | 14 | 11 | 3 |
| DaVita | 14 | 11 | 3 |
| DOH | 14 | 11 | 3 |

As shown in the table above, when the results are rounded as required in WAC 246-310-284(4)(c), both applicants and the department’s methodology show need for an additional 3 stations in Island County in year 2014.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for these projects is August 1, 2011. [WAC 246-310-282] The quarterly modality report from NRN available at that time was 1st quarter 2011, available on May 16, 2011. There are two dialysis centers currently operating in Island County—one is owned by PSKC and the other is owned by DaVita. The table below shows the utilization of both facilities. [source: NRN data year 2011, 1st quarter available May 16, 2011]

**Table 2
March 31, 2011 - Facility Utilization Data**

| Facility Name | # of Stations | # of Pts | Pts/Station |
|---------------------------------------|----------------------|-----------------|--------------------|
| PSKC-Whidbey Island | 6 | 32 | 5.33 |
| DaVita Whidbey Island Dialysis Center | 5 | 26 | 5.20 |

The table above demonstrates that both facilities satisfy this 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 Island County the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, each applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Puget Sound Kidney Centers

PSKC expects to add the three stations by the end of year 2012. Under this timeline, PSKC-Whidbey Island would begin operating 9 dialysis stations in 2012. Calendar year 2013 would be the facility’s first full calendar year of operation with all 9 stations and 2015 would be year three. A summary of PSKC’s projected utilization for the third year of operation is shown in the table below. [source: Application, p18]

**Table 3
PSKC-Whidbey Island - Third Year Projected Facility Utilization**

| Year 3 | # of Stations | # of In-Center Patients | Patients/Station |
|---------------|----------------------|--------------------------------|-------------------------|
| 2015 | 9 | 50 | 5.55 |

As shown in the table above, PSKC projects to exceed this standard with 9 dialysis stations. **This sub-criterion is met.**

DaVita, Inc.

DaVita anticipates its five-station Whidbey Island Dialysis Center would relocate and the additional 3 stations would be added by the end of year 2012. Under this timeline, year 2013 would be the facility’s first full calendar year of operation with 8 stations and 2015 would be year three. A summary of DaVita’s projected utilization for the third year of operation is shown in the table below. [source: Application, p15]

Table 4
DaVita’s Whidbey Island Dialysis Center - Third Year Projected Facility Utilization

| Year 3 | # of Stations | # of In-Center Patients | Patients/Station |
|---------------|----------------------|--------------------------------|-------------------------|
| 2015 | 8 | 42 | 5.25 |

As shown above, DaVita projects to meet this standard with 8 dialysis stations. **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.

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 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 used for PSKC as a whole. The policy 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. [source: 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 in its dialysis centers, including this Island County facility. Details provided in the application demonstrate that PSKC intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [source: Application, p9]

PSKC currently provides services to Medicare eligible patients in its dialysis centers, including this Island County facility. Details provided in the application demonstrate that PSKC intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [source: Application, p9]

PSKC demonstrated its intent to provide charity care to its Island County residents by including a 'charity' line item as a deduction from revenue within the pro forma income statement for PSKC-Whidbey Island. [source: Application, Exhibit 10]

The department concludes that all residents of the service area would continue to have adequate access to the health services at PSKC-Whidbey Island. **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 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 use to admit patients for treatment, and ensures that patients 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: 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, including Whidbey Island Dialysis Center. Details provided in the application demonstrate that DaVita intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [source: Application, p21 and Appendix 9]

DaVita currently provides services to Medicare eligible patients at its existing dialysis centers, include Whidbey Island Dialysis Center. Details provided in the application demonstrate that DaVita intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare reimbursements. [source: Application, p10 and Appendix 9]

DaVita demonstrated its intent to provide charity care to Island County residents by submitting the 'Indigent Care Policy' currently used within its facilities, including WDIC. 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 the facility. [source: Application, Appendices 9 and 14]

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

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

Based on the source information reviewed, the department concludes:

- Puget Sound Kidney Centers’ project has met the financial feasibility criteria in WAC 246-310-220 provided the applicant agrees with the conditions identified in the ‘conclusion’ section of this evaluation; and
- DaVita, Inc.’s project has met the financial feasibility criteria in WAC 246-310-220, provided the applicant agrees with the conditions identified in the ‘conclusion’ section of this evaluation.

(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 additional three stations would be added to the six-station facility by the end of year 2012. Using the calendar years provided in the application, year 2013 would be PSKC-Whidbey Island’s first calendar year of operation with 9 dialysis stations. The table below illustrates the projected revenue, expenses, and net income for years 2013 through 2015 for PSKC-Whidbey Island. [source: November 30, 2011, supplemental information, Attachment 1]

**Table 5
PSKC-Whidbey Island
Projected Revenue and Expenses for Full Years 2013 - 2015⁷**

| | Year 1 - 2013 | Year 2 - 2014 | Year 3 - 2015 |
|----------------------|----------------------|----------------------|----------------------|
| # of Stations | 9 | 9 | 9 |
| # of Treatments [1] | 6,192 | 6,912 | 7,200 |
| # of Patients [2] | 43 | 48 | 50 |
| Utilization Rate [2] | 4.78 | 5.33 | 5.56 |
| Net Revenue | \$ 1,731,558 | \$ 1,955,892 | \$ 2,072,452 |
| Total Expense | \$ 1,697,377 | \$ 1,838,694 | \$ 1,919,759 |
| Net Profit or (Loss) | \$ 34,181 | \$ 117,198 | \$ 152,693 |

[1] Includes in-center treatments only; [2] in-center patients only.

The ‘Net Revenue’ line item is gross revenue minus any deductions for charity care and bad debt. The ‘Total Expenses’ line item includes salaries and wages, depreciation, and allocated costs for the corporate medical director and PSKC. As shown in the table above, at the projected volumes identified in the application, PSKC anticipates that the 9-station facility would be operating at a profit in each year.

⁷ Whole numbers may not add due to rounding.

PSKC has owned the property at 430 East Midway Boulevard in Oak Harbor since 2004. Initially the property was identified as two separate parcels. PSKC provided a copy of its Statutory Warranty Deed for the site to demonstrate ownership of two separate parcels of land. PSKC also provided documentation from the City of Oak Harbor, Development Services Department demonstrating that the two parcels have been combined.⁸ [source: Application, p 12 and Exhibits 7 and 8] PSKC also provided a copy of the November 17, 2003, letter from the City of Oak Harbor demonstrating that the property has been zoned for dialysis center use. [source: Application, Exhibit 6] Since PSKC owns the site, no lease agreement is necessary. The pro forma financial statements include depreciation for the old and new building. [source: November 30, 2011, supplemental information, Attachment 1]

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. Alan Haakenstad, MD is the Corporate Medical Director for PSKC and he is also the facility medical director for PSKC-Whidbey Island. PSKC provided a copy of the executed Corporate Medical Director Agreement and the executed Facility Medical Director Agreement between PSKC and Dr. Haakenstad. [source: Application, Exhibit 2] The medical director service costs are identified in each agreement. The costs for the facility medical director are identified in the pro forma statements and the costs for the corporate medical director are included in the allocated costs line item. [source: November 30, 2011, supplemental information, Attachment 1]

During the review of this project, DaVita submitted extensive comments related to two areas: equipment costs and depreciation expenses. Below is a summary by topic of the comments provided by DaVita.

DaVita Public Comments

Equipment Costs [source: DaVita public comment, pp6-7]

PSKC only identified \$77,000 for new equipment and identifies only three new dialysis machines. PSKC denies any equipment purchases would be needed for three years following project completion, which means PSKC intends to relocate its used dialysis machines. PSKC has not properly reported the machine replacement costs it would incur within three years. DaVita estimates that PSKC underreported its equipment costs by about \$78,000.

Depreciation Expenses [source: DaVita public comment, pp7-9, and supplemental attachments]

Since PSKC did not properly identify the equipment replacement costs, it also substantially understated its depreciation expenses. A comparison of PSKC's depreciation approach with past applications reveals that PSKC calculates a much lower expense.⁹ DaVita estimates that PSKC's depreciation expense should be \$173,009 more than the amount identified in the application. At a minimum, PSKC should explain and justify how it calculates depreciation expenses.

⁸ The property is large enough to accommodate the construction of a new facility while the currently facility is operational.

⁹ 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.

PSKC provided responses to DaVita's assertions above which are summarized below by topic.

PSKC Rebuttal Comments

Equipment Costs [source: PSKC rebuttal documents, pp5-6]

PSKC is purchasing new equipment for its project—the 3 station expansion. All costs for the equipment have been fully disclosed. The age, maintenance status, useful life, or any other aspect of the 6 relocated stations is not subject to this CN review.

Depreciation Expenses [source: PSKC rebuttal documents, p6]

DaVita mis-compares other dialysis projects with PSKC's 3-station addition project to demonstrate that PSKC's depreciation expenses are an 'outlier.' PSKC's depreciation expenses take into account the remaining useful life and accelerated depreciation associated with its relocation. This approach is different than DaVita's approach, but is not incorrect. DaVita also fails to acknowledge that the accounting rules for depreciation differ for a building that is owned (PSKC's project) than one that is leased (DaVita's project) Since PSKC will own its building, accounting rules require that PSKC depreciate the building asset over a 40-year estimated useful life as required in Accounting Standard Codification 360-10-35-4.

Department's Evaluation

After reviewing the issues raised by DaVita and the responses provided by PSKC, the department concludes the following.

Equipment Costs

DaVita's assertion that PSKC did not properly identify the equipment needed for the dialysis center is related to DaVita's earlier assertion that PSKC did not qualify for the relocation exemption under WAC 246-310-289(3). This issue was already addressed in this evaluation and will not be re-addressed here. Based on the information reviewed, the department concludes PSKC has properly identified the equipment and related construction costs for this station addition project.

Depreciation Expenses

In its public comments, DaVita acknowledges that publicly-held applicants, such as DaVita, are governed by strict accounting rules regarding depreciation, yet DaVita compared PSKC's depreciation information with only 3 other dialysis providers besides itself. Regardless of the outcome of DaVita's comparison, PSKC provided the rationale and an explanation of its depreciation approach as suggested by DaVita. The approach identified by PSKC 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 WIDC would be relocated and the additional three stations would become operational by the end of year 2012. Under this timeline, calendar year (CY) 2013 would be WIDC's first full year of operation with 8 stations and 2015 would be year three. The table on the following page illustrates the projected revenue, expenses, and net income for calendar years 2013 through 2015 for WIDC with 8 stations. [source: Application, Appendix 9]

Table 6
Whidbey Island Dialysis Center-Relocation and Expansion
Projected Revenue and Expenses Calendar Years 2013 - 2015

| | CY 1 - 2013 | CY 2 - 2014 | CY 3 - 2015 |
|--------------------------|--------------------|--------------------|--------------------|
| # of Stations | 8 | 8 | 8 |
| # of Treatments [1] | 4,717 | 5,466 | 6,215 |
| # of Patients [2] | 32 | 37 | 42 |
| Utilization Rate [2] | 4.00 | 4.63 | 5.25 |
| Net Revenue [1] | \$ 2,288,719 | \$ 2,768,808 | \$ 2,513,710 |
| Total Expense [1] | \$ 1,810,412 | \$ 2,052,622 | \$ 2,294,099 |
| Net Profit or (Loss) [1] | \$ 478,307 | \$ 716,186 | \$ 219,611 |

[1] Includes in-center treatments only; [2] in-center patients only.

The 'Net Revenue' line item is gross revenue minus any deductions for charity care and bad debt. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for WIDC. As shown in the table above at the projected volumes identified in the application, DaVita anticipates profits in the first three years of operation with 8 stations.

DaVita also provided the projected revenue, expenses, and net income for calendar years 2013 through 2015 for WIDC with 5 stations at the new site. [source: November 30, 2011, supplemental information, Exhibit B, p6] The table below summarizes this information.

Table 7
Whidbey Island Dialysis Center-Relocation Only
Projected Revenue and Expenses Calendar Years 2013 - 2015

| | CY 1 - 2013 | CY 2 - 2014 | CY 3 - 2015 |
|--------------------------|--------------------|--------------------|--------------------|
| # of Stations | 5 | 5 | 5 |
| # of Treatments [1] | 4,418 | 4,418 | 4,418 |
| # of Patients [2] | 30 | 30 | 30 |
| Utilization Rate [2] | 6.00 | 6.00 | 6.00 |
| Net Revenue [1] | \$ 1,884,374 | \$ 2,067,149 | \$ 2,269,603 |
| Total Expense [1] | \$ 1,822,806 | \$ 1,994,338 | \$ 2,128,627 |
| Net Profit or (Loss) [1] | \$ 61,568 | \$ 72,811 | \$ 140,976 |

[1] Includes in-center treatments only; [2] in-center patients only.

The 'Net Revenue' line item is gross revenue minus any deductions for charity care and bad debt. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for WIDC. As shown in the table above at the projected volumes identified in the application, DaVita anticipates profits in the first three years of operation after the relocation of the 5-station center.

In addition to the financial documents summarized above, DaVita also provided a copy of its executed lease agreement for new site at 32650 State Route 20, #D-101 in Oak Harbor. The lease is between DaVita (Total Renal Care, Inc.) and KT Harbor Station, LLC. The lease agreement outlines the roles and responsibilities for both the lessor and lessee and outlines the terms and the annual rent for the space. The agreement commenced on August 30, 2011 and extends for ten years. The executed agreement was notarized on August 30, 2011. [source: Application, Attachment 15]

DaVita identified Cha-Jen Kuan, MD as the current medical director for WIDC and provided a copy of the medical director's agreement. The agreement outlines the roles and responsibilities of both DaVita and Dr. Kuan and identifies the annual compensation for the medical director services. [source: Application, Appendix 3] The medical director agreement is not expected to change with the addition of three stations. The medical director service costs are also substantiated in the pro forma documents. [source: Application, Attachment 9]

During the review of this project, PSKC submitted comments related to the lease agreement and the pro forma revenue and expense statements provided in the application. Below is a summary of the comments provided by PSKC.

PSKC Public Comments [source: PSKC public comments, p7]

- Supplemental Information - The table of contents provided with DaVita's application indicates that the lease agreement provided in Appendix 15 would be supplemented. No supplemental information was submitted by DaVita related to the lease agreement. DaVita cannot now supplement the application.
- Holding Fee - Page 2 of the lease agreement notes that DaVita is required to pay, beginning September 1, 2011, a holding fee of \$3,530.63 per month. This amount is payable until either possession date or the date the lessee or lessor terminates the lease, whichever is first. If this project is approved, this amount could total tens of thousands of dollars. This lease amount identified in the pro forma revenue and expense statements do not account for this cost.
- Common Area Maintenance - The pro forma revenue and expense statements also do not account for the common area maintenance expenses that are typical for this type of lease. This cost is identified in the lease agreement, but omitted in the statements.

DaVita provided responses to PSKC's comments above which are summarized below. [source: DaVita, rebuttal comments, pp3-4]

DaVita Rebuttal Comments

- Supplemental Information – No response to PSKC's statements were provided.
- Holding Fee – The holding fee is a pre-opening expense. Once possession of the site occurs, then the relevant operating expense is 'rent' not 'holding fee.' In its comments, PSKC suggests that the holding fee be mis-characterized in the revenue and expense statement.
- Common Area Maintenance – This comment has been raised by other dialysis providers for DaVita's projects, and the department has appropriately disregarded the argument.

Department's Evaluation

- Supplemental Information – Regardless of whether DaVita intended to provide supplemental information related to the lease agreement, no additional information was provided. PSKC's comments imply that regardless of whether DaVita omitted any lease agreement information, because DaVita indicated in the table of contents that it would provide supplemental information, and then did not, the application should be denied. The department does not make this determination until it reviews the project.
- Holding Fee – DaVita identified a holding fee within its lease agreement to demonstrate its commitment to the project and the new site. For this project, a holding fee is appropriate because even if the station addition portion of DaVita's project is denied, the relocation of the existing 5-station dialysis center could be approved. As a result, the holding fee is

confirmation of DaVita’s intent to relocate the facility in a different building at the existing site. DaVita’s characterization of the holding fee as a rent expense if site possession occurs is appropriate.

- Common Area Maintenance – This issue has been raised by other dialysis providers when commenting on projects. Typically, dialysis applicants have not included estimates for these related lease expenses on new facilities. DaVita’s project is reviewed as a ‘new’ facility and its approach to this expense is consistent with past applications.

After reviewing the issues raised by both PSKC and DaVita, the department concludes that both DaVita and PSKC have been diligent in providing accurate estimates in their applications. For this project, DaVita separately identified the costs for the relocation of the 5-station facility and the relocation plus the addition of 3 stations.

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

As previously stated, PSKC received approval to relocate the 6-station facility under WAC 246-310-289(3). For this application, the department considers the capital expenditure to be the costs for the 3 station addition, with allocated construction costs, which is \$294,375. [source: Application, p26] The capital cost breakdown is shown in the table below.

**Table 8
PSKC Estimated Capital Costs**

| Item | Cost | % of Total |
|--------------------------------------|-------------------|-------------------|
| Building Construction | \$ 217,375 | 73.8% |
| Moveable Equipment | \$ 75,000 | 25.5% |
| Sales Tax for Equipment | \$ 2,000 | 0.7% |
| Total Estimated Capital Costs | \$ 294,375 | 100.0% |

PSKC intends to finance the project entirely from available board reserves. A review of the historical financial statements provided in the application indicates that PSKC has sufficient cash assets and board approval to fund the project. [source: Application, Appendix 1 and November 30, 2011, supplemental information, Attachment 2]

During the review of this project, DaVita submitted comments asserting that PSKC would obtain debt financing for this project, rather than funding with cash reserves. [source: DaVita public comment, pp5-7] DaVita’s assertion is related to its earlier assertion that PSKC did not qualify for the relocation exemption under WAC 246-310-289(3). Since PSKC is debt financing the

relocation of the 6 stations, DaVita concludes that PSKC’s project would be funded by two sources: 1) debt financing; and 2) board reserves. The issue of whether PSKC appropriately qualified for and obtained an exemption was already addressed in this evaluation and will not be re-addressed here. Based on the information reviewed, the department concludes PSKC has properly identified the capital costs for the station addition and accurately identified the funding source of the project.

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD reimbursements. To further demonstrate compliance with this sub-criterion, PSKC also provided the current sources of patient revenue for PSKC-Whidbey Island shown in the table below. [source: Application, p9]

Table 9
PSKC-Whidbey Island
Sources and Percentages of Revenue

| Source of Revenue | % of Revenue |
|--------------------------|---------------------|
| Medicare | 75% |
| Medicaid | 3% |
| Other [1] | 22% |
| Total | 100% |

[1] Other sources include managed care, private pay and other insurances

As shown above, the Medicare and Medicaid reimbursements currently equal are equal 78% of the revenue at PSKC-Whidbey Island. PSKC states that the addition of 3 stations is not expected to change the sources above. The department concludes that since the majority of revenue is dependent upon sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining 22% will be derived through a variety of reimbursement sources.

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

DaVita, Inc.

Since DaVita’s project does not qualify for the relocation exemption outlined in WAC 246-310-289, DaVita appropriately identified all costs associated with the relocation of the 5-station center, in addition to the costs to add 3 stations. The capital expenditure associated with the relocation of WIDC and the addition is \$1,514,133. Of that amount, approximately 75% is related to leasehold improvements, 15% for fixed/moveable equipment; 5% is related to professional fees; and the remaining 5% is the landlord’s portion of costs. [source: Application, Appendix 7] The capital cost breakdown for the relocation and the addition of 3 stations is shown in the table on the following page.

Table 10
DaVita Estimated Capital Costs-Relocation and Station Addition

| Item | Cost | % of Total |
|--------------------------------------|---------------------|-------------------|
| Leasehold Improvements | \$ 1,125,000 | 75% |
| Landlord Project Costs | \$ 81,750 | 5% |
| Fixed & Moveable Equipment (w/ tax) | \$ 227,383 | 15% |
| Professional Service Fees | \$ 80,000 | 5% |
| Total Estimated Capital Costs | \$ 1,514,133 | 100% |

DaVita also provided a breakdown of the capital costs for the relocation of the 5-station center without the addition of 3 stations. The capital expenditure associated with only the relocation of WIDC is \$1,446,139. Of that amount, approximately 78% is related to leasehold improvements, 11% for fixed/moveable equipment; 6% is related to professional fees; and the remaining 5% is the landlord's portion of costs. [source: November 30, 2011, supplemental information, p3] The capital cost breakdown for the relocation only is shown in the table below

Table 11
DaVita Estimated Capital Costs-Relocation Only

| Item | Cost | % of Total |
|--------------------------------------|---------------------|-------------------|
| Leasehold Improvements | \$ 1,125,000 | 78% |
| Landlord Project Costs | \$ 81,750 | 6% |
| Fixed & Moveable Equipment (w/ tax) | \$ 159,389 | 11% |
| Professional Service Fees | \$ 80,000 | 5% |
| Total Estimated Capital Costs | \$ 1,446,139 | 100% |

Regardless of whether DaVita relocates the facility and adds stations or just relocates the facility, DaVita intends to finance its portion of the project entirely from available board reserves. For the relocation and station addition, DaVita's portion is \$1,434,133; for the relocation only, its portion is \$1,366,139. A review of the historical financial statements provided in the application indicates that DaVita has sufficient cash assets and board approval to fund either project. [source: Application, Appendix 10]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD reimbursements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue. DaVita stated that its sources and percentages are not expected to change if additional stations are added after the relocation. DaVita's sources of patient revenue are shown in the table below. [source: Application, p10]

Table 12
Whidbey Island Dialysis Center
Sources and Percentages of Revenue

| Source of Revenue | % of Revenue |
|--------------------------|---------------------|
| Medicare | 72% |
| Medicaid | 4% |
| Other [1] | 24% |
| Total | 100% |

[1] Other sources include managed care, private pay and other insurances

As shown above, the Medicare and Medicaid reimbursements are projected to equal 76% of the revenue at WIDC. The department concludes that since the majority of revenue is dependent upon sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining 24% will be derived through a variety of reimbursement sources.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is 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 additional 3 stations is \$294,375. PSKC intends to finance the project entirely from available board reserves. A review of the historical financial statements provided in the application indicates that PSKC has sufficient cash assets and board approval to fund the project. [source: Application, Appendix 1 and November 30, 2011, supplemental information, Attachment 2]

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 relocation and addition of stations is \$1,514,133, and DaVita's portion of the costs is \$1,434,133. For its relocation project only, DaVita noted that the costs for equipment and the landlord's project costs would be reduced. DaVita identified the relocation project to be \$1,446,139 and its portion to be \$1,366,139.

DaVita intends to finance its portion entirely from available board reserves. A review of the historical financial statements provided in the application indicates that DaVita has sufficient cash assets to fund the project. [source: Application, Appendix 10]

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 Centers’ project has met the structure and process of care criteria in WAC 246-310-230 provided the applicant agrees with the conditions identified in the ‘conclusion’ section of this evaluation; and
- DaVita, Inc.’s project has met the structure and process of care criteria in WAC 246-310-230 provided the applicant agrees with the conditions identified in the ‘conclusion’ section of this evaluation.

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

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

PSKC-Whidbey Island has been operational since 2006 with 6-stations. To accommodate the additional patients associated with the 3 new stations, PSKC expects to add a total of 3.62 FTEs [full time equivalents] to the center. A breakdown of the current and additional FTEs by year is shown in the table below. [source: Application, p29]

**Table 13
PSKC-Whidbey Island Current and Projected FTEs**

| Staff/FTEs | Current | 2013 Increase | 2014 Increase | 2015 Increase | Total |
|--------------------|----------------|----------------------|----------------------|----------------------|--------------|
| Medical Director | Contract | | | | |
| Direct Care Manger | 0.35 | 0.00 | 0.00 | 0.00 | 0.35 |
| Registered Nurse | 2.40 | 0.00 | 0.60 | 0.00 | 3.00 |
| Dialysis Techs | 5.33 | 0.67 | 0.50 | 0.50 | 7.00 |
| Biomed Techs | 0.20 | 0.00 | 0.00 | 0.00 | 0.20 |
| Reuse Techs | 1.00 | 0.20 | 0.00 | 0.00 | 1.20 |
| Stock Tech | 0.20 | 0.60 | 0.00 | 0.00 | 0.80 |
| Computer Tech | 0.10 | 0.00 | 0.00 | 0.00 | 0.10 |
| MSW | 0.20 | 0.05 | 0.05 | 0.00 | 0.30 |
| Dietitian | 0.30 | 0.10 | 0.10 | 0.00 | 0.50 |
| Secretary | 0.10 | 0.00 | 0.00 | 0.00 | 0.10 |
| Office Clerk | 0.25 | 0.00 | 0.25 | 0.00 | 0.50 |
| Total FTEs | 10.43 | 1.62 | 1.50 | 0.50 | 14.05 |

As shown in the table above, PSKC plans for small annual increases in FTEs that coincide with the increase in patients and dialyses each year. PSKC states that it does not anticipate any difficulty in recruiting staff for PSKC-Whidbey Island due to its location, competitive wage package, and philosophy that encourages existing staff to receive training and additional education. [source: Application, p30]

PSKC identified Alan Haakenstad, MD as the current corporate medical director and facility medical director. PSKC provided a copy of both executed medical director agreements. Each agreement outlines the roles and responsibilities for both PSKC and the medical director. Each agreement also identifies the annual compensation for the medical director services. [source: Application, Exhibit 2]

Based on the information reviewed, the department concludes adequate staffing for the additional 3 stations and the 9-station PSKC-Whidbey Island is available or can be recruited. **This sub-criterion is met.**

DaVita, Inc.

WIDC has been in operation since May 2010. DaVita provided a breakdown of current staff and proposed staff beginning in partial year 2012 through full year 2015. [source: Application, p22 and November 30, 2011, supplemental information, p4]

Table 14 below shows a breakdown of staffing for the relocated facility and the addition of 3 stations.

**Table 14
Whidbey Island Dialysis Center Projected FTEs
Relocation and Station Addition**

| Staff/FTEs | 2012 Current | 2013 Increase | 2014 Increase | 2015 Increase | Total |
|---------------------|--------------------------------|--------------------------|--------------------------|--------------------------|--------------|
| Medical Director | Professional Services Contract | | | | |
| Administrator | 1.00 | 0.00 | 0.00 | 0.00 | 1.00 |
| Registered Nurse | 2.30 | 0.00 | 0.20 | 0.10 | 2.60 |
| Patient Care Techs | 3.50 | 0.00 | 0.20 | 0.10 | 3.80 |
| Biomedical Techs | 0.30 | 0.00 | 0.00 | 0.00 | 0.30 |
| Administrative Asst | 0.00 | 0.00 | 0.50 | 0.00 | 0.50 |
| MSW | 0.40 | 0.00 | 0.10 | 0.00 | 0.50 |
| Dietician | 0.40 | 0.00 | 0.10 | 0.00 | 0.50 |
| Total FTEs | 7.90 | 0.00 | 1.10 | 0.20 | 9.20 |

As shown in the table above, DaVita expects minimal FTEs added beginning in years two and three with the addition of 3-station at WIDC.

Table 15 on the following page shows a breakdown of staff for the relocated facility with no additional stations. [source: November 30, 2011, supplemental information, p4]

Table 15
Whidbey Island Dialysis Center Projected FTEs
Relocation Only

| Staff/FTEs | 2012 Current | 2013 Increase | 2014 Increase | 2015 Increase | Total |
|---------------------|--------------------------------|------------------|------------------|------------------|-------------|
| Medical Director | Professional Services Contract | | | | |
| Administrator | 1.00 | 0.00 | 0.00 | 0.00 | 1.00 |
| Registered Nurse | 2.30 | 0.00 | 0.00 | 0.00 | 2.30 |
| Patient Care Techs | 3.50 | 0.00 | 0.00 | 0.00 | 3.50 |
| Biomedical Techs | 0.30 | 0.00 | 0.00 | 0.00 | 0.30 |
| Administrative Asst | 0.00 | 0.00 | 0.50 | 0.00 | 0.50 |
| MSW | 0.40 | 0.00 | 0.00 | 0.00 | 0.40 |
| Dietician | 0.40 | 0.00 | 0.00 | 0.00 | 0.40 |
| Total FTEs | 7.90 | 0.00 | 0.50 | 0.00 | 8.40 |

As shown in the table above, DaVita expects to add additional administrative support in year two and no other staff for the 5-station WIDC.

DaVita states that it does not anticipate any difficulty in recruiting staff for WIDC because it already has a presence in the community and its 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: Application, p23]

DaVita identified Cha-Jen Kuan, MD as the current medical director for WIDC and provided a copy of the medical director’s agreement. The agreement outlines the roles and responsibilities of both DaVita and Dr. Kuan and identifies the annual compensation for the medical director services. [source: Application, Appendix 3] The medical director agreement is not expected to change with the addition of three stations.

Based on the information reviewed, the department concludes adequate staffing 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

As a provider of dialysis services in Washington State, PSKC currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For this project, PSKC provided a copy of its current transfer agreement between itself and Providence Everett

Medical Center in Everett. The agreement confirms that PSKC maintains the appropriate relationships with ancillary and support services for PSKC-Whidbey Island. Ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, human resources, material management, administration, and technical services are currently provided on-site at PSKC-Whidbey Island. [source: Application, p30 and Exhibit 11]

Based on this information, the department concludes PSKC currently has access to the necessary ancillary and support services for the existing facility and approval of this project is not expected to change these relationships. **This sub-criterion is met.**

DaVita, Inc.

As a provider of dialysis services in Washington State, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For its Whidbey Island Dialysis Center, 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 are provided on site. Additional services are coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: Application, p23]

Since WIDC is currently operating, DaVita provided a copy of the existing patient transfer agreement between itself and Whidbey General Hospital in Island County. The agreement confirms that DaVita maintains the appropriate relationships with ancillary and support services for the facility. [source: Application, Appendix 12]

Based on this information, the department concludes DaVita currently has access to the necessary ancillary and support services for the existing facility and approval of this project is not expected to change these 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.*

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, and operates four kidney dialysis treatment centers in two 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.¹⁰

¹⁰ WAC 246-310-230(5).

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 provided a copies of the Corporate and Facility Medical Director Agreements currently in effect between itself and Alan Haakenstad, MD, the current medical director at PSKC-Whidbey Island. A review of the compliance history for Dr. Haakenstad revealed no recorded sanctions. [source: Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of PSKC, and that of the current medical director, the department concludes that there is reasonable assurance that the PSKC-Whidbey Island would continue to operate in compliance with state and federal regulations with the addition of 3 stations. **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.¹¹ 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.¹² The compliance history of the remaining 19 states and the District of Columbia is unknown.¹³

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 reopened, none of the deficiencies is reported to have resulted in fines or enforcement action.¹⁴ All other facilities are reported to be currently in compliance with applicable regulations. [source: compliance history from state licensing and/or surveying entities] The department concludes that considering the more than 1,642 facilities

¹¹ WAC 246-310-230(5).

¹² 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

¹³ 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.

¹⁴ 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.

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.¹⁵ 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 current medical director agreement with Chia-Jen Kuan, MD, for medical director services at Whidbey Island Dialysis Center. A review of the compliance history for Dr. Kuan revealed no recorded sanctions. [source: Application, Appendix 3 and Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of DaVita and that of the medical director, the department concludes that there is reasonable assurance that the Whidbey Island Dialysis Center would continue to operate in compliance with state and federal regulations with the additional stations. **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 expansion would change these relationships.

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 3 dialysis stations in Island County. This project proposes to add 3 stations to the 6-station PSKC-Whidbey Island located in Oak Harbor.

¹⁵ 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.

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. Further, PSKC demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area. **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.

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 3 dialysis stations in Island County. This project proposes to relocate the 5-station WIDC and add 3 stations.

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. Further, DaVita demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area. **This sub-criterion is met.**

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

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 that

- Puget Sound Kidney Centers' project has met the cost containment criteria in WAC 246-310-240(1) and (2) provided the applicant agrees to the conditions identified in the 'conclusion' section of this evaluation; and
- DaVita, Inc.'s project has met the cost containment criteria in WAC 246-310-240(1) and (2) provided the applicant agrees to the conditions identified in the 'conclusion' section of this evaluation.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable. To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one 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 step two 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

Puget Sound Kidney Centers and DaVita, Inc.

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

Step Two

Puget Sound Kidney Centers

The PSKC board and leadership planned for future growth when it decided to relocate the 5-station facility to a building that would accommodate 12 stations in the future. The existing building was constructed in 1972 to accommodate a dental office, but requires construction to meet PSKC's standards. The 5-station relocation is expected to be complete in mid-year 2012. The 3 station expansion is expected to occur shortly after opening the new building. With the numeric need demonstrated in the planning area, PSKC concludes that other than this project, no other meaningful alternative exists. [source: Application, p33]

DaVita, Inc

Within the application, DaVita identified and rejected only the alternative of 'do nothing.' DaVita rejected this alternative because the numeric methodology demonstrated a need for 3 stations in the planning area. [source: Application, p25]

Step Three

WAC 246-310-288 identifies specific tie-breaker criteria that must be 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. Under this tie-breaker 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 Centers

A total of five points is possible. The table below shows the distribution of tie-breaker points under this sub-criterion for PSKC.

**Table 16
WAC 246-310-288(1)
PSKC Tie-Breaker Review**

| WAC 246-310-288(1) | Point | Source |
|--|--------------|--|
| (a)(i) & (ii) Training services | 0 | Application, p3 and mileage maps; CMS data |
| (b) Private room(s) for isolating patients | 1 | Application, p7 |
| (c) Permanent bed stations at the facility | 1 | Application, p7 |
| (d) Evening shift | 1 | Application, p7 |
| (e) Meeting the projected need | 1 | Application, Appendix 17 |
| Total Points | 4 | |

DaVita

A total of five points is possible. The table on the following page shows the distribution of tie-breaker points under this sub-criterion for DaVita.

Table 17
WAC 246-310-288(1)
DaVita Tie-Breaker Review

| WAC 246-310-288(1) | Point | Source |
|--|--------------|---------------------------|
| (a)(i) & (ii) Training services | 0 | Application, p9; CMS data |
| (b) Private room(s) for isolating patients | 1 | Application, p9 |
| (c) Permanent bed stations at the facility | 1 | Application, p9 |
| (d) Evening shift | 1 | Application, p9 |
| (e) Meeting the projected need | 1 | Application, p17 |
| Total Points | 4 | |

Under WAC 246-310-288(1) where each applicant could receive a maximum of 5 points, PSKC and DaVita each received 4 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. The table below shows the distribution of tie-breaker points under this sub-criterion for PSKC.

Table 18
WAC 246-310-288(2)
PSKC Tie-Breaker Review

| WAC 246-310-288(2) | Point | Source |
|---------------------------------|--------------|-----------------------------|
| (a) Economies of Scale | 1 | Application, p26 [\$98,125] |
| (b) Historical Provider | 0 | |
| (c) Patient Geographical Access | 0 | |
| (d) Provider Choice | 0 | |
| Total Points | 1 | |

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

Table 19
WAC 246-310-288(2)
DaVita Tie-Breaker Review

| WAC 246-310-288(2) | Point | Source |
|---------------------------------|--------------|-------------------------------------|
| (a) Economies of Scale | 0 | Application, Appendix 7 [\$168,237] |
| (b) Historical Provider | 0 | |
| (c) Patient Geographical Access | 0 | |
| (d) Provider Choice | 0 | |
| Total Points | 0 | |

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

Table 20
WAC 246-310-288 – Tie-Breaker Summary Table

| | Tie-Breaker Point Distribution | |
|------------------------------|--------------------------------|----------|
| | PSKC | DaVita |
| 1(a) – Training services | 0 | 0 |
| 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 | 1 | 0 |
| 2(b) – Historical Provider | 0 | 0 |
| 2(c) – Geographical Access | 0 | 0 |
| 2(d) – Provider Choice | 0 | 0 |
| Cumulative Total | 5 | 4 |

At the completion of the tie-breaker point allocations, PSKC accumulated a total of five (5) points and DaVita accumulated a total of four (4) 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 3 of the stations projected for the planning area, there are no stations remaining to award to DaVita as the application earning the next highest point total.

DaVita's application also proposes a relocation of the existing 5-station dialysis center. Within its application, DaVita provided the following documents for the relocation of the 5-station center only:

- a pro forma revenue and expense statement;
- a capital expenditure breakdown;
- a breakdown of the projected number of patients and treatments; and
- a staffing table for a 5-station facility.

[source: November 30, 2011, supplemental information, pp3-6]

A review of the documents identified above demonstrates that DaVita's 5-station relocation project meets the review criteria.

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, PSKCs 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 for the relocation of its existing 5-station dialysis center and the addition of 3 station. However, DaVita's project would meet this criteria for the relocation of the dialysis center, without adding dialysis stations. **Provided that DaVita would agree to relocate the 5-station center and not add dialysis stations, this project is approved.**

(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 does not involve construction. **This sub-criterion is does not apply to this project.**

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 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
Island County
ESRD Need Projection Methodology**

| Planning Area | | 6 Year Utilization Data - Resident Incenter Patients | | | | | |
|--|--|--|------------------------------------|----------------|----------------|----------------|----------------|
| Island | | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
| Island County | | 28 | 37 | 41 | 49 | 49 | 59 |
| Less 98282 to Sno#1 | | -4 | -9 | -7 | -10 | -11 | -9 |
| TOTALS | | 24 | 28 | 34 | 39 | 38 | 50 |
| 246-310-284(4)(a) | Rate of Change | | 16.67% | 21.43% | 14.71% | -2.56% | 31.58% |
| | 6% Growth or Greater? | | TRUE | TRUE | TRUE | FALSE | TRUE |
| | Regression Method: | Linear | | | | | |
| 246-310-284(4)(c) | | | | Year 1 2011 | Year 2 2012 | Year 3 2013 | Year 4 2014 |
| Projected Resident Incenter Patients | from 246-310-284(4)(b) | | | 52.20 | 57.00 | 61.80 | 66.60 |
| Station Need for Patients | Divide Resident Incenter Patients by 4.8 | | | 10.8750 | 11.8750 | 12.8750 | 13.8750 |
| | Rounded to next whole number | | | 11 | 12 | 13 | 14 |
| 246-310-284(4)(d) | subtract (4)(c) from approved stations | | | | | | |
| Existing CN Approved Stations | | | | 11 | 11 | 11 | 11 |
| Results of (4)(c) above | | | | 11 | 12 | 13 | 14 |
| Net Station Need | | | | 0 | -1 | -2 | -3 |
| Negative number indicates need for stations | | | | | | | |
| 246-310-284(5) | | | | | | | |
| Name of Center | # of Stations | Patients | Utilization (Patients per Station) | | | | |
| PSKC Whidbey Island | 6 | 29 | 4.83 | | | | |
| DaVita Oak Harbor | 5 | 17 | 3.40 | | | | |
| Total | 11 | 46 | | | | | |
| Source: Northwest Renal Network data 2005-2010 | | | | | | | |
| Most recent year-end data: 2010 year-end data as of 02/16/2011 | | | | | | | |
| Most recent quarterly data as of the 1st day of application submission period: 1st quarter 2011 as of 05/16/2011 | | | | | | | |

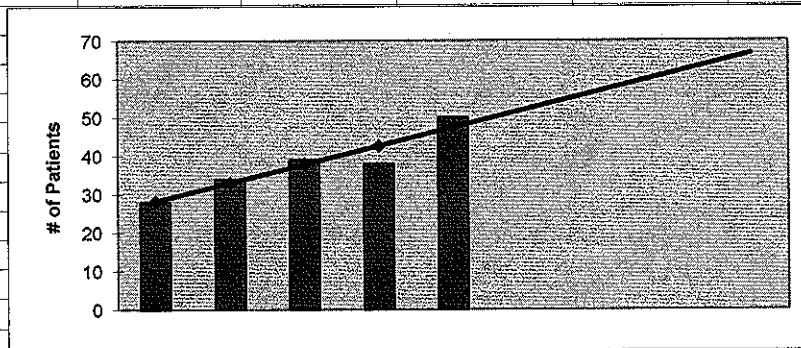


**2011
Island County
ESRD Need Projection Methodology**

| x | y | Linear |
|------|----|--------|
| 2006 | 28 | 28 |
| 2007 | 34 | 33 |
| 2008 | 39 | 38 |
| 2009 | 38 | 43 |
| 2010 | 50 | 47 |
| 2011 | | 52.200 |
| 2012 | | 57.000 |
| 2013 | | 61.800 |
| 2014 | | 66.600 |

SUMMARY OUTPUT

| Regression Statistics | |
|-----------------------|-------------|
| Multiple R | 0.93991254 |
| R Square | 0.883435583 |
| Adjusted R Square | 0.844580777 |
| Standard Error | 3.183289703 |
| Observations | 5 |



| ANOVA | | | | | |
|------------|----|-------|-------------|-------------|----------------|
| | df | SS | MS | F | Significance F |
| Regression | 1 | 230.4 | 230.4 | 22.73684211 | 0.017520887 |
| Residual | 3 | 30.4 | 10.13333333 | | |
| Total | 4 | 260.8 | | | |

| | Coefficients | Standard Error | t Stat | P-value | Lower 95% | Upper 95% | Lower 95.0% | Upper 95.0% |
|--------------|--------------|----------------|--------------|-------------|--------------|-------------|--------------|-------------|
| Intercept | -9600.6 | 2021.342841 | -4.749614863 | 0.017708982 | -16033.41505 | -3167.78495 | -16033.41505 | -3167.78495 |
| X Variable 1 | 4.8 | 1.006644591 | 4.768316485 | 0.017520887 | 1.59640764 | 8.00359236 | 1.59640764 | 8.00359236 |

RESIDUAL OUTPUT

| Observation | Predicted Y | Residuals |
|-------------|-------------|-----------|
| 1 | 28.2 | -0.2 |
| 2 | 33 | 1 |
| 3 | 37.8 | 1.2 |
| 4 | 42.6 | -4.6 |
| 5 | 47.4 | 2.6 |