



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

September 27, 2013

CERTIFIED MAIL # 7011 2000 0000 5082 0305

Jason Bosh, Regional Operations Director
DaVita HealthCare Partners Inc.
32275-32nd Avenue South
Federal Way, Washington 98001

RE: CN13-14A2

Dear Mr. Bosh:

In the Department of Health's evaluation released on September 24, 2013, the table showing the breakdown of approved dialysis stations for DaVita's Belfair project was omitted from the project description. This letter corrects the error. Please note the approved number of stations does not change.

The application submitted is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

DaVita, Inc. proposes to establish a new five-station dialysis facility in the Mason County Dialysis Planning Area. The facility will be located in the city of Belfair within Mason County. This dialysis center will provide in-center dialysis, home hemodialysis training, back-up dialysis services for home dialysis patients, and visiting or transient hemodialysis. The station breakdown for the facility at project completion is shown below:

| | |
|--------------------------|----------|
| Private Isolation Room | 1 |
| Permanent Bed Station | 1 |
| Home Training Station | 1 |
| Other In-Center Stations | 2 |
| Total | 5 |

Conditions:

1. Approval of project description as stated above. DaVita, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

2. Prior to providing services at the Belfair Dialysis Center, DaVita, Inc. will provide an executed copy of the facility lease consistent with the draft lease provided in the application.
3. Prior to providing services at the DaVita, Inc. will provide an executed copy of the Medical Director Agreement consistent with the draft Medical Director Agreement provided in the application.
4. Prior to providing services at the Belfair Dialysis Center. DaVita, Inc. will provide an executed copy of the dialysis center ancillary and support services agreement for the department's review and approval. The executed ancillary and support services agreement must be consistent with the draft provided in the application

Approved Cost:

The approved capital expenditure associated with this project is \$1,344,100 which represents the total capital expenditure of \$1,414,061, minus the landlord's cost of \$69,961

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.

Appeal Option 1:

You or any interested or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

| | |
|-----------------------------|-----------------------------|
| <u>Mailing Address:</u> | <u>Other Than By Mail</u> |
| Department of Health | Department of Health |
| Certificate of Need Program | Certificate of Need Program |
| Mail Stop 47852 | 111 Israel Road SE |
| Olympia, WA 98504-7852 | Tumwater, WA 98501 |

Appeal Option 2:

You or any affected person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

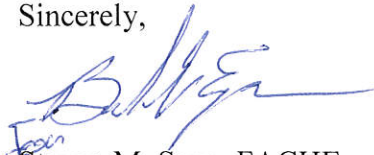
Jason Bosch, Regional Operational Director
DaVita Inc.
September 27, 2013
Page 3 of 3

Mailing Address:
Adjudicative Clerk Office
Mail Stop 47879
Olympia, WA 98504-7879

Other Than By Mail
Adjudicative Clerk Office
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, Community Health Systems

cc: Gary Pete, Fresenius Medical Care
Jeff Lehman, Olympic Peninsula Kidney Center

Enclosure

EXECUTIVE SUMMARY

EVALUATION DATED SEPTEMBER 24, 2013 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO MASON COUNTY:

- **RENAL CARE GROUP NORTHWEST, INC. PROPOSING TO ADD 5 KIDNEY DIALYSIS STATIONS TO THE EXISTING SHELTON DIALYSIS CENTER IN SHELTON**
- **OLYMPIC PENINSULA KIDNEY CENTER PROPOSING TO ESTABLISH A 5 STATION DIALYSIS CENTER IN BELFAIR**
- **DAVITA, INC. PROPOSING TO ESTABLISH A 5 STATION DIALYSIS CENTER IN BELFAIR**

BRIEF PROJECT DESCRIPTIONS

Renal Care Group Northwest, Inc.

Renal Care Group Northwest, Inc. (RCGNW) proposes to add five dialysis stations to its Shelton Dialysis Center for a facility total of 11 stations. The dialysis center would continue to serve the residents of Mason County. Services currently provided at the Shelton Dialysis Center include hemodialysis, backup dialysis service, isolation station and permanent bed station. [Source: Amended Application, p10]

The approved capital expenditure associated with this project is \$514,524. Of the total amount 64% is related to construction; 24% for equipment; 4% for professional fees, and the remaining 7% is related to applicable taxes. [Source: Amended Application, p28]

If this project is approved, RCGNW anticipates the station would be available by March 2014. Under this timeline, year 2015 would be the facility's first full calendar year of operation with 11 stations and 2017 would be year three. [Source: Amended Application, Face Page & p10]

Olympic Peninsula Kidney Centers

Olympic Peninsula Kidney Centers (OPKC) proposes to establish a new five station dialysis facility in the Mason County Dialysis Planning Area.

The facility will be located at 320 NE Roy Boad Road, in the city of Belfair within Mason County. This dialysis center will provide in-center dialysis, home hemodialysis training, back-up dialysis services for home dialysis patients, and visiting or transient hemodialysis.

If this project is approved, OPKC anticipates the dialysis center would be available by mid-2014. Under this timeline, year 2015 would be the Center's first full calendar year of operation and 2017 would be year three. [Source: Amended Application, p7]

The capital expenditure associated with this project is \$1,581,490. Of the total capital expenditure 70% is related to construction; 20% for moveable equipment; 4% for professional fees, 4% for sales tax and the remaining 2% is for permits. [Source: Amended Application, p25]

DaVita, Inc.

DaVita, Inc. (DaVita) proposes to establish a new five station dialysis facility in the Mason County Dialysis Planning Area.

The DaVita Belfair Dialysis Center will be located at 23961 NE State Route 3, Suite B, in the city of Belfair within Mason County. This dialysis center will provide in-center dialysis, peritoneal dialysis training, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station, hemodialysis patients requiring treatment shifts that begin after 5:00 pm, back-up dialysis services for home dialysis patients, and visiting or transient hemodialysis. [Source: Application, p9]

If this project is approved, DaVita anticipates the station would be available by January 1, 2014. Under this timeline, year 2014 would be the facility's first full calendar year of operation and 2016 would be year three. [Source: Amended Application, p18]

The capital expenditure associated with this project is \$1,344,100. This amount represents the total capital expenditure of \$1,414,061 minus the landlord's project costs of \$69,961. Of that total amount 65% is related to construction; 25% for moveable equipment; 5% for professional fees and the remaining 5% is related to the landlord's portion of the costs. [Source: Amended Application, p8]

APPLICABILITY OF CERTIFICATE OF NEED LAW

The projects are subject to Certificate of Need (CN) review as the increase in number of dialysis stations at a dialysis facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

CONCLUSIONS

RCGNW

For the reasons stated in this evaluation, the application submitted by Renal Care Group Northwest proposing to add five dialysis stations to the Shelton Dialysis Center is not consistent with applicable criteria and a Certificate of Need is denied.

OPKC

For the reasons stated in this evaluation, the application submitted by OPKC proposing to establish a five station dialysis facility in Belfair is not consistent with applicable criteria and a Certificate of Need is denied.

DaVita Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a new five station dialysis facility in Belfair within Mason County is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

DaVita, Inc. proposes to establish a new five-station dialysis facility in the Mason County Dialysis Planning Area. The facility will be located in the city of Belfair within Mason County. This dialysis center will provide in-center dialysis, home hemodialysis training, back-up dialysis services for home dialysis patients, and visiting or transient hemodialysis. The station breakdown for the facility at project completion is shown below:

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|--------------------------|----------|
| Private Isolation Room | 1 |
| Permanent Bed Station | 1 |
| Home Training Station | 1 |
| Other In-Center Stations | 2 |
| Total | 5 |

Conditions:

1. Approval of project description as stated above. DaVita, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Prior to providing services at the Belfair Dialysis Center, DaVita, Inc. will provide an executed copy of the facility lease consistent with the draft lease provided in the application.
3. Prior to providing services at the DaVita, Inc. will provide an executed copy of the Medical Director Agreement consistent with the draft Medical Director Agreement provided in the application.
4. Prior to providing services at the Belfair Dialysis Center. DaVita, Inc. will provide an executed copy of the dialysis center ancillary and support services agreement for the department's review and approval. The executed ancillary and support services agreement must be consistent with the draft provided in the application

Approved Cost:

The approved capital expenditure associated with this project is \$1,344,100 which represents the total capital expenditure of \$1,414,061, minus the landlord's cost of \$69,961

EVALUATION DATED SEPTEMBER 24, 2013 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO MASON COUNTY:

- **RENAL CARE GROUP NORTHWEST, INC. PROPOSING TO ADD 5 KIDNEY DIALYSIS STATIONS TO THE EXISTING SHELTON DIALYSIS CENTER IN SHELTON**
- **OLYMPIC PENINSULA KIDNEY CENTER PROPOSING TO ESTABLISH A 5 STATION DIALYSIS CENTER IN BELFAIR**
- **DAVITA, INC. PROPOSING TO ESTABLISH A 5 STATION DIALYSIS CENTER IN BELFAIR**

APPLICANT DESCRIPTION

RCGNW

Renal Care Group Northwest is one of three entities owned by Renal Care Group, Inc. (RCG). RCGNW is responsible for the operation of facilities under four separate legal entities. These four entities are Pacific Northwest Renal Services, Renal Care Group of the Northwest, In-land Northwest Renal Care Group and Renal Care Group of Alaska. On March 31, 2006, thorough stock acquisition, Fresenius Medical Care Holdings, Inc. (FMC) became the sole owner of Renal Care Group, Inc., and its subsidiaries Listed below are the five entities owned by FMC. [Source: Department’s historical record and Amended Application, page 3]

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

In Washington State, FMC or one of its four subsidiaries owns, operates or manages 19 kidney dialysis facilities in fourteen separate counties. Below is a listing of the 19 facilities in Washington. [Application: p3-6

Adams County

Fresenius Leah Layne Dialysis Center

Benton County

Columbia Basin Dialysis Center

Clark County

Fort Vancouver Dialysis Facility
Salmon Creek Dialysis Facility

Lewis County

Chehalis Facility

Grant County

Moses Lake Dialysis Facility
Western Grant County Dialysis Facility

Spokane County

Northpointe Dialysis Facility
Spokane Kidney Center
North Pines Dialysis Facility
North Spokane Dialysis Center

Mason County

Shelton Dialysis Center

Okanogan County

Omak Dialysis Facility

Stevens County

Colville Dialysis Center

Thurston County

Cowlitz County

Fresenius Longview Dialysis center

Fresenius Lacey Dialysis Center

Grays Harbor County

Aberdeen Dialysis Facility

Franklin County

Columbia Basin Dialysis Center

Walla Walla County

QualiCenters Walla Walla

OPKC

Olympic Peninsula Kidney Centers is a private, non-profit entity that provides dialysis services through three facilities located in Kitsap County and one facility located in Jefferson County. OPKC also has CN approval to open an additional facility that will be located in Kitsap County.

OPKC is governed by an 11-member Board of Directors comprised of medical, civic, and business leaders from the community. An appointed executive director and appointed administrator oversee day-to-day operations of OPKC. [Source: OPKC Application, p2 and Appendix 1]

Below is a listing of the four OPKC facilities in Kitsap County and one in Jefferson County. [Source: OPKC Application, p3]

Kitsap County

OPKC-Bremerton

OPKC-South

OPKC-North

OPKC-Care Coordination Unit¹

Jefferson County

OPKC-Northwest

DaVita

DaVita is a for-profit corporation that provides dialysis services in over 1,912 outpatient centers located in 43 states, the District of Columbia, and San Juan, Puerto Rico. DaVita also provides acute inpatient dialysis services in approximately 720 hospitals throughout the country. [Source: Application, p5; DaVita website]

In Washington State, DaVita owns or operates a total of 30 kidney dialysis facilities in 14 separate counties. Below is a listing of the DaVita facilities in Washington. [Source: CN historical files; DaVita Application, p2]

Benton

Chinook Dialysis Center

Kennewick Dialysis Center

Pacific

Seaview Dialysis Center

Chelan

DaVita Dialysis Center²

Pierce

Graham Dialysis Center

Lakewood Dialysis Center

Parkland Dialysis Center

Clark

Puyallup Dialysis Center

¹ OPKC Care Coordination Unit not yet open

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.

Vancouver Dialysis Center

Tacoma Dialysis Center

Douglas

East Wenatchee Dialysis Center

Snohomish

Everett Dialysis Center³

Mill Creek Dialysis Center

Franklin

Mid Columbia Kidney Center

Spokane

Downtown Spokane Renal Center

North Spokane Renal Center

Spokane Valley Renal Center

Island

Whidbey Island Dialysis Center

King

Bellevue Dialysis Center

Des Moines Dialysis Center

Federal Way Dialysis Center

Kent Dialysis Center

Olympic View Dialysis Center

(management only)

Westwood Dialysis Center

Thurston

Olympia Dialysis Center

Yakima

Mt. Adams Dialysis Center

Union Gap Dialysis Center

Yakima Dialysis Center

Zillah Dialysis Center

Kittitas

Ellensburg Dialysis Center

PROJECT DESCRIPTION

RCGNW

RCGNW proposes to add five dialysis stations to its Shelton Dialysis Center for a facility total of 11 stations. The dialysis center would continue to serve the residents of Mason County. Services currently provided at the Shelton Dialysis Center include hemodialysis, backup dialysis service, isolation station, and permanent bed station. [Source: Amended Application, p10]

The approved capital expenditure associated with this project is \$514,524. Of the total amount 64% is related to construction; 24% for equipment; 4% for professional fees, and the remaining 7% is related to applicable taxes. [Source: Amended Application, p28]

If this project is approved, RCGNW anticipates the station would be available by March 2014. Under this timeline, year 2015 would be the facility's first full calendar year of operation with 11 stations and 2017 would be year three. [Source: Amended Application, Face Page & p10]

OPKC

OPKC proposes to establish a new five station dialysis facility in the Mason County Dialysis Planning Area. The facility will be located at 320 NE Roy Boad Road, in the city of Belfair within Mason County. This dialysis center will provide in-center dialysis, home hemodialysis training, back-up dialysis services for home dialysis patients, and visiting or transient hemodialysis.

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

If this project is approved, OPKC anticipates the dialysis center would be available by mid-2014. Under this timeline, year 2015 would be the Center's first full calendar year of operation and 2017 would be year three. [Source: Amended Application, p7]

The capital expenditure associated with this project is \$1,581,490. Of the total capital expenditure 70% is related to construction; 20% for moveable equipment; 4% for professional fees, 4% for sales tax and the remaining 2% is for permits. [Source: Amended Application, p25]

DaVita

DaVita proposes to establish a new five station dialysis facility in the Mason County Dialysis Planning Area. The DaVita Belfair Dialysis Center will be located at 23961 NE State Route 3, Suite B, in the city of Belfair within Mason County. This dialysis center will provide in-center dialysis, peritoneal dialysis training, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station, hemodialysis patients requiring treatment shifts that begin after 5:00 pm, back-up dialysis services for home dialysis patients, and visiting or transient hemodialysis.

If this project is approved, DaVita anticipates the station would be available by January 1, 2014. Under this timeline, year 2014 would be the facility's first full calendar year of operation and 2016 would be year three. [Source: Amended Application, p18]

The capital expenditure associated with this project is \$1,344,100. This amount represents the total capital expenditure of \$1,414,061 minus the landlord's project costs of \$69,961. Of that total amount 65% is related to construction; 25% for moveable equipment; 5% for professional fees and the remaining 5% is related to the landlord's portion of the costs. [Source: Amended Application, p8]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they increase the number of dialysis stations in a kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

EVALUATION CRITERIA

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 CN 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 and 288.⁴

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted these two projects under the year 2012 Kidney Disease Treatment Centers-Concurrent Review Cycle #4.

The purpose of the concurrent review process is to comparatively analyze and evaluate competing or similar projects to determine which of the projects may best meet the identified need. In the case of the projects submitted by RCGNW, OPKC and DaVita, the department will issue one single evaluation regarding whether one, all, or neither of the projects should be issued a CN.

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 246-310-240(3), and WAC 246-310-287, and 289.

APPLICATION CHRONOLOGY

Below is a chronologic summary of the projects.

| Action | RCGNW | OPKC. | DaVita Inc |
|---|---|-------------------|-------------------|
| Letter of Intent Submitted | October 31, 2012 | October 31, 2012 | October 31, 2012 |
| Application Submitted | November 31, 2012 | November 31, 2012 | November 31, 2012 |
| 1st Amendment Application Submitted | January 15, 2013 | January 15, 2013 | January 2, 2013 |
| 2 nd Amendment Application Submitted | None | None | January 15, 2013 |
| Department's pre-review Activities including screening and responses | January 16, 2013 through March 21, 2013 | | |
| Beginning of Review | March 22, 2012 | | |
| End of Public Comment <ul style="list-style-type: none"> • No public hearing conducted • Public comments accepted through end of public comment | May 20, 2013 | | |
| Rebuttal Comments Received | June 20, 2013 | | |
| Department's Anticipated Decision Date | August 5, 2012 | | |
| Department's Actual Decision Date | September 24, 2013 | | |

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.”*

For each application, the other applicant sought and received affected person status under WAC 246-310-010. No other entities sought and received affected person status for any of the three projects

SOURCE INFORMATION REVIEWED

- Renal Care Group Northwest’s Certificate of Need application submitted October 31, 2012
- Olympic Peninsula Kidney Center’s Certificate of Need application submitted October 31, 2012
- DaVita, Inc.’s Certificate of Need application submitted October 31, 2012
- Renal Care Group Northwest’s Amended Certificate of Need application submitted January 15, 2013
- Olympic Peninsula Kidney Center’s Amended Certificate of Need application submitted January 15, 2013
- DaVita, Inc.’s Amended Certificate of Need application submitted January 2, 2013
- DaVita Inc.’s Second Amended Certificate of Need application submitted January 15, 2013
- Renal Care Group Northwest’s supplemental information February 27, 2013
- Olympic Peninsula Kidney Center’s supplemental information submitted February 28, 2013
- DaVita Inc.’s supplemental information submitted February 28, 2013
- Public comment submitted prior to end of public comment period
- Renal Care Group Northwest’s rebuttal submitted June 16, 2013
- Olympic Peninsula Kidney Center’s rebuttal submitted June 19, 2013

- DaVita’s Rebuttal submitted June 20, 2013
- Years 2007 through 2012 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2012 Northwest Renal Network 3rd Quarter Utilization Data
- Licensing and/or survey data provided by the Department of Health’s Investigations and Inspections Office
- Data obtained from Northwest Kidney Center’s webpage (www.nwkidney.org)
- Data obtained from DaVita, Inc.’s webpage
- Data obtained from Medicare webpage (www.medicare.gov)
- Certificate of Need historical files

CONCLUSIONS

RCGNW

For the reasons stated in this evaluation, the application submitted by Renal Care Group Northwest proposing to add five dialysis stations to the Shelton Dialysis Center is not consistent with applicable criteria and a Certificate of Need is denied.

OPKC

For the reasons stated in this evaluation, the application submitted by OPKC proposing to establish a five station dialysis facility in Belfair is not consistent with applicable criteria and a Certificate of Need is denied.

DaVita Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a new five station dialysis facility in Belfair within Mason County is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

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Conditions:

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2. Prior to providing services at the Belfair Dialysis Center, DaVita, Inc. will provide an executed copy of the facility lease consistent with the draft lease provided in the application.
3. Prior to providing services at the DaVita, Inc. will provide an executed copy of the Medical Director Agreement consistent with the draft Medical Director Agreement provided in the application.
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Approved Cost:

The approved capital expenditure associated with this project is \$1,344,100 which represents the total capital expenditure of \$1,414,061, minus the landlord's cost of \$69,961

CRITERIA DETERMINATION

A. Need (WAC 246-310-210)

Based on the source information provided and reviewed, the department concludes:

- RCGNW'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;
- OPKCs 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;
- 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.

(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)]

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 this project, the base year is 2012.

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

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

RCGNW's Application of the Numeric Methodology

RCGNW proposes to add five dialysis stations to the Shelton Dialysis Center. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was applied to project need. Given that the Shelton Dialysis Center is located in Mason County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, p19]

OPKC's Application of the Numeric Methodology

OPKC proposes to establish a five station dialysis facility located in Belfair within Mason County. Based on the calculation of the annual growth rate in the planning area as described above, OPKC used the same linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Amendment Application, p15]

DaVita's Application of the Numeric Methodology

DaVita proposes to establish a 5-station dialysis facility located in Belfair within Mason County. Based on the calculation of the annual growth rate in the planning area as described above, DaVita used the same linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Second Amendment Application, pp18-19]

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 Mason County. The department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

The table below shows a summary of the projected net need provided by the applicants and the department for Mason County. The complete methodology is attached as appendix A.

Table 1
Mason County Numeric Methodology
Summary of Projected Net Station Need

| | 4.8 in-center patients per station | | |
|---------------|---|--|----------------------|
| | 2017 Projected # of stations | Minus Current # of stations | 2017 Net Need |
| RCGNW | 11 | 6 | 5 |
| OPKC | 11 | 6 | 5 |
| DaVita | 11 | 6 | 5 |
| DOH | 11 | 6 | 5 |

The table above demonstrates that the projections of the three applicants match the department's figures. As a result, the net station need for Mason County is five.

Public Comment

Each applicant commented on the low numbers of potential dialysis patients for Mason County and the difficulty that the other applicants might face in achieving their projected dialysis utilization.

Rebuttal

RCGNW argued that their facility is closest to the population center of Mason County. The other two applicants argued their projects would improve access and serve a population area with a growing population. OPKC contends that their Kitsap facilities are already serving the existing dialysis patients and that this facility can relieve pressure on the Kitsap facilities.

Department's Evaluation

The department concludes that the methodology shows a need for 5 new stations in the target year. Each applicant will face different challenges in achieving the potential utilization and no applicant appears to have a clear cut advantage.

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 November 30, 2012. [WAC 246-310-282] The quarterly modality report from NRN available at that time was September 30, 2012. For Mason County there are 6 stations located in the city of Shelton. The table below shows the reported utilization of the stations in Mason County.

Table 2
September 30, 2012 - Facility Utilization Data

| Facility Name | # of Stations | # of Pts | Pts/Station |
|-------------------------------|----------------------|-----------------|--------------------|
| RCGNW Shelton Dialysis Center | 6 | 31 | 5.2 |

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

RCGNW

RCGNW anticipates their new stations would become operational by March 2014, OPKC anticipates their new stations would become operational by Mid-2014, and DaVita anticipates their new stations would become operational by January 1, 2014. Under this timeline, year 2015 would be the first full calendar year of operation for RCGNW and OPKC and 2017 would be the third year of operation. DaVita's first full calendar year of operation would be 2014 and 2016 would be year three. A summary of the three applicants' projected utilization for their respective third year of operation is shown in the table below. [Source: RCGNW Amended Application, p20; OPKC Amended Application, p 17; DaVita Amended Application, p16]

**Table 3
Third Year Projected Facility Utilization**

| Facility Name | # of Stations | # of Pts | Pts/Station |
|--------------------------------|----------------------|-----------------|--------------------|
| RCGNW Shelton Dialysis Center | 11 | 54 | 4.91 |
| OPKC Belfair | 5 | 25 | 5.00 |
| DaVita Belfair Dialysis Center | 5 | 29 | 5.80 |

As shown in the table above, this standard is met for RCGNW, OPKC and DaVita.

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

RCGNW

RCGNW proposes to add five stations to their dialysis center in Shelton within Mason County dialysis planning area. Based on the above standards and criteria, the project is consistent with applicable criteria of the CN Program and **this sub-criterion is met.**

OPKC

OPKC proposes to establish a five station dialysis center in Belfair within Mason County dialysis planning area. Based on the above standards and criteria, the project is consistent with applicable criteria of the CN Program and **this sub-criterion is met.**

DaVita

DaVita proposes to establish a five station dialysis center in Belfair within Mason County dialysis planning area. Based on the above standards and criteria, the project is consistent with applicable criteria of the CN Program and **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.

Both applicants currently provide health care services to residents of Washington State.

RCGNW

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of Mason County planning area would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, RCGNW provided a copy of its current Admission Criteria that would continue to be used at the facility. The Admission Criteria outlines the process/criteria that the Shelton Dialysis Center uses to admit patients for treatment, and ensure that patients will receive appropriate care at the dialysis center. The Admission Criteria also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, religion, sex, national origin, or age. [Source: Amended Application, p21, Exhibit 8 & 9]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. RCGNW currently provides services to Medicare eligible patients in this dialysis center. Details provided in the application demonstrate that RCGNW intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [Source: Application, p8, Exhibit 10]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. RCGNW currently provides services to Medicaid eligible patients in this dialysis center. Details provided in the application demonstrate that NKC intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Application, p8, Exhibit 10]

RCGNW demonstrated its intent to provide charity care to Mason County dialysis planning area residents by submitting the Charity Care policy currently used within the facility. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. RCGNW also included a 'charity' line item as a deduction from revenue within the pro forma income statements for their facility. [Source: Amended Application, pg. 6 & 11, Exhibit 10]

OPKC

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of Mason County dialysis 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. The admission policy must also include language to ensure all residents of the service area would have access to services. This is

accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, OPKC provided a copy of its proposed Admission Criteria that would be used at the facility. The Admission Criteria outlines the process/criteria that OPKC Belfair would use to admit patients for treatment, and ensure that patients will receive appropriate care at the dialysis center. The Admission Criteria also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, religion, sex, national origin, or age. [Source: Amended Application, p18, Exhibit 9]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. OPKC currently provides services to Medicare eligible patients in this dialysis center. Details provided in the application demonstrate that OPKC intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [Source: Application, p4, Exhibit 9]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. OPKC currently provides services to Medicaid eligible patients in their dialysis centers. Details provided in the application demonstrate that OPKC intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Application, p4, Exhibit 9]

OPKC demonstrated its intent to provide charity care to Mason County dialysis planning area residents by submitting the Charity Care policy proposed for use in the facility. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. OPKC also included a 'charity' line item as a deduction from revenue within the pro forma income statements for their facility. [Source: Amended Application, pg. 6 &11, Exhibit 10]

DaVita

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of Mason County dialysis 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. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its proposed Admission Criteria that would be used at the facility. The Admission Criteria outlines the process/criteria that DaVita Belfair Dialysis Center would use to admit patients for treatment, and ensure that patients will receive appropriate care at the dialysis center. The Admission Criteria also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, religion, sex, national origin, or age. [Source: Amended Application, p20, Appendix 14]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. DaVita currently provides services to Medicare eligible patients in their dialysis centers. Details provided in the application demonstrate that DaVita intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [Source: Application, p4, Appendix 14]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. DaVita currently provides services to Medicaid eligible patients in their dialysis centers. 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, p4, Appendix 14]

DaVita demonstrated its intent to provide charity care to Mason County dialysis planning area residents by submitting the Charity Care policy proposed for use in the facility. 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 their facility. [Source: Amended Application, p20, Appendix 14]

RCGNW

The department concludes that all residents of the service area would have adequate access to the health services at the proposed RCGNW's Shelton Facility. **This sub-criterion is met.**

OPKC

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

DaVita

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

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

Based on the source information provided and reviewed, and provided the applicants agree to the conditions stated in the ‘conclusion’ section of this evaluation, the department concludes:

- RCGNW’S project has met the financial feasibility criteria in WAC 246-310-220;
- OPKC’S project has met the financial feasibility criteria in WAC 246-310-220;
- DaVita, Inc.’s project has met the financial feasibility criteria in WAC 246-310-220.

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

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.

RCGNW

RCGNW anticipates the new stations at the Shelton Dialysis Center will become operational by March 2014. Based on this timeline, fiscal year (FY) 2015 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, the table below illustrates the projected revenue, expenses, and net income for FY 2015 through 2017 for the Shelton Dialysis Center. [Source: Amended Application: Exhibit 10]

**Table 4
RCGNW-Shelton Dialysis Center
Projected Revenue and Expenses Calendar Years 2015 - 2017⁷**

| | FY 1 - 2015 | FY 2 - 2016 | FY 3 - 2017 |
|--|--------------------|--------------------|--------------------|
| # of Stations | 11 | 11 | 11 |
| # of Treatments ^[1] | 5,848 | 6,664 | 7,344 |
| # of Patients ^[1] | 43 | 49 | 54 |
| Utilization Rate ^[1] | 3.91 | 4.45 | 4.91 |
| Net Patient Revenue ^[1] | \$3,669,841 | \$4,285,440 | \$4,754,794 |
| Total Operating Expense ^[1,2] | \$2,018,717 | \$2,313,401 | \$2,217,579 |
| Net Profit or (Loss) ^[1] | \$1,651,125 | \$1,972,039 | \$2,217,579 |

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

As shown in the table above, at the projected volumes identified in the application, RCGNW anticipates that the Shelton Dialysis Center would be operating at a profit in each of the forecast years.

RCGNW currently operates the facility at 1872 North 13th Loop Road in the city of Shelton. The lease provided in the application outlines the initial terms and the annual rent for the space. The annual lease costs are substantiated in the pro forma financial documents presented. [Source: Amended Application, Exhibit 10 pA12 & Supplement 2]

⁷ Whole numbers may not add due to rounding.

Additionally, RCGNW provided a copy of the Medical Director Agreement and current compensation between itself and Michael Mondress, MD. The medical director service costs are also substantiated in the proforma revenue and expense statements.

OPKC

OPKC anticipates the new stations at OPKC Belfair will become operational by Mid-2014. Based on this timeline, fiscal year (FY) 2015 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, the table below illustrates the projected revenue, expenses, and net income for FY 2015 through 2017 for OPKC Belfair. [Source: Amended Application: Exhibit 10]

**Table 5
OPKC Belfair
Projected Revenue and Expenses Calendar Years 2015 - 2017⁸**

| | FY 1 - 2015 | FY 2 - 2016 | FY 3 - 2017 |
|--|--------------------|--------------------|--------------------|
| # of Stations | 5 | 5 | 5 |
| # of Treatments ^[1] | 2,496 | 3,276 | 3,900 |
| # of Patients ^[1] | 16 | 21 | 25 |
| Utilization Rate ^[1] | 3.2 | 4.2 | 5.0 |
| Net Patient Revenue ^[1] | \$911,041 | \$1,195,740 | \$1,423,499 |
| Total Operating Expense ^[1,2] | \$1,069,949 | \$1,235,834 | \$1,378,331 |
| Net Profit or (Loss) ^[1] | (\$158,908) | (\$40,094) | \$45,168 |

[1] Includes in-center patients only; [2] includes bad debt, charity care

As shown in the table above, at the projected volumes identified in the application, OPKC anticipates that the OPKC Belfair Dialysis Center would be operating at a profit by the third year of operation. The total expenses are only direct facility expenses and do not include a contribution to overhead.

The proposed OPKC Belfair will be located at 320 NE Roy Boad Road, in the city of Belfair within Mason County. The draft lease provided in the application outlines the initial terms and the annual rent for the space. The annual lease costs are substantiated in the pro forma financial documents presented. [Source: Amended Application, Exhibit 7 &10]

Additionally, OPKC provided a copy of the draft Medical Director Agreement and proposed compensation between itself and, Fred Albrecht, MD. The medical director service costs are also substantiated in the proforma revenue and expense statements.

DaVita

DaVita anticipates the new stations at DaVita Belfair will become operational by January1, 2014. Based on this timeline, fiscal year (FY) 2014 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, the table below illustrates the projected revenue, expenses, and net income for FY 2014 through 2016 for DaVita Belfair. [Source: Amended Application: P12 & Appendix 9]

⁸ Whole numbers may not add due to rounding.

Table 6
DaVita’s Belfair Dialysis Center5
Projected Revenue and Expenses Calendar Year 2015-2017

| | F Y1-2014 | FY2-2015 | FY3-2016 |
|---|------------------|--------------------|-----------------|
| # of Stations | 5 | 5 | 5 |
| # of Treatments ^[1] | 1,112 | 2,742 | 3,779 |
| # of Patients ^[1] | 15 | 22 | 29 |
| Utilization Rate ^[1] | 3.0 | 4.4 | 5.8 |
| Net Patient Revenue ^[1] | \$566,865 | \$1,413,383 | \$1,965,888 |
| Total Operating Expense ^[1,2] | 1,636,491 | \$1,634,990 | \$1,942,758 |
| Net Profit or (Loss) ^[1] | (557,865) | (\$222,108) | \$23,130 |

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

As shown in the table above, at the projected volumes identified in the application, DaVita anticipates that the DaVita Dialysis Center will be operating at a profit in full year three.

The proposed DaVita Belfair Dialysis Center will be located at 23961 NE State Route 3, Suite B in the city of Belfair, within Mason County. The draft lease agreement provided in the application outlines the terms and the annual rent for the space through year 2018. The annual lease costs are substantiated in the pro forma financial documents and the supporting least cost worksheet in appendix 9. [Source: Amended Application, Appendix 9 & 15]

Additionally, DaVita provided a copy of the Medical Director Agreement between itself and Pacific Nephrology Group. The medical director service costs are also substantiated pro forma documents. [Source: Amended Application, Appendix 3 & 9]

Public Comment

Site control for both of the new applicants was questioned in the public comment. DaVita also questioned whether OPKC had a contractor or the ability to have a facility constructed based on their interpretation of language in the draft lease agreement.

Rebuttal

OPKC provided documentation from their landlord and contractor (who is part owner of the property) confirming the ownership and ability to construct a dialysis facility for OPKC on this property. DaVita provided documentation confirming their site control on the property for their project.

Department Evaluation

Both applicants submitted similar documentation on the properties proposed for their projects. The department realizes that there are business reasons for limited disclosure of property transactions, but also notes that it is the applicant’s responsibility to submit clear, concise and complete documentation of property transactions for these projects. The department concludes with the rebuttal information submitted both applicants have confirmed site control and clarified concerns about OPKC’s agreement for facility construction.

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

RCGNW

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

OPKC

Based on the above information, the department concludes that OPKC’s projected revenues and expenses are reasonable and can be substantiated. If this project is approved, the department would include a condition requiring OPKC to provide a copy of the executed lease agreement and a copy of the executed Medical Director agreement. **This sub-criterion is met.**

DaVita

Based on the above information, the department concludes that DaVita’s projected revenues and expenses are reasonable and can be substantiated. If this project is approved, the department would include a condition requiring OPKC to provide a copy of the executed lease agreement and a copy of the executed Medical Director agreement. **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.

RCGNW

The capital expenditure associated with the expansion of the Shelton Dialysis Center is \$514,624 of which 64% is related to space construction; 24% for additional equipment; 7% is related to architect and engineering fees, and 4% related to sales tax. The capital cost breakdown is shown in the table below. [Source: Amended Application, p5]

**Table 7
Estimated Capitals Costs of RCGNW Shelton Dialysis Center Expansion**

| Item | Cost | % of Total |
|--------------------------------------|------------------|-------------------|
| Space Construction | \$ 330,000 | 64% |
| Fixed Equipment | \$126,000 | 24% |
| Architect & Engineering Fees | \$ 22,500 | 4% |
| Sales Tax | \$36,024 | 7% |
| Total Estimated Capital Costs | \$514,624 | 100% |

RCGNW intends to finance the project entirely from existing reserves from RCGNW’s parent company Fresenius. A review of the financial statement provided in the application indicates that Fresenius had sufficient cash assets in both 2010 and 2011 to fund the project. [Source: Amended Application, Appendix 3]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare End Stage Renal Disease (ESRD) entitlements. To further demonstrate compliance with this sub-criterion, RCGNW also provided the sources of patient revenue shown in the table on the next page. [Source: Amended Application, p11]

Table 8
RCGNW-Shelton Dialysis Center
Sources and Percentages of Revenue

| Source of Revenue | % of Revenue |
|-------------------|--------------|
| Medicare | 80.60% |
| Medicaid | 6.56% |
| Commercial | 9.56% |
| Other | 3.28% |
| Total | 100% |

As shown above, the Medicare and State entitlements are projected to equal 87.16% of the revenue at the Shelton Dialysis Center. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS has recently implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate.

However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Given the department understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by RCGNW may not have an unreasonable impact on charges for services within the planning area. Based on the review of the application materials, the department concludes **this sub-criterion is met.**

OPKC

The capital expenditure associated with the establishment of the OPKC Belfair Dialysis Center is

Table 9
Estimated Capitals Costs of OPKC Belfair Dialysis Center

| Item | Cost | % of Total |
|--------------------------------------|--------------------|-------------|
| Construction | \$1,114,000 | 70% |
| Movable and Fixed Equipment | \$311,450 | 20% |
| A & E Fees | \$68,640 | 4% |
| Sales Tax | \$62,400 | 4% |
| Permits | 25,000 | 2% |
| Total Estimated Capital Costs | \$1,581,490 | 100% |

OPKC intends to finance the project entirely from existing reserves. OPKC provided a letter of funding commitment in the supplemental materials submitted in February 2013. A review of the financial statement provided in the application indicates that OPKC had sufficient cash assets in both 2010 and 2011 to fund the project. [Source: Amended Application, Appendix 2, Supplemental Materials, Attachment 3]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, OPKC also provided the sources of patient revenue shown in the table below. [Source: Amended Application, p27]

Table 10
OPKC Belfair
Sources and Percentages of Revenue

| Source of Revenue | % of Revenue |
|-------------------|--------------|
| Medicare | 74.1% |
| Medicaid | 2.3% |
| Other | 22.6 |
| Total | 100% |

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS has recently implemented an ESRD PPS. Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate.

However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Given the department understanding of how dialysis patients may quality for Medicare payments, the department concludes that the information presented by DaVita may not have an unreasonable impact on charges for services within the planning area. Based on the review of the application materials, the department concludes **this sub-criterion is met.**

DaVita

The total capital expenditure associated with the expansion of the DaVita Belfair Dialysis Center is \$1,414,061. Of that amount 65% is related to leasehold improvements, 25% for fixed/movable equipment, 5% is related to professional fees, and the remaining 5% is the Landlord’s portion of the project costs. The capital cost breakdown is shown in the table below. [Source: Amended Application, p9]

Table 11
Estimated Capitals Costs of DaVita Belfair Dialysis Center

| Item | Cost | % of Total |
|--------------------------------------|--------------------|-------------|
| Leasehold Improvements | \$915,000 | 65% |
| Movable and Fixed Equipment | \$355,100 | 25% |
| Professional Fees | \$74,000 | 5% |
| Landlord Project Costs | \$69,961 | 5% |
| Total Estimated Capital Costs | \$1,414,061 | 100% |

DaVita intends to finance the project entirely from the DaVita capital expenditures budget. A review of the financial statement provided in the application indicates that DaVita had sufficient cash assets in both 2010 and 2011 to fund the project. [Source: Amended Application, Appendix 10]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in the table below. [Source: Amended Application, p10]

Table 12
DaVita “Company Wide”
Sources and Percentages of Revenue

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

As shown above, the Medicare and State entitlements are projected to equal 70% of the revenue at the DaVita Belfair facility. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS has recently implemented an ESRD PPS. Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate.

However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Given the department understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by DaVita may not have an unreasonable impact on charges for services within the planning area. Based on the review of the application materials, the department concludes **this sub-criterion is met.**

RCGNW

Based on the above information, the department concludes 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.**

OPKC

Based on the above information, the department concludes 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

Based on the above information, the department concludes 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.

RCGNW

As previously stated, the capital expenditure associated with the expansion of RCGNW's Mason County facility is \$514,524. RCGNW states that the project will be financed through RCGNW's parent company, Fresenius. A review of Fresenius's statements of financial position show the funds necessary to finance the project are available. [Source: Amended Application, p11 & Appendix 3]

OPKC

As previously stated, the capital expenditure associated with the establishment of OPKC's Belfair Dialysis Center is \$1,581,490. OPKC states that the project will be funded with internal reserves. A review of OPKC's statements of financial position show the funds necessary to finance the project are available. [Source: Amended Application: p26 & Appendix 2]

DaVita

As previously stated, the capital expenditure associated with the expansion of DaVita's Belfair Dialysis Center is \$1,414,061. DaVita states that the project will be funded from DaVita's capital expenditures budget. A review of DaVita's statements of financial position show the funds necessary to finance the project are available. [Source: Amended Application, p22 & Appendix 10]

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

RCGNW

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of RCGNW as a whole. **This sub-criterion is met.**

OPKC

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of RCGNW as a whole. **This sub-criterion is met.**

DaVita

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 provided and reviewed, the department concludes:

- RCGNW’s project has met the structure and process of care criteria in WAC 246-310-230
- OPKC’s project has not met the structure and process of care criteria in WAC 246-310-230
- DaVita, Inc.’s project has met the structure and process of care criteria in WAC 246-310-230.

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

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.

RCGNW

RCGNW’s Shelton Dialysis Center has been operational for many years. To accommodate the additional patients associated with the additional station, RCGNW intends to add 2.80 FTEs by the end of 2017. A breakdown of the proposed FTEs is shown in the table below. [Source: Amended Application p31]

**Table 13
RCGNW Shelton Dialysis Center 2014 – 2016 Projected Total FTEs**

| Staff/FTEs | Current | 2014 Increase | 2015 Increase | 2016 Increase | 2017 Increase | Total FTEs |
|------------------------------|----------------|----------------------|----------------------|----------------------|----------------------|-------------------|
| Nurse Manager | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 | 1.00 |
| RNs | 2.00 | 0.50 | 0.00 | 0.00 | 0.50 | 3.00 |
| Patient Care Tech | 4.00 | 0.00 | 0.00 | 0.00 | 1.00 | 5.00 |
| Equipment Tech. ⁹ | 0.30 | 0.00 | 0.00 | 0.00 | 0.00 | 0.30 |
| Social Worker | 0.25 | 0.00 | 0.05 | 0.00 | 0.20 | 0.50 |
| Dietitian | 0.20 | 0.00 | 0.10 | 0.00 | 0.20 | 0.50 |
| Secretary | 0.00 | 0.00 | 0.00 | 0.25 | 0.00 | 0.25 |
| Total FTE’s | 7.75 | 0.50 | 0.15 | 0.25 | 1.90 | 10.55 |

As shown above, RCGNW expects a minimal increase 2.8 FTEs over a four year period of time. RCGNW states that it expects no difficulty in recruiting staff for the Shelton facility. Several of the positions will be an increase in hours, not an addition of staff. RCGNW also has a comprehensive documented staff training program that will facilitate filling any staffing needs. [Source: Amended Application, p32]

OPKC

OPKC does not anticipate any difficulty in recruiting staff for the new Belfair Dialysis Center. OPKC offers a competitive wage and benefit package, a positive and supportive work environment, and a philosophy that encourages existing staff to receive training and additional education. For each of these reasons, OPKC has historically not experienced any difficulty recruiting and retaining qualified staff. Specific to OPKC Belfair, OPKC has already had existing

⁹ Includes BioMed

staff express an interest in working at the Belfair facility. A breakdown of the proposed FTEs is shown in the table below. [Source: Amended Application p]

**Table 14
OPKC Belfair Dialysis Center 2014 -2016 Total Projected FTEs**

| Staff/FTEs | 2014 | 2015 Increase | 2016 Increase | 2017 Increase | Total FTEs |
|--------------------|-------------|--------------------------|--------------------------|--------------------------|-----------------------|
| Manager | 0.50 | 0.50 | 0.00 | 0.00 | 1.00 |
| RN | 0.50 | 0.50 | 1.00 | 0.00 | 2.00 |
| Patient Care Tech | 0.50 | 0.50 | 1.00 | 0.00 | 2.00 |
| Admin Assistant | 0.25 | 0.75 | 0.00 | 0.00 | 1.00 |
| Social Worker | 0.10 | 0.05 | 0.05 | 0.00 | 0.20 |
| Dietician | 0.10 | 0.05 | 0.05 | 0.00 | 0.20 |
| Bio Med. Tech. | 0.10 | 0.05 | 0.05 | 0.00 | 0.20 |
| Total FTE's | 2.05 | 2.40 | 2.15 | 0.00 | 6.60 |

As shown in the table above, OPKC intends to start with 2.05 FTEs in 2014 add 2.4 FTEs in 2015, and add 2.15 FTEs in 2016. This will result in a total staff of 6.6 FTEs.

DaVita

DaVita does not anticipate any difficulty in recruiting staff for the new Belfair Dialysis Center. DaVita offers a competitive wage and benefit package to employees and advertises both locally and nation ally. Specific to the DaVita Belfair Dialysis Center, DaVita claims it is located in a desirable geographical location and its Proximity to an urban area will support recruitment. A breakdown of the proposed FTEs is shown in the table below. [Source: Amended Application, p23 & 24]

**Table 15
DaVita Kent Dialysis Center 2014 – 2017 Projected FTEs**

| Staff/FTEs | Year 1 FTE | Year 2 Increase | Year 3 Increase | Year 4 Increase | Total FTEs |
|--------------------------|--------------------------------|----------------------------|----------------------------|----------------------------|-----------------------|
| Medical Director | Professional Services Contract | | | | |
| Administrator | 1.00 | 0.0 | 0.00 | 0.00 | 1.00 |
| RN | 2.10 | 0.80 | 0.20 | 0.40 | 3.50 |
| Patient Care Techs | 1.60 | 0.80 | 0.20 | 0.40 | 3.00 |
| Biomedical Techs | 0.20 | 0.00 | 0.00 | 0.00 | 0.20 |
| Administrative Assistant | 0.50 | 0.30 | 0.20 | 0.00 | 1.00 |
| Social Worker | 0.50 | 0.00 | 0.00 | 0.00 | 0.50 |
| Dietitian | 0.50 | 0.00 | 0.00 | 0.00 | 0.50 |
| Total FTE's | 6.40 | 1.90 | 0.60 | 0.80 | 9.70 |

As shown in the table above, DaVita intends to start with 6.40 FTEs in Year 1 add 1.9 FTEs in Year 2, add 0.6 FTEs in Year 3 and add 0.80 FTEs in Year 4. This will result in a total staff of 9.7 FTEs.

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

RCGNW

Based on the information reviewed, the department concludes adequate staffing for the five station increase for the Shelton Dialysis Center is available or can be recruited. **This sub criterion is met.**

OPKC

Based on the information reviewed, the department concludes adequate staffing for the new five station Belfair Dialysis Center is available or can be recruited. **This sub criterion is met.**

DaVita

Based on the information reviewed, the department concludes adequate staffing for the new five station Belfair Dialysis Center 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 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.

RCGNW

The information provided in the application confirms that RCGNW maintains the appropriate relationships with ancillary and support services for this facility. RCGNW provided a list of existing providers in service area they currently work with. The Shelton Dialysis Center Currently has a transfer agreement with Providence St. Peter Hospital. A copy of the existing transfer agreement was included in the amended application. [Source: Amended Application, p33 & Exhibit 12]

OPKC

As a provider of dialysis services in Washington State, OPKC currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers.

DaVita

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 Belfair 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 will be 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: Amended Application, p24] DaVita provided a template of their proposed agreements, therefore if approved prior to providing services; DaVita will need to submit a final transfer agreement with a local hospital.

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

RCGNW

Based on this information, the department concludes RCGNW currently has appropriate relationships with ancillary and support services and would continue to have appropriate relationships if this project is approved. **This sub-criterion is met.**

OPKC

Based on this information, the department concludes OPKC will have the appropriate relationships with ancillary and support services if the project is approved. **This sub-criterion is met.**

DaVita

Based on this information, the department concludes DaVita will have the appropriate relationships with ancillary and support services provided that the department is provided a final transfer agreement with a local hospital if the project is approved. **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 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.

RCGNW

RCGNW is currently a provider of dialysis services within Washington State, and operates 16 kidney dialysis treatment centers in six 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 and in conformance with applicable state licensing requirements and or Medicare/Medicaid certification.¹⁰

The department reviewed information available to the public at Medicare.gov “dialysis facility compare” website to verify the number of Medicare certified stations, services offered at the location such as types of home training and shifts starting after 5 pm at this RCGNW facility. RCGNW Shelton Dialysis Center is certified for 6 dialysis stations (CN approved for 6), does not have shifts starting after 5 pm, and is not providing in-center, peritoneal dialysis, and home hemodialysis training. The RCGNW Shelton Dialysis Center is consistent with the CN approvals and records. Therefore the Department concludes that there is reasonable assurance the RCGNW Shelton Dialysis Center will operate in compliance with be operated in conformance with all state and federal rules and regulations.

For Washington State, since January 2008, the Department of Health’s Investigations and Inspections Office has completed 20 compliance surveys for the operational facilities that RCGNW either owns or manages. Of the compliance surveys completed, all revealed minor non-compliance issues. These non-compliance issues were typical of a dialysis facility and RCGNW submitted and implemented acceptable plans of correction. [Source: facility survey data provided by the Investigations and Inspections Office]

¹⁰ WAC 246-310-230(5).

For medical director services, RCGNW provided a copy of the Medical Director Agreement and compensation amendment currently in effect between itself and Richard Mondress, M.D. at the Shelton Dialysis Center. A review of the compliance history for Dr. Richard Mondress revealed no recorded sanctions. [Source: Amended Application, p 7]

OPKC

As stated earlier, OPKC is currently a provider of dialysis services within Washington State. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public and in conformance with applicable state licensing requirements and or Medicare/Medicaid certification.¹¹

Since January 2010, the department of Health's Office of Investigations and Inspections has completed four compliance surveys for OPKC 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 OPKC submitted and implemented acceptable plans of correction. [Source: Compliance history provided by IIO facility files]

In reviewing the application, the department noted that OPKC is purchasing equipment for 7 dialysis stations even though the application is for 5 CN approved/ Medicare certified dialysis stations' Under the OPKC Belfair Capital Equipment table, OPKC states that "*NOTE: CoN request for five stations, will also need an isolation station and a home training station. CAN ONLY USE FIVE STATIONS AT ANY ONE TIME.*" [Source: Application: p62] The department concludes that the applicant is proposing to seek Medicare Certification for 7 stations, since all stations must be Medicare Certified before using. The department further concludes that this would put OPKC in violation of state law since only CN approved dialysis stations in a facility, in this case 5 dialysis stations, can be Medicare Certified. Medicare regulations require the individual dialysis stations of a facility, in states with a CN program, to be CN approved before Medicare Certification. Certification of more stations in a Washington State dialysis facility than are CN approved is considered a violation of state and federal law. The department concludes that OPKC is proposing to request Medicare Certification for 7 dialysis stations in their proposed Belfair Dialysis Facility.

The department recently approved a 4 station dialysis facility in Kitsap County for OPKC with a specific condition on the approval that no more than 4 stations could be Medicare certified. The department's Medicare survey staff recently received a request to allow OPKC to operate 5 dialysis stations in this Kitsap County facility. [Source: Email dated July 15, 2013] Since each dialysis station has to be Medicare Certified, the department concludes OPKC was requesting to have 5 Medicare Certified dialysis stations even though only 4 stations were CN approved. The department also specifically provided a condition that all OPKC dialysis facilities would not operate with more dialysis stations than CN approved for a facility.

Therefore, based on the information about OPKC in the records reviewed, the department concludes there is not reasonable assurance that the OPKC Belfair Dialysis Center will be operated in conformance with all state and federal rules and regulations.

¹¹ WAC 246-310-230(5).

For medical director services, OPKC provided a copy of its draft contract with Fred Albrecht, MD. The term of the contract is two years, with annual automatic renewals. It outlines the roles and responsibilities of both Dr. Albrecht and OPKC, and identifies compensation for medical director services. A review of the compliance history for Dr. Albrecht revealed no recorded sanctions. [Source: Application, Exhibit 2]

DaVita

DaVita, Inc. is a provider of dialysis services in over 1,912 outpatient centers located in 43 states (including Washington State), the District of Columbia. [Source: DaVita website at www.davita.com] Currently within Washington State, DaVita owns and 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 and in conformance with applicable state licensing requirements and or Medicare/Medicaid certification.¹²

To accomplish this task, in February 2010 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the each of the states, the District of Columbia, and San Juan Puerto Rico, where DaVita, Inc. or any subsidiaries have health care facilities. The department received responses from 21 states or 47% of the 45 entities.¹³ The compliance history of the remaining 24 states, the District of Columbia, and San Juan Puerto Rico is unknown.¹⁴

Ten of the 24 states responding to the survey indicated that minor 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, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported to have no deficiencies and are currently in compliance with applicable regulations. 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.

The department concludes that considering the more than 1,912 facilities owned/managed by DaVita, one out-of-state facility listed above demonstrated substantial non-compliance issues; therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2009, the Department of Health's Office of Investigations and Inspections has completed more than 27 compliance surveys for the operational facilities that DaVita either owns or manages.¹⁵ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-

¹² WAC 246-310-230(5).

¹³ States that provided responses are: Arizona, California, Colorado, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, Washington, and Wisconsin. San Juan Puerto Rico also provided a response.

¹⁴ States that did not provide responses are: Alabama, Arkansas, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maine, New Mexico, New Jersey, New York, North Carolina, Ohio, South Carolina, South Dakota, Tennessee, and West Virginia. The District of Columbia also did not respond to the survey.

¹⁵ As of the writing of this evaluation, five facilities—East Wenatchee Dialysis Center, Battle Ground Dialysis Center, Whidbey Dialysis Center, Everett Dialysis Center, and Kennewick Dialysis Center—were recently approved by the department and are not yet operational. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita.

compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [Source: Facility survey data provided by the Investigations and Inspections Office]

For medical director services, DaVita provided a copy of its executed contract with Dimitri Vasin, MD. The initial term of the contract is four years, with annual automatic renewals. It outlines the roles and responsibilities of both Dr. Vasin and DaVita, and identifies compensation for medical director services. A review of the compliance history for Dr. Vasin revealed no recorded sanctions. [Source: Application, p 7 & Appendix 3]

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

RCGNW

Based on the source information reviewed, the department concludes **this sub-criterion is met.**

OPKC

Based on the source information reviewed, the department concludes **this sub-criterion is not met.**

DaVita

Based on the source information reviewed, the department concludes **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.

RCGNW

The department considered RCGNW'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 five dialysis stations in Mason County dialysis planning area. This project proposes to add 5 dialysis stations to the Shelton Dialysis Center.

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

OPKC

The department considered OPKC's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Source: Amended Application Page 30; CN historical files]

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for five dialysis stations in Mason County dialysis planning area. This project proposes to establish a five station Dialysis Center in Belfair.

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

Based on the information, the department concludes that approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **This sub-criterion is met.**

DaVita

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 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 five dialysis stations in Mason County dialysis planning area. This project proposes to establish a five station Dialysis Center in Belfair.

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

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

RCGNW

RCGNW demonstrated that it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. **This sub-criterion is met.**

OPKC

OPKC demonstrated that it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. **This sub-criterion is met.**

DaVita

DaVita demonstrated that it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. **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.*

RCGNW

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

OPKC

This sub-criterion is addressed in sub-section (3) above. **This sub-criterion is not met.**

DaVita

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 provided and reviewed, the department concludes:

- RCGNW's project has met the cost containment criteria in WAC 246-310-240(1) and (2);
- OPKC's proposed project failed to meet the review criteria under WAC 246-310-230;
- DaVita, Inc.'s project has met the cost containment criteria in WAC 246-310-240.

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

OPKC

OPKC's proposed project failed to meet the review criteria under WAC 246-310-230. Since OPKC failed 2 sub-criteria under the quality of care and the department determined that the proposal would not meet the compliance with rules and regulations, the OPKC proposal does not advance to step two of 246-310-240. Therefore the department concludes **this sub-criterion is not met.**

RCGNW and DaVita

RCGNW and DaVita's 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

RCGNW

Within the application, RCGNW identified one alternative before submitting this application. A summary of each and RCGNW's rationale for rejection is below. [Source: Application, p22-26]

Alternative 1-Construction of a new dialysis facility

A new dialysis facility will be more costly than expansion, will not be available as soon as an expansion project, will require more personnel than expansion, and will not necessarily improve accessibility to dialysis services.

DaVita

Within the application, DaVita identified two alternatives before submitting this application. A summary of each and DaVita's rationale for rejection is below. [Source: Application, p26-27]

Alternative 1-Add no new facility in the Belfair area within the Mason County Planning Area

DaVita determined that there is sufficient interest by other providers and the community to indicate that the establishment of a new facility in Belfair would be reasonable for them to consider. The department's methodology indicates a need for 5 stations in Mason County. The project chosen by DaVita is to establish a new 5 station dialysis facility in Belfair within Mason County. The methodology indicates a new dialysis stations are needed in Mason County. Da Vita states that a new 5 station facility will improve patient access as well as provider choice. DaVita has facilities in adjacent counties to provide support services and administrative support.

Step Three

WAC246-310-288 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 these 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 criterion in this subsection.

(a) Training services (1 point):

- (i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or*
- (ii) The applicant is an existing provider in the planning area that offers training services in any of its existing facilities within thirty-five miles of the proposed new facility and either intends to offer training services at the new facility or through those existing facilities; or*
- (iii) The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and*
- (iv) Northwest Renal Network's most recent year-end facility survey must document the provision of these training services by the applicant.*

- (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.*

RCGNW

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

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

| WAC 246-310-288(1) | Point | Source |
|---|--------------|--------------------------|
| <i>(a) Training services</i> | 0 | Application, p24 |
| <i>(b) Private room(s) for isolating patients</i> | 1 | Application, p7 |
| <i>(c) Permanent bed stations at the facility</i> | 1 | Application, p7 |
| <i>(d) Evening shift</i> | 1 | Application, p7 |
| <i>(e) Meeting the projected need</i> | 1 | Application, Appendix 19 |
| Total Points | 4 | |

The department was not able to verify from Medicare Compare that RCGNW was providing home hemodialysis training at the Shelton dialysis facility or at the Lacey dialysis facility as reported in their application.

DaVita

A total of five points is possible. The table below 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 |
|---|--------------|----------------------|
| <i>(a) Training services</i> | 0 | Application, p9 |
| <i>(b) Private room(s) for isolating patients</i> | 1 | Application, p9 |
| <i>(c) Permanent bed stations at the facility</i> | 1 | Application, p9 |
| <i>(d) Evening shift</i> | 1 | Application, p9 |
| <i>(e) Meeting the projected need</i> | 1 | Application, p1 & 18 |
| Total Points | 4 | |

Under WAC 246-310-288(1) where each applicant could receive a maximum of 5 points, RCGNW, OPKC and DaVita all received the four (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 tables below shows the distribution of tie-breaker points under this sub-criterion for RCGNW, OPKC, and DaVita.

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

| WAC 246-310-288(2) | Point | Source |
|--|--------------|--|
| <i>(a) Economies of Scale</i> | 1 | [\$102,905/station Application, Face Page] |
| <i>(b) Historical Provider</i> | 0 | Application, p 25 |
| <i>(c) Patient Geographical Access</i> | 0 | Application, p 26 |
| <i>(d) Provider Choice</i> | 0 | Application, p 26 |
| Total Points | 1 | |

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

| WAC 246-310-288(2) | Point | Source |
|-------------------------------|--------------|--|
| <i>(a) Economies of Scale</i> | 0 | [\$282,812/station, Application, p1 & 8] |

| | | |
|--|----------|----------------------------|
| <i>(b) Historical Provider</i> | 0 | Application, N/A |
| <i>(c) Patient Geographical Access</i> | 1 | Application, pp. 1, 4, & 8 |
| <i>(d) Provider Choice</i> | 1 | Application, p 1 |
| Total Points | 2 | |

The table below shows the total accumulation of tie-breaker points for RCGNW, OPKC, and DaVita.

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

| | Tie-Breaker Point Distribution | |
|---------------------------------|--------------------------------|----------|
| | RCGNW | DaVita |
| 1(a) – <i>Training services</i> | 0 | 0 |
| 1(b) – Private Room | 1 | 1 |
| 1(c) – Permanent Bed Station | 1 | 1 |
| 1(d) – <i>Evening Shift</i> | 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 | 1 |
| 2(d) – Provider Choice | 0 | 1 |
| Cumulative Total | 5 | 6 |

At the completion of the tie-breaker point allocations, RCGNW accumulated a total of five (5) points and DaVita accumulated a total of six (6) points. Due to the results outlined in this section, the department concludes that DaVita’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 DaVita project accounts for all 5 of the stations projected for the planning area, there are no stations remaining to award to RCGNW as the application earning the next highest point total.

RCGNW

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

DaVita

Based on the results of the tie-breaker criteria above, DaVita’s project does meet this sub-criterion. **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.

DaVita

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.*

DaVita

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**

APPENDIX A



**2013
Mason County
ESRD Need Projection Methodology**

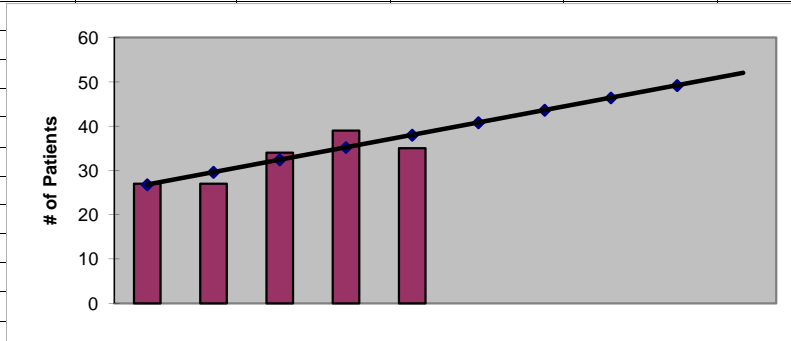
| Planning Area | | 6 Year Utilization Data - Resident Incenter Patients | | | | | |
|---|--|--|-----------|-----------|-----------|----------------|---------|
| Mason | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | |
| Mason County | 24 | 27 | 27 | 34 | 39 | 35 | |
| TOTALS | 24 | 27 | 27 | 34 | 39 | 35 | |
| 246-310-284(4)(a) | Rate of Change | | 12.50% | 0.00% | 25.93% | 14.71% | -10.26% |
| | 6% Growth or Greater? | | TRUE | FALSE | TRUE | TRUE | FALSE |
| | Regression Method: | Linear | | | | | |
| 246-310-284(4)(c) | | | Year 1 | Year 2 | Year 3 | Year 4 | |
| | | | 2013 | 2014 | 2015 | 2016 | |
| Projected Resident Incenter Patients | from 246-310-284(4)(b) | | 40.80 | 43.60 | 46.40 | 49.20 | |
| Station Need for Patients | Divide Resident Incenter Patients by 4.8 | | 8.5000 | 9.0833 | 9.6667 | 10.2500 | |
| | Rounded to next whole number | | 9 | 10 | 10 | 11 | |
| 246-310-284(4)(d) | subtract (4)(c) from approved stations | | | | | | |
| Existing CN Approved Stations | | | 6 | 6 | 6 | 6 | |
| Results of (4)(c) above | | | - 9 | 10 | 10 | 11 | |
| Net Station Need | | | -3 | -4 | -4 | -5 | |
| Negative number indicates need for stations | | | | | | | |
| Planning Area Facilities | | | | | | | |
| Name of Center | # of Stations | | | | | | |
| FMC Shelton | 6 | | | | | | |
| Total | 6 | | | | | | |
| Source: Northwest Renal Network data 2007-2012 | | | | | | | |
| Most recent year-end data: 2012 posted 02/11/2013 | | | | | | | |

**2013
Mason County
ESRD Need Projection Methodology**

| x | y | Linear |
|------|----|--------|
| 2008 | 27 | 27 |
| 2009 | 27 | 30 |
| 2010 | 34 | 32 |
| 2011 | 39 | 35 |
| 2012 | 35 | 38 |
| 2013 | | 40.800 |
| 2014 | | 43.600 |
| 2015 | | 46.400 |
| 2016 | | 49.200 |

SUMMARY OUTPUT

| <i>Regression Statistics</i> | |
|------------------------------|-------------|
| Multiple R | 0.839664201 |
| R Square | 0.705035971 |
| Adjusted R Square | 0.606714628 |
| Standard Error | 3.306559138 |
| Observations | 5 |



| ANOVA | | | | | | | |
|--------------|----|-------|-------------|-------------|----------------|--|--|
| | df | SS | MS | F | Significance F | | |
| Regression | 1 | 78.4 | 78.4 | 7.170731707 | 0.075188044 | | |
| Residual | 3 | 32.8 | 10.93333333 | | | | |
| Total | 4 | 111.2 | | | | | |

| | Coefficients | Standard Error | t Stat | P-value | Lower 95% | Upper 95% | Lower 95.0% | Upper 95.0% |
|--------------|--------------|----------------|--------------|-------------|--------------|-------------|--------------|-------------|
| Intercept | -5595.6 | 2101.708397 | -2.662405502 | 0.076182103 | -12284.17412 | 1092.974122 | -12284.17412 | 1092.974122 |
| X Variable 1 | 2.8 | 1.045625809 | 2.677822195 | 0.075188044 | -0.527647993 | 6.127647993 | -0.527647993 | 6.127647993 |

RESIDUAL OUTPUT

| Observation | Predicted Y | Residuals |
|-------------|-------------|-----------|
| 1 | 23.8 | 2.2 |
| 2 | 25.7 | -1.7 |
| 3 | 27.6 | -0.6 |
| 4 | 29.5 | -2.5 |
| 5 | 31.4 | 2.6 |