



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH

August 22, 2013

CERTIFIED MAIL # 7011 1570 0002 7810 2693

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

CN: 12-39

Dear Mr. Bosh:

We have completed review of the Certificate of Need application submitted by Refuge Dialysis, LLC proposing to establish an 8 station facility in Marysville. For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided Refuge Dialysis LLC agrees to the following in its entirety.

**Project Description:**

This certificate approves the establishment of a 8-station dialysis center in Marysville within Snohomish County planning area #2. At project completion, the dialysis center will be approved to certify and operate eight dialysis stations. The dialysis facility will offer at least home peritoneal dialysis and hemodialysis dialysis. Services to be provided at the facility include in-center hemodialysis and peritoneal dialysis with treatments shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. A breakdown of all eight stations is below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
<b>Total</b>	<b>8</b>

After the 8-stations are relocated from the 21-station Everett Dialysis Center, the dialysis center would have 13-stations remaining. A breakdown of the remaining 13-stations is shown below.



**Everett Dialysis Center**

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	11
<b>Total</b>	<b>13</b>

**Conditions:**

1. Refuge Dialysis, LLC agrees with the project description as stated above. Refuge Dialysis, LLC 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. Refuge Dialysis, LLC must decertify 8-stations from the 21-station Everett Dialysis Center no later than 30 days following the opening of the new 8-station dialysis center. At project completion, 13 dialysis stations would remain in operation at Everett Dialysis Center
3. Prior to providing services, Refuge Dialysis LLC will provide an executed copy of the Patient Transfer Agreement for department review and approval. The executed transfer agreement must be consistent with the draft provided in the application.
4. Prior to providing services, Refuge Dialysis, LLC will provide a copy of the adopted Accepting Patients for Treatment Policy for the department's review and approval. The adopted admission policy must be consistent with the draft provided in the application.
5. Prior to providing services, Refuge Dialysis, LLC will provide a copy of the adopted Indigent Care Policy for the department's review and approval. The adopted charity care policy must be consistent with the draft provided in the application.

**Approved Capital Costs:**

The approved capital expenditure associated with this project is \$1,534,197. This amount represents the total capital expenditure of \$1,584,400, minus property owner real estate commission costs of \$50,203.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

**Mailing Address:**

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

**Other Than By Mail:**

Department of Health  
Certificate of Need Program  
111 Israel Road SE  
Tumwater, WA 98501

Jason Bosh, Regional Operations Director  
DaVita, Inc.—North Star Division, Region 1  
Certificate of Need Application #12-39  
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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,

A handwritten signature in blue ink, appearing to read "Saxe", is written over a faint, illegible printed name.

Steven M. Saxe, FACHE  
Director, Health Professions and Facilities

Enclosure

**EVALUATION DATED AUGUST 22, 2013 FOR THE CERTIFICATE OF NEED  
APPLICATION SUBMITTED BY REFUGE DIALYSIS, LLC PROPOSING TO ESTABLISH  
A NEW EIGHT STATION KIDNEY DIALYSIS FACILITY IN SNOHOMISH COUNTY  
PLANNING AREA #2**

**APPLICANT DESCRIPTION**

Refuge Dialysis, LLC is a Washington State corporation established in 2009 as a joint venture between DaVita, Inc. as the majority owner and managing member and the Everett Clinic as the minority owner. DaVita, Inc. holds 80% ownership of Refuge Dialysis, LLC and the Everett Clinic holds the remaining 20% ownership. [Source: Application, Page 1 and correspondence received from DaVita, Inc. on April 16, 2012]

DaVita, Inc. is a for profit end stage renal care provider with facilities throughout the nation. The Everett Clinic is a for profit physician group practice that specializes in medical, surgical, and diagnostic practices with locations in Snohomish County. [Source: Application, page 1 and <http://www.everettclinic.com/>]

Currently, DaVita owns, operates, or provides administrative services to approximately 1,777 dialysis facilities located in 43 states and the District of Columbia. In Washington State, DaVita owns or operates 31<sup>1</sup> kidney dialysis facilities in 14 separate counties. Below is a listing of the 31 facilities. [Source: CN historical files & Application, page 2]

<b>Benton</b>	<b>Pacific</b>
Chinook Dialysis Center	Seaview Dialysis Center
Kennewick Dialysis Center	
	<b>Pierce</b>
<b>Clark</b>	Graham Dialysis Center
Vancouver Dialysis Center	Lakewood Dialysis Center
Battle Ground Dialysis Center	Parkland Dialysis Center
	Puyallup Dialysis Center
<b>Chelan</b>	Tacoma Dialysis Center
DaVita Dialysis Center <sup>2</sup>	
Wenatchee Valley Dialysis Center	<b>Snohomish</b>
	Everett Dialysis Center <sup>3</sup>
<b>Douglas</b>	Mill Creek Dialysis Center
East Wenatchee Dialysis Center	
	<b>Spokane</b>
<b>Franklin</b>	Downtown Spokane Renal Center
Mid-Columbia Kidney Center	North Spokane Renal Center
	Spokane Valley Renal Center

<sup>1</sup> Battle Ground Dialysis Center, East Wenatchee Dialysis Center, Kennewick Dialysis Center, Renton Dialysis Center and Zillah Dialysis Center are CN approved but not yet operational.

<sup>2</sup> This facility was recently purchased from Central Washington Hospital

<sup>3</sup> Refuge Dialysis, LLC, is owned 80% by DaVita, Inc. and 20% by The Everett Clinic and managed by DaVita.

<b>Island</b>	<b>Thurston</b>
Whidbey Island Dialysis Center	Olympia Dialysis Center
<b>King</b>	<b>Yakima</b>
Bellevue Dialysis Center	Mt. Adams Dialysis Center
Renton Dialysis Center	Union Gap Dialysis Center
Federal Way Dialysis Center	Yakima Dialysis Center
Kent Dialysis Center	
Olympic View Dialysis Center (management only)	<b>Kittitas</b>
Westwood Dialysis Center	Ellensburg Dialysis Center

### **PROJECT DESCRIPTION**

Refuge Dialysis LLC proposes to relocate 8-stations from the existing 21-station Everett Dialysis Center to a new location within the same planning area. The new 8-station facility would be located at 1250 State Avenue, within the city of Marysville and known as 'DaVita Marysville Dialysis Center.' [Source: Application, page 5 and Supplemental information received August 14, 2012, page 6] Services to be provided at DaVita Marysville Dialysis Center include home dialysis, hemodialysis, peritoneal dialysis, treatment shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. [Source: Application, page 2 and Supplemental information received August 14, 2012, Exhibit B]

The capital expenditure associated with the establishment of the 8-station facility is \$1,584,400. Of that amount \$1,050,000, (66%) is related to leasehold improvements, and \$480,197 (26%) is related to both fixed and moveable equipment's and the remaining \$126,203 (8%) is related to taxes and fees. [Source: Application, page 10]

If this project is approved, Refuge Dialysis, LLC (Refuge Dialysis) anticipates the new 8-station facility would become operational within seven months of approval. Under this timeline, calendar year 2014 would be the first full calendar year of operation and 2016 would be the year three. [Source: Application, page 13]

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

WAC 246-310-289(2) states:

*“When an existing facility proposes to relocate a portion of its stations to either another planning area or within the same planning area, a new health care facility is considered to be established under WAC 246-310-020(1).”*

Because Refuge Dialysis plans to relocate 8 of the 21 stations from Everett Dialysis Center, this project is reviewed as the establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a) and WAC 246-310-289(2).

## **EVALUATION CRITERIA**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on 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 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 that must be used to make the required determinations. To obtain Certificate of Need approval, Refuge Dialysis must demonstrate compliance with the 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)<sup>4</sup>. Additionally, Refuge Dialysis must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.

## **TYPE OF REVIEW**

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Concurrent Review Cycle #2 for year 2012. No other kidney disease

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<sup>4</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), (6); WAC 246-310-240(3), WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

treatment center applications were received for Snohomish County planning area #2 during Cycle #2. The review was converted to a regular review. A chronological summary of the review activities is below.

### **APPLICATION CHRONOLOGY**

<b>Action</b>	<b>Refuge Dialysis, LLC</b>
Letter of Intent Submitted	April 30, 2012
Application Submitted	May 31, 2012
Department's pre-review activities including screening and responses	June 1, 2012 through August 22, 2012
Beginning of Review	August 23, 2012
End of Public Comment/No Public Hearing Requested or Conducted	September 26, 2012
Rebuttal Comments <sup>5</sup>	October 10, 2012
Department Declares Pivotal Unresolved Issue (PUI)	December 26, 2012
Applicant Submits PUI Documents	January 10, 2013
Public Comments on PUI Documents <sup>6</sup>	January 31, 2013
Rebuttal Comments Submitted for PUI Documents	February 15, 2013
Department's Anticipated Decision Date	March 28, 2013
Department's Actual Decision Date	August 22, 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."*

Puget Sound Kidney Centers (PSKC) a dialysis provider located within the planning area sought and received interested person status under WAC 246-310-010(2). PSKC requested that a copy of the department's decision and copies of all documents related to the application. However, PSKC did not submit any comment during the public comment period. Only after the department declared a pivotal unresolved issue (PUI) did PSKC submit comments.

### **SOURCE INFORMATION REVIEWED**

- Refuge Dialysis, LLC's Certificate of Need application submitted May 31, 2012
- Refuge Dialysis, LLC's supplemental information received August 14, 2012
- Refuge Dialysis, LLC's pivotal unresolved issue (PUI) documents received on January 15, 2013
- Refuge Dialysis, LLC PUI documents received January 10, 2013
- Puget Sound Kidney Centers public comments on PUI documents received January 31, 2013

<sup>5</sup> The department did not receive any public comment therefore, no rebuttal comments from the applicant were submitted.

<sup>6</sup> Puget Sound Kidney Centers did not provide public comments during the initial review of the application, but submitted public comments when the department declared pivotal unresolved issue.

- Refuge Dialysis, LLC’s rebuttal comments received February 15, 2013
- Years 2006 through 2011 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 4th Quarter Data available on February 13, 2012
- Licensing and/or survey data provided by the Department of Health’s Inspections and Investigation Office (IIO)
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- <http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission.aspx> - Medical Quality Assurance compliance data
- <http://www.medicare.gov> - Dialysis Facilities Compare
- <http://www.medicare.gov> – Medicare Coverage of Kidney Dialysis and Kidney Transplant Services

**CONCLUSION**

For the reasons stated in this evaluation, the application submitted by Refuge Dialysis, LLC proposing to establish a new 8-station kidney dialysis center in the city of Marysville within Snohomish County planning area #2 is with applicable criteria of the Certificate of Need Program, provided Refuge Dialysis, LLC agrees to the following in its entirety.

**Project Description:**

This certificate approves the establishment of an 8-station dialysis center in Marysville within Snohomish County planning area #2. At project completion, the dialysis center will be approved to certify and operate eight dialysis stations. The dialysis facility will offer at least home peritoneal dialysis and hemodialysis dialysis. Services to be provided at the facility include in-center hemodialysis and peritoneal dialysis with treatments shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. A breakdown of all eight stations is below:

**DaVita Marysville Dialysis Center**

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
<b>Total</b>	<b>8</b>

After the 8-stations are relocated from the 21-station Everett Dialysis Center, the dialysis center would have 13-stations remaining. A breakdown of the remaining 13-stations is shown below.

**Everett Dialysis Center**

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	11
<b>Total</b>	<b>13</b>



**Conditions:**

1. Refuge Dialysis, LLC agrees with the project description as stated above. Refuge Dialysis, LLC 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. Refuge Dialysis, LLC must decertify 8-stations from the 21-station Everett Dialysis Center no later than 30 days following the opening of the new 8-station dialysis center. At project completion, 13 dialysis stations would remain in operation at Everett Dialysis Center
3. Prior to providing services, Refuge Dialysis LLC will provide an executed copy of the Patient Transfer Agreement for department review and approval. The executed transfer agreement must be consistent with the draft provided in the application.
4. Prior to providing services, Refuge Dialysis, LLC will provide a copy of the adopted Accepting Patients for Treatment Policy for the department's review and approval. The adopted admission policy must be consistent with the draft provided in the application.
5. Prior to providing services, Refuge Dialysis, LLC will provide a copy of the adopted Indigent Care Policy for the department's review and approval. The adopted charity care policy must be consistent with the draft provided in the application.

**Approved Capital Costs:**

The approved capital expenditure associated with this project is \$1,534,197. This amount represents the total capital expenditure of \$1,584,400, minus property owner real estate commission costs of \$50,203.

## **CRITERIA DETERMINATIONS**

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

Based on the source information reviewed and the applicant's agreement to the conditions stated in the 'conclusion' section of this evaluation, the department determines that the Refuge Dialysis, LLC project has met the applicable need criteria in WAC 246-310-210 and the kidney disease treatment standards in WAC 246-310-289.

- (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 center 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 in 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.<sup>7</sup>

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.<sup>8</sup> In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

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

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<sup>7</sup> Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

<sup>8</sup> 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 2011.

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 projected 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)]

Refuge Dialysis Application of the Numeric Methodology

Refuge Dialysis did not provide a methodology. Instead, it stated, “No new stations are proposed as part of this project. In previous certificate of need decisions, wherein a “new” facility is being established by relocation of existing stations, the department has concluded that the methodology in WAC 246-310-284 is not applicable.” [Source: Application, Page 17]

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning area, the department used linear regression to project need. Given that the facility would be located in Snohomish County planning area #2, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. The table below is the department’s application of the numeric methodology for the planning area. [Source: Appendix A of this evaluation]

**Table 1  
Snohomish County ESRD Planning Area #2 Numeric Methodology**

	Year 2012	Year 2013	Year 2014	Year 2015
In-center Patients	292.40	302.80	313.20	323.60
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need Rounded Up	61	64	66	68
Minus # CN Approved Stations	58	58	58	58
Net Station Need / (Surplus)	-3	-6	-8	-10

\*Negative number indicates need for additional stations

Though the applicant is not proposing adding stations to the planning area, the department’s projections show a need for 10 additional dialysis stations in year 2015. The department and Refuge Dialysis, LLC agree that this project is required to obtain a CN before proceeding because this project would result in a new health care facility within the planning area. If approved, the project will not increase the number of CN approved dialysis stations in the planning area.

WAC 246-310-284(1) states that applications for new stations may only address projected station need in the planning area in which the facility is to be located. WAC 246-310-284(2) thru (4) describe the detailed steps then used to calculate the projected station need.

The department calculated the methodology as prescribed in WAC 246-310-284 that demonstrated a forecasted need in the planning area for additional stations in year 2015. Review of licensing data indicates the eight stations to be relocated are currently Medicare certified and patients are being treated in them. The department included them as CN approved stations when applying the numeric methodology. Therefore, the numeric need methodology is not applicable to this project.

**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 is May 1, 2012. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 2011, which became available on February 13, 2012. Currently there are two facilities operational in the planning area. The table below shows the utilization of both facilities

**Table 2  
NWRN Facility Utilization Data**

<b>Facility Name</b>	<b># of Stations</b>	<b># of Pts.</b>	<b>Pts./Station</b>
Puget Sound Kidney Center (PSKC)	37	178	4.81
Everett Dialysis Center	21	41	1.90

As shown above, PSKC is operating above the required 4.8 standard and Everett Dialysis Center is operating below the 4.8 standard. The standard states that all CN approved stations within the planning area must be at the applicable utilization standard before new stations are added to the planning area. Since the applicant is proposing to relocate CN approved stations already counted as available in planning area, the department concludes that **this sub-criterion is not applicable**.

**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. DaVita Marysville Dialysis Center would be located in the Snohomish County ESRD planning area #2; therefore, the standard for this criterion is 4.8 in-center patients per approved station. The table below shows DaVita Marysville Dialysis Center's projected utilization in the third year of operation. [Source: Supplemental information received August 14, 2012, Exhibit C]

**Table 3  
DaVita Marysville Dialysis Center  
Third Full Year Projected (2016) Facility Utilization**

<b>Facility Name</b>	<b>#of Stations</b>	<b># of Pts.</b>	<b>Pts./Station</b>
DaVita Marysville Dialysis Center	8	42	5.25

As shown above, the DaVita Marysville Dialysis Center projected, it would meet this standard in year 2016 with all 8 stations operational. The department concludes **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.

DaVita and Everett Clinic jointly own refuge Dialysis. DaVita also operates the dialysis facility. Both DaVita and the Everett Clinic currently provide health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of Snohomish County ESRD planning area

#2 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, Refuge Dialysis majority stakeholder DaVita provided a copy of its current Accepting Patients for Treatment Policy used at its dialysis centers. Since this facility is a new facility, the policy submitted with the application is a draft. The draft policy outlines the process and guidelines that DaVita uses to admit patients for treatment at any of its dialysis centers and it included the appropriate non-discrimination language. [Source: Application, Appendix 14] If approved, a condition would be necessary for the submission of an adopted Accepting Patients for Treatment Policy.

To determine whether low-income residents would have access to the proposed services, the department uses the Medicaid eligibility or contracting with Medicaid. Refuge Dialysis currently provides services to Medicaid eligible patients in the planning area at the Everett Dialysis Center. The applicant intends to continue to provide services to Medicaid patients in the planning area at the new facility. A review of the anticipated revenue sources indicates that the facility expects to receive Medicaid reimbursements. [Source: application, page 8 and Appendix 9]

The department uses Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. Refuge Dialysis intends to provide services to Medicare patients at the proposed facility. A review of the anticipated revenue sources indicates that it expects to receive Medicare reimbursements. [Source: Application, page 8 and Appendix 9]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

Refuge Dialysis demonstrated its intent to provide charity care to patients receiving treatment at the proposed facility by submitting DaVita's current Indigent Care Policy used at its operational facilities. Since this facility is a new facility, the policy submitted with the application is a draft. The policy outlines the process one would use to access this service. Refuge Dialysis also included a 'charity care' line item as a deduction from revenue within the pro forma income statements documents. [Source: Application, Appendix 9 and 14] If approved, a condition would be necessary for the submission of an adopted Indigent Care Policy.

With the agreement to the conditions stated in the 'conclusion' section of this evaluation, the department concluded that all residents of the planning area would have access to the health services at the proposed DaVita Marysville Dialysis Center. **This sub-criterion is met.**

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

Based on the source information reviewed and provided the applicant agrees to the conditions stated in the ‘conclusion’ section of this evaluation, the department determines that Refuge Dialysis, LLC, 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.

As stated in the project description portion of this evaluation, if this project is approved, Refuge Dialysis anticipates that the new stations would become operational within seven months of approval. Under this timeline, year 2014 would be the facility’s first full calendar year of operation and 2016 would be year three. [Source: Application, page 13]

Refuge Dialysis provided its projected revenue and expense statement for the proposed dialysis center. The table below summarizes that information. [Source: Application Appendix 9 and Supplemental information received August 14, 2012 Exhibit C]

**Table 4  
DaVita Marysville Dialysis Center  
Projected Revenue and Expenses for Full Years 2014-2016**

	<b>Year 1-2014</b>	<b>Year 2-2015</b>	<b>Year 3-2016</b>
# of Stations	8	8	8
# of Treatments [1]	3,854	6,117	8,221
# of Patients [2]	20	31	42
Utilization Rate [2]	2.5	3.9	5.5
Net Patient Revenue[1]	\$1,098,194	\$2,101,248	\$3,045,893
Total Operating Expenses [1, 3]	\$1,254,984	\$1,741,715	\$2,387,403
Net Profit or (Loss)[1]	(\$156,790)	\$359,533	\$658,490

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

As shown above, DaVita Marysville Dialysis Center would be operating at a loss during the first full year of operation and a profit in years two and three.

Refuge Dialysis provided an executed lease agreement between Inland Western Marysville, LLC (“Landlord”) and Refuge Dialysis, LLC (“Tenant”). [Source: Application, Appendix 15] The department’s review of the executed lease agreement shows that rent costs identified in the lease are consistent with the pro-forma financial projections.

Refuge Dialysis provided a copy of its medical director’s services agreement for the proposed dialysis center. The agreement identifies the annual compensation for the medical director position. Additionally, Refuge Dialysis pro-forma financial statement also confirms the annual compensation for the medical director. [Source: Application, Appendices 3 and 9 and Supplemental information received August 14, 2012 Exhibit C] Refuge Dialysis identified Dr. Thao Pascual as the medical director for Marysville Dialysis Center and provided a copy of an executed medical director agreement. The agreement identifies the annual compensation for the medical director position. [Source: Application, Appendix 3]

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

The capital expenditure associated with the establishment of the DaVita Marysville Dialysis Center is \$1,584,400. Of these costs, \$1,534,197 is the responsibility of Refuge Dialysis LLC and \$50,203 is the real estate commission cost that is the responsibility of Inland Western Marysville, LLC. [Source: Application, page 10 and Appendix 7]

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

<b>Item</b>	<b>Cost</b>	<b>% of Total</b>
Leasehold improvements	\$1,050,000	66%
Fixed and Moveable Equipment	\$408,197	26%
Professional Services Fee	\$76,000	5%
Real Estate Commission	\$50,203	3%
<b>Total Project Cost</b>	<b>\$1,584,400</b>	<b>100%</b>

To further demonstrate compliance with this sub-criterion, Refuge Dialysis provided the sources of its revenue by payer expected at the facility shown in the table below. [Source: Application, page 10]

**Table 6  
DaVita Marysville Dialysis Center Source of Patient Revenue**

<b>Revenue Source</b>	<b>% of Revenue</b>
Medicare	24%
Medicaid	2%
Commercial /HMO	74%
<b>Total</b>	<b>100%</b>

The proposed DaVita Marysville Dialysis Center is expected to have 26% of its revenue from Medicare and Medicaid entitlement programs and for commercial insurance/HMO, the applicant expected it would get 74%. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, Refuge Dialysis stated expectations that 74% of its revenue would come from commercial/HMO is unusual. On December 26, 2012, the department declared a pivotal unresolved issue to give Refuge Dialysis the opportunity to provide clarification related to the correct percentages of revenue it expects for commercial/HMO. Summarized below are the PUI comments provided by Refuge Dialysis related to the percentage of commercial revenue expected at the dialysis facility. [Source: Refuge Dialysis PUI response received January 15, 2013]

### Refuge PUI Response

- The information contained in the Refuge Dialysis application was a correct reflection of a very narrow snapshot of the ESRD patients treating at the single Refuge Dialysis facility at the close of operations on April 30, 2012. This snapshot is different from previous applications submitted by DaVita that used company-wide estimations and not reflective of the of the expected payor mix at the Marysville facility.
- DaVita believes the information presented in a table within the application stating it expects 74% of its revenue from commercial/HMO is reflective of the expected payor mix at the Marysville center. The information contained in table was created looking at a very narrow set of data and period. Utilizing this narrow set of data and period resulted in a misleading projection of expected payor mix. We believe a better projection would be 79% revenue from Medicare and 9% revenue from Medicaid and 12% revenue from commercial/HMO. These projections are reflective of the revenue estimates in the pro forma financial statement and are similar to the data presented in the table contained in the application.
- Using the updated information provided in response to the department's PUI Refuge believes that the language of in financial feasibility section it stated in the application, stated correctly. The majority of reimbursement would be from Medicare ESRD entitlements and the proposed project would not have impact on charges for services within the planning area.

In response to the information provided by the applicant, PSKC provide public comments related to the PUI documents submitted by Refuge Dialysis. Below is a summary of the comments provided by PSKC. [Source: Public Comments on PUI Documents provided by Puget Sound Kidney Centers received January 31, 2013]

### PSKC Public Comments

- The information provided by DaVita/Refuge seems to suggest that the new information is a snap shot of the data previously provided in its application, but this is new information that is different from what was presented in the application.
- It is known that DaVita often uses "company-wide" or national figures in its applications. DaVita/Refuge claims the significant change in its projections have no bearing on the pro-forma financials because the 'the pro forma financials reflects a projection based upon actual revenue experienced at comparable facilities. Revenue projections incorporate baseline assumptions concerning projected payor mix and DaVita has admitted as much in other proceedings.



- DaVita may claim that it does not build its pro-forma statements using facility specific payer mix assumptions but instead uses a blended rate per treatment or in the selection of facilities that are comparable. But however DaVita approaches it, significant changes in payer mix drive the financial performance of a facility because Medicare and Medicaid generally pays less, often significantly less, than commercial payers.

In response to the public comments submitted by PSKC to the department, the applicant provided rebuttal comments summarized below. [Source: Refuge Dialysis rebuttal comments received February 15, 2013]

### Refuge Rebuttal Comments

- PSKC argues the Program should believe PSKC that a payer mix is necessary to project new-facility revenue and should not believe Refuge/DaVita that a payer mix is not necessary. PSKC admits it cannot show any impact on our revenue projection. Instead, PSKC argues, the Program simply does not have sufficient information to determine the financial feasibility of this project.
- Payer mix changes over time especially at a new facility during its startup period. New facilities tend to attract new dialysis patients and new patients tend to have commercial coverage. After 33 months of treatments, all dialysis patients obtain Medicare coverage, but during the first 33 months of treatments, many new patients have commercial coverage. New DaVita facilities typically experience a greater percentage of commercial pay patients than existing facilities. PSKC operates more facilities in Snohomish County than any other provider does and it cannot guess what the different payer mix would be at its Marysville facility in years 2013, 2014, 2015 and 2016. Because of substantial variations from place to place and from time to time, estimating a payer mix for the first several operating years at a new facility is highly uncertain. Because of the uncertainty in estimating new facility payer mix, DaVita generally uses its companywide payer mix and Refuge/DaVita used that mix in this application.
- Refuge/DaVita projected its Marysville revenue using reasonable and conservative annual revenue per treatment values obtained by considering the revenue per treatment experience at other DaVita facilities in the area. We obtained projected revenue by simply multiplying total annual treatments by the revenue per treatment estimate. The projections involves three elements namely estimated revenue per treatment, estimated patient census and estimated annual treatment for each year.
- Making the payer mix approach even more problematic, many patients participate in Medicare assigned benefits program with commercial payers that could be characterized as either Medicare or commercial. The applicant's decision about what category in which to place such patients can dramatically affect the payer mix. For example, PSKC's past projects separated out the Medicare assigned programs in its payer mix using the category name Medicare managed care while DaVita includes patients in its commercial category.

### Departments Evaluation

After reviewing the comments provided by Refuge Dialysis in response to the department's PUI, it is noted the applicant did not directly address the issues identified by the PUI. New information provided by the applicant in response to the PUI stated the new payor mix it identified in PUI document are a better reflection of the revenue estimate in its pro-forma financial statement and are similar to previous payor mix identified in its application. The new payor mix projections are 79%

Medicare, 9% Medicare and 12% Insurance/HMO, these new payor mix projections addressed previous statements and payor mix made in the application.

Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. Under the new ESRD PPS payment system, 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 Refuge Dialysis may not have an unreasonable impact on charges for services within the planning area.

Based on the information provided, the department concludes that this project would not result in an unreasonable impact on the costs and charges for health 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.

The capital expenditure associated with the establishment of the 8-station DaVita Marysville Dialysis Center is \$1,584,400 and Refuge Dialysis LLC's portion of the costs is \$1,534,197. Refuge Dialysis states its portion of the project will be funded from its own reserves. A letter from Refuge Dialysis chief operating officer was provided confirming the corporate funding. A review of Refuge Dialysis audited financial statements shows the funds necessary to finance the project are available. [Source: Application, Appendices 6 and 10] Based on the information provided, the department concludes **this sub-criterion is met.**

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that Refuge Dialysis, LLC's project has met the structure and process (quality) of care criteria in WAC 246-310-230.

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

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 (full time equivalents) that should be employed for projects of this type or size.

Since DaVita Marysville Dialysis Center would be a new facility, Refuge Dialysis provided a breakdown of all proposed staff beginning with year 1 through year three (2014-2016). [Source: Application, page 21] A breakdown of the proposed staffing is summarized below.

**Table 7**  
**DaVita Marysville Dialysis Center proposed FTE's Year 2014 – 2016**

Staff/FTEs	Year 1 - 2014	Year 2-2015 Increase	Year 3-2016 Increase	Total FTEs
Medical Director	Professional Services Contract			
Administrator	1.0	0.0	0.0	1.0
Registered Nurses	1.8	0.6	1.2	3.6
Patient Care Tech	1.6	0.8	0.8	3.2
Biomedical Tech	0.2	0.0	0.0	0.2
Administrative Assistant	0.5	0.3	0.2	1.0
MSW	0.5	0.0	0.3	0.8
Dietician	0.5	0.0	0.3	0.8
<b>Total FTEs</b>	<b>6.1</b>	<b>1.7</b>	<b>2.8</b>	<b>10.6</b>

As shown above, Refuge Dialysis expects to open the facility with 6.1 FTEs and increase staffing as the utilization increases through year 2016. Refuge Dialysis states it does not anticipate any difficulty recruiting staff because it offers competitive wage and benefit packages to employees. Additionally, the applicant stated that DaVita the majority stakeholder, posts job openings nationally and internally and it has an extensive employee traveling program that guarantees it will maintain staffing at its facilities. [Source: Application Page 22]

Refuge Dialysis identified Thao Pascual, MD as the medical director for the proposed DaVita Marysville Dialysis Center and provided a draft Medical Director Agreement between Total Renal Care, Inc., (“Company”), a California Corporation and The Everett Clinic, P.S (“Group”) and Thao Pascual, M.D. (“Physician”). [Source: Application, page 9 and Appendix 3] The medical director agreement outlines the roles and responsibilities of the Company, Group, and Physician. The agreement proposes to commence on the date the new center dialyzes its first patient and continue for three years. The agreement has a yearly automatic renewal clause at the expiration of the initial three years term. The agreement also identifies the annual compensation for the medical director and the applicant’s pro-forma financial statement substantiates the medical director’s compensation. [source: Application Appendix 3 and August 14, 2012, supplemental information, Exhibit C]

If this project is approved, the department would include a condition requiring the applicant to provide a copy of the executed medical director agreement that is consistent with the draft provided in the application. With agreement to the condition, the department concludes **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) 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 relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

Refuge Dialysis, LLC is a joint venture between DaVita, Inc. and the Everett Clinic. As a current provider of dialysis services in Washington State, Refuge Dialysis maintains appropriate relationships with ancillary and support services in the planning area.

For the proposed DaVita Marysville 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 will be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [Source: Application, page 22]

Refuge Dialysis acknowledges that since this would be a new facility in Snohomish County planning area #2, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, the applicant provided an example of a draft transfer agreement. [Source: Application, page 22 and Appendix 12]

Based on this information, the department concludes that with DaVita as the majority stakeholder, Refuge Dialysis currently has access to the necessary ancillary and support services that could support the new facility. If this project were approved, the department would include a condition requiring Refuge Dialysis to provide a copy of the executed transfer agreement that is consistent with the example presented in the application. With agreement to the condition, the department concludes **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. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

Refuge Dialysis, LLC is a joint venture with DaVita, Inc. as the majority owner and managing member and the Everett Clinic as the minority owner. The Everett Clinic is owned by a physician group practice that specializes in medical, surgical and diagnostic practices with locations throughout Snohomish County. [Source: Application Page 1] DaVita, Inc. the majority owner and managing member Refuge Dialysis, LLC is a provider of dialysis services in over 1,777 outpatient centers located in 43 states (including Washington State), and the District of Columbia. [Source: Application, page 1] As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.<sup>9</sup>

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<sup>9</sup> WAC 246-310-230(5).

For Washington State, DaVita owns or operates 30 kidney dialysis treatment centers in 14 separate counties. To comply with this sub-criterion, DaVita provided a contact list of the regulatory agencies responsible for surveying its out-of-state facilities and the District of Columbia. [Source: Application, Appendix 2] In February 2010, the department requested quality of care compliance history from out-of-state licensing and/or surveying entities and the District of Columbia where DaVita, Inc. or any subsidiaries have health care facilities. Of the 42 states and entities, the department received responses from 21 states or 50% of the 42 states.<sup>10</sup>

The compliance history of the remaining 19 states and the District of Columbia is unknown.<sup>11</sup> Five of the 21 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Iowa that decertified and later reopened, none of the deficiencies is reported to have resulted in fines or enforcement action.<sup>12</sup> All other facilities are reported to be currently in compliance with applicable regulations. [Source: compliance history from state licensing and/or surveying entities]

The department concludes that considering the more than 1,777 facilities owned/managed by DaVita, one out-of-state facility listed above demonstrated substantial non-compliance issues. The department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2008, the Department of Health's Investigations and Inspections Office has completed 26 compliance surveys for the operational facilities that DaVita either owns or manages.<sup>13</sup> Of the compliance surveys completed, there were minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues are typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [Source: facility survey data provided by the Investigations and Inspections Office]

The minority owner of Refuge Dialysis, LLC is the Everett Clinic that is owned by a physician group practice and it specializes in medical, surgical and diagnostic practices with locations throughout Snohomish County. Since January 2008, the Department of Health's Investigations and Inspections Office has completed more than 10 compliance surveys for healthcare facilities owned or operated by Everett Clinic or any of its affiliates.<sup>14</sup> Of the compliance surveys completed, there were minor non-compliance issues related to the care and management at those facilities and the

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<sup>10</sup> States that provided responses are: California, Colorado, Connecticut, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nevada, New Mexico, North Dakota, Ohio, Oregon, South Carolina, Tennessee, South Dakota and West Virginia

<sup>11</sup> States that did not provide responses are Alabama, Arizona, Arkansas, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Texas, Utah, Virginia and Wisconsin. The department did not send survey to itself. The District of Columbia did not respond to the survey.

<sup>12</sup> 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.

<sup>13</sup> Battle Ground Dialysis Center, East Wenatchee Dialysis Center, Kennewick Dialysis Center, Renton Dialysis Center and Zillah Dialysis Center are CN approved but not yet operational.

<sup>14</sup> Healthcare facilities owned or operated by Everett Clinic are: Everett Campus, Marysville Clinic, Mill Creek Clinic, Harbor Pointe Pediatrics, Snohomish Clinic, Cancer Partnership, Trask Surgery Center, Lake Stevens Clinic, Marysville Eye Center, Harbor Pointe Clinic, Silver Lake Clinic, Stanwood Clinic and Pavilion for Women and Children

Everett Clinic submitted and implemented acceptable plans of corrections. [Source: facility survey data provided by the Investigations and Inspections Office]

For medical director services, Refuge Dialysis provided a copy of its draft medical director agreement with Dr. Thao Pascual who is part of the Everett Clinic, P.S. The department's review of the compliance history for Dr. Pascual revealed no recorded sanctions or license restrictions.

Given the compliance history of DaVita, the Everett Clinic, and the medical director, the department concludes that there is reasonable assurance the proposed DaVita Marysville Dialysis Center would be operated in conformance with state and federal regulations. **This sub-criterion is met.**

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

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.

In response to this criterion, the applicant provided a summary of DaVita, Inc. the majority owner and managing member quality and continuity of care indicators used at facilities operated or managed by DaVita, Inc. The quality of care program provided by the applicant incorporates all areas of the dialysis program it monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, the applicant provided examples of DaVita, Inc. quality index data known as 'Empower'.

Additionally, Refuge Dialysis provided a draft sample of the patient transfer agreement used at the majority owner and managing member existing facilities in Washington. [Source: Application, Appendices 12, 17 & 18] Since the patient transfer agreement is a draft, the department would attach a condition to the approval of this project.

With agreement to the condition related to the patient transfer agreement, the department concludes approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **This sub-criterion is met.**

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

For this project, this sub-criterion is addressed in sub-section (3) above and **is met**

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that Refuge Dialysis, LLC's project 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 thru 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 criteria (tiebreaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more equally 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

Refuge Dialysis proposed to establish a new 8-station kidney dialysis facility by relocating existing stations in Snohomish County planning area #2 to a new site within the same planning area. The department concludes that the project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

#### Step Two

Before submitting this application, Refuge Dialysis considered the two alternatives summarized below. [Source: Supplemental information received August 14, 2012, page 5]

#### Alternative 1: Do nothing

Refuge Dialysis asserted that about 27% of ESRD patients live within two zip codes located in Marysville and Lake Stevens, therefore demand for improved access is difficult to overlook. The applicant rejected this option.

#### Alternative 2: Establish a new 10-station facility in Marysville

The applicant stated the planning area current utilization level does not support a 10-station facility. Therefore, this option was rejected.

**Departments Evaluation**

Given the options considered by the applicant, and given that Refuge Dialysis is relocating existing stations already counted as dialysis station in the planning area capacity, the department did not identify any other alternative to the ones proposed by the applicant. The department concludes the project described is the applicant best available alternative. **This sub-criterion is met.**

**Step Three**

This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted in Snohomish County ESRD planning area #2 during Review Cycle #2. Therefore, this step is not applicable to the project.

(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.

Refuge Dialysis proposes to lease a “built to suit” facility from a real estate developer. Refuge Dialysis states that the scope and methods of the facility will meet Medicare certification and the local authority construction and energy conservation code. The cost the developer would incur to construct the proposed dialysis center building is reflected in the negotiated lease costs provided by Refuge Dialysis. The proposed property lease costs were evaluated in the financial feasibility section of this analysis. Within this evaluation, the department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes **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.*

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes **this sub-criterion is met.**



# APPENDIX A



**2012**  
**Snohomish County 2**  
**ESRD Need Projection Methodology**

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Snohomish Two (2)		2006	2007	2008	2009	2010	2011
98201		32	41	41	39	41	43
98203		26	26	26	22	24	29
98204		29	31	30	33	33	31
98205		7	4	1	6	2	1
98208		32	33	31	37	43	41
98224		0	0	0	0	0	1
98251		3	3	3	3	1	1
98258		12	16	13	14	17	20
98270		37	37	45	60	61	55
98272		16	16	17	22	15	8
98275		9	7	11	9	12	16
98288		0	0	0	0	0	0
98290		22	20	23	22	22	24
98294		2	3	6	5	4	5
<b>TOTALS</b>		<b>227</b>	<b>237</b>	<b>247</b>	<b>272</b>	<b>275</b>	<b>275</b>
<b>246-310-284(4)(a)</b>	Rate of Change		4.41%	4.22%	10.12%	1.10%	0.00%
	6% Growth or Greater?		FALSE	FALSE	TRUE	FALSE	FALSE
	Regression Method:	Linear					
<b>246-310-284(4)(c)</b>				Year 1 2012	Year 2 2013	Year 3 2014	Year 4 2015
Projected Resident Incenter Patients	from 246-310-284(4)(b)			292.40	302.80	313.20	323.60
Station Need for Patients	Divide Resident Incenter Patients by 4.8			60.9167	63.0833	65.2500	67.4167
	Rounded to next whole number			61	64	66	68
<b>246-310-284(4)(d)</b>	subtract (4)(c) from approved stations						
Existing CN Approved Stations				58	58	58	58
Results of (4)(c) above				- 61	- 64	- 66	- 68
Net Station Need				-3	-6	-8	-10
Negative number indicates need for stations							
<b>246-310-284(5)</b>							
Name of Center	# of Stations	# of Patients	Utilization (Patients per Station)				
PSKC Everett	37	178	4.81				
DaVita Everett	21	41	1.95				
Total	58	219					
Source: Northwest Renal Network data 2006-2011							
Most recent year-end data: 2011 year-end data as of 02/13/2012							
Most recent quarterly data as of the 1st day of application submission period: 4th quarter 2011 as of 02/13/2012							

	x	y	Linear				
	2007	237	240				
	2008	247	251				
	2009	272	261				
	2010	275	272				
	2011	275	282				
	2012		292.40				
	2013		302.80				
	2014		313.20				
	2015		323.60				
<b>SUMMARY OUTPUT</b>							
<i>Regression Statistics</i>							
Multiple R	0.917520075						
R Square	0.841843088						
Adjusted R Square	0.789124118						
Standard Error	8.230026326						
Observations	5						
<b>ANOVA</b>							
	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>		
Regression	1	1081.6	1081.6	15.96850394	0.028080764		
Residual	3	203.2	67.73333333				
Total	4	1284.8					
	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i> <i>Upper 95.0%</i>
Intercept	-20832.4	5228.55004	-3.946103574	0.02901903	-37271.97975	-3992.82025	-37271.97975   -3992.82025
X Variable 1	10.4	2.602562839	3.996061053	0.028080764	2.117483508	18.68251649	2.117483508   18.68251649
<b>RESIDUAL OUTPUT</b>							
	<i>Observation</i>	<i>Predicted Y</i>	<i>Residuals</i>				
	1	225.4	1.6				
	2	238.5	-1.5				
	3	251.6	-4.6				
	4	264.7	7.3				
	5	277.8	-2.8				

