



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

December 20, 2012

Certified Mail 7011 1570 0002 7809 5476

Jean Stevens, Regional Vice President
Fresenius Medical Care
2121 SW Broadway, Suite 111
Portland, OR 97201

RE: CN12-36A

Dear Ms. Stevens:

It has come to my attention that the cover letter sent to you on December 19, 2012 did not provide you with the correct information for responding to our Certificate of Need offer letter. This letter replaces the December 19 letter. I apologize for any confusion this may have caused.

For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided Renal Care Group Northwest, Inc. agrees to the following in its entirety.

Project Description:

This project approves the establishment of a six station dialysis facility in Lacey, Washington within Thurston County. At project completion, the dialysis facility will be approved to certify and operate six dialysis stations. Services provided include hemodialysis and peritoneal home training, in-center hemodialysis, a permanent bed station and an isolation station. The six dialysis stations operational at the facility are listed below:

Fresenius Thurston County Dialysis Facility

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	4
Total	6

After the 6-stations are relocated from the 25-station Fresenius Medical Care Lacey, the facility would have 19-stations remaining. A breakdown of the remaining 19-stations is shown below.

Fresenius Medical Care Lacey Dialysis Facility

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	17
Total	19

Conditions:

1. Renal Care Group Northwest, Inc agrees with the project description as stated above. Renal Care Group Northwest, 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. Renal Care Group Northwest, Inc. must decertify 6-stations from the 25-stations Fresenius Lacey Dialysis Facility no later than 30 days following the opening of the new 6-stations dialysis facility. At project completion, 19-dialysis stations would remain in operation at Fresenius Lacey Dialysis Facility.
3. Prior to providing services, Renal Care Group Northwest, Inc. will provide a copy of the executed lease agreement for the department's review and approval. The executed lease agreement must be consistent with the draft provided in the application.
4. Prior to providing services, Renal Care Group Northwest, Inc. will provide an executed copy of the patient transfer agreement for the department's review and approval. The executed patient transfer agreement must be consistent with the draft provided in the application.
5. Prior to providing services, Renal Care Group Northwest, Inc. will provide a copy of the executed medical director agreement for the department's review and approval. The executed medical director agreement must be consistent with the draft provided in the application.

Approved Capital Costs:

The approved capital expenditure associated with this project is \$1,844,480. This amount represents the total capital expenditure of \$2,587,359, minus the property owner's costs of \$742,879.

Jean Stevens, Regional Vice President
Fresenius Medical Care
December 20, 2012
Page 3

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

Your written response should be sent to Janis Sigman the program manger of the Certificate of Need Program, at one of the following addresses:

Mailing Address:

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

Other Than By Mail

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

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

Sincerely,

Lisa Hodgson for

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

Enclosure (previously provided)

EVALUATION DATED DECEMBER 19, 2012, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY RENAL CARE GROUP NORTHWEST, INC. A SUBSIDIARY OF FRESenius MEDICAL CARE PROPOSING TO ESTABLISH A NEW SIX STATION KIDNEY DIALYSIS FACILITY IN LACEY, THURSTON COUNTY, WASHINGTON.

APPLICANT DESCRIPTION

Renal Care Group Northwest (RCGNW) 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, Inland 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. Information provided within the application indicates that RCGNW is jointly owned by RCG and Sacred Heart Medical Center a healthcare provider located in Spokane County. Listed below are the five entities owned by FMC. [Source: Department's historical record and Amended Application, page 3]

QualiCenters Inc.
Inland Northwest Renal Care Group, LLC
National Medical Care, Inc.

Pacific Northwest Renal Services
Renal Care Group Northwest, Inc.

Under four of the five subsidiaries listed above, FMC operates 1,700 outpatient dialysis centers in 45 states and the District of Columbia.¹ [Source: CN historical files and Application, Pages 2-6] 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. [CN historical files]

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

Cowlitz County

Fresenius Longview Dialysis center

Spokane County

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

Mason County

Shelton Dialysis Facility

Okanogan County

Omak Dialysis Facility

Stevens County

Colville Dialysis Center

Thurston County

Fresenius Lacey Dialysis Center

Grays Harbor County

Aberdeen Dialysis Facility

¹ National Medical Care, Inc. subsidiary does not operate any dialysis facilities.

PROJECT DESCRIPTION

RCGNW proposes to relocate 6-stations from the existing 25-station Fresenius Medical Care Lacey Dialysis Center to new location within the same planning area. The new 6-station facility to be located at 8770 Tallon Lane NE within the city of Lacey would be known as 'Fresenius Thurston County Dialysis Center'. Services to be provided at Thurston County Dialysis facility include hemodialysis and peritoneal home training, in-center hemodialysis, a permanent bed station and an isolation station. [Source: Amended Application, page 8]

The capital expenditure associated with this project is \$2,587,359. Of that amount, approximately 63% of the cost is related to construction, 17% is related to fixed and moveable equipment, 17% is related to taxes and fees, and the remaining 4% is related to architect and engineering fees. [Source: Amended Application, Page 24] RCGNW anticipates the relocated 6-stations would become operational by the end of September 2013. Under this timeline, calendar year 2014 would be the first full year of operation and 2016 would be year three. [Source: Amended Application, Page 8]

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 RCGNW plans to relocate only six stations from the existing twenty-five station Fresenius Lacey Dialysis Center, to a new location, 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).

CRITERIA EVALUATION

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 and must be used to make the required determinations. To obtain Certificate of Need approval, RCGNW 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)². Additionally, RCGNW 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 Review Cycle #2 for year 2012. No other kidney disease treatment center applications were received for Thurston County during Cycle #2; therefore, the review was converted to a regular review. A chronological summary of the review activities is shown below.

APPLICATION CHRONOLOGY

Action	Dates
Letter of Intent Submitted	April 30, 2012
Application Submitted	May 31, 2012
Amended Application Received	June 29, 2012
Department's Pre-Review Activities including screening and responses	June 5, 2012 through September 9, 2012
Beginning of Review	September 10, 2012
End of Public Comment/No Public Hearing Requested or Conducted	October 15, 2012 ³
Department's Anticipated Decision Date	December 13, 2012
Department's Actual Decision Date	December 19, 2012

² 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); and WAC 246-310-240, (3); WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

³ The department did not receive any public comment. Therefore no rebuttal comments from the applicant were submitted

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.”

Throughout the review of this project, no entity sought or received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Renal Care Group Northwest, Inc. Certificate of Need application received May 30, 2012⁴
- Renal Care Group Northwest, Inc. supplemental information received August 30, 2012
- Year 2006 through 2011 historical kidney dialysis data obtained from 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 Office of Investigation and Inspections Office
- Medical Quality Assurance compliance data
- Certificate of Need historical files
- Medical Quality Assurance compliance data
- Medicare.gov—Dialysis Compare
- Secretary of State.WA.gov/corps/search

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Renal Care Group Northwest, Inc. proposing to establish a new 6-station kidney dialysis center in the city of Lacey within Thurston County is consistent with applicable criteria of the Certificate of Need Program, provided Renal Care Group Northwest, Inc. agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a six station dialysis facility in Lacey, Washington within Thurston County. At project completion, the dialysis facility will be approved to certify and operate six dialysis stations. Services provided include hemodialysis and peritoneal home training, in-center hemodialysis, a permanent bed station and an isolation station. A breakdown of all six stations is below:

Fresenius Thurston County Dialysis Facility

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	4
Total	6

⁴ RCGNW submitted an amended application on June 29, 2012

After the 6-stations are relocated from the 25-station Fresenius Medical Care Lacey, the facility would have 19-stations remaining. A breakdown of the remaining 19-stations is shown below.

Fresenius Medical Care Lacey Dialysis Facility

Private Isolation Room	1
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Conditions:

1. Renal Care Group Northwest, Inc agrees with the project description as stated above. Renal Care Group Northwest, 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. Renal Care Group Northwest, Inc. must decertify 6-stations from the 25-stations Fresenius Lacey Dialysis Facility no later than 30 days following the opening of the new 6-stations dialysis facility. At project completion, 19-dialysis stations would remain in operation at Fresenius Lacey Dialysis Facility.
3. Prior to providing services, Renal Care Group Northwest, Inc. will provide a copy of the executed lease agreement for the department's review and approval. The executed lease agreement must be consistent with the draft provided in the application.
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5. Prior to providing services, Renal Care Group Northwest, Inc. will provide a copy of the executed medical director agreement for the department's review and approval. The executed medical director agreement must be consistent with the draft provided in the application.

Approved Capital Costs:

The approved capital expenditure associated with this project is \$1,844,480. This amount represents the total capital expenditure of \$2,587,359, minus the property owner's costs of \$742,879.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210) and Need Forecasting Methodology (WAC 246-310-284)

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 Renal Care Group Northwest, Inc 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 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology, adopted January 1, 2007, projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.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. 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 department uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

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

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

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

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]

RCGNW Application of the Numeric Methodology

Within the application RCGWN states, "This project does not address a need for additional dialysis capacity in Thurston County. Rather, RCGWN is proposing to relocate 6 stations from the existing 25 station Fresenius Lacey". [Source: Amended Application, page 13] RCGWN also stated that, "No new stations are proposed as part of this project. In previous CN decisions wherein a "new" facility is being established via relocation of exiting stations, the Department of Health (Department) has concluded that the need methodology in WAC 246-310-284 is not applicable". [Source: Amended Application, page 16]

Department's Application of the Numeric Methodology

The department uses the kidney dialysis methodology outlined within this evaluation for projecting numeric need for dialysis stations within a service area. Based on the calculation of the annual growth rate in the planning area, the department used linear regression to project need. Given that the facility is located in Thurston County, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. The table below provides a summary of the department's application of the numeric methodology.

Table 1
Summary of Department's Numeric Methodology

	Year 2012	Year 2013	Year 2014	Year 2015
In-center Patients	166.40	175.60	184.80	194.00
Patient: Station Conv. Factor	4.8	4.8	4.8	4.8
Total Station Need	34.666	36.583	38.500	40.416
Total Station Need Rounded Up	35	37	39	41
Minus # of CN Approved Stations	31	31	31	31
Net Station Need	-4	-6	-8	-10

As shown in the table above, although the applicant is not proposing to add stations in the planning area, the department need projections show a potential need for 10 additional dialysis stations in year 2015. The department's methodology is attached to this evaluation as Appendix A.

The department and RCGWN agree that this project is required to obtain a CN because the applicant's proposal to relocate 6-stations from its existing facility to new location 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.

Although the department calculated the methodology as prescribed in WAC 246-310-284 and it resulted in a forecasted need for additional stations in the planning area, RCGNW proposed project is not requesting a station increase. The six stations are currently Medicare certified and patients are being treated in them. The department included those stations as CN approved stations when it calculated 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. In addition to Fresenius Lacey, DaVita, Inc. operates a six-station DaVita Olympia Dialysis Center in Thurston County planning area. 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 31, 2011, which became available on February 13, 2012. The table below shows the utilization of the two facilities as of December 31, 2011.

**Table 2
NWRN Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
DaVita Olympia Dialysis Center	6	26	4.33
Fresenius Lacey Dialysis Center	25	135	5.40

As shown above, between the two providers, there are thirty-one stations available in the planning area and only one provider is operating above the required 4.8 standard. DaVita's facility is operating below the standard. However, 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. The six stations involved in this project are already CN approved and counted with the planning area available capacity. Since the project does not propose to add any new stations to the 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 to be operating at a required number of in-center patients per approved station by the end of the third full year of operation. Fresenius Thurston County Dialysis Center is located in Thurston County and the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] Fresenius Thurston County Dialysis Center third full year of operation is year 2016. A summary of the applicant's projected utilization for year 2016 is shown in the table below. [Source: Amended Application, page 9]

**Table 3
Fresenius Thurston Dialysis Center Projected Facility Utilization**

Year 3	Stations	# of Pts	Utilization
2016	6	38	5.0

As shown in the table above Fresenius Thurston County Dialysis Center projected it would meet this standard in year 2016 with all 6 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.

To determine whether all residents of the Thurston 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, the applicant provided a copy of FMC Clinical Services Admission Policy used at dialysis centers owned or operated by FMC subsidiaries. The Admission Policy outlines the process/criteria that all FMC's subsidiaries use to admit patients for treatments. The policy shows that patients will receive appropriate care at any of the facilities owned or operated by RCGNW or FMC. The Admission Policy states any patient needing treatment will be accepted for treatment at any FMC facility without regards to race, creed, color, age, sex, or national origin. [Source: Amended Application, Exhibit 9]

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. RCGNW currently provides services to Medicaid eligible patients at the existing dialysis center. The applicant intends to continue to provide services to Medicaid patients at the Fresenius Thurston County Dialysis Center. A review of the anticipated revenue sources indicates that the facility expects to continue to receive Medicaid reimbursements.

To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination. RCGNW currently provides services to Medicare patients at its existing dialysis center in the planning area. RCGNW intends to continue to provide services to Medicare patients at the existing facility. A review of the anticipated revenue sources indicates that it expects to continue to receive Medicare reimbursements. [Source: Amended Application page 25]

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. To demonstrate compliance with this sub-criterion RCGWN provided its parent entity charity care policy Billing Waivers for Indigent Patients used by all the dialysis facilities owned or operated by FMC. The Billing Waivers for Indigent Patients submitted by RCGNW outlines the process a dialysis patient would use to access charity care. [Source: Amended Application, Exhibit 10]

RCGNW's pro-forma income statement also included a 'charity care' line item as a deduction from revenue. [Source: Amended Application, Exhibit 12] Based on the above information and standards, the department concludes **this sub-criterion is met.**

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

Based on the source information reviewed and provided the applicant agree to the conditions identified in the ‘conclusion’ section of this evaluation, the department concludes that Renal Care Group Northwest, Inc 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, RCGNW anticipates that the new stations would become operational by the end of September 2013. Under this timeline, year 2014 would be the facility’s first full calendar year of operation with six stations and 2016 would be the third full year of operation. [Source: Amended Application, Exhibit 12] RCGNW provided its projected 3-year revenue and expense statement for Fresenius Thurston County Dialysis Center as a 6-station facility. The table below summarizes that information. [Source: Amended Application page 150, Exhibit 12]

**Table 4
Fresenius Thurston County Dialysis Center
Projected Revenue and Expenses Years 2013-2016**

	Partial Year 2013	Full Year 2014	Full Year 2015	Full Year 2016
# of Stations	6	6	6	6
# of Treatments [1]	544	3,370	4,310	5,120
# of Patients [2]	12	25	32	38
Utilization Rate [2]	1.7	3.3	4.2	5.0
Net Patient Revenue[1]	\$226,302	\$1,401,908	\$1,792,944	\$2,129,902
Total Operating Expenses [1, 3]	\$412,817	\$1,356,894	\$1,613,984	\$1,831,078
Net Profit or (Loss)[1]	-\$186,515	\$45,014	\$178,960	\$298,824

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

As shown in the table above, Fresenius Thurston County Dialysis Center would be operating at a loss in partial year 2013 and a profit beginning in year 2014 through 2016. Based on its experience, the department expects RCGNW would meet it operating costs as a six-station facility.

As a new facility, the applicant provided a draft lease agreement between Tallon, LLC (“Landlord”) and Renal Care Group Northwest (“Tenant”). [Source: Amended Application, Exhibit 7] The department’s review of the draft lease agreement shows that rent costs identified in the lease are consistent with the pro-forma financial projections used to prepare the information in the table above. RCGNW provided copy of a draft medical director’s agreement and the agreement identifies the annual compensation for the medical director’s position.

The draft medical director's agreement is consistent with the amount identified in the applicant's pro-forma income statement. If this project were approved, the department would include conditions requiring RCGNW to provide executed lease and medical director's agreements that are consistent with the draft agreements provided in the application. Based on the information reviewed, the department concludes and with agreement to the condition above, **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 six-stations to be relocated is \$2,587,359. This amount includes the landlords costs of \$742,879. The capital expenditure breakdown is shown in the table below.

Table 5
Fresenius Thurston County Dialysis Center Capital Cost

Item	Cost	% of Total
Building Construction	\$1,175,755	45%
Landlord Costs	\$742,879	29%
Fixed & Moveable Equipment	\$432,600	17%
Sales Tax and Fees	\$139,927	5%
Architect and Engineering Fees	\$96,198	4%
Total Project Cost	\$2,587,359	100%

To further demonstrate compliance with this sub-criterion, RCGNW provided the sources of its patient revenue shown in table below. [Source: Amended Application, Page 24]

Table 6
Fresenius Thurston County Dialysis Center
Source of Revenue

Source of Revenue	% of Revenue
Medicare	83%
Medicaid	4.2%
Commercial	11.5%
Other	1.3%
Total	100%

Fresenius Thurston County Dialysis Center is expected to have 87.2% of its revenue from Medicare and Medicaid entitlement programs. These programs are not cost based reimbursement and are not expected to have an unreasonable impact on the charges for services. Based on the department's review of the application materials, this same conclusion can be made for insurance or HMO patients that make up 12.8% of the projected revenue. Therefore, the department concludes that this project would probably 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 six-stations to be relocated is \$2,587,359. RCGNW's portion of the total capital expenditure is \$1,844,480 and the landlord portion is \$742,879. RCGNW states its portion of the project will be funded from Fresenius Medical Care reserves. A letter from Fresenius Medical Care vice president of finance was provided confirming the corporate funding. [Source: Supplemental Information received August 30, 2012, Attachment 2] A review of Fresenius Medical Care financial statements shows the funds necessary to finance the project are available. [Source: Amended Application, Appendix 3 Audited Financial Statements] 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 in the 'conclusion' section of this evaluation, the department determines that Renal Care Group Northwest, Inc. 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 that should be employed for projects of this type or size.

RCGNW proposes to relocate 6-stations and staff from an existing facility to a new facility within the same planning area. RCGNW states that only minor staffing is anticipated. Additionally, information within the application states given the ongoing interest in employment with RCGNW, it does not anticipate difficulty meeting additional staffing need. [Source: Amended Application, page 28] Summarized below is RCGNW's projected staffing for the new dialysis facility.

**Table 7
Fresenius Thurston County Dialysis Facility FTE's 2013 – 2016**

Category	Partial Year 2013	Year 1 2014 Increase	Year 2 2015 Increase	Year 3 2016 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	0.50	0.00	0.50	0.00	1.00
Registered Nurse	1.00	0.00	0.25	0.00	1.25
Patient Care Tech	2.00	0.50	0.0	0.50	3.00
Bio-Medical Tech	0.40	0.00	0.20	0.00	0.60
Admin Assistance	0.20	0.00	0.0	0.05	0.25
Social Worker	0.20	0.00	0.05	0.00	0.25
Dietician	0.20	0.00	0.05	0.00	0.25
Total FTE's	4.50	0.50	1.05	0.55	6.60

As shown in Table 7, RCGNW expects a steady increase in FTE's for Fresenius Medical Thurston County Dialysis Center beginning from partial year 2013 through the third year of operation or by year 2016. RCGNW identified Vo Nyugen, MD as the medical director for Fresenius Thurston County Dialysis Center and provided a draft medical director services agreement between Renal Care Group, Inc. referred to as the ("Company") and RVS, LLC referred to as (the "Consultant") a Washington professional corporation. The Consultant includes several physicians collectively known as ("Member Physicians"). [Source: Amended Application, Exhibit 2] The draft medical director's agreement outlines the roles and responsibilities of Company and Consultant.

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 this 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.

RCGNW states, "*The establishment of a second facility in Thurston County, owned and operated by RCGWN will allow for maximum efficiency, coordination and continuity of care through shared staff, administration and other functions*". Additionally, the applicant stated it has relationships with some vendors and providers in the community and it provided a listing of those providers. [Source: Amended Application, page 29] The department acknowledges that as an existing dialysis provider in the planning area, RCGNW already has ancillary and support services in place. The proposed relocation of stations from an existing facility to a new facility within the same planning area may require additional agreements.

The applicant provided an executed ancillary and support services agreement for the existing Fresenius Medical Care Lacey, but it did not provide an agreement for the proposed new facility.

Since the applicant did not provide an ancillary and support agreement for the new dialysis facility, the department will attached a condition that it provides an executed ancillary and support services agreement prior to providing services at the new facility. With agreement to this 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.

Fresenius Medical Care is the parent company of RCGNW. Information available at Fresenius Medical Care North America's website stated, in the United States, Fresenius Medical Care is the largest provider of dialysis products and services with over 1,800 kidney dialysis clinics, and it provides care for nearly 138,000 patients. [Source: <http://www.fmcna.com/fmcna/DialysisCompany/dialysis-company.html>] 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.

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 conducting surveys where Fresenius Medical Care or any of its subsidiaries have healthcare facilities. Of the 45 states⁶ and the non-state entities surveyed, the department received 26 responses or 55% of those surveyed⁷.

Six of the 26 states responding to the survey indicated that non-compliance deficiencies were cited at Fresenius facilities in the past three years, but none was reported to have resulted in fines or enforcement action. Fresenius submitted and implemented acceptable plans of correction. Given the results of the out-of-state compliance history of the facilities owned or operated by Fresenius, the department concludes that considering that it owns or operates more than 1,800 facilities the number of out-of-state non-compliance surveys is acceptable. [Source: Licensing and/or survey data provided by out of state health care survey programs]

In Washington State, Fresenius or its subsidiaries, including RCGNW, currently owns, operates and/or manages 19 kidney dialysis treatment facilities in 14 separate counties. Fresenius facilities in Washington have collectively been surveyed 33 times within the last six years. Of the 33 surveys, one survey revealed potentially hazardous condition that was promptly corrected; nine surveys revealed no deficiencies. The remaining 23 surveys revealed minor non-compliance issues and the facilities submitted plans of corrections for the non-compliance issues within the allowable response time. [Source: compliance survey data provided by Office of Health Care Survey (OHCS)]

RCGNW is 80% owned by RCG and 20% by Providence Sacred Heart Medical Center a healthcare provider located in Spokane County. [Source: Application, page 3] The department also reviewed Providence Sacred Heart Medical Center's quality of care compliance history. That review shows that five compliance surveys were completed for Providence Sacred Heart Medical Center between 1999 and 2011.

⁶ This figure excludes Washington. The department did not send a survey to itself for compliance.

⁷ Those not responding are Alabama, Arkansas, District of Columbia, Georgia, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, New Jersey, New York, Oklahoma, Pennsylvanian, Rhode Island, Texas, Vermont, Wisconsin, and Puerto Rico.

The compliance surveys revealed deficiencies typical for the type of facility and Providence Sacred Heart Medical Center submitted plan of corrections and implemented the required corrections. [Compliance survey data provided by Investigation and Inspection's Office] RCGNW provided a draft medical director agreement with Dr. Vo Nyugen. A review of Dr. Vo Nyugen's compliance history with the Department of Health's Medical Quality Assurance Commission did not revealed any recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of Fresenius Medical Care and its subsidiaries and that of Dr. Vo Nyugen the department concludes that there is reasonable assurance Fresenius Thurston County 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.

RCGNW stated, "As with our existing facility, RCGNW will provide regular social services and dietary support for all patients. For the other typical ancillary and support services utilized by a dialysis program including pharmacy, laboratory, and radiology, we will access the same relationships and vendors used by Fresenius Lacey. This will ensure continuity of care for individual patient and overall system efficiency". [Source: Amended Application, Page 28]

RCGNW has an existing facility within the planning area and is relocating station from the facility to new facility therefore, the department considered RCGNW's history of providing care in the planning area and concluded it has relationships with providers in the community.

There is nothing in the material reviewed by staff that suggests the approval of this project would change those relationships. Based on this information, the department concludes RCGWN has demonstrated it has, and will continue to have, appropriate relationships to the service area's existing health care system within the planning area. **This sub-criterion is met.**

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

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

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that Renal Care Group Northwest, Inc. 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

For this project, RCGNW met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

The only option considered by the applicant is do nothing. RCGNW stated it reject the doing nothing option because it did not improve access or services for patients. The applicant stated it elected to relocate stations by downsizing stations at the existing facility. The applicant stated by decreasing the operational stations at existing Fresenius Lacey to 19-stations, space would be freed to create some additional efficiency at the facility. [Source: Amended Application, page 31] The department did not identify any other alternative to the ones proposed by the applicant. 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 Thurston County during the Kidney Disease Treatment Centers 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 application that addressed reasonableness of their construction projects that exceeded the minimum standards

To comply with this sub-criterion, the applicant states the type of construction proposed for the new facility will meet all RCGWN and Fresenius internal standards. [Source: Application, Page 37] Given that, the new facility lease costs are reflected in the negotiated lease provided by the applicant. The department evaluated the applicant's lease costs in the financial feasibility section of this analysis and concluded the overall project met the financial feasibility criterion. Based on the information, the department concludes that **this sub-criterion is met.**

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

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

APPENDIX A



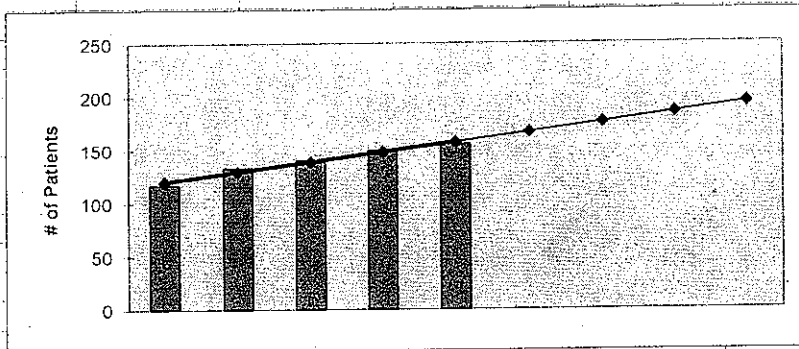
2012
Thurston County
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Thurston		2006	2007	2008	2009	2010	2011
Thurston		122	117	133	140	149	155
TOTALS		122	117	133	140	149	155
246-310-284(4)(a)	Rate of Change		-4.10%	13.68%	5.26%	6.43%	4.03%
	6% Growth or Greater?		FALSE	TRUE	FALSE	TRUE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2012	Year 2 2013	Year 3 2014	Year 4 2015
Projected Resident Incenter Patients	from 246-310-284(4)(b)			166.40	175.60	184.80	194.00
Station Need for Patients	Divide Resident Incenter Patients by 4.8			34.6667	36.5833	38.5000	40.4167
	Rounded to next whole number			35	37	39	41
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				31	31	31	31
Results of (4)(c) above				35	37	39	41
Net Station Need				-4	-6	-8	-10
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
FMC-Lacey	25	135	5.40				
DaVita Olympia	6	26	4.33				
Total	31	161					
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							



2012
Thurston County
ESRD Need Projection Methodology

x	y	Linear
2007	117	120
2008	133	130
2009	140	139
2010	149	148
2011	155	157
2012		166.400
2013		175.600
2014		184.800
2015		194.000



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.982511306
R Square	0.965328467
Adjusted R Square	0.95377129
Standard Error	3.183289703
Observations	5

ANOVA					
	df	SS	MS	F	Significance F
Regression	1	846.4	846.4	83.52631579	0.002769028
Residual	3	30.4	10.13333333		
Total	4	876.8			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-18344	2022.349485	-9.070637956	0.00283057	-24780.01865	-11907.9814	-24780.01865	-11907.9814
X Variable 1	9.2	1.006644591	9.139273264	0.002769028	5.99640764	12.40359236	5.99640764	12.40359236

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	116.8	5.2
2	124.5	-7.5
3	132.2	0.8
4	139.9	0.1
5	147.6	1.4