

EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF INLAND NORTHWEST RENAL CARE GROUP PROPOSING TO ADD FIVE KIDNEY DIALYSIS STATIONS TO THE EXISTING FRESENIUS MEDICAL CARE LEAH LAYNE DIALYSIS CENTER IN ADAMS COUNTY

APPLICANT DESCRIPTION

Inland Northwest Renal Care Group (IN-RCG) is one of three legal entities in Washington, Oregon and Idaho owned by Renal care Group (RCG). These three entities include Pacific Northwest Renal Services (PNRS), Renal Care Group of the Northwest, Inc. (RCGNW) and IN-RCG. IN-RCG is jointly owned by RCG and Sacred Heart Medical Center. On March 31, 2006, through stock acquisition, Fresenius Medical Care Holding, Inc (FMC) became the sole owner of RCG. FMC owns or operates five subsidiaries listed below are the five subsidiaries:

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

Under four of the five subsidiaries listed above, FMC operates 1,700 outpatient dialysis centers in 46 states and the District of Columbia.¹ [Source: CN historical files and Application, Pages 1-5]

In Washington State, FMC or one of its subsidiaries owns, operates, or manages 19 kidney dialysis facilities in fourteen separate counties. Below is a listing of the 19 facilities in Washington.² [CN historical files]

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

Thurston County

Lacey Dialysis Facility

Cowlitz County

QualiCenters Longview

Pend Oreille

Pend Oreille Dialysis Facility

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

Gray Harbor County

Aberdeen Dialysis Facility

Walla Walla County

QualiCenters Walla Walla

Adams County

Leah Layne Dialysis Center

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

² Three facilities—Pend Oreille Dialysis Center, Western Grant County Dialysis Center and North Spokane Dialysis Center—were recently approved by the department and are not yet operational.

PROJECT DESCRIPTION

Under its Inland Northwest Renal Care Group subsidiary, FMC proposes to add five dialysis stations to the existing four stations Fresenius Medical Care Leah Layne Dialysis Center located at 530 South 1st Avenue in the city of Othello, within Adams County. [Source: Application, Page 1]³

The capital expenditure associated with the addition of five addition stations is \$136,419. Of this amount, approximately 55% of the costs are related to fixed and moveable equipment, 37% is related to remodeling construction, and the remaining 8% is related to taxes and fees. [Source: Application, Page 30]

IN-RCG anticipates the additional five stations would become operational by the end of August 2010. Under this timeline, calendar year 2011 would be the dialysis center's first full year of operation with nine stations, and 2013 would be year three. [Source: IN-RCG Application, Page 12]

This facility currently provides in-center dialysis, home training, and isolation. If approved, one of the new stations would be a permanent bed station.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need (CN) review as the increase in the number of dialysis stations at an existing kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

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;*

³ CMS records show this facility is certified for five states. CN 1371 issued 5/21/08 approved a maximum of four stations.

- (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, IN-RCG 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) Additionally, IN-RCG must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284⁴.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Review Cycle #4. No other kidney disease treatment center applications were received for Adams County for Review Cycle #4. A chronological summary of the review is shown below.

Action	Dates
Letter of Intent Submitted	October 30, 2009
Application Submitted	November 30, 2009
Department’s Pre-Review Activities including Screenings and Responses	December 1, 2009 through May 2, 2010
Beginning of Review	May 3, 2010
End of Public Comment	June 7, 2010
Rebuttal Comments	June 21, 2010 ⁵
Department's Anticipated Decision Date	August 5, 2010
Department's Actual Decision Date	December 28, 2010

AFFECTED AND INTERESTED 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).

⁴ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), (6); WAC 246-310-240(3); WAC 246-310-286; WAC 246-310-287; WAC 246-310-288; and WAC 246-310-289.

⁵ The department did not receive any public or rebuttal comment

SOURCE INFORMATION REVIEWED

- Inland Renal Care Group Northwest Certificate of Need application received November 30, 2009.
- Inland Renal Care Group Northwest supplemental information received February 16, 2010
- Inland Renal Care Group Northwest supplemental information received April 22, 2010
- Year 2003 through 2008 year end historical kidney dialysis data obtained from Northwest Renal Network
- Year 2009 Northwest Renal Network 3rd Quarter Data, dated November 1, 2009
- Licensing and/or survey data provided by the Department of Health’s Investigation and Inspections Office
- Licensing and/or survey data provided by out of state health care survey programs
- CMS certification data and Dialysis Facility compare data
- Certificate of Need historical files
- Medical Quality Assurance compliance data

CONCLUSION

For the reasons stated in this evaluation, Inland Northwest Renal Care Group, LLC application to add five in-center dialysis stations to the existing Fresenius Medical Care Leah Layne Dialysis Center is not consistent with the applicable criteria of the Certificate of Need Program. However, the addition of four stations to Fresenius Medical Care Leah Layne Dialysis Center is consistent with the applicable criteria, provided Inland Northwest Renal Care Group, LLC agrees to the following term..

Term

IN-RCG must provide a signed copy of the updated or amended Medical Director’s agreement reflecting any re-negotiated fees for the Othello facility.

At project completion, Fresenius Medicare Care Leah Layne Dialysis Center would be approved to certify and operate a total of eight dialysis stations. The stations are listed below.

Private Isolation Room	1
Permanente Bed Station	1
Home Training Station	1
Other In-Center Stations	5
Total	8

The approved capital expenditure associated with the four-station expansion is \$136,419.

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

Based on the source information reviewed and agreement to the term identified in the “conclusion” section of this evaluation, the department determines that the applicant has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

WAC 246-310-284 requires the department to evaluate kidney disease treatment 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 under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

Kidney Disease Treatment Center Methodology WAC 246-310-284

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using data obtained from the Northwest Renal Network (NRN).⁶

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.⁷ 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 (un-rounded) 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 (un-rounded) is divided by 3.2 to determine needed stations. The number of stations projected as needed in the target year is then rounded up to the nearest whole number.

⁶ 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]

⁷ 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 2008.

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

IN-RCG Application of the Numeric Methodology

IN-RCG proposes to add five stations to the existing four stations at Fresenius Medical Care Leah Layne Dialysis Center in Othello.

To determine the type of regression analysis to be used to project station need, IN-RCG used 2003 through 2008 data for Adams County. Based on that data IN-RCG used linear regression. Tables 1 and 2 summarize IN-RCG’s application of the numeric methodology for Adams County. [Source: Application, Pages 19-20]

Table 1
IN-RCG Projected Year-End Resident In-Center Patients

	Year 2009	Year 2010	Year 2011	Year 2012 (Projection Year)
Number of Patients	20	22	24	26

Per WAC 246-310-284(3), IN-RCG used 3.2 to divide the number of projected patients to determine the number of new stations needed. [Source: Application, Pages 19-20]

Table 2
IN-RCG Projected Station Need

	Number of Stations
Current Supply	4
Total Supply	4
2012 Projected Need	9
Need Station Need	5

As shown in Tables 1 and 2 above, IN-RCG projected need for five new dialysis stations in the planning area in year 2012. Based on the result above, IN-RCG requested five stations to be added to existing capacity.

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning areas as described above, the department used linear regression to project need. The number of projected patients (un-rounded) was divided by 3.2 to determine the number of new stations needed in the planning area. The net station need for Adams County is four stations. Table 3 on the following page summarizes the department’s application of the numeric methodology for the planning area. The department’s full numeric methodology for Adams County is attached to this evaluation as Appendix A.

**Table 3
Summary of Department's Numeric Methodology for Adams County**

	Year 2009	Year 2010	Year 2011	Year 2012 (Projection Year)
In-center Patients	19.90	21.80	23.70	25.60
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	6.218	6.815	7.406	8.000
Total Station Need Rounded Up	7	7	8	8
Minus # CN Approved Stations	4	4	4	4
Net Station Need / (Surplus)	3	3	4	4

IN-RCG's numeric methodology projected a total station need of nine while the department's method projected a need for eight. IN-RCG's application did not include the detail application of their projection method. However, the department was able to determine the difference between the two projections was that IN-RCG rounded up the projected number of patients and then again rounded up the projected number of stations needed to serve those patients. Only the projected number of stations is to be rounded. (WAC 246-310-284(4)(c)). Therefore, the projected number of stations needed is four.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 3.2 in-center patients per station before new stations can be added. Fresenius Medical Care Leah Layne Dialysis Center is the only facility operating in Adams County. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for this project is November 1, 2009. [WAC 246-310-282] The most recent quarterly modality report from NRN available at that time was September 30, 2009, which became available on November 1, 2009. Table 4 below shows Fresenius Medical Care Leah Layne Dialysis Center's utilization as of September 30, 2009.

**Table 4
Current Facility Utilization**

Facility Name	#of Stations	# of Pts	Pts/Station
FMC Leah Layne Dialysis Center	4	13	3.25

Table 4 above demonstrates that Fresenius Medical Care Leah Layne Dialysis Center meets this utilization requirement.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For Fresenius Medical Care Leah Layne Dialysis Center in Adams County, the requirement is 3.2 in-center patients per approved station. IN-RCG states that year 2013 would be the third year of operation with nine stations. IN-RCG's projected utilization for year 2013 is shown in Table 5 below.

Table 5
Fresenius Medical Care Leah Layne Dialysis Center
Third Year Projected (2013) Facility Utilization

Facility Name	#of Stations	# of Pts	Pts/Station
FMC Leah Lane Dialysis Center	9	30	3.33

As shown in Table 5 above, Fresenius Medical Care Leah Layne Dialysis Center would be operating at 3.33 patients per station by year 3. [Source: Application, Page 21 and Supplemental Information February 16, 2010, Attachment 3] The department expects the facility would also meet this standard as an eight-station facility. This sub-criterion is met

Base on the above information, the application submitted by IN-RCG proposing to add five dialysis stations to the Fresenius Medical Care Leah Layne Dialysis Center in Adams County is not consistent with the applicable review criteria. However, with the addition of four stations to the dialysis center, 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.

FMC and its subsidiaries currently provide health care services to out-of-state residents or residents of Washington State. To determine whether all residents of the Adams County service area would have access to an applicant’s proposed services the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion, IN-RCG provided a copy of its current Admission Policy used at the dialysis center. The Admission Policy outlines the process/criteria that IN-RCG uses to admit patients for treatment at the dialysis center. The policy shows that patients will receive appropriate care at the facility. The Admission Policy also states that any patient needing treatment will be accepted to any FMC facility without regard to race, creed, color, age, sex, or national origin. [Source: Application, Exhibit 9]

To determine whether low-income residents would have access to the proposed services, the department uses the facility’s Medicaid eligibility or contracting with Medicaid as the measure to make that determination. IN-RCG 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 Medical Care Leah Layne 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. IN-RCG currently provides services to Medicare patients at the existing dialysis center. IN-RCG intends to continue to provide services to Medicare patients at the existing facility. A review of the facility-anticipated revenue sources indicates that it expects to continue to receive Medicare reimbursements.

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.

IN-RCG demonstrated its intent to continue to provide charity care to patients receiving treatment at the facility by submitting its current charity care policy that outlines the process one would use to access this service.[Source: Application, Exhibit 10] IN-RCG also included a ‘charity care’ line item as an expense within the pro forma income statements documents. [Source: Supplemental information received February 16, 2010, Attachment 3]

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

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

Based on the source information reviewed and the applicant’s agreement to the term identified in the conclusion section of this evaluation, the department determines that the applicant 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, IN-RCG anticipates that the 5-stations would become operational by the end of August 2010. Under this timeline, year 2011 would be the facility’s first full calendar year of operation as a 9-stations facility and 2013 would be year three. [Source: Application, Page 12] IN-RCG provided its projected 3-year revenue and expense statement for the Fresenius Medical Care Leah Layne Dialysis Center as a 9-station facility. Table 6 below summarizes that information. [Source: Supplemental Information February 16, 2010, Attachment 3]

**Table 6
Fresenius Medical Care Leah Layne Dialysis Center
Projected Revenue and Expenses**

	Partial Year 2010	Full Year 2011	Full Year 2012	Full Year 2013
# of Stations	9	9	9	9
# of Treatments [1]	924	3,456	4,032	4,608
# of Patients [2]	18	23	26	30
Utilization Rate [2]	2.00	2.56	2.89	3.33
Net Patient Revenue[1]	\$358,579	\$1,314,563	\$1,573,376	\$1,784,526
Total Operating Expenses [1, 3]	\$501,331	\$1,127,282	\$1,280,295	\$1,421,066
Net Profit or (Loss)[1]	(\$142,752)	\$187,281	\$293,081	\$363,460
Operating Revenue / Treatment [1]	\$388.07	\$380.37	\$390.22	\$387.27
Operating Exp./ Treatment [1]	\$542.57	\$326.18	\$317.53	\$308.39
Net Profit per Treatment [1]	(\$154.49)	\$54.19	\$72.69	\$78.88

[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 Table 6 above, Fresenius Medical Care Leah Layne Dialysis Center would be operating at a loss in partial year 2010 and then it turns profit through 2013.

In the ‘need’ section of this evaluation, the department concluded the addition of four stations was consistent with the projected need. Even with this one station reduction, the department expects the facility to have a net profit by the end of the 3rd year of operation.

As an existing facility, the applicant provided an executed lease agreement between KLM Othello, LLC (“Landlord”) and Renal Care Group Northwest, Inc (RCGNW)/Inland Northwest Renal Care Group, LLC (“Tenant”). [Source: Application, Exhibit 7] The department’s review of the executed lease agreement shows that rent costs identified in the lease are consistent with the facility’s pro-forma financial projections.

IN-RCG provided a copy of its current Medical Director’s Services Agreement. The 3rd amendment to this agreement relates specifically to the Othello facility and runs through December 31, 2012. The 3rd amendment also identifies the annual compensation for the Medical Director position. IN-RCG’s pro-forma financial statement identified the annual compensation for the Medical Director. The Medical Director’s services contract is consistent with the stated amount in the applicant’s pro-forma income statement. The 3rd amendment includes a provision that states, in part, beginning no later than ninety (90) days prior to October 31, 2010, the parties agree to meet and in good faith, negotiate new Othello fees. [Source: Application, Page 53 and Exhibit 3] While the financial statements provided in this application are consistent with the current fee structure of the executed 3rd amendment, if this project is approved, the department would include a term requiring IN-RCG to provide a signed copy of the updated or amended Medical Director’s agreement reflecting the re-negotiated fees for this facility.

Based on the information reviewed and with agreement to the term described above, 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 what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project’s source of financing to those previously considered by the department.

IN-RCG identified the capital expenditure associated with the five-station addition to be \$136,419. These costs are summarized in Table 7 below.

**Table 7
Fresenius Leah Layne Dialysis Center Capital Cost**

Item	Cost	% of Total
Building Construction	\$50,000	37%
Fixed & Moveable Equipment	\$75,500	55%
Sales Tax and Fees*	\$10,915	8%
Total Project Cost	\$136,415	100%

To further demonstrate compliance with this sub-criterion, IN-RCG provided the sources of its patient revenue shown in Table 8 below. [Source: Application, Page 32]

Table 8
IN-RCG/Fresenius Source of Revenue

Source of Revenue	% of Revenue
Medicare	86.6%
State (Medicaid)	2.2%
Other	3.1%
Total	100%

The existing Fresenius Medical Care Leah Layne is expected to have 88.8% 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 those with insurance or HMO patients that make up 3.1% of the project’s 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.

As previously stated, the capital expenditure associated with the additional of stations is \$136,419. IN-RCG states that the project will be funded from its own reserves. This statement is supported with a letter confirming the commitment of the corporate funding. [Source: Supplemental Information received February 16, 2010, Attachment 2] A review of IN-RCG’s financial statements shows the funds necessary to finance the project are available. [Source: Application, Appendix 2]

Based on the information provided, the department concludes tthe project can be appropriately financed. This sub-criterion is met.

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

Based on the source information reviewed the department determines that the applicant 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.

As an existing facility, Fresenius Leah Layne Dialysis Center currently has 3.9 FTE’s and by the third full calendar of operation, the applicant proposes that it will have 7.55 FTE’s or an increase of 3.65 FTEs over the three-year period. The applicant’s existing and incremental staff increases are summarized in Table 9 on the following page.

**Table 9
Fresenius Medical Care Leah Layne Dialysis Center FTE's 2009 – 2013**

Category	Current 2009	Partial 2010 Increase	Year 1 2011 Increase	Year 2 2012 Increase	Year 3 2013 Increase	Total FTEs
Medical Director	Professional Services Contract					
Nurse Manager	0.50	0	0.25	0.25	0	1.00
Out-Patient Nurse	1.00	0.50	0	0.15	0.35	2.00
Patient Care Tech	1.50	0	0.50	0.40	0.60	3.00
Social Worker	0.10	0	0.05	0.05	0.05	0.25
Dietician	0.10	0	0.15	0.05	0.05	0.25
Secretary	0.50	0	0.25	0	0	0.75
Bio-Med	0.20	0.05	0	0.05	0	0.30
Total FTE's	3.90	0.55	1.10	0.95	1.05	7.55

As shown in Table 9 above, IN-RCG expects a steady increase in FTEs for the Fresenius Leah Layne Dialysis Center through year 2013.

IN-RCG states it offers competitive wage and benefits packages and has never had trouble in recruiting and retaining staff. Further, the applicant states *“We are able to recruit the staff for opening Fresenius Leah Layne by supporting several key Moses Lakes Staff (that live closer to Othello) in relocating. Having the flexibility afforded by WAC to operate (and hence staff) just 2 shifts per day also helped considerably in the recruitment of staff. The small number of incremental FTEs needed to expand will come largely from allowing existing part time staff to increase to full time status. For these reasons we expect no unusual difficulties”*. [Source: Application, Page 34]

The applicant identified Curtis Wickre, MD as the current medical director for Fresenius Leah Layne Dialysis Center and provided an executed medical director service agreement between Renal Care Group, Inc. referred to as the (“Company”) and Rockwood Clinic, PS referred to as (the “Consultant”) a Washington professional corporation which includes several physicians collectively known as (Member Physicians). The Medical Director’s agreement outlines the roles and responsibilities of Company and Consultant. 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.

IN-RCG states, *“As this project proposes the expansion of an existing unit, Fresenius Leah Layne already has the appropriate ancillary and support services in place”*. [Source: Application, Page 34]

Based on the evaluation of supporting documents provided, the department concludes that there is reasonable assurance that Fresenius Leah Layne Dialysis Center will continue to have appropriate ancillary and support services with a healthcare provider in Adams County. 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.

To comply with this sub-criterion, within the application IN-RCG provided a contact list of the regulatory agencies responsible for surveying its facilities in Washington and the United States. [Source: Application, Exhibit 2] As stated earlier in this evaluation, Fresenius is the parent company of IN-RCG. Information available at Fresenius Medical Care North America website stated that Fresenius is a provider of dialysis and related renal services in the United States with more than 1,700 outpatient centers located in 46 states (including Washington State), the District of Columbia, and Puerto Rico. [Source: <http://www.fmcna.com/company.html> and Application, Exhibit 2]

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.⁸ 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 states⁹ and the 2 non-state entities surveyed, the department received 26 responses or 55% of those surveyed¹⁰.

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 own or operated by Fresenius, the department concludes that considering that it owns or operates more than 1,700 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]

Within the application, IN-RCG stated that it is jointly own by RCG and Providence Sacred Heart Medical Center. In Washington State, Fresenius or its subsidiaries, including IN-RCG, currently owns, operates and/or manages 19 kidney dialysis treatment facilities in fourteen separate counties. The IN-RCG/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 the department's Investigation and Inspections Office]

According to the applicant, IN-RCG is 80% owned by RCG and 20% by Providence Sacred Heart Medical Center a healthcare provider in Spokane County. [Source: Application, Page 2] The department also reviewed Providence Sacred Heart Medical Center's quality of care compliance history. That

⁸ WAC 246-310-230(5).

⁹ This figure excludes Washington. The department did not send a survey to itself for compliance.

¹⁰ Those not responding were: 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.

review shows that five compliance surveys were completed for Providence Sacred Heart Medical Center between 1999 and 2010. 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 the department's Investigation and Inspections Office]

IN-RCG identified Curtis Wickre, MD, as the Medical Director for Fresenius Medical Care Leah Layne Dialysis Center and provided a medical director services agreement within the application. A review of Dr. Wickre'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]

Based on recent surveys of Fresenius Leah Layne Dialysis Center and its affiliates and Providence Sacred Heart Medical Center, it is reasonable to expect that Fresenius Leah Layne Dialysis Center would continue to operate in compliance with the applicable standards and regulations of Washington State. 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.

The applicant stated, "*As this project proposes an expansion of an existing facility, no change in the provision of health care services is planned. All existing working relationships will continue. Fresenius Leah Layne provides a collaborative, comprehensive, and patient-centered approach to the provision of dialysis services in the community. With the expansion of our facility, we will continue to maintain all existing working relationships with other providers in our service area, including: Othello Community Hospital, Special Mobility Services, and Northwest Cabulance. Fresenius Leah Layne also maintains a transfer agreement with Sacred Heart Medical center*". [Source: Application, Page 35 and Exhibit 12]

The department also considered IN-RCG's history of providing care in the planning area and concluded that it has been providing dialysis services to the residents of Washington for several years and has been appropriately participating in relationships with community providers. 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 the applicant 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) and WAC 246-310-288 (Tie Breakers)

Based on the source information reviewed the department determines that the applicant has met the cost containment criteria in WAC 246-310-240.

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

WAC 246-310 does not contain specific WAC 246-310-240(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 how to measure superior alternatives. Therefore, using its experience and expertise the department assessed the materials in the application.

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 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, IN-RCG has met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

IN-RCG stated it considered one option before submitting this application. The option considered was to wait for the existing facility to achieve higher occupancy, which IN-RCG anticipated would be in early 2010. This option, and the applicant's rationale for rejecting the option, is summarized below.

IN-RCG stated that neither the community nor IN-RCG wants the four-station Leah Layne Dialysis Center to begin using a third shift to accommodate patients. There is extremely limited evening public transit in the county and a third shift may force patients to travel or relocate to another facility with more station capacity. Further, the third shift would be difficult for IN-RCG to staff. [Source: Application, Page 36]

IN-RCG stated this project is directed at meeting future kidney dialysis need for Adams County because the facility is operating at high capacity. Currently, the center is operating at 3.25 patients per station as stated in the need section of this analysis. The station use is just above the required level

that must be met before additional stations are added. , The results of the numeric need methodology shows need for additional stations. Therefore, the department concludes that the project described is the best available alternative for the planning area.

Step Three

This step is used to determine the best available alternative between two or more approvable projects. There were no other competing projects submitted for Adams County during the Kidney Disease Treatment Centers Review Cycle #4. 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, IN-RCG states, it would add the new stations to existing space within the facility and only minor construction is required. [Source: Application, Page 37] The existing facility's lease costs are reflected in the negotiated lease provided by the applicant. The lease costs were evaluated in the financial feasibility section of this analysis. The department 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.*

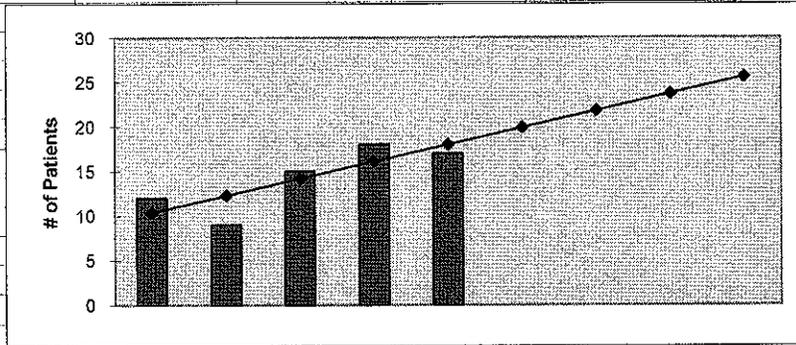
This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.

APPENDIX A

Adams County ESRD Need Projection Methodology							
Planning Area	6 Year Utilization Data - Resident Incenter Patients						
Adams	2003	2004	2005	2006	2007	2008	
Adams	12	12	9	15	18	17	
TOTALS	12	12	9	15	18	17	
246-310-284(4)(a)	Rate of Change		0.00%	-25.00%	66.67%	20.00%	-5.56%
	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2009	Year 2 2010	Year 3 2011	Year 4 2012
Projected Resident Incenter Patients	from 246-310-284(4)(b)			19.90	21.80	23.70	25.60
Station Need for Patients	Divide Resident Incenter Patients by 3.2			6.2188	6.8125	7.4062	8.0000
	Rounded to next whole number			7	7	8	8
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				4	4	4	4
Results of (4)(c)above				-7	-7	-8	8
Net Station Need				-3	-3	-4	-4
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
FMC Othello	4	13	3.25				
Total	4	13					
Source: Northwest Renal Network data 2003-2008							
Most recent year-end data: 2008 year-end data as of 01/26/2009							
Most recent quarterly data as of the 1st day of application submission period: 3rd quarter 2009 as of 11/01/09							

**Adams County
ESRD Need Projection Methodology**

x	y	Linear
2004	12	10
2005	9	12
2006	15	14
2007	18	16
2008	17	18
2009		19.900
2010		21.800
2011		23.700
2012		25.600



SUMMARY OUTPUT

<i>Regression Statistics</i>	
Multiple R	0.811639775
R Square	0.658759124
Adjusted R Square	0.545012165
Standard Error	2.496664441
Observations	5

ANOVA					
	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	36.1	36.1	5.79144385	0.095312489
Residual	3	18.7	6.233333333		
Total	4	54.8			

	<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	-3797.2	1583.766719	-2.397575321	0.096083804	-8837.452542	1243.052542	-8837.452542	1243.052542
X Variable 1	1.9	0.789514619	2.406541886	0.095312489	-0.612587881	4.412587881	-0.612587881	4.412587881

RESIDUAL OUTPUT

<i>Observation</i>	<i>Predicted Y</i>	<i>Residuals</i>
1	10.4	1.6
2	12.3	-3.3
3	14.2	0.8
4	16.1	1.9
5	18	-1