

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF INLAND NORTHWEST RENAL CARE GROUP, LLC/FRESENIUS MEDICAL CARE HOLDINGS, INC. PROPOSING TO ESTABLISH A NEW SIX STATION KIDNEY DIALYSIS FACILITY IN PEND OREILLE COUNTY**

**PROJECT DESCRIPTION**

Inland Northwest Renal Care Group, LLC is one of three entities owned by Renal Care Group, Inc. On March 31, 2006, thorough stock acquisition, Fresenius Medical Care Holdings, Inc. became the sole owner of Renal Care Group, Inc. Information provided to the department indicates that IN-RCG is jointly owned by Renal Care Group, Inc. and Sacred Heart Medical Center a local healthcare provider in Spokane County. Fresenius Medical Care Holdings, Inc. the applicant parent company owns the subsidiary companies listed below.

QualiCenters Inc.

Inland Northwest Renal Care Group, LLC

National Medical Care, Inc.

Pacific Northwest Renal Services

Renal Care Group, Inc.

Under four of the five subsidiaries listed above, Fresenius Medical Care Holdings, Inc. owns, operates or manages dialysis centers in 45 states, the District of Columbia and Puerto Rico.<sup>1</sup> [Source: Application pages 4-6 and Appendix 1]

In Washington State, Fresenius Medical Care Holdings, Inc. or one of its subsidiaries owns, operates, or manages seventeen kidney dialysis facilities in thirteen separate counties. Listed below, are the seventeen facilities in Washington<sup>2</sup>. [Source: CN historical files and Application, pages 4-6]

**Adam County**

Othello Dialysis Center

**Benton County**

Columbia Basin Dialysis Center

**Clark County**

Fresenius Fort Vancouver Dialysis Facility

Fresenius Salmon Creek Dialysis Facility

**Grant County**

Fresenius Moses Lake Dialysis Facility

**Gray Harbor County**

Fresenius Aberdeen Dialysis Facility

**Spokane County**

Fresenius Northpointe Dialysis Facility

Fresenius Spokane Kidney Center

Fresenius Valley Dialysis Facility

**Cowlitz County**

QualiCenters Longview

**Stevens County**

Colville Dialysis Center

**Lewis County**

Fresenius Chehalis Facility

**Mason County**

Fresenius Shelton Dialysis Facility

**Okanogan County**

Fresenius Omak Dialysis Facility

**Thurston County**

Hawks Prairie Dialysis Facility

Fresenius Lacey Dialysis Facility

**Walla Walla County**

QualiCenters Walla Walla

The application submitted on behalf of Inland Northwest Renal Care Group, LLC proposes to establish a new six station kidney dialysis facility in Pend Oreille County. The facility to be known as Pend Oreille County Dialysis Center would be located on site at 1621 West 7<sup>th</sup> Street within the

<sup>1</sup> The National Medical Care, Inc. subsidiary does not operate any dialysis facilities.

<sup>2</sup> Othello Dialysis Center, QualiCenters Longview, Colville Dialysis Center, and Hawks Prairie Dialysis Facility are CN approved but not yet operational.

City of Newport and would serve the residents of Pend Oreille County. [Source: Application, Page 8 and Supplemental Information June 30, 2008; Page 1]

The capital expenditure associated with the new 6-station dialysis center is \$971,560, of which approximately 65% is related to architect, engineering and leasehold improvements at the site; 23% is related to fixed and moveable equipment and the remaining 12% is related to taxes and fees. [Source: Application, Page 26]

If this project is approved, Inland Northwest Renal Care Group, LLC anticipates the dialysis facility would be operational by March 2010. Under this timeline, year 2011 would be the dialysis center first full calendar year of operation as a 6-station facility and 2013 would be year three. [Source: Application, page 11] For ease of reference, the department would refer to the proposed Pend Oreille County Dialysis Center as “POCDC” and the applicant Inland Northwest Renal Care Group, LLC as “IN-RCG”.

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

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

### **CRITERIA EVALUATION**

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); 246-310-240 (cost containment); and 246-310-280 through 286 (the dialysis station projection methodology and standards).<sup>3</sup>

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<sup>3</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(2) and (3) WAC 246-310-287.

## **APPLICATION CHRONOLOGY**

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1. IN-RCG was the only applicant that submitted an application to provide dialysis services for Pend Oreille County during Review Cycle #1; therefore, as allowed under WAC 246-310-282(5), IN-RCG's application was converted to a regular review

January 31, 2008	Letter of Intent Submitted
February 29, 2008	Application Submitted
March 10, 2008 through July 31, 2008 <sup>4</sup>	Department's Pre-Review Activities <ul style="list-style-type: none"><li>• 1<sup>st</sup> screening activities and responses</li><li>• 2<sup>nd</sup> screening activities and responses</li></ul>
August 6, 2008	Department Begins Review of Application
September 10, 2008	End of Public Comment/No Public Hearing Conducted
September 25, 2008	Rebuttal Documents due date <sup>5</sup>
November 10, 2008	Department's Anticipated Decision Date
December 12, 2008	Department's Actual Decision Date

## **AFFECTED AND INTERESTED PERSONS**

Throughout the review of this project, no entities sought and received affected person status under WAC 246-310-010.

## **SOURCE INFORMATION REVIEWED**

- IN-RCG's Certificate of Need application submitted February 29, 2008
- IN-RCG's supplemental information dated June 30, 2008 and July 31, 2008
- Years 2001 through 2007 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2007 Northwest Renal Network 4<sup>th</sup> Quarter Data
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from Fresenius Medical Care's webpage
- Certificate of Need historical files
- Medical Quality Assurance compliance data

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<sup>4</sup> IN-RCG requested 45 days extension to supplemental information submission.

<sup>5</sup> The department did not receive public comments regarding this project.

## **CONCLUSIONS**

For the reasons stated in this evaluation, the application submitted on behalf of Inland Northwest Renal Care Group, LLC proposing to establish a new 6-station dialysis center in the city of Newport to serve the residents of Pend Oreille County is consistent with the applicable criteria. Provided that Inland Northwest Renal Care Group, LLC agrees to the terms identified below.

### **Terms**

1. Prior to commencing this project, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval the executed copy of the Turnkey Lease Agreement to the proposed site located at 1621 West 7<sup>th</sup> Street in Newport, Pend Oreille County. The proposed site is also legally known as Pend Oreille County Parcel/Tax number 453124570002. The executed Turnkey Lease Agreement must be consistent with the draft provided in the application.
2. Prior to providing services, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval an executed copy of the addendum to the Medical Director's agreement. The executed agreements must be consistent with the draft addendum agreement provided within the application.
3. Prior to providing services at the Pend Oreille County Dialysis Center, Inland Northwest Renal Care Group, LLC will provide an executed copy of the Amended Patient Transfer Agreement that will include the Pend Oreille County Dialysis Center.

The approved capital expenditure associated with the establishment of the Pend Oreille County Dialysis Center is \$971,560.

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

Based on the source information reviewed, 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 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.<sup>6</sup>

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4) (a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year. In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last 5 annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

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

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

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

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<sup>6</sup> Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

IN-RCG's Application of the Numeric Methodology

IN-RCG proposes to establish a 6-station kidney dialysis facility in Newport to serve the residents of Pend Oreille County. Consistent with WAC 246-310-284 (4), IN-RCG applied the numeric methodology for the planning area using linear regression. Given that the facility would be located in Pend Oreille County, the number of projected patients was divided by 3.2 to determine the number of stations needed in the planning area. [Source: Application Page 19]

The department's application of the numeric methodology

Based on the calculation of the annual growth rate in the planning areas as described above, the department also used linear regression to project need for Pend Oreille County and divided the projected number of patients by 3.2 to determine the number of stations needed as required under WAC 246-310-284(4).

Based on the numeric methodology, Table 1 below shows a summary of the projected net need provided by IN-RCG and the department for Pend Oreille County. The department's numeric methodology for Pend Oreille County is attached to this evaluation as Appendix A.

**Table 1**  
**Pend Oreille County Numeric Methodology Summary of Projected Net Station Need**

	3.2 in-center patients per station			
	2011 Projected # of In-center Patients	Minus Current # of stations	2011 Net Need	2011 Net Need (Rounded)
<b>IN-RCG</b>	17	0	6	6
<b>DOH</b>	17	0	5.312	6

When comparing the results shown in Table 1 above, it is noted that IN-RCG projections and the department's projections are exactly the same. In summary, the numeric needs methodology result in a need for 6-stations in Pend Oreille County.

WAC 246-310-284(5) requires that all CN approved stations in the planning area must be operating at 3.2 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period was February 1, 2008. [Source: WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2007, which became available on January 21, 2008. Currently, Pend Oreille County does not have a dialysis facility. This criterion is met.

WAC 246-310-284 (6) requires PO CDC to be operating at 3.2 in-center patients per approved station by the end of year three or year 2013. IN-RCG provided the projected third year utilization for the PO CDC as a 6-station facility. A summary of the projections for year 2013 is shown in Table 2 below. [Source: Screening responses received July 31, 2008, Attachment 8]

**Table 2**  
**Year 2013 Projected Facility Utilization**

Facility Name	# of Stations	# of Pts	Pts/Station
PO CDC	6	20	3.33

As shown in the table above, IN-RCG projects POCDC would be operating above the 3.2 standard by the end of the third year of operation or year 2013.

Based on IN-RCG projections with all 6 stations operational, the facility would be operating above 3.2 patients per in-center station by the third year of operation or year 2013. The department concludes that IN-RCG's proposal to establish a new six dialysis station dialysis center in Pend Oreille County to serve the residents of the planning area meets this criterion.

Based on the numeric methodology and the information provided need for a new six station dialysis facility in Newport within Pend Oreille County has been demonstrated. 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.

IN-RCG is currently a provider of health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the service area would continue to 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 determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

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 IN-RCG provided a copy of its Admission Policy and Indigence Policy that would be used at the proposed POCDC. Within its application, IN-RCG states, "All individuals identified as being in need of dialysis services will have access to this unit". [Source: Application, page 21 and Exhibits 6 and 7] A review of IN-RCG's Admission and Indigence Policies shows that the policies prohibit discrimination on the basis of race, color, national origin, sex, age, religion or disability. The policies outlines the eligibility criteria's and stated the income levels at which charity care is provided to prospective recipients. Additionally, the pro-forma income statements provided by IN-RCG with its application, included charity care expenses at 1.52% of the total revenue.

The department also reviewed the historical financial statements provided by IN-RCG and those statements shows charity care expenses.

Fresenius and its subsidiary IN-RCG currently provides services to Medicare and Medicaid eligible patients at existing dialysis centers in Washington. IN-RCG states that it would provide services to Medicare and Medicaid patients at the proposed POCDC. The department's review of the proposed facility anticipated revenue shows that both Medicare and Medicaid reimbursements is expected. [Source: Supplemental Information received July 31, 2008, Attachment 8]

Based upon source information reviewed, the department concludes that all residents of the service area could reasonably be expected to have adequate access to healthcare services at the proposed POCDC. 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 terms identified in 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.*

As stated in the project description portion of this evaluation, if this project is approved IN-RCG anticipates all 6-stations would be operational by March 2010. Under this timeline, year 2011 would be the facility's first full calendar year of operation and 2013 would be year three. [source: Application, Page 11]

Summarized in Table 3 below is IN-RCG year one through year three projected financial revenue, expenses, and net income for the six station POCDC facility. [Source: Supplemental Information received July 31, 2008, Attachment 8]

**Table 3  
POCDC Projected Revenue and Expenses for Years 2009 through 2013**

	<b>Partial Year 2010</b>	<b>Year 1- 2011</b>	<b>Year 2 - 2012</b>	<b>Year 3- 2013</b>
# of Stations	6	6	6	6
# of Treatments [1]	1,680	2,232	2,664	3,024
# of Patients [2]	13	16	18	20
Utilization Rate [2]	2.17	2.66	3.0	3.33
Net Patient Revenue[1]	\$ 654,380	\$864,490	\$1,045,827	\$1,200,753
Total Operating Expenses [3]	\$654,756	\$838,210	\$946,922	\$1,037,953
Net Profit or (Loss)[1]	(\$376)	\$26,280	\$98,905	\$162,800
Net Patient Revenue / Treatment [1]	\$389.51	\$387.32	\$392.58	\$397.07
Total Operating Exp./ Treatment [3]	\$389.74	\$375.54	\$355.45	\$343.24
Net Profit per Treatment [1,3]	(\$0.22)	\$11.77	\$37.13	\$53.84

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

As shown in Table 3 above, at the projected volumes identified, IN-RCG would be operating the 6-station dialysis center at a loss in partial year 2010 and a profit in years 2011 through 2013. The applicant provided a draft Turnkey Lease Agreement for the proposed site between Inland Northwest Renal Care Group, LLC (Tenant) and MDG-FRE XIII, LP (Landlord)<sup>7</sup>. The costs identified in the draft Turnkey Lease Agreement are consistent with the pro-forma financial projections used to prepare Table 3 above.

If approved, the Department would include a term that IN-RCG provide for review and approval an executed copy of the Turnkey Lease Agreement consistent with the draft agreement provided with supplemental information.

#### Term

- *Prior to commencing this project, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval the executed copy of the Turnkey Lease Agreement to the proposed site located at 1621 West 7<sup>th</sup> Street in Newport, Pend Oreille County. The proposed site is also legally known as Pend Oreille County Parcel/Tax number 453124570002. The executed Turnkey Lease Agreement must be consistent with the draft provided in the application.*

IN-RCG identified Dr. John Musa as the proposed POCDC Medical Director and provided a draft Medical Director Agreement Addendum. The document identifies the medical director scope of service and the annual compensation for the position. Additionally, IN-RCG also provided a pro-forma income statement for the facility and the medical director's compensation identified in the pro-forma is consistent with the data used to prepare the information in Table 3. [Source: Supplemental Information received July 31, 2008, Attachment 8]

The department review of the document shows that medical director cost identified in the pro-forma income statement is consistent with the data used to produce the information contained in Table 3.

Based on the above information and with agreement to the term above, the department concludes the immediate and long range capital and operating costs can be met. 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.*

IN-RCG identified the capital expenditure associated with the establishment of the 6-station dialysis to be \$971,560. Summarized in the table below is the capital expenditure for the proposed POCDC. [Source: Supplemental Information received July 31, 2008, Attachment 1]

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<sup>7</sup> Turnkey Agreement is a term used for any construction project that is turned over in finished form to the user entity. [Source: <http://encyclopedia.thefreedictionary.com/turnkey>]

**Table 4  
IN-RCG POCDC Capital Cost**

<b>Item</b>	<b>Cost</b>	<b>% of Total</b>
Building Construction & Tenant Improvements	\$631,434	65%
Fixed & Moveable Equipment	\$221,000	23%
Sales Tax and Fees	\$119,072	12%
<b>Total Project Cost</b>	<b>\$971,506</b>	<b>100%</b>

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, IN-RCG also provided the sources of its patient revenue shown in Table 5 below. [Source: Application, Page 32]

**Table 5  
IN-RCG Source of Revenue**

<b>Source of Revenue</b>	<b>% of Revenue</b>
Medicare	67%
State (Medicaid)	5%
Other	28%
<b>Total</b>	<b>100%</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 72% of the revenue at the POCDC. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. The remaining 28% will be derived through other or private insurance reimbursements. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals; the average cost per dialysis is reasonable.

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

(3) *The project can be appropriately financed.*

To demonstrate compliance with this sub-criterion, IN-RCG provided a letter from its parent company Fresenius Medical Care. The letter stated that financial and operational support would be available to the proposed facility. [Source: Supplemental information received July 8, 2008] Additionally, IN-RCG provided Fresenius Medical Care's most recent historical financial statements for years 2003 through 2005. [Source: Application, Appendix 2] That review shows that its parent company's financial reserves are more than adequate to fund the establishment a new six station dialysis facility.

Based on the information provided, the department concludes the source of the project financing is appropriate. 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.

To implement this project IN-RCG proposes to hire the equivalent of 4.7 new staff during the first partial year of operation and thereafter, increase the number of new staff to 6.5 by the end of the third full years of operation. The proposed POCDC staffing is summarized in Table 6 below.

**Table 6  
POCDC 2010 – 2013 Projected FTEs**

Staff/FTEs	Partial Year 2010	Year 2011	Year 2012	Year 2013
Medical Director	Professional Services Contract			
Nurse manager	0.5	0.5	0.5	1.0
Outpatient RN	1.0	1.0	1.0	1.0
Patient Care Techs	2.0	2.0	2.6	2.6
Equipment Techs	0.8	0.8	1.0	1.0
MSW	0.1	0.1	0.2	0.2
Dietitian	0.1	0.1	0.2	0.2
Secretary	0.2	0.2	0.5	0.5
<b>Total FTE's</b>	<b>4.7</b>	<b>4.7</b>	<b>6.0</b>	<b>6.5</b>

IN-RCG states that staffing in rural communities is an ongoing challenge but it does not expect any difficulty in recruiting staff for the new facility because of its competitive wage and benefit package. Further, the applicant states that it operates five facilities throughout eastern Washington and having this number of facilities in the eastern parts of the state will allow IN-RCG to realize economies of scale by sharing administrative staff and regional-level support staff. [Source: Application, Page 34]

IN-RCG identified John Musa, MD as the Medical Director for the proposed POCDC and provided a draft medical director's addendum agreement between IN-RCG and Dr. Musa's practice at the Rockwood Clinic. The draft addendum medical director's agreement outlines the roles and responsibilities of both IN-RCG and Rockwood Clinic. The draft addendum contract also identifies the annual compensation for the medical director's position. [Source: Application, Page 7 and Supplemental Information received July 31, 2008, Attachment 2]

If approved, the Department would include a term that IN-RCG provide for review and approval an executed addendum to the medical director's contract which includes the relevant terms and compensation as identified in the draft agreement.

Term

- *Prior to providing services, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval an executed copy of the addendum to the Medical Director's agreement. The executed agreements must be consistent with the draft addendum agreement provided within the application.*

Base on information provided the department concludes that staffing is expected to be available for the proposed center. 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.

Information provided by IN-RCG states that ancillary services such as social and nutrition services would be provided on site while support services such as pharmacy, laboratory and radiology will be available through working relationship with local providers. [Source: Application, Page 35]

To further demonstrate compliance with this sub-criterion, IN-RCG states that it would “contemplate having a formal transfer agreement with Sacred Heart Medical Center in Spokane” and provided the existing executed agreement between some of IN-RCG facilities in eastern Washington and Sacred Heart Medical Center. [Source: Application, Appendix 9]

If this project is approved, the department would include a term requiring IN-RCG to provide a copy of the executed transfer agreement with Sacred Heart Medical Center.

#### Term

- *Prior to providing services at the Pend Oreille County Dialysis Center, Inland Northwest Renal Care Group, LLC will provide an executed copy of the Amended Patient Transfer Agreement that will include the Pend Oreille County Dialysis Center.*

Based on the information provided and with agreement to the term above, the department concludes that there is reasonable assurance that the Pend Oreille County Dialysis Center will have appropriate ancillary and support services. 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.

Inland Northwest Renal Care Group, LLC (IN-RCG) is also known as Renal Care Group Northwest, Inc (RCGNW) and is owned by Renal Care Group (RCG). On March 31, 2006, through stock acquisition Fresenius Medical Care Holdings, Inc became the sole owner of Renal Care Group. Inland Northwest Renal Care Group, LLC an indirect subsidiary of Fresenius Medical Care, a German corporation. Inland Northwest Renal Care Group is jointly owned by Renal Care Group Northwest and Sacred Heart Medical Center, a hospital located in Spokane County.

The department’s survey of other states with oversight authority over kidney dialysis facility revealed minor non-compliance issues typical of a dialysis facility related to the care, medical records, and management at Fresenius facilities the applicant parent company. In summary, in those states that license and/or survey dialysis facilities, Fresenius or one of its subsidiaries submitted plans of correction and implemented the required corrections when these non-compliance issues were identified. [Source: Licensing and/or survey data provided by out of state health care survey programs]

In Washington State, Fresenius or one of its subsidiaries owns, operates, or manages thirteen kidney dialysis facilities in thirteen separate counties. In addition, four facilities have been approved; but are not yet operational. The Fresenius owned or operated facilities in Washington have collectively been surveyed 33 times in the last six years. Of the 33 surveys, one survey revealed a potentially hazardous condition that was promptly corrected and 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: Office of Health Care Survey compliance survey data]

On the basis of recent surveys of the facilities owned, operated, or managed by subsidiaries of Fresenius Medical Care, it is reasonable to expect that the Pend Oreille County Dialysis Center would be operated in compliance with the applicable state and federal standards and regulations.

IN-RCG identified John Musa, MD as its medical director under a draft medical director's addendum agreement provided with the application supplemental information. A review of Dr. John Musa's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

Based on Fresenius and its subsidiaries compliance history and the compliance history of the Dr. John Musa as medical director, the department concludes that there is reasonable assurance that the proposed Pend Oreille County Dialysis Center would be operated in conformance with applicable laws and 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.*

The applicant stated that it does not contemplate entering into formal working agreements, but will work with local providers to make sure patient's needs are met. Within the application, IN-RCG states that it would work with the following providers Newport Community Hospital, Pend Oreille Medical Clinic and Rural Resource Community Action. [Source: Application, Page 35]

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

Based on this information reviewed, the department concludes that approval of this project would not result in an unwarranted fragmentation of services and would have appropriate relationships with healthcare systems 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.

This sub-criterion is addressed in sub-criterion (3) of this evaluation. The department concludes that there is reasonable assurance that the services to be provided will ensure safe and adequate care to the public and in accordance with applicable federal and state laws, rules, and regulations. This sub-criterion is met.

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

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.

To comply with this sub-criterion, IN-RCG considered two other alternatives besides the project. Listed below are the alternatives considered by IN-RCG.

- Expand the existing Northpointe facility in Spokane County.
- Expand the new Colville facility in Stevens County.

IN-RCG states that it rejected the alternatives listed above because the vast majority of Pend Oreille patients use the Northpointe facility in Spokane County. Further, the applicant stated that most of the dialysis facilities in Spokane County are operating below 80% capacity and therefore, those facilities cannot expand. IN-RCG stated that it rejected the two alternatives considered and decided to establish a new facility in Pend Oreille County instead.

The department agrees the two alternatives IN-RCG identified are not the best available alternatives. Neither alternative addresses the department's goal of having stations located close to the patients needing dialysis. The current application however meets that goal.

The department concludes that the applicant proposal to establish a new 6-station facility in Newport to serve the residents of Pend Oreille County is the best available alternative. This criterion is met.

- (2) In the case of a project involving construction:

- (a) The costs, scope, and methods of construction and energy conservation are reasonable;

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, 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.

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.