

**REVIEW OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON  
BEHALF OF INLAND NORTHWEST - RENAL CARE GROUP PROPOSING TO  
ESTABLISH A FOUR STATION KIDNEY DIALYSIS CENTER TO SERVE THE  
RESIDENTS OF ADAMS COUNTY**

**PROJECT DESCRIPTION**

Fresenius Medical Care Holdings, Inc. is the parent corporation of the following five subsidiaries:

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

Under the four of the five subsidiaries listed above, Fresenius Medical Care Holdings, Inc. (Fresenius) operates dialysis centers in 45 states, the District of Columbia, and Puerto Rico.<sup>1</sup> [CN historical files; Application, p1]

In Washington State, Fresenius or one of its subsidiaries owns, operates, or manages fifteen kidney dialysis facilities in twelve separate counties. Below is a listing of the fifteen facilities in Washington.<sup>2</sup> [CN historical files; Application, p2 & Exhibit #1]

**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**

Fresenius Lacey Dialysis Facility

**Walla Walla County**

QualiCenters Walla Walla

This application proposes to establish a four station dialysis facility to be known as the Othello Dialysis Center, to serve the patients residing in Adams County. The estimated capital expenditure for the establishment of the Othello facility is \$923,681. If this project is approved,

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

<sup>2</sup> Two facilities—Colville Dialysis Center and QualiCenters Longview—were recently approved by the department and are not yet operational.

IN-RCG anticipates commencement on the project to be in the Spring of 2008 and that all approved stations would be available for patient use by March 2009. Under this timeline, year 2010 would be the facility's first full calendar year of operation. [Application, p11]

<b>Breakdown Of Costs</b>	<b>Total</b>	<b>% of Total</b>
Leasehold Improvements	\$ 588,000	64%
Fixed & Moveable Equipment	\$ 220,071	24%
Professional Fees & Taxes	\$ 44,500	5%
Taxes	\$ 71,110	8%
<b>Total Estimated Capital Costs</b>	<b>\$ 923,681</b>	<b>100.00%</b>

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

This project is subject to Certificate of Need review in 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 (CN) approval, IN-RCG must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment).<sup>3</sup> Additionally, the applicant must demonstrate compliance of the project according to relevant sections of WAC 246-310-280 through 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 #4. No other kidney disease treatment center applications were reviewed for the Adams County during Review Cycle #4. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

October 31, 2007	Letter of Intent Submitted
November 30, 2007	Application Submitted
December 1, 2007 through March 18, 2008	Screening Activities and Responses
March 19, 2008	Department Begins Review of Application
April 24, 2008	Public Hearing / End of Public Comment
June 23, 2008	Department's Anticipated Decision Date
May 13, 2008	Department's Decision Date

### **AFFECTED PARTIES**

There were no affected parties on this application.

<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(3); WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

## **SOURCE INFORMATION REVIEWED**

- IN-RCG's Certificate of Need Application dated November 30, 2007.
- IN-RCG's supplemental information dated February 15, 2008
- IN-RCG's supplemental information dated March 12, 2008
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2007 Northwest Renal Network 3<sup>rd</sup> Quarter Data
- Public comments received from community members
- 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
- Northwest Renal Network Historical Modality Reports
- Data obtained from the Internet regarding Fresenius and its subsidiaries and facilities.
- Medical Quality Assurance compliance data
- Data obtained from the Washington Secretary of State website
- Certificate of Need historical files

## **CONCLUSION**

For the reasons stated in this evaluation, the application submitted on behalf of IN-RCG proposing to establish a 4-station dialysis center in Othello, within Adams County is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is approved.

The total approved costs associated with this project are \$923,681.

## 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 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>4</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 five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

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

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

### IN-RCG's Application of the Numeric Methodology

IN-RCG proposes to establish a 4 station facility in Othello. Based on the calculation of the annual growth rate in the planning area as described above, a linear regression was used to project need. Given that the facility would be located in Adams County, the number of projected patients is divided by 3.2 to determine the number of stations needed in the planning area. Table

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<sup>4</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]

1 is a summary of IN-RCG’s application of the numeric methodology based upon the reported NRN data. [Application, p18]

**Table 1**  
**Summary of IN-RCG’s 4-Station Numeric Methodology**

	<b>Year 2007</b>	<b>Year 2008</b>	<b>Year 2009</b>	<b>Year 2010</b>
Incenter Patients	10	10	9	8
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need (Div. by 3.2)	3.125	3.125	2.813	2.500
Total Station Need Rounded Up	4	4	3	3
Minus # of CN Approved Stations	0	0	0	0
<b>Net Station Need / (Surplus)</b>	<b>4</b>	<b>4</b>	<b>3</b>	<b>3</b>

As shown in Table 1 above, based upon the projected patients for 2010, IN-RCG projected a need for 3 dialysis stations.

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project need. Table 2 below is a summary of the department’s application of the numeric methodology. [Appendix A]

**Table 2**  
**Summary of Department’s Numeric Methodology**

	<b>Year 2007</b>	<b>Year 2008</b>	<b>Year 2009</b>	<b>Year 2010</b>
Resident Patients	10.5	9.6	8.7	7.8
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	3.281	3.000	2.719	2.437
Total Station Need Rounded Up	4	3	3	3
Minus # of CN Approved Stations	0	0	0	0
<b>Net Station Need / (Surplus)</b>	<b>4</b>	<b>3</b>	<b>3</b>	<b>3</b>

As shown in Table 3, the department projects a need for 3 dialysis stations in year 2010. Based on the numeric methodology alone, dialysis service is needed in the Adams County planning area.

WAC 246-310-286 states, in relation to the standards for planning areas without an existing facility, “The department will award the first project proposing to establish a facility in each of these planning areas a minimum of four stations.” The rule also states, “...the applicant may supplement data obtained from the Northwest Renal Network with other documented demographic and utilization data to demonstrate station need”.

As part of the application, IN-RCG acknowledges that strict application of the methodology identifies a need for only three stations. To support this application for a 4-station facility, IN-RCG reviewed historical patient data in an effort to identify a cause for the calculated drop in patient volumes. Table 3 summarizes the patient data reported by the applicant from 1998 through 2006. [Application, p20; NRN Modality Reports]

**Table 3**

**Historical Year-end Patient Data – Adams County**

	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Mean</b>	<b>St. Dev.</b>
Patients	10	12	10	11	18	12	12	9	15	<b>12.11</b>	<b>2.80</b>

As indicated above, a simple average of the annual numbers equals 12.11 patients per year with a calculated standard deviation of 2.80. When considered against the methodology’s date range of 2002 through 2006, the data set includes values that are statistically unrepresentative of the population on both tails of the distribution<sup>5</sup>. Coupled with the small sample size, these figures have the potential to negatively influence the validity of the linear regression used in the projections. [Application, p19]

Further review of the exemptions relating to kidney treatment centers listed under WAC 246-310-287 indicate that an exemption may be considered if one or more of a set of criteria can be met. Applicable to this application is whether the department finds the additional stations are needed to be located reasonably close to the people they serve. Further, the Department must also find that exceptional circumstances exist within the planning area which explains the approval of additional stations.

Testimony supplied as part of public comment from the community supports IN-RCG’s contention that there is need beyond that indicated in the numeric projections. Testimony largely addressed concerns over travel times to the neighboring county to receive treatments and current patient counts. Though reports of the current patient counts varied, NRN modality reports for the 4<sup>th</sup> quarter of 2007 identify 18 patients within Adams County. [Public Comment; NRN]

In summary, the Department concludes that, due to factors particular to this data set, the linear regression used in the forecasted need methodology for Adams County may be adversely affected by statistical anomalies. In addition, there is indication that the forecast may be underestimating the patient count as reported by the local community and as evidenced by the most recent NRN modality reports. As a result, though the need for Adams County is forecasted to equal three (3) stations, this application will be granted an exemption under WAC 246-310-287 and will be reviewed as the establishment of a 4-station facility.

There is no dialysis facility located within the county, therefore, the utilization requirement under WAC 246-310-284(5) does not apply to this application.

WAC 246-310-284(6) requires the Othello Dialysis Center to be operating at 3.2 in-center patients per approved station by the end of year three (2012). IN-RCG provided the projected third year utilization as a 4-station facility. A summary of the projections for year 2012 is shown in Table 4 below. [February 15, 2008 Screening Responses, Attachment 5]

**Table 4  
Year 2012 Projected Facility Utilization**

<b>Facility Name</b>	<b>Year 3</b>	<b># of Stations</b>	<b># of Pts</b>	<b>Pts/Station</b>
Othello Dialysis Center	2012	4	18	4.50

As shown in Table 4 above, the applicant projects the Othello Dialysis Center to be operating above the 3.2 standard by the end of the third year of operation, or year 2012.

<sup>5</sup> 2002 shows a patient total of 18 patients, 3 standard deviations above the mean, and 2005 shows 9 patients, 2 standard deviations below the mean.

Based on the above information, the application submitted by IN-RCG proposing to establish a 4 station dialysis center in Adams County is consistent with this criterion. 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.

As previously stated, Fresenius or one of its subsidiaries, currently provides dialysis services to residents of specific service areas within 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 demonstrate compliance with this sub-criterion, IN-RCG provided a copy of its current Admission and Indigence policies that would also be used at the new Othello facility. The documents outline the process/criteria that the dialysis center uses to admit patients for treatment. It is intended to ensure that patients will receive appropriate care at the dialysis center. The Admission criteria states that any patient with end stage renal disease needing treatment will be accepted to a IN-RCG facility without regard to race, creed, color, age, sex handicap, disability, national origin, social status, or ability to pay [Application, p23; Exhibit 7]

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.

The Admission Policy also states that any patient with end stage renal disease needing dialysis will be accepted for treatment at the facility without regard to race, color, national origin, sex, age, religion, or disability. A review of the Admission and Indigence policies for this proposed facility identifies financial resources, including both Medicare and Medicaid revenues.

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.

The applicant also provided a copy of IN-RCG's indigence policy in Exhibit 8 of the application. That policy clearly states the process to allow a patient to apply for a waiver of their balance, as well as the objective criteria used by FMG to determine eligibility.

IN-RCG demonstrated its intent to continue to provide charity care to residents by submitting its Indigence Policy that outlines the process a patient would use to access service. Further, IN-RCG pro-forma financial statement included a charity care line item as a deduction from revenue within the pro-forma. [Application, Exhibit 8; February 15, 2008 Screening Responses, Attachment 5]

Based on this information, the department concludes that all residents of the service area could reasonably be expected to continue to have reasonable access to the health services at the Othello Dialysis Center. This sub-criterion is met.

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

Based on the source information reviewed, 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 approved, the applicant anticipates commencement of the project in the Spring of 2008 with services beginning in March 2009. [Application, p11] As a result, the first full year of operation would be 2010.

For financial review of applications, the department requests data for the first three full years following project completion. Using the updated financial information provided by IN-RCG, Table 5 illustrates the projected revenue, expenses, and net income for the first three years of operation for Othello as a 4 station facility. [February 15, 2008 Screening Responses, Attachment 5]

**Table 5  
Othello Dialysis Center  
Projected Revenue and Expenses 2010 – 2012**

	<b>Year 1 - 2010</b>	<b>Year 2 - 2011</b>	<b>Year 3 - 2012</b>
# of Stations	4	4	4
# of Treatments [1]	2,232	2,376	2,520
# of Patients [2]	16	17	18
Utilization Rate [2]	4.00	4.25	4.50
Net Revenue [1]	\$ 951,874	\$ 1,100,954	\$ 1,250,033
Total Expense [1,3]	\$ 872,725	\$ 950,988	\$ 1,029,251
Net Profit or (Loss) [1]	\$ 79,149	\$ 149,966	\$ 220,782
Net Patient Revenue/Treatment [1]	\$ 388.84	\$ 402.40	\$ 413.37
Total Operating Exp./Treatment [1]	\$ 356.51	\$ 347.58	\$ 340.36
Net Profit (Loss) per Treatment [1]	\$ 32.33	\$ 54.81	\$ 73.01

[1] includes both in-center and home dialysis patients; [2] in-center patients only;

[3] includes deductions for bad debt, charity care and allocated costs

As shown in Table 5, at the projected volumes identified in the application, IN-RCG would be operating the 4 station dialysis facility at a profit in each of the first three full years of operation.

IN-RCG has selected a site for the Othello facility that is located in a commercial area within the City of Othello. The draft lease that is provided in the application outlines the annual rent and multiple renewal terms for the space through 2034. Documents were also provided to show that the Landlord, KLM Othello, has an executed Purchase and Sales Agreement and term extension with the current property owner, Cumulus Associates. IN-RCG also supplied confirmation from the City of Othello that identifies the location as eligible for commercial activities such as a

medical facility. [February 15, 2008 Screening Responses, Attachment 1, 2, & 4; March 12, 2008 Screening Responses, Attachment 1]

Based on the above information, if this project is approved, the department would attach a term requiring IN-RCG to provide to the department a copy of the executed Sale and Lease Agreement. The executed Lease Agreement must be consistent with the draft Lease Agreement provided in the application. Further, the executed agreements must be provided to the department before commencement of the project. With agreement to this term, this sub-criterion would be 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.

To demonstrate compliance with this sub-criterion, IN-RCG provided the following statements: “This project has no impact on either charges or payment, as reimbursement for kidney dialysis services is based on a prospective composite per diem rate”. [Application, p32]

The capital expenditure associated with the establishment of a 4 station Othello Dialysis Center is \$923,681, of which 64% is related to construction, 24% for both fixed and moveable equipment; and the remaining 13% is related to applicable fees and taxes. The capital cost breakdown is restated below. [Application, p11]

<b>Breakdown Of Costs</b>	<b>Total</b>	<b>% of Total</b>
Leasehold Improvements	\$ 588,000	64%
Fixed & Moveable Equipment	\$ 220,071	24%
Professional Fees	\$ 44,500	5%
Taxes	\$ 71,110	8%
<b>Total Estimated Capital Costs</b>	<b>\$ 923,681</b>	<b>100.00%</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 patient revenue shown below in Table 6. [February 15, 2008 Screening Responses, p2]

**Table 6**  
**Anticipated Revenue Sources - QualiCenters**

<b>Source of Revenue</b>	<b>Percentage of Revenue</b>
Medicare	88
State (Medicaid)	4.4
Insurance/HMO	7.6
<b>Total</b>	<b>100%</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal approximately 92% of the revenue at the Othello facility. 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

7.6% 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.*

As previously stated, the source of financing for this facility is IN-RCG’s cash reserves.

IN-RCG proposes that funding will be provided from existing cash reserves. The financial health of the organization indicates that there would be sufficient resources to support the proposed project. The applicant states, “[T]his method results in the lowest overall impact on operating costs as no debt is involved. Review of the financial position of Fresenius shows the funds necessary to finance the project is available. [Application, p32 & Appendix 2]

Based on the information provided, the department concludes that the applicant has demonstrated that establishment of the Othello Dialysis Center will not adversely affect the organization’s financial stability. 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 initially hire the equivalent of 4.05 new employees to operate the dialysis center through the first full year of operation. IN-RCG intends to recruit an additional .45 FTE’s to address the projected growth in years two and three. The proposed plan for the first three years of operation is shown in Table 7, below: [February 15, 2008 Screening Responses, p3]

**Table 7  
Othello Dialysis Center Projected FTE’s**

	<b>Partial 2009</b>	<b>Year 1 2010</b>	<b>Year 2 2011</b>	<b>Year 3 2012</b>
Medical Director	Contracted Position			
Nurse Manager	0.50	0.50	0.50	0.50
Outpatient RN	1.00	1.00	1.00	1.00
Patient Care Tech	1.80	1.80	2.10	2.10
Social Worker	0.20	0.20	0.25	0.25
Dietician	0.20	0.20	0.25	0.25
Secretary	0.15	0.15	0.20	0.20
BioMed	0.20	0.20	0.20	0.20

<b>FTE Total</b>	<b>4.05</b>	<b>4.05</b>	<b>4.50</b>	<b>4.50</b>
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A review of Table 6 illustrates the staffing for the facility will be nearly complete in the first partial year of operation. IN-RCG notes that, under the news rules regarding the number of patient shifts, “we expect staffing to be much less of an issue”. [Application, p30]

IN-RCG notes that sharing administrative staff and regional level support staff, throughout IN-RCG’s other Eastern Washington facilities will provide the necessary support and will allow for temporary relocation of staff if unanticipated problems arise. [Application, p34]

IN-RCG has identified Dr. Curtis Wickre, MD as the contracted Medical Director for the facility. The applicant supplied a draft contract that outlines the roles and responsibilities of both entities and identifies the compensation for the medical director in a contract amendment. If approved, the Department would include a term that IN-RCG provide an executed contract amendment with Dr. Wickre which includes the relevant terms identified in the draft agreement and amendment before providing services. [Application, Exhibit 3]

Based on this information, and in lieu of the acceptable completion of the term cited above, the department concludes that the applicant has proposed a staffing plan that can reasonably be expected to be accomplished and that adequate staffing for the dialysis center is either readily available or can be recruited. This sub-criterion is met.

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

In response to this sub-criterion, IN-RCG noted that “we have already had conversations with the local hospital, and they expressed great interest in helping us get established”. Possible service providers include the Othello Community Hospital and the local transit service, People for People. [Application, p35]

The applicant did not identify vendors for such services as bio-hazard waste disposal, janitorial and uniforms, but costs for these contracted services were identified in the applicant’s pro forma statements and appear to be consistent with similar applications reviewed by the department. The application also states that IN-RCG intends to extend the transfer agreement with Sacred Heart Medical Center for hospital care and support services as currently provided at the region’s IN-RCG facilities. [February 15, 2008 Screening Responses, Attachment 5]

The department concludes that the applicant currently has appropriate relationships with ancillary and support services and approval is not expected to affect those relationships negatively. 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.

Renal Care Group Northwest, Inc also known as Inland Northwest Renal Care Group, LLC is owned by Renal Care Group. 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 revealed minor non-compliance issues typical of a dialysis facility related to the care, medical records, and management at the Fresenius facilities. 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. [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 fifteen kidney dialysis facilities in twelve separate counties. 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. [Compliance survey data provided by Office of Health Care Survey (OHCS)]

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 new Othello facility would operate in compliance with the applicable state and federal standards and regulations.

As previously stated, the Othello Dialysis Center has identified Curtis Wickre, MD, as its medical director under an amendment to the contract provided. A review of Dr. Wickre's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of IN-RCG and the contracted medical director, the department concludes that there is reasonable assurance that the dialysis center would continue to operate in conformance with state and federal regulation. Pending satisfactory completion of the term cited in the prior section, 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.*

In response to this criterion, the applicant noted that "As with all of our other existing facilities, [Othello] will provide regular social services and dietary support for all patients". The applicant continues, "other typical ancillary and support services utilized by a dialysis program including pharmacy, laboratory and radiology will be available through working relationship[s] we intend to establish with local providers". [Application, p35]

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 many years and has been appropriately participating in relationships with community facilities, such as Sacred Heart, to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Office of Health Care Survey Historical Record]

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a potential need for 3 dialysis stations in the Adams planning area. However, as outlined in the need portion of this evaluation, an exemption was made to allow the review for a 4 station facility. Within the application, IN-RCG demonstrated it met the remaining standards to receive approval for a 4 station facility in Adams County.

Based on this information, the department concludes that approval of this project would promote continuity in the provision of healthcare for the planning area and would not result in an unwarranted fragmentation of services. Further, IN-RCG demonstrated it has, and will continue to have, appropriate relationships with the service areas existing health care system within the planning areas. 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 subsection is addressed in sub section (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 accord 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.

Before submitting this application, IN-RCG considered two alternatives to this application. The alternatives and IN-RCG's rationale for rejecting them are summarized below.

##### Alternative #1: Do nothing in Grant County

IN-RCG states that consideration was give to this application in conjunction with plans to address needs for additional capacity in Grant County. Doing nothing was eliminated due to increasing patients in the Moses Lake facility. [Application, p34]

##### Alternative #2: Establish a satellite facility in Grant County

IN-RCG states that this was considered in depth. A review of patient origin data indicated to the applicant that improving patient access was more likely to be achieved with a new facility in Adams County. [Application, p34]

Based on IN-RCG discussion of the two options above, each option was rejected before submitting this project.

Based on IN-RCG's discussions of the alternatives considered before submitting this application and considering the results of the numeric methodology, the department concludes the establishment of a 4-station facility in Adams 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.

This sub-criterion is also 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