

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

**PROJECT DESCRIPTION**

Fresenius Medical Care Holdings, Inc. (FMCH) is a New York corporation and a subsidiary of Fresenius Medical Care AG (FMCAG), a German corporation. FMCH operates approximately 2,100 dialysis clinics worldwide, of which 1,500 are located in North America. [FMCH website]

On May 31, 2006, Renal Care Group became a wholly-owned subsidiary of FMCH. FMCH operates one dialysis facility in Washington.<sup>1</sup> Renal Care Group Northwest, Inc. (RCGNW), a subsidiary of RCG, currently owns, operates and/or manages eleven kidney dialysis treatment facilities in Washington State - two in Clark County;<sup>2</sup> three in Spokane County<sup>3</sup>; and one facility in each of the counties of Thurston, Lewis, Mason, Grays Harbor, Grant and Okanogan.<sup>4</sup> [CN files]

One of the five subsidiaries of FMCH, National Medical Care, Inc. also conducts its operations through two subsidiaries: QCI Holdings, Inc. and QualiCenters, Inc. QualiCenters, Inc. and National Medical Care, Inc. (reporting a 10% or greater ownership) are the corporate parents of QualiCenters Inland Northwest LLC. QualiCenters Inland Northwest, LLC provides dialysis services in one Washington State facility<sup>5</sup>.

This application proposes to establish a nine station dialysis facility to be known as the Othello Dialysis Unit, to serve the patients residing in Adams County. The estimated capital expenditure for the establishment of the Othello facility is \$975,905. If this project is approved, IN-RCG anticipates commencement on the project to be in January, 2008 and that all approved stations would be available for patient use by October 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation. [August 10, 2007 Screening Responses, Attachment 2]

<b>Breakdown Of Costs</b>	<b>Total</b>	<b>% of Total</b>
Construction	\$ 588,000	60%
Fixed & Moveable Equipment	\$ 268,071	27%
Architect/Engineering	\$ 44,500	5%
Taxes	\$ 75,334	8%
<b>Total Estimated Capital Costs</b>	<b>\$ 975,905</b>	<b>100.00%</b>

<sup>1</sup> Columbia Basin Dialysis Center

<sup>2</sup> Fresenius Salmon Creek and Fresenius Ft. Vancouver

<sup>3</sup> Fresenius Northpointe, Fresenius Spokane Kidney Center and Fresenius Valley

<sup>4</sup> Fresenius Lacey, Fresenius Chehalis, Fresenius Shelton, Fresenius Aberdeen, Fresenius Moses Lake, and Fresenius Omak, respectively.

<sup>5</sup> QualiCenters Walla Walla

## **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>6</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 #2. No other kidney disease treatment center applications were reviewed for the Adams County during Review Cycle #2. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

April 30, 2007	Letter of Intent Submitted
May 31, 2007	Application Submitted
June 1, 2007 through August 22, 2007	Screening Activities and Responses
August 23, 2007	Department Begins Review of Applications
September 27, 2007	End of Public Comment
November 26, 2007	Department's Anticipated Decision Date
November 26, 2007	Department's Decision Date

## **AFFECTED PARTIES**

There were no affected parties on this application.

## **SOURCE INFORMATION REVIEWED**

- IN-RCG's Certificate of Need Application dated May 31, 2007.
- IN-RCG's supplemental information dated August 10, 2007
- 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 1<sup>st</sup> Quarter Data
- Data obtained from the Internet regarding Fresenius and its subsidiaries and facilities.
- Data obtained from the Washington Secretary of State website
- Data obtained from the Pierce County Assessor website
- Certificate of Need historical files

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<sup>6</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.

## **CONCLUSION**

For the reasons stated in this evaluation, the application submitted on behalf of IN-RCG proposing to establish a 9-station dialysis center in Othello, within Adams County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

## 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>7</sup>

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year. 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 9 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>7</sup> Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

1 is a summary of IN-RCG’s application of the numeric methodology based upon the reported NRN data. [Application, p17]

**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.

As part of the application, IN-RCG is asserting that the application qualifies for exemption consideration under WAC 246-310-287. IN-RCG states, “We are confident that the number of stations projected under WAC 246-310-284 understates need and would not allow stations to be located reasonably close to the people they are intended to serve”. The applicant concedes that it is unable to produce any data to support the concern stated above and that IN-RCG relies primarily on anecdotal reports of patients exiting the county due to the lack of local dialysis. As a result, the applicant has included two methodologies for review. In addition to the methodology outlined above that would only support the establishment of a facility minimum 4-stations, IN-RCG included a need methodology supporting a projected 9 station need. This, the applicant contends, would more accurately reflect the trend for the planning area from 2008 through 2011. These exemption projections are summarized below in Table 2. [Application, p8, 14 & 19]

**Table 2**  
**Summary of IN-RCG’s 9-Station Numeric Methodology**

	<b>Year 2008</b>	<b>Year 2009</b>	<b>Year 2010</b>	<b>Year 2011</b>
Incenter Patients	20	24	27	30
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need (Div. by 3.2)	6.250	7.500	8.738	9.375
Total Station Need Rounded Up	7	8	9	10
Minus # of CN Approved Stations	0	0	0	0
<b>Net Station Need / (Surplus)</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>

As shown in Table 2 above, IN-RCG believes that, based upon the projected patients it feels have otherwise relocated out of Adams County, there is potential for a need of 9 stations. This version of the need methodology for Adams County supports the application submitted by IN-RCG. The applicant states, “with 4 stations and our estimated patient volume, [Othello] is projected to operate in excess of 3.2 in-center patients per station upon opening”.

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 3 below is a summary of the department’s application of the numeric methodology. [Appendix A]

**Table 3**  
**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.

To respond to the applicant's exemption request, the department reviewed the applicable rules and the information submitted in support of the increase in projected patients. 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". The applicant concedes that they do not have any data beyond the anecdotal reports to support their claim that the volumes are being understated. [Application, p14]

Further review of the exemptions relating to kidney treatment centers listed under WAC 246-310-287(2) indicate that an exemption may be considered if one or more of a set of criteria can be met. Those applicable to this application include whether the department finds the additional stations are needed to be located reasonably close to the people they serve and/or that the applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area.

In support of these factors, the applicant provided a breakdown of the potential travel times for the 15 patients [NRN 2006 Data] currently residing in Adams County. Though it is clear that patients are currently traveling to receive treatment, the amount of travel may be decreased for some patients through the establishment of a new facility in the planning area. The applicant also includes statements regarding the "very limited public transportation" for residents of the area. These conditions were addressed in the development of the new rules concerning Kidney Disease Treatment Centers. Lowering the utilization standard to 3.2 for the more rural counties listed above was intended to increase the number of stations available for rural residents and provide better staffing options for the operators. Factoring these issues in a second time to justify yet more stations appears to be unwarranted. No information was submitted regarding any significant changes in the treatment of ESRD patients. [Application, p13 & 14]

In summary, the Department concludes that this application does not meet the standards necessary for approval under the exemption standards. Further, there is no data to support a linear growth rate that would result in a three-fold increase in the projected in-center patients for the planning area in 2010. Although, applicant is able to show that there are potential benefits to

the patients is Adams County and the anecdotal information to consider a facility that would have met the patient needs at the high point of 4 stations in the years included in the forecast. As a result, the net station need for Adams County is determined to be three (3) and this application will be reviewed according to the information supplied supporting the establishment of a minimum sized, 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.

Based on the above information, the application submitted by IN-RCG proposing to add 9 stations at the Othello Dialysis Unit is not consistent with this criterion. Although, with the possibility that the exemption request may not be accepted, the applicant included the methodology necessary to substantiate a 4 station facility. This sub-criterion is met.

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

To determine whether all residents of the 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, the applicant asserts, "All individuals identified as being in need of dialysis services will have access to this unit. IN-RCG's admission policies prohibit discrimination on the basis of race, income, ethnicity, sex or handicap." [Application, p19] The policy provided as Exhibit 8 prohibits discrimination "...on the basis of race, color, religion, sex national origin, age, disability, or any other characteristic protected by law."

The applicant also provided a copy of IN-RCG's indigence policy in Exhibit 9 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 currently provides services to Medicare and Medicaid eligible patients at its existing dialysis centers and intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to receive both Medicare and Medicaid reimbursements. Additionally, IN-RCG demonstrated its intent to provide charity care to residents by including a 'charity care'

line item as a deduction from revenue within the pro forma financial documents as well as in the audited financial statements of Fresenius. [Application, Exhibit 8; Appendix 2]

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 Unit. 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 not 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 January 2008 with services beginning in October 2008. [Application, p11] As a result, the first full year of operation would be 2009.

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 4 illustrates the projected revenue, expenses, and net income for the first three years of operation for Othello as a 4 station facility. [August 10, 2007 Screening Responses, Attachment 3]

**Table 4  
Othello Dialysis Unit  
Projected Revenue and Expenses 2009 – 2011**

	<b>Year 1 - 2009</b>	<b>Year 2 - 2010</b>	<b>Year 3 - 2011</b>
# of stations	4	4	4
# of Treatments	3,744	3,744	3,744
# of Patients	24	24	24
Utilization Rate	6.00	6.00	6.00
Net Patient Revenue	\$ 1,175,879	\$ 1,175,879	\$ 1,175,879
Total Operating Expense	\$ 1,156,632	\$ 1,156,632	\$ 1,156,632
Net Profit or (Loss)*	\$ 19,247.00	\$ 19,247.00	\$ 19,247.00
Net Patient Revenue/Treatment	\$ 314.07	\$ 314.07	\$ 314.07
Total Operating Exp./Treatment	\$ 308.93	\$ 308.93	\$ 308.93
Net Profit per Treatment	\$ 5.14	\$ 5.14	\$ 5.14

As shown in Table 4, at the projected volumes identified in the application, IN-RCG would be operating the 4 station dialysis facility at a profit for 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 provided in the application outlines the multiple renewal terms and the annual rent for the space through 2017. IN-RCG also supplied confirmation from the City of Othello that identifies the location as eligible for commercial activities such as a medical facility. [August 23, 2007 Screening Supplemental]

However, a closer look at the financials is necessary. IN-RCG is basing the 4 station pro forma outlined above upon the requested exemption projected patient totals. As stated in the Need section above, there is not sufficient data to support the approval of a facility that is larger than the 4 station minimum. As a result, the pro forma for the 4 station portion of the IN-RCG Othello application should then be based upon the projected 8-10 resident patients that were identified in the methodology that was based on NRN data alone. (Evaluation Tables 1 & 3 above) To justify the use of 24 projected patients, the department would have to be supplied with data which would indicate that the new facility was likely to achieve a 100% utilization rate by the end of the facility's first full year. Therefore, the applicant has not provided the necessary pro forma that would identify whether the reduction in patients would be sufficient to cover the fixed and variable expenses in a new, minimum sized, facility. This omission does not allow for the complete evaluation of the proposed facility's ability to maintain services.

Based on the above information, the department concludes that the project's long-range capital and operating costs cannot be evaluated. This sub-criterion is not 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, p29]

The capital expenditure associated with the establishment of a 4 station Othello Dialysis Unit is \$975,905, of which 60% is related to construction, 27% for both fixed and moveable equipment; and the remaining 13% is related to applicable taxes. The capital cost breakdown is shown below. [August 10, 2007 Screening Responses, Attachment 2]

<b>Breakdown Of Costs</b>	<b>Total</b>	<b>% of Total</b>
Construction	\$ 588,000	60%
Fixed & Moveable Equipment	\$ 268,071	27%
Architect/Engineering	\$ 44,500	5%
Taxes	\$ 75,334	8%
<b>Total Estimated Capital Costs</b>	<b>\$ 975,905</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 patient revenue shown in the chart shown on the following page. [Application, p30]

<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 88% 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 department is not able to calculate the average cost per dialysis with any certainty due to in-consistent pro-forma data and the reported income. The department is unable to conclude the average cost per dialysis is reasonable or accurate.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care facilities. This sub-criterion is not 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 NKC shows the funds necessary to finance the project is available. [Application, p29 & Appendix 2]

Based on the information provided, the department concludes that the applicant has demonstrated that establishment of the Othello Dialysis Unit 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 not 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 8.0 new employees to operate the dialysis center through the first three full years of operation based on the projected number of patients in those years. The proposed plan for the first three years of operation are shown in Table 5, below: [Application, p30]

**Table 5  
Othello Dialysis Unit  
FTE Increases**

	<b>Partial 2008</b>	<b>Year 1 2009</b>	<b>Year 2 2010</b>	<b>Year 3 2011</b>	<b>Total FTE’s</b>
Medical Director	Contracted Position				
Nurse Manager	1.00	0.00	0.00	0.00	1.00
Outpatient RN	2.40	0.00	0.00	0.00	2.40
Patient Care Tech	3.00	0.00	0.00	0.00	3.00
Social Worker	0.20	0.00	0.00	0.00	0.20

Dietician	0.20	0.00	0.00	0.00	0.20
Secretary	1.00	0.00	0.00	0.00	1.00
BioMed	0.20	0.00	0.00	0.00	0.20
<b>FTE Total</b>	<b>8.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>8.00</b>

A review of Table 5 illustrates the staffing for the facility will be completed in the first partial year of operation. IN-RCG notes that, under the news rules regarding of the number of patients on a single shift, “we expect a much easier recruitment and retention effort”. [Application, p30]

IN-RCG notes that sharing administrative staff and regional level support staff, throughout IN-RCG’s five Eastern Washington facilities, will provide the necessary support and will allow for temporary relocation of staff if unanticipated problems arise. In addition, IN-RCG plans to hire and train the necessary staff in one of the existing Spokane areas facilities prior to the opening of the Othello facility. [Application, p28]

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 the issuance of the CN. [August 10, 2007 Screening Responses, Attachment 6]

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 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, p29]

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. [Application, Exhibit 11]

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.

As stated earlier, FMCH operates approximately 2,100 dialysis clinics worldwide, of which 1,500 are located in North America. Currently within Washington State, Fresenius or its subsidiaries, owns and operates thirteen kidney dialysis treatment centers. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public<sup>8</sup>.

To accomplish this task, the department reviewed Washington State compliance surveys, in the most recent 6 years (since January 2001), recorded in the Department of Health's Office of Health Care Survey (OHCS). As stated in the project description portion of this evaluation, Fresenius, through its subsidiaries RCGNW and QualiCenters, owns and/or operates the following thirteen kidney dialysis treatment facilities in Washington State:

<b>Facility Name</b>	<b>City/County Location</b>	<b># of stations</b>
Fresenius - Aberdeen	Aberdeen, Grays Harbor County	16
Fresenius - Chehalis	Chehalis, Lewis County	12
Fresenius - Ft. Vancouver	Vancouver, Clark County	24
Fresenius - Lacey	Lacey, Thurston County	25
Fresenius - Moses Lake	Moses Lake, Grant County	20
Fresenius - Northpointe	Spokane, Spokane County	24
Fresenius - Omak	Omak, Okanogan County	15
Fresenius - Salmon Creek	Vancouver, Clark County	16
Fresenius - Shelton	Shelton, Mason County	6
Fresenius - Spokane	Spokane, Spokane County	27
Fresenius - Valley	Spokane Valley, Spokane County	20
Columbia Basin Dialysis	Kennewick, Benton County	13
QualiCenters Walla Walla	Walla Walla, Walla Walla County	12

The Fresenius-owned or operated facilities in Washington have collectively been surveyed 25<sup>9</sup> times in the last six years. Ten of those surveys revealed no deficiencies. The Omak facility was surveyed in 2007 and revealed three patient care issues that were corrected. A previous survey of Ft. Vancouver also revealed potentially hazardous conditions that were promptly corrected by the applicant. The remaining 13 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)]

The Othello Dialysis Unit 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]

<sup>8</sup> WAC 246-310-230(5)

<sup>9</sup> Omak, 2007 (three issues out of compliance – all met with acceptable corrective actions), 2004, 2001; Ft. Vancouver, 2006 (condition-level deficiency regarding water quality testing – acceptable plan of corrections submitted. Follow-up surveys indicate facility in substantial compliance) 2003, no def; QualiCenters Walla Walla, 2006, 2003, no def; Aberdeen, 2006 no def; Lacey 2001, 2000, 2004; Shelton, 2006 no def; Moses Lake, 2006 no def; Salmon Creek 2006, 2003, no def; Spokane Kidney Center 2005, 2004, 2002; Spokane Valley 2005, 2002, 2001; Northpointe 2005, 2002 no def; Chehalis 2002, 2005

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, p33]

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 stated in the financial feasibility portion of this evaluation, inaccurate projections in the revenues cited in the pro forma for a 4 station facility prevent an accurate evaluation of the proposed location and the forecasted viability. In the long-term, this may lead to the unnecessary opening and closing of a facility, leading to a loss of service.

Therefore, the department concludes that approval of an uncorroborated 4 station dialysis center in Adams County would have the potential of future fragmentation of dialysis services within the service area, and this sub-criterion is not 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 not 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 three 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 given 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]

Alternative #3: Establish a 4 station facility in Adams County

As addressed previously in this evaluation, IN-RCG applied for a 9-station facility but acknowledged that the methodology only substantiated a 3-station need. After considering staffing and travel times, IN-RCG chose to consider this only in the instance that the 9-station consideration was not able to be an approvable project.

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

In determining the best available alternative the department considered its findings on the other applicable review criteria. The department cannot conclude that the current IN-RCG Othello project is the best available alternative. While the department determined that a need was demonstrated, the project as proposed failed to meet financial feasibility and structure and process of care criteria. Therefore, this criterion is not 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 not 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 not met.

# APPENDIX A