

**REVIEW OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON
BEHALF OF RENAL CARE GROUP OF THE NORTHWEST PROPOSING TO ADD
SIX STATIONS TO THE EXISTING SIX-STATION KIDNEY DIALYSIS FACILITY
KNOWN AS THE OMAK DIALYSIS FACILITY**

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 1,645 dialysis clinics worldwide, of which 1,510 are located in North America.

FMCH conducts its operations through five subsidiaries:

- National Medical Care, Inc.
- Fresenius USA Marketing, Inc.
- Fresenius USA Manufacturing Inc.
- SRC Holding Company
- Fresenius USA Inc.

One of the above entities, National Medical Care, Inc. also conducts its operations through two subsidiaries: QCI Holdings, Inc. and QualiCenters, Inc. QualiCenters, Inc. and National Medical Care, Inc. (owning 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 facility¹.

On May 4, 2005, FMCH and Renal Care Group announced a definitive agreement for the purchase of Renal Care Group for approximately \$3.5 billion. The purchase was approved by Renal Care Group shareholders on August 24, 2005. The transaction closed on March 31, 2006. With the closure of the transaction, Renal Care Group became a wholly-owned subsidiary of FMCH, under the control of Fresenius Medical Care North America (FMCNA). 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;² three in Spokane County³; and one facility in each of the counties of Thurston, Lewis, Mason, Grays Harbor, Grant and Okanogan.⁴ [source: CN files] This application proposes to add six dialysis stations to the existing six-station facility known as the Omak Dialysis Center (ODC), which is owned and operated by Inland Northwest Renal Care Group, LLC (IN-RCG). IN-RCG is jointly owned by RCGNW and Sacred Heart Medical Center.

The estimated capital expenditure for the expansion of the Omak facility is \$700,000. The applicant anticipates adding two stations immediately upon CN approval and completion of the expanded facility in April, 2008.

¹QualiCenters Walla Walla

²PNRS Salmon Creek and PNRS Ft. Vancouver

³IN-RCG Northpointe, IN-RCG Spokane Kidney Center and IN-RCG Spokane Valley

⁴RCGNW Lacey, RCGNW Chehalis, RCGNW Shelton, RCGNW Aberdeen, RCGNW Moses Lake, and IN-RCG Omak, respectively.

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

CRITERIA EVALUATION

To obtain Certificate of Need approval, each applicant 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 246-310-280⁵ (the dialysis station projection methodology and standards).⁶

APPLICATION CHRONOLOGY

May 12, 2006	Letter of Intent Submitted
October 23, 2006	Application Submitted
November 16, 2006 through December 28, 2006	Screening Activities and Responses
January 3, 2007	Department Begins Review of Applications
February 7, 2007	End of Public Comment
April 9, 2007	Department's Anticipated Decision Date
May 4, 2007	Department's Decision Date

AFFECTED PARTIES

There were no affected parties other than the applicant.

SOURCE INFORMATION REVIEWED

- Omak Dialysis Center's Certificate of Need Application dated May 12, 2006.
- Omak Dialysis Center's supplemental information
- 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.
- Utilization data provided by the Northwest Renal Network
- Data obtained from Center for Medicare and Medicaid (CMS) "Dialysis Facility Compare" website (<http://www.medicare.gov/Dialysis/home.asp>).
- Data obtained from the Internet regarding health care providers.
- Population data obtained from the Office of Financial Management.
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, using the rules in place at the time of the application, Fresenius Medical Care's proposal for the addition of six in-center dialysis stations to the existing Omak Dialysis Center is not consistent with the application criteria of the Certificate of Need Program and a Certificate of Need should be denied.

⁵ New kidney dialysis rules were adopted by the department on January 1, 2007. This application was reviewed for compliance with WAC 246-310-280 as it read at the time this application was declared complete (December 29, 2007). Changes to WAC 246-310-280 through 289 adopted on January 1, 2007 were not considered in this evaluation.

⁶ 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); and WAC 246-310-240(3).

A. Need (WAC 246-310-210)

Based on the source information reviewed the department determines that the applicant has not met the need criteria in WAC 246-310-210(1) and (2) and WAC 246-310-280.

(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.

The applicant is proposing to add an additional six dialysis stations to an existing six-station facility. The Omak Dialysis Center is the only provider of dialysis services in Okanogan County. The two nearest dialysis facilities are the Moses Lake Dialysis Facility, also operated by IN-RCG, and a dialysis facility operated by Central Washington Hospital in Wenatchee. At the time IN-RCG submitted this application, the Omak facility was operating at approximately 86% of capacity.

In recent evaluations, the department has evaluated need by examining both linear and non-linear projections of the data. One measure of the accuracy of a regression equation is the determinant of regression, or R^2 . R^2 is a value that describes the relation of actual data to the expected values based on the regression analysis of that data. In general, the closer an equation's R^2 value is to one, the more reliable a regression equation is perceived to be. The department concludes that each value to be estimated should be evaluated using both linear and non-linear regression methods and the regression equation deemed more reliable should be used to predict that data element. In some cases, this will be the non-linear equation; in others, the data may be better described by a linear equation. For those values with small and widely varying numbers, such as the numbers of patients trained for home hemodialysis and peritoneal dialysis, both methods tend to return regression equations with very small R^2 values, indicating that neither method returns a particularly reliable result.

For this project, the department determined that the more reliable determinant of regression, or R^2 , was linear regression projections for the number of dialyses and non-linear for the number of patients.

In its application, IN-RCG also provided need projections for the proposed service area using the "best fit" method of combining linear and non-linear regression practiced by the department since January 2004.

Based on its review of dialysis utilization by the residents of their proposed service area for the years 2002-2006, the applicant provided the following projected need for dialysis stations in Okanogan County using linear regression:

Table I
Determination of Station Need in Service Area Through 2011
IN-RCG Best Fit Projections

Year	Resident Stations Needed	Visitor Stations Needed	Training Stations Needed	Approved Stations	Net Need
2007	8	0	0	6	2
2008	9	0	0	6	3
2009	11	0	0	6	5
2010	13	0	0	6	7

The Department of Health’s Certificate of Need Program uses the methodology found in WAC 246-310-280 for projecting numeric need for dialysis stations within a county. The department’s need projections, based on data obtained from the Northwest Renal Network for years 2002-2006 is contained in Table II, on the following page: [source: Department’s methodology based on Northwest Renal Network facility utilization data]

Table II
Department’s Dialysis Station Projections
For Okanogan County
Based on 2002-2006 Historical Data

Year	In-center Stations Needed	Visitor Stations Needed	Training Stations Needed	Existing Capacity	Net Need *
2007	8	-1	0	(subtract) 6	1
2008	9	-2	0		2
2009	11	-3	0		3
2010	13	-4	0		3

* numbers may not sum due to rounding

As shown in Table II above, the department projects a net need in the Okanogan County area for approximately one additional dialysis station in year 2007, which increases to approximately three stations by the end of year 2010. This need projection was derived by evaluating each of the four variables in the department’s methodology (in-center dialyses, in-center dialysis patients, home hemodialysis training patients and peritoneal dialysis training patients) using both linear and non-linear regression and applying whichever method is deemed most accurate at portraying the behavior of each particular variable.

The applicant’s projections and the department’s projections differ significantly in the number of stations projected as being needed in 2010. The department has examined the data used by IN-RCG in preparation of its application and has noted that IN-RCG did not follow all of the provisions of the methodology. The methodology contained in WAC246-310-280(3) at the time this application was received requires projection of four different variables: the number of dialysis treatments provided in centers in the planning area, the number of dialysis patients residing in the planning area, the number of patients trained for home hemodialysis in the planning area, and the number of patients trained for peritoneal dialysis in the area. Each of these numbers is then adjusted to identify a projected number of dialysis stations needed. The number of stations projected based on the dialysis treatments provided in the area and the

number of stations projected based dialysis treatments needed by patients residing in the area is subtracted from one another. The difference between these numbers is termed “visitor stations” and indicates the number of stations needed in an area to accommodate patients from outside the area who obtain dialysis services there. If the number of treatments projected in an area is smaller than would be expected by the number of patients projected in the area, this “visitor station” amount is negative, indicating that patients who live in the service area are being treated outside the area. This appears to be the case in Okanogan County.

In preparing its projections for this application, IN-RCG only projected the number of resident patients expected to live in Okanogan County in the future. Because IN-RCG did not perform a projection of treatments and perform the “visitor station” calculation, its projections exceed the department’s projections by the four negative visitor stations in the department’s methodology. In making this omission, IN-RCG explained that, due to difficulty retaining sufficient nursing staff to operate a third shift, it has frequently been unable to operate ODC for three full shifts and has been forced to refer some Okanogan County residents to other facilities outside the county. IN-RCG further contended that its experience with its Moses Lake dialysis center supports its contention that establishment or expansion of geographically isolated facilities like ODC results in short-term increases in dialysis patients that are greater than would be predicted by the methodology, because the migration of service area patients out of the area is reversed, rather than continuing, as is assumed by the methodology. IN-RCG also supported this argument by noting that, since recruiting an additional nurse in October 2006, ODC anticipates being able to serve several of the patients currently being referred to other facilities. [source: Application, p3] On the basis of this argument, the department concludes that although the methodology projects a need for only three additional dialysis stations, approval of more than three additional stations might be permissible under the provisions of WAC 246-310-280(6)(a), which allows for approval of such stations when “The department finds such additional stations are needed to be located reasonably close to the people they serve.”

WAC 246-310-280(4) requires that existing dialysis centers that would stand to lose market share by approval of a project must be operating at or above 80% utilization (748.8 dialyses per year) before more stations can be added. As stated earlier, the two nearest dialysis facilities to Omak Dialysis Center are located in Wenatchee and Moses Lake, approximately 96 and 121 miles away, respectively. As of March 31, 2007, the Central Washington Hospital dialysis facility in Wenatchee was operating at 70% of capacity; IN-RCG Moses Lake was operating at 83% of capacity.

In a letter to the program supporting this project, Central Washington Hospital provided a letter noting that several Okanogan County patients dialyzing at its facility were required to travel over 100 miles each way to obtain treatment. Central Washington hospital also articulated concerns about the ability of some of its Okanogan County patients to physically and financially withstand the rigors of such long distances.

As noted above, the two nearest facilities to the proposed location are 96 and 121 miles away, or 120 and 165 minutes, respectively, under optimal driving conditions. The department does not have an established standard for travel distances and times in rural counties; however State Health Plan documents from the 1980’s identify the standard that “An ESRD facility should be located within 90 minutes normal driving time of 90% of the ESRD inpatient population who

live in HSAs III and IV.”⁷ If this standard were to be applied, the conclusion might be reached that the Omak Dialysis Facility meets this standard,. Another document expressed the standard that all facilities within 90 minute driving time from a proposed facility in this region should be operating at 80% utilization before additional stations could be approved⁸. There are no facilities within 90 minutes drive time from ODC. Each of these documents noted that areas of dense population have shorter expected driving times than areas of less-dense population. The department notes, however, that neither the subsequent 1987 State Health Plan, nor the rules in effect at the time this application was submitted, nor the current rules, contain such drive time standards, therefore the language of WAC 246-310-280(4) is not limited by distance.

In support of its application, IN-RCG provided the department with 15 letters of support. Of those letters, 8 were written by Okanogan County resident dialysis patients or their family members. Of the remaining 7 letters, 3 were written by nephrologists serving patients from Okanogan County, and 4 letters were written by the social worker at Omak Dialysis, a representative of the regional Medicaid transportation broker, a representative of the Colville Confederated Tribes and a representative of a local Latino civic group. The Okanogan County residents’ letters each described the various challenges they experience in reaching their current facility. Several of the patients noted that they live north of Omak, and experience longer travel distances to Central Washington than indicated above.

As noted in IN-RCG’s application, Okanogan County is the largest county in the state and is ranked 34th of the state’s 39 counties in population density. Omak is the largest city in the county and two of the remaining four largest cities are located north of Omak⁹ and farther from existing providers. It is reasonable to conclude that many Okanogan County residents must travel farther to obtain dialysis services in those facilities than the distance from Omak to the Central Washington or Moses Lake dialysis facilities. A representative of TranCare, a provider of medical assistance transportation in the region, discussed the difficulty Okanogan residents face obtaining transportation to dialysis facilities outside the county. The social worker at Omak Dialysis noted that many of the patients treatment days span 12 to 14 hours because of the difficulty obtaining transportation to and from dialysis procedures that may only last 3 to 4 hours.

The department evaluated the assumptions used by IN-RCG to support its request for additional stations and finds that the data, analysis and public comment provided by IN-RCG support several of its key arguments. Because ODC has been unable to consistently operate a third shift, it is reasonable to conclude that the outmigration reflected in the negative visitor stations predicted by the methodology may be a result of low capacity, rather than patient or physician choice. The department’s examination of the long travel distances, well in excess of historical access standards, endured by those patients who cannot dialyze at ODC, also supports this conclusion. The department concludes that IN-RCG has presented a reasonable explanation for requesting more stations than indicated by application of the methodology and the department concludes that approval of more than three stations would be appropriate under the provisions of WAC 246-310-280(6)(a).

⁷ 1980 State Health Plan. HSA III was composed of all or most of 8 counties in Central Washington (including Okanogan and Chelan). HSA IV was composed of all or most of the 11 east-most counties in Washington.

⁸ 1982 State Health Plan

⁹Tonasket, 23.7 mi. north; Oroville, 40.7 mi. north. Okanogan is 4.7 mi. south and Brewster is 31.7 mi. south.

The department cannot, however, conclude that IN-RCG's contention that Central Washington Dialysis does not "compete" (i.e., stand to lose market share) with ODC is supported by the same evidence discussed above. The historical driving distance standards discussed above do not appear in current rule and cannot be relied upon to supersede the language of WAC 246-310-280(4). Despite Central Washington Dialysis' support of the project, the department cannot over-ride its own rule and approve expansion of ODC when Central Washington Dialysis remains below 80% utilization. It is clear from the record that Okanogan County patients have historically used that facility and appear to do so now, therefore it stands to lose market share by approval of IN-RCG's facility. This standard is not met.

WAC 246-310-280(5) requires that new in-center kidney disease treatment stations must reasonably project to be operating at 80% capacity (748.8 dialyses per non-training station) by the end of year three. Based on the applicant's projections, with all 12 in-center stations operational, the dialysis center would be operating at 82% capacity by the end of year 2011, which is the third full year of operation. The department concludes that IN-RCG's proposal for a 12-station facility would meet this criterion

Based on the methodology for the service area, the number of dialysis stations in operation in the service area, and the applicant's projections, the applicant has demonstrated that additional in-center dialysis stations would be needed in Okanogan County, however the expansion would not be consistent with WAC246-310-280(4) (minimum volume of existing providers) and this sub-criterion is not 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.

The applicant asserts, "All individuals identified as being in need of dialysis services will have access to this facility. IN-RCG's admission policies prohibit discrimination on the basis of race, income, ethnicity, sex or handicap." [source: application, p24] The policy provided as Exhibit 12 to the applicant's screening responses 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 charity care policy in Exhibit 13 of the screening responses. That charity care policy clearly states the income levels at which charity care is provided, as well as the other objective criteria used by IN-RCG to determine eligibility.

The pro-forma income statements provided as Exhibit 15 of the application project charity care at 1% of total revenue. The department reviewed the historical financial statements provided for the facility as Attachment 2 to its December 27, 2006, screening responses for evidence of provision of charitable care. Those statements, for 2002 through 2005, reported between \$ - 6,290 and \$30,535 per year in charity care. Based on this information, the department concludes that all residents of the service area could reasonably be expected to continue to have adequate access to the health services at the Omak 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 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 bringing two additional stations on-line immediately upon CN approval and completion of the proposed expansion by April, 2008 [source: application, p4] As a result, the first full year of operation should be 2009. Using the financial information provided by IN-RCG, Table III, on the following page, illustrates the projected revenue, expenses, and net income for the first three years of operation for Omak as a 12-station facility [source: June 29, 2006 screening responses, Attachment 3]:

Table III
Omak Dialysis Center
Projected Revenue and Expenses 2008 – 2010

	Year (2009)	One Year (2010)	Two Year (2011)
Treatments	8,268	8,736	9,204
Net Patient Revenue*	\$ 3,621,880	\$ 3,826,892	\$ 4,031,904
Total Operating Expense**	1,968,312	2,066,438	2,164,563
Net Profit or (Loss)	\$ 1,653,568	\$ 1,760,454	\$ 1,867,341
Operating Revenue per Treatment	438.06	438.06	438.06
Total Operating Exp. per Treatment	238.06	236.54	235.18
Net Profit per Treatment	\$ 200.00	\$ 201.52	\$ 202.88

*Includes deductions for charity care and provision for doubtful accounts

**Includes depreciation expense

As shown in Table III, above, at the projected volumes identified in the application, IN-RCG would be operating the 12-station dialysis facility at a profit for the first three full years of operation. Based on the information presented above, the department concluded that the project is financially feasible and the method of financing for the project is reasonable.

IN-RCG is leasing the site for the facility from Okanogan County Public Hospital No.3, dba Mid-Valley Hospital. The applicant provided the lease for the existing site as Exhibit 8 of the application. The applicant also provided an amendment to the lease that pertains to the additional 3300 square feet required to build out the additional stations requested. Costs associated with the amended lease were included and appear to be consistent with the Building Rental line item in the financial projections used to prepare Table III, above. This sub-criterion is met.

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

The costs and charges per dialysis for this project were compared to those of recent kidney dialysis proposals. On the basis of that comparison, the average cost per dialysis is reasonable.

The capital expenditure associated with establishing the proposed facility is estimated to be \$700,000. [source: Application, p26] The total capital expenditure of \$700,000 is broken down as follows:

Item	Cost
Construction	384,184
Fixed and Moveable Equipment (incl taxes)	207,500
Sales Tax	52,407
A&E and Certificate of Need Fees	<u>55,909</u>
Total	\$ 700,000

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” [source: Application, p26]

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. [source: Application, p13]

Source of Revenue	Percentage of Revenue
Medicare	43%
State (Medicaid)	17%
Insurance/HMO	39%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 60% of the revenue at ODC. 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. 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.

However, in the need section of this evaluation, the department concluded that the applicant failed to demonstrate that existing facilities are not available to meet the future need for dialysis services for the residents of Okanogan County. Given that the project could reduce utilization at an existing facility currently operating at less than 80% capacity¹⁰, the department also concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the community. 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. A review of IN-RCG’s historical financial statements of years 2003 through 2005, demonstrates the funds necessary to finance the project are available. [source: December 27, 2006, screening responses, attachment 3]

To further assure the department of appropriate financing, the applicant provided a letter from FMC’s controller for the Western Business Unit, stating “...the funds necessary for the Omak Dialysis Center’s expansion will come from Inland Northwest Renal Care Group, LLC’s cash reserves, not from any new or existing debt sources. As the balance sheets included within the

¹⁰ As discussed on pp5-9 of this evaluation and in WAC 246-310-280(4) as it read prior to January 1, 2007.

request for supplemental information demonstrates, current reserves are more than adequate to fund the project.” [source: December 27, 2006, screening responses, attachment 3]

Based on the information provided, the department concludes that the applicant has demonstrated that expansion of the Omak Dialysis Center will not adversely affect their financial stability. This sub-criterion is met and the department concludes that the project described in this application can be appropriately financed.

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 hire the equivalent of 5.26 new employees to the dialysis center through the first three full years of operation based on the projected number of patients in those years. The proposed increases for the first three years of operation are shown in Table IV, below:

**Table IV
Omak Dialysis Center
FTE Increases**

Type of Personnel	2006 Actual	2008 (Partial Year) Incremental	2009 (Year 1) Incremental	2010 (Year 2) Incremental	2011 (Year 3) Incremental	2011 (Year 3) Total FTE's
Nurse Manager	1.00	0.00	0.00	0.00	0.00	1.00
Outpatient RN	4.00	0.00	0.00	0.00	0.00	4.00
PCT	4.50	1.50	2.50	0.25	1.00	9.75
Reuse Tech	0.00	0.00	0.00	0.00	0.00	0.00
Social Worker	0.30	0.03	0.10	0.05	0.05	0.53
Dietitian	0.30	0.03	0.10	0.05	0.05	0.53
Secretary	0.50	0.10	0.20	0.20	0.00	1.00
Biomed	0.25	0.15	0.00	0.00	0.00	0.40
Total	10.85	1.81	2.90	0.55	1.10	17.21

As shown in Table IV above, IN-RCG expects to add 6.36 FTEs to the facility by 2011. The applicant notes that some of the increased staffing will result in increasing the hours of existing employees, rather than increasing the number of employees. IN-RCG notes that expansion of the number of patients on a single shift (as opposed to adding additional shifts) does not require additional nursing staff. A review of Table IV supports this argument, with the exception of Patient Care Technicians, who will more than double in number, from 4.5 to 9.75 FTEs. No management positions or nursing staff will be added. IN-RCG notes that it has had some difficulty recruiting new nurses for the Omak facility, but has not experienced any difficulty recruiting patient care technicians. [source: December 27, 2006, screening responses, p3]

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 “As this project proposes the expansion of an existing unit, ODC already has the appropriate ancillary and support services in place.” [source: application, p30] The applicant did not identify vendors for such services as hazardous waste disposal or laundry, 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 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 1,645 dialysis clinics worldwide, of which 1,510 are located in North America... [source: FMC Webpage] Prior to the April 1, 2006 acquisition of the dialysis operations of Renal Care Group, FMC operated over 1,000 centers in the United States. Currently within Washington State, FMC owns and operates twelve 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 public¹¹. To accomplish this task, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the out-of-state facilities where FMCNA, Inc. or any subsidiaries of the parent company has health care facilities. Besides Washington State, the applicant identified 46 states and the District of Columbia where FMCNA is currently providing patient services. In January 2007, the department surveyed the 47 entities and received responses from 31 states¹². Additionally, only Arizona and Iowa had licensing or survey information available via the internet. Therefore, of the 47 states, the department obtained quality of care history for 33 or 70%. The compliance history of the remaining states is unknown.¹³

Fifteen of the 31 states responding to the survey indicated that significant non-compliance deficiencies had been cited at Fresenius facilities in the past three years. Of those states, with the exception of one facility in Delaware, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2004 due to several condition-level citations, but was operating in compliance at the time of survey.

The department concludes that considering the 1,500 facilities owned/managed by FMCNA, few out-of-state facilities listed above demonstrated substantial non-compliance issues, with only

¹¹ WAC 246-310-230(5)

¹² Alabama, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Missouri, Mississippi, Nevada, New Hampshire, New York, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Virginia, Wisconsin and West Virginia

¹³ Alaska, Arkansas, Arizona, California, Colorado, District of Columbia, Georgia, Massachusetts, Montana, Nebraska, New Jersey, New Mexico, North Carolina, Ohio and South Carolina

three reported as subject to fines or actually decertified. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

The department’s survey of other states generally revealed minor non-compliance issues typical of a dialysis facility, related to the care, medical records, and management at the FMC facilities. [source: Licensing and/or survey data provided by out of state health care survey programs] In summary, in those states that monitored dialysis facilities, FMC submitted plans of correction and implemented the required corrections. [source: Licensing and/or survey data provided by out of state health care survey programs]

As stated in the project description portion of this evaluation, Fresenius, through its subsidiaries RCGNW and QualiCenters, owns and/or operates the following twelve kidney dialysis treatment facilities in Washington State:

Facility Name	City/County Location	# of stations
PNRS- Salmon Creek	Vancouver, Clark County	16
PNRS-Ft. Vancouver	Vancouver, Clark County	24
INRCG-Northpointe	Spokane, Spokane County	24
INRCG-Spokane	Spokane, Spokane County	27
INRCG-Spokane Valley	Spokane Valley, Spokane County	20
INRCG-Omak	Omak, Okanogan County	5
RCGNW-Aberdeen	Aberdeen, Grays Harbor County	16
RCGNW-Chehalis	Chehalis, Lewis County	12
RCGNW-Lacey	Lacey, Thurston County	25
RCGNW-Moses Lake	Moses Lake, Grant County	17
RCGNW-Shelton	Shelton, Mason County	10
QualiCenters Walla Walla	Walla Walla, Walla Walla County	12

In addition to the twelve facilities listed above, FMC operated three additional facilities in the Spokane area until April, 2006. Those facilities were sold to DCI as a requirement of the Federal Trade Commission’s approval for FMC’s purchase of RCG. Those facilities identified in the table above with the prefix “INRCG” are owned by RCGNW and Sacred Heart Medical Center, with RCGNW having a majority share and operational responsibility. Those facilities identified with the prefix “PNRS” are owned by RCGNW, Legacy Health Systems, and Oregon Health Sciences University, with RCGNW having a majority share and operational facility. The facilities identified with the prefix “RCGNW” are wholly owned and operated by RCGNW. FMC will continue to provide dialysis services to the residents of its service areas through its twelve dialysis centers listed above.

The FMC-owned or operated facilities in Washington have collectively been surveyed 30¹⁴ times in the last six years. Nine of those surveys revealed no deficiencies. One of those surveys revealed potentially hazardous conditions that were promptly corrected by the applicant. The remaining 20 revealed minor non-compliance issues and the facilities submitted plans of

¹⁴ IN-RCG Omak, 2001 and 2004; PNRS Ft. Vancouver, 2006 (condition-level deficiency regarding water quality testing – acceptable plan of corrections submitted. Follow-up surveys indicate facility in substantial compliance) 2003, 2000 no def; QualiCenters Walla Walla, 2006, 2003, 2000 no def; RCGNW-Aberdeen, 2006 no def; 2004 no def; 2003, 2000; RCGNW-Lacey 2001, 2000, 2004; Shelton 2006 no def; PNRS-Salmon Creek 2006, 2003, 2000 no def; INRCG Spokane Kidney Center 2005, 2003, 2002; INRCG Spokane Valley 2005, 2002, 2001; INRCG-Northpointe 2005, 2002 no def, 1999 no def; RCGNW-Chehalis 2002 no def, 2005

corrections for the non-compliance issues within the allowable response time. [source: compliance survey data provided by Office of Health Care Survey (OHCS)]

The Omak Dialysis Center has identified Curtis Wickre, MD, as its medical director under a contract provided in the application. A review of Dr. Wickre'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]

Given the compliance history of FMC's other Washington facilities and its proposed medical director; there is reasonable assurance that FMC would operate this facility in conformance with applicable state and federal licensing and certification requirements.

The department concludes that the applicant has provided, through application materials or practice patterns, reasonable assurance that the expanded facility would be in conformance with applicable state and federal laws and regulations. The department notes, however, that the applicant (both as Fresenius and its subsidiary, RCG) is currently under investigation by the US Attorney's Offices for the Eastern District of Missouri and the Eastern District of New York. Little information is publicly available about these investigations. Depending on the outcome of these investigations, future applications by Fresenius may be impacted.

The department concludes that this sub-criterion at this time is met by FMC. The department will continue to monitor the progress of the governmental investigations and if the conclusions of the investigations affect the applicant's ability to participate in the Medicare program, the department will re-evaluate its conclusions concerning this criterion in future analyses.

(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 noted that "As this project proposes the expansion of an existing facility, no change in the provision of health care services is planned. All existing formal and informal relationships will continue. ODC provides a collaborative, comprehensive and patient-centered approach to the provision of dialysis services in the community." [source: application, p31] The applicant also provided a list of area nursing homes and senior services with which it has informal relationships, noting that it does not maintain contracts with those entities. IN-RCG did provide a copy of a transfer agreement between the facility and Sacred Heart Medical Center for hospitalization. [source: application, exhibit 16]

Additionally, the department used the most recent utilization data—December 2006--obtained from the Northwest Renal Network to assist in its evaluation of this sub-criterion. According to that data, the other existing dialysis center currently serving Okanogan County's dialysis patients is operating below the 80% utilization standard required before additional stations may be added. Based on this information, the department must reasonably conclude that the existing facility would have capacity to serve the patients from Okanogan County. Therefore, the department concludes that approval of this project has the potential of adversely impacting existing providers of dialysis services in the region, 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 sub-criterion is addressed in sub-section (3) above.

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.

In its application, IN-RCG notes that it considered and rejected two alternatives to the proposed project: wait until new CN rules for ESRD are in place, and submit a request for fewer stations (only the number indicated by strict adherence to the methodology in WAC 246-310-280).

The applicant discarded the first option because it concluded that waiting for new rules would delay approval for several months – an option unacceptable to IN-RCG because of the high census at ODC.

The second option was discarded for several reasons. First, IN-RCG believes that addition of fewer than six stations “would not maximize the operating efficiencies available to ODC that the 12-station facility offers.” [source: Application, p32] IN-RCG also rejected this option because it believes that building only the number of stations indicated by the methodology would “‘short change’ the community in that the number of stations needed to meet the demand would not be sufficiently available. ODC was especially concerned that in the not to distant future, patients would once again, be traveling long distances for services (sic).” [source: Application, p32]

The department recognizes that the need methodology projects a need for additional dialysis stations in the county. However, as previously concluded in this evaluation, this application fails because the facility that stands to lose market share by expansion of ODC (Central Washington) is operating below 80%. Therefore, on the basis of the information above, the department concludes that the project proposed in this application is not the best available alternative at this time when evaluating impact on existing providers and this sub-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 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.