

CERTIFICATE OF NEED EVALUATION OF THE QUALICENTERS INLAND NORTHWEST, LLC (QUALICENTERS)—FRESENIUS MEDICAL CARE HOLDINGS, INC. APPLICATION PROPOSING TO ADD FOUR DIALYSIS STATIONS TO THE EXISTING TWELVE STATION DIALYSIS CENTER IN WALLA WALLA COUNTY

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.¹ [source: CN historical files; & Application, Pages 1-2]

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.² [Source: CN historical files and Application, pp2-4 & Exhibit #1]

Benton County Columbia Basin Dialysis Center	Stevens County Colville Dialysis Center
Clark County Fresenius Fort Vancouver Dialysis Facility Fresenius Salmon Creek Dialysis Facility	Lewis County Fresenius Chehalis Facility
Grant County Fresenius Moses Lake Dialysis Facility	Mason County Fresenius Shelton Dialysis Facility
Gray Harbor County Fresenius Aberdeen Dialysis Facility	Okanogan County Fresenius Omak Dialysis Facility
Spokane County Fresenius Northpointe Dialysis Facility Fresenius Spokane Kidney Center Fresenius Valley Dialysis Facility	Thurston County Fresenius Lacey Dialysis Facility
Cowlitz County QualiCenters Longview	Walla Walla County QualiCenters Walla Walla

This application, submitted on behalf of QualiCenters, Inc., (QualiCenters), proposes to add four dialysis stations to the existing 12-station facility known as QualiCenters Walla Walla located 301

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

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

West Poplar Street, #120 in the city of Walla Walla. Approval of this project would not change the location of the facility. [source: Application, p7] Once the facility is operating with 16 stations, QualiCenters proposes it would also serve residents in the neighboring Columbia County, where no dialysis facility currently exists. [source: Application, p5]

The capital expenditure associated with the addition of four dialysis stations is \$385,000, of which approximately 69% is related to leasehold improvements at the site; 22% is related to both fixed and moveable equipment; and the remaining 9% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p28]

If this project is approved, QualiCenters anticipates the dialysis facility would be operating 16 stations by the end of year 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation as a 16-station facility, and 2011 would be year three. [source: Application, p9]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as an increase in the number of dialysis stations in a kidney disease center 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, QualiCenters must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment). Additionally, QualiCenters must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.³

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #3. No other kidney disease treatment center applications were submitted for Walla Walla or Columbia counties during Review Cycle #3; therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review

July 31, 2007	Letter of Intent Submitted
August 31, 2007	Application Submitted
September 1, 2007, through January 27, 2008	Department's Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses• 2nd screening activities and responses
January 28, 2008	Department Begins Review of Application

³ 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 246-310-286; WAC 246-310-287; and WAC 246-310-288.

APPLICATION CHRONOLOGY (continued)

March 3, 2008	End of Public Comment/No Public Hearing Conducted
March 18, 2008	Rebuttal Documents Received at the Department
May 2, 2008	Department's Anticipated Decision Date
May 1, 2008	Department's Actual Decision Date

AFFECTED AND INTERESTED PERSONS

Throughout the review of this project, no entities sought and received affected person status under WAC 246-310-010. One entity—DaVita, Inc.—sought and received interested person status for this application.

SOURCE INFORMATION REVIEWED

- QualiCenters, Inc.'s Certificate of Need application submitted August 31, 2007
- QualiCenters, Inc.'s supplemental information dated November 13, 2007, and January 21, 2008
- DaVita' Inc. public comments received January 28, 2008
- Public comments received from community members
- QualiCenters, Inc.'s rebuttal comments received October 3, 2007
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2007 Northwest Renal Network 2nd Quarter Data
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from Fresenius Medical Care's webpage
- Certificate of Need historical files
- Medical Quality Assurance compliance data
- Data obtained from the Washington Secretary of State website
- Data obtained from the Walla Walla County Assessor website

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of QualiCenters, Inc. proposing to add four stations to the existing 12-station facility known as QualiCenters Walla Walla is consistent with the applicable criteria, provided the applicant agree to the following term:

Before commencing the project, QualiCenters, Inc. must provide to the department a copy of the executed Second Amendment to the Lease Agreement. The executed Second Amendment to the Lease Agreement must be consistent with the draft Second Amendment to the Lease Agreement provided in the application.

At project completion, QualiCenters Walla Walla would be operating 16 dialysis stations and would serve the residents of both Walla Walla and Columbia counties.

The approved capital expenditure associated with the four-station addition is \$385,000.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284.

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

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology, adopted January 1, 2007, projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.⁴

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

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

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

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

⁴ 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]

QualiCenters Application of the Numeric Methodology

QualiCenters proposes to add four dialysis stations to the existing 12-station facility located in Walla Walla County to serve patients in two separate planning areas—Walla Walla and Columbia counties. Consistent with WAC 246-310-280 (9), QualiCenters applied the numeric methodology separately for each planning area using linear regression for both counties. Given that the facility would be located in Walla Walla County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: Application pp16-18]

Department’s Application of the Numeric Methodology

For the reader ease, the department will address the numeric methodology separately for each county.

Walla Walla County

Based on the calculation of the annual growth rate in the planning areas as described above, the department also used linear regression to project need for Walla Walla County and divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

Based on the numeric methodology, Table 1 below shows a summary of the projected net need provided by QualiCenters and the department’s for Walla Walla County. The department’s numeric methodology for Walla Walla County is attached to this evaluation as Appendix A.

Table 1
Walla Walla County Numeric Methodology Summary of Projected Net Station Need

	4.8 in-center patients per station			
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
QualiCenters	15	12	3	3
DOH	14.92	12	2.92	3

When comparing the project results shown in Table 1 above, it is noted that the results of QualiCenters projections match the department’s projections.

Columbia County

Based on the calculation of the annual growth rate in the planning areas as described above, the department used linear regression to project need for Columbia County. As required in WAC 246-310-284(5), the department divided the projected number of patients by 3.2 to determine the number of stations in Columbia County.

Based on the numeric methodology, Table 2 on the following page depicts a summary of the projected net need provided by QualiCenters and the department’s projected net need for Columbia County. The department’s numeric methodology for Columbia County is attached to this evaluation as Appendix B.

Table 2
Columbia County Numeric Methodology Summary of Projected Net Station Need

	3.2 in-center patients per station			
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
QualiCenters	1	0	1	1
DOH	0.188	0	0.188	1

When comparing the results of QualiCenters and the department’s projections shown in Tables 1 and 2, it is noted that both projections are exactly the same. In summary, the numeric need methodology results in a need for four additional dialysis stations to serve the residents of Walla Walla and Columbia counties.

WAC 246-310-284(5) requires QualiCenters Walla Walla to be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period was August 1, 2007. [Source: WAC 246-310-282] The quarterly modality report from NRN available at that time was June 31, 2007, which became available on July 27, 2007. Currently, QualiCenters Walla Walla is the only dialysis provider operational in Walla Walla County and according to data available to the department, it is currently operating at 4.92 utilization rate. This criterion is met.

WAC 246-310-284(6) requires QualiCenters Walla Walla to be operating at 4.8 in-center patients per approved station by the end of year three (2011). QualiCenters provided the projected third year utilization as a 16-station facility. A summary of the projections for year 2011 is shown in Table 3 below. [source: January 21, 2008, supplemental information, Attachment 2]

Table 3
Year 2011 Projected Facility Utilization

Facility Name	# of Stations	# of Pts	Pts/Station
QualiCenters Walla Walla	16	80	5.0

As shown in Table 3 above, the applicant projects QualiCenters Walla Walla to be operating above the 4.8 standard by the end of the third year of operation, or year 2011.

Based on QualiCenters projections with all 16 stations operational, the facility would be operating above 4.8 patients per in-center station by the third year of operation or year 2011. The department concludes that QualiCenters proposal to add four dialysis stations to the existing 12-station facility located in Walla Walla meets this criterion.

Based on the numeric methodology and resident’s historical dialysis utilization data for Walla Walla and Columbia counties, QualiCenters has demonstrated need for an additional four dialysis stations at QualiCenters Walla Walla to serve the residents of both Walla Walla and Columbia counties. 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 areas 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, QualiCenters provided a copy of its current Admission Policy and Indigence Policy used at the existing Walla Walla facility. The Admission Policy outlines the process and criteria that the new facility would use to admit patients for treatment and ensures that patients receive appropriate care at the proposed facility. [source: Application, Exhibit 8 and 9]

To determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. 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 QualiCenters' Walla Walla identifies financial resources, including both Medicare and Medicaid revenues. [source: Application, p8 and Exhibit 9]

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.

QualiCenters 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, QualiCenters pro-forma financial statement included a charity care line item as a deduction from revenue within the pro-forma. [source: January 21, 2008, supplemental information, Attachment 1]

Based on the above information, the department concludes that all residents of the service area would continue to have access to health services at QualiCenters Walla Walla. This sub-criterion is met

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

Based on the source information reviewed and the applicant’s agreement to the term identified on page 3 of this evaluation, the department determines that the applicant has met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

As stated in the project description portion of this evaluation, if this project is approved QualiCenters anticipates all 16-stations would be operational by the end year 2008. Under this timeline, year 2009 would be the facility’s first full calendar year of operation and 2011 would be year three. [source: Application, p9]

Summarized in Table 4 below is QualiCenters year one through year three projected financial revenue, expenses, and net income for the Walla Walla facility with 16 dialysis stations. [source: November 13, 2007, supplemental information, Attachment 2; and January 21, 2008, supplemental information, Attachment 1]

Table 4
QualiCenters Walla Walla
Projected Revenue and Expenses for Years 2009 through 2011⁵

	Year 1 - 2009	Year 2 - 2010	Year 3 - 2011
# of Stations	16	16	16
# of Treatments [1]	11,664	12,528	13,392
# of Patients [2]	72	76	80
Utilization Rate [2]	4.50	4.80	5.00
Net Patient Revenue[1]	\$ 4,120,219	\$ 4,671,014	\$ 5,107,570
Total Operating Expenses [1, 3]	\$ 2,724,919	\$ 2,974,868	\$ 3,209,097
Net Profit or (Loss)[1]	\$ 1,395,300	\$ 1,696,146	\$ 1,898,473
Operating Revenue / Treatment [1]	\$ 408.75	\$ 438.35	\$ 454.73
Operating Exp./ Treatment [1]	\$ 270.33	\$ 279.17	\$ 285.71
Net Profit per Treatment [1]	\$ 138.42	\$ 159.17	\$ 169.02

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

As shown in Table 4 above, at the projected volumes identified, QualiCenters would be operating the Walla Walla dialysis center at a profit in all three years of operation as a 16-station facility.

To accommodate the additional four stations, QualiCenters must expand the square footage of the existing facility. QualiCenters provided a copy of its current lease agreement and a copy of the draft amendment to the lease agreement identifying the additional square footage and associated costs. The existing lease agreement between St. Mary Medical Center (landlord) and QualiCenters (tenant) was executed in July 1996 for lease of 3,545 sf of space. In September 2003, the lease agreement was amended (First Amendment to Lease) to incorporate an additional 989 square feet, resulting in 4,534 sf lease agreement with costs adjustments based

⁵ Whole numbers may not add due to rounding.

on the additional space. The draft amendment to the lease agreement provided with this application (Second Amendment to Lease) increases the square footage another 2,120 to 6,654 sf, adjusts the costs based on the additional space, and extends the lease to August 31, 2013. [source: Application, Exhibit 7 and November 13, 2007, supplemental information, Attachment 4] The costs identified in the draft Second Amendment to Lease are consistent with the pro-forma financial projections used to prepare Table 4.

If this project is approved, the department would attach a term requiring QualiCenters to provide to the department a copy of the executed Second Amendment to the Lease Agreement. The executed Second Amendment to the Lease Agreement must be consistent with the draft Second Amendment to the Lease Agreement provided in the application. Further, the executed agreement must be provided to the department before commencement of the project.

During the review of this application, DaVita, Inc. provided comments focused on the proposed capital expenditure and the pro forma balance sheet provided for the Walla Walla facility. In summary, DaVita asserts that FMC improperly understated its true estimated capital expenditure amounts by reducing the amounts with the first year depreciation. DaVita further asserts that once this inaccuracy is corrected to show the actual capital costs as they would be in relation to the balance sheet figures, there would be an increase in capital expenditures in excess of 12% beyond the \$350,000 identified in the letter of intent.⁶ DaVita states the remedy for this understatement is to return the application to QualiCenters with no further action as instructed under WAC 246-310-080(6) because of a significant change from the letter of intent. [source: DaVita, Inc. January 25, 2008, public comment, pp1-5 and Exhibit 1]

In response, QualiCenters provided the following statements. [source: FMC, March 18, 2008, rebuttal statements, pp1-2]

“DaVita has offered an argument which suggests (wrongfully) that our Walla Walla application contains a systemic error that results in our actual capital expenditure being more than 12% different than our Letter of Intent. Before addressing the specific comments raised by DaVita, QualiCenters must first note the irony of DaVita, Inc. criticizing our balance sheet submissions simply because they have a long and consistent history of not providing any balance sheets for the Program to evaluate or consider in review. With that said, we note that the format of the balance sheet [Application, Exhibit 10] did not show the first year (2008). In addition, in the normal course of business, QualiCenters does not prepare balance sheets for its facilities. This one was prepared for CN purposes only and therefore, only includes the Property, Plant, and Equipment related to the CN project. The information contained in the balance sheet is consistent with our capital expenditure of \$385,000. Table 1 [provided in the QualiCenters responses] refutes DaVita’s claim that our balance sheet is not consistent with the capital expenditure in our application. ...Table 1 demonstrates the line item, “Property, Plant, and Equipment, net” is, in fact, correct for a project with an estimated capital expenditure of \$385,000. The pro forma revenue and expense statement submitted with the screening responses include all the

⁶QualiCenters letter of intent for this project identified an estimated capital cost of \$350,000. WAC 246-310-100 requires an applicant to amend an application if the costs of the project exceed 12% or \$50,000 (whichever is greater). Under this rule, QualiCenters could not submit an application with a capital expenditure beyond \$400,000.

depreciation associated with this facility (not just the depreciation associated with the project as reflected in Table 1 above)."

QualiCenters continues to point out that the accuracy or omission of a balance sheet has not prejudiced a review since the implementation of the new ESRD rules in January 2007. In fact, this point is augmented by DaVita in their rebuttal response for a project in Snohomish County, where DaVita states,

"A project-specific balance sheet for a single new facility owned by a multi-facility company, such as DaVita or FMC, is a largely hypothetical and meaningless document."

[source: CN historical files, CN App #08-0711, DaVita March 7, 2008 rebuttal documents, p7]

The department, in this particular review, concurs with both QualiCenters and DaVita. A balance sheet is generally a statement of the financial position of a business at a particular point in time. The department will not prejudice the QualiCenters application by holding it to a different standard of review than DaVita's or any other multi-facility organization.

Based on the information provided in this application, if this project is approved, the department would include a term requiring QualiCenters to provide for review and approval an executed Second Amendment to the Lease Agreement. The executed Second Amendment to the Lease Agreement must be consistent with the draft Second Amendment to the Lease Agreement provided in the application. Further, the executed agreement 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.

QualiCenters identified the capital expenditure associated with the additional four stations is \$385,000. The capital expenditure is summarized in Table 5 below. [source: Application, p28]

Table 5
QualiCenters Walla Walla Capital Cost

Item	Cost	% of Total
Building Construction & Tenant Improvements	\$ 266,544	69%
Fixed & Moveable Equipment	\$ 87,316	22%
Sales Tax and Fees	\$ 31,140	9%
Total Project Cost	\$ 385,000	100%

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, QualiCenters also provided the sources of its patient revenue shown in Table 6 on the following page. [source: Application, p29]

Table 6
QualiCenters Walla Walla Source of Revenue

Source of Revenue	% of Revenue
Medicare	84.0%
State (Medicaid)	7.0%
Other	9.0%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 91% of the revenue at the existing Walla Walla 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 9% will be derived through other or private insurance reimbursements. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals; the average cost per dialysis is reasonable.

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

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

To demonstrate compliance with this sub-criterion, QualiCenters provided a letter from its West Division CEO demonstrating financial and operational support for the additional four stations at its Walla Walla center. The letter assured financial support for the additional stations at a capital cost of \$385,000. [source: November 13, 2007, Appendix 5] Additionally, QualiCenters provided its most recent historical financial statements for years 2003 through 2005 for Fresenius Medical Care. [source: Application, Appendix 2] That review shows that its parent company's financial reserves are more than adequate to fund the additional four stations at QualiCenters Walla Walla.

Based on the information provided, the department concludes the costs associated with addition of four stations at the Walla Walla facility would not adversely affect the financial stability of QualiCenters or Fresenius Medical Care as a whole. 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.*

QualiCenters Walla Walla is currently operating 12 dialysis stations with 14.45 FTEs. To staff the additional four stations, QualiCenters intends to recruit another 3.05 FTEs, resulting in a total of 17.50 FTEs by the end of full calendar year three (2011). A breakdown of the current

and proposed FTEs is shown in Table 7 below. [source: Application p30 and November 13, 2007, supplemental information, Attachment 1]

**Table 7
QualiCenters Walla Walla Dialysis Center 2008 – 2011 Projected FTEs**

Staff/FTEs	2008 Current Year	2009 Increase	2010 Increase	2011 Increase	Total FTEs
Medical Director	Professional Services Contract				
Nurse manager	1.00	0.00	0.00	0.00	1.00
Outpatient RN	2.40	0.60	0.60	0.00	3.60
Patient Care Techs	7.20	0.60	0.60	0.00	8.40
Equipment Techs	1.00	0.20	0.00	0.00	1.20
MSW	1.00	0.00	0.00	0.00	1.00
Dietitian	0.60	0.10	0.10	0.00	0.80
Secretary	1.25	0.25	0.00	0.00	1.50
Total FTE's	14.45	1.75	1.30	0.00	17.50

As shown in Table 7 above, QualiCenters expects to add FTEs in years one and two only. QualiCenters states that while considered an increase in FTEs, for the most part, existing part-time staff will expand to full time. In addition, QualiCenters states that several employees have already expressed interest in expanding working hours. [source: Application, p31]

The current medical director at QualiCenters Walla Walla is Mathias Stroemel, DO, and Dr. Stroemel intends to continue as medical director once the four stations are added. QualiCenters provided a copy of the current medical director agreement extended through year 2017. The agreement identifies roles and responsibilities for both QualiCenters and Dr. Stroemel and identifies the annual compensation for the services. Compensation identified in the agreement is substantiated in the pro forma revenue and expense statements summarized in Table 4 of this evaluation. [source: November 13, 2007, supplemental information, Attachment 1]

Based on the above information, the department concludes that additional staffing for the Walla Walla facility is 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, QualiCenters stated that “As this project proposes the expansion of an existing facility, no change in the provisions of health care services is planned. All existing working relationships will continue.” [source: Application, p32]

QualiCenters also provided a listing of its existing vendors for its ancillary services. The applicant also states that it intends to continue the transfer agreement with St. Mary Medical Center for hospital care and support services and provided a copy of the existing agreement. [source: Application p32, and Attachment 11]

The department concludes that the applicant currently has appropriate relationships with ancillary and support services and approval of an additional four stations would not negatively affect those relationships. 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. [source: Licensing and/or survey data provided by out of state health care survey programs]

In Washington State, Fresenius or one of its subsidiaries owns, operates, or manages 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. [source: Office of Health Care Survey compliance survey data]

On the basis of recent surveys of the facilities owned, operated, or managed by subsidiaries of Fresenius Medical Care, it is reasonable to expect that the QualiCenters Walla Walla facility would continue to operate in compliance with the applicable state and federal standards and regulations.

As previously stated, the current medical director at QualiCenters Walla Walla is Mathias Stroemel, DO, and Dr. Stroemel intends to continue as medical director once the four stations are added. A review of Dr. Stroemel's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Based on QualiCenters compliance history and the compliance history of the identified medical director, the department concludes that there is reasonable assurance that the QualiCenters Walla Walla dialysis facility would continue to operate in conformance with state and federal regulations. This sub-criterion is met.

- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

QualiCenters states that it has been providing dialysis services to the residents of Washington State for several years, and has been appropriately participating in relationships with community facilities to provide a variety of medical services. The department concludes that nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

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 demonstrates need for three dialysis stations in Walla Walla County and one dialysis station for Columbia County. Within the application, QualiCenters demonstrated it met the standards to receive approval to add four stations to the existing 12-station facility in Walla Walla.

Based on this information, the department concludes that approval of this project would promote continuity in the provision of healthcare for the two planning areas and would not result in an unwarranted fragmentation of services. Further, QualiCenters 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 sub-criterion is addressed in sub-criterion (3) of this evaluation. The department concludes that there is reasonable assurance that the services to be provided will ensure safe and adequate care to the public and in accordance with applicable federal and state laws, rules, and regulations. This sub-criterion is met.

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

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

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

Before submitting this application, QualiCenters considered and rejected one other option. The option—to establish a new satellite facility within Walla Walla County—was rejected by QualiCenters after its review of current patient travel patterns. QualiCenters determined that there was no advantage to establishing a new satellite facility because most of the patients reside within a 20-minute commute to the existing Walla Walla facility. [source: Application, p34 and November 13, 2007, supplemental information, p4]

The department notes that QualiCenters did not consider the option of status quo or do nothing. Given the numeric need demonstration of four stations to allow patient access for both Walla

Walla and Columbia counties, the status quo option would not meet the projected need in the two counties.

Based on QualiCenters discussions of the alternative considered before submitting this application and considering the results of the numeric methodology, the department concludes the addition of four dialysis stations to the existing 12-station facility in Walla Walla is the best available alternative. This criterion is met.

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

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

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

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

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