

EXECUTIVE SUMMARY

EVALUATION OF THE TWO CERTIFICATE OF NEED APPLICATIONS SUBMITTED BY DAVITA, INC. AND RENAL CARE GROUP NORTHWEST, INC. (RCGNW) PROPOSING TO ESTABLISH NEW DIALYSIS STATIONS IN THURSTON COUNTY

- **DAVITA, INC. IS PROPOSING THE ESTABLISHMENT OF A SIX-STATION DIALYSIS CENTER IN THE CITY OF OLYMPIA TO SERVE THE RESIDENTS OF THURSTON COUNTY.**
- **RCGNW IS PROPOSING THE ESTABLISHMENT OF A TEN-STATION DIALYSIS CENTER IN THE CITY OF LACEY TO SERVE THE RESIDENTS OF THURSTON COUNTY.**

BRIEF PROJECT DESCRIPTIONS

DaVita Inc.

This project proposes to establish a new 6-station facility to be located at 335 Cooper Point Road Northwest in the City of Olympia within Thurston County. The new dialysis center would serve the residents of Thurston County. [Source: DaVita Application, Page 1 and October 31, 2007, Supplemental Information, Page 1]

The capital expenditure associated with the establishment of the 6-station facility is \$1,308,804. [Source: Application, Page 7] If this project is approved, DaVita anticipates all 6-stations would become operational by the end of November 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [Source: DaVita Application, Page 11]

Renal Care Group Northwest, Inc.

This project proposes to establish a new 10-station facility to be located at 8729 Commerce Drive Northeast, Suite A, Lot 2, in the City of Lacey within Thurston County. The new dialysis center would serve the residents of Thurston County. [Source: RCGNW Application, Page 5 and October 31, 2007; Supplemental Information, Page 1]

The capital expenditure associated with the establishment of the 10-station facility is \$860,662. [Source: Application, Page 1] If this project is approved, RCGNW anticipates all 10-stations would become operational by the end of March 2009. Under this timeline, year 2010 would be the facility's first full calendar year of operation and 2012 would be year three. [Source: RCGNW Application, Page 10 and October 31, 2007; Supplemental Information, Page 2]

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

CONCLUSIONS

DaVita Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a new 6-station dialysis center in the City of Olympia to serve the residents of Thurston County is consistent with applicable criteria.

If approved, the Department would include terms that DaVita provide for review and approval of the items listed below. Provided that DaVita agrees to the terms identified below, a Certificate of Need would be issued for the establishment of the 6-station DaVita Olympia Dialysis Center to be located in the city of Olympia within Thurston County. The approved capital expenditure associated with the establishment of the dialysis center is \$1,308,804.

Terms

1. Prior to providing services, DaVita, Inc. must provide to the department for review and approval copy of the executed Medical Director's agreement. The executed agreements shall be consistent with the draft agreements and information provided within the application and must identify the compensation.
2. Prior to providing services at the DaVita Olympia Dialysis Center, DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval.
3. Prior to commencing this project, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located at 335 Cooper Point Road NW, Olympia, WA 98502.

Renal Care Group Northwest, Inc.

For the reasons stated in this evaluation, the application submitted on behalf of RCGNW proposing to establish a new 10-station dialysis center in the City of Lacey within Thurston County is not consistent with the applicable criteria of the Certificate of Need Program and a Certificate of Need is denied.

EVALUATION OF THE TWO CERTIFICATE OF NEED APPLICATIONS SUBMITTED BY DAVITA, INC. AND RENAL CARE GROUP NORTHWEST, INC. (RCGNW) PROPOSING TO ESTABLISH NEW DIALYSIS STATIONS IN THURSTON COUNTY

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PROJECT DESCRIPTIONS

DaVita Inc.

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,300 outpatient centers located in 42 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [Source: DaVita Application, Page 4]

In Washington State, DaVita owns or operates a total of fourteen kidney dialysis facilities in six separate counties Clark, Franklin, King, Kittitas, Pierce, and Yakima. Below is a listing of the fourteen DaVita facilities in Washington. [Source: CN historical files; & Application, Page 1]

Clark

Vancouver Dialysis Center

Pierce

Lakewood Community Dialysis Center

Puyallup Community Dialysis Center

Tacoma Dialysis Center

Yakima

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

Franklin

Mid-Columbia Kidney Center

Kittitas

Ellensburg Dialysis Center

King

Bellevue Dialysis Center

Federal Way Community Dialysis Center

Kent Community Dialysis Center

Olympic View Dialysis Center (management only)

Westwood Dialysis Center

DaVita's application proposes to establish a new 6-station facility in Thurston County. The new facility to be known as DaVita Olympia Dialysis Center would be located at 335 Cooper Point Road Northwest in the City of Olympia within Thurston County. The proposed dialysis center would serve the residents of Thurston County. [Source: DaVita Application, Page 1 and October 31, 2007, Supplemental Information, Page 1]

The capital expenditure associated with the establishment of the 6-station dialysis center is \$1,308,804 of which approximately 55% is related to leasehold improvements at the site; 34.3% is related to both fixed and moveable equipment; and the remaining 10.7% is related to architect, engineering, application, consulting, and legal fees. [Source: Application, Page 7]

If this project is approved, DaVita anticipates all 6-stations would become operational by the end of November 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [Source: DaVita Application, Page 11]

Renal Care Group Northwest, Inc.

Renal Care Group Northwest, Inc (RCGNW) is owned by Renal Care Group (RCG). On March 31, 2006, Fresenius Medical Care Holdings, Inc (FMCHI) became the sole owner of RCG through stock acquisition. RCG is an indirect subsidiary of Fresenius Medical Care—AG (FMCAG) a German corporation. RCGNW currently owns and operates or manages dialysis centers throughout the Northwestern United States and its regional office is located in Portland, Oregon. The regional office is responsible for the operations of facilities under three separate legal entities. These entities are Pacific Northwest Renal Services (PNRS), IN-RCG and Renal Care Group of the Northwest, Inc. [Source: CN historical files; & Application, Pages 2-3]

In Washington State, RCGNW currently owns, operates and/or manages fourteen kidney dialysis treatment facilities in eleven separate counties. Below is a listing of the thirteen facilities in Washington. [Source: CN historical files; & Application, Pages 4-6]

Benton

Columbia Basin Dialysis Center

Clark

Fresenius Fort Vancouver Dialysis Facility

Fresenius Salmon Creek Dialysis Facility

Grant

Fresenius Moses Lake Dialysis Facility

Gray Harbor

Fresenius Aberdeen Dialysis Facility

Spokane

Fresenius Northpointe Dialysis Facility

Fresenius Spokane Kidney Center

Fresenius Valley Dialysis Facility

Stevens

Colville Dialysis Center¹

Lewis

Fresenius Chehalis Facility

Mason

Fresenius Shelton Dialysis Facility

Okanogan

Fresenius Omak Dialysis Facility

Thurston

Fresenius Lacey Dialysis Facility

Walla Walla

QualiCenters Walla Walla

Fresenius Medical Care Holdings, Inc. the sole owner of RCGNW conducts its operations through five subsidiaries listed below.

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

National Medical Care, Inc. one of the entities listed above also conducts its operations through two subsidiaries: QualiCenter Inland Holdings, Inc. and QualiCenter, Inc. These two entities serve as the corporate parents of QualiCenter Northwest, LLC. This entity provides kidney dialysis services in one Washington State facility².

RCGNW's application proposes to establish a 10-station dialysis facility in Thurston County. The new facility to be known as Fresenius Hawks Prairie will be located at 8729 Commerce Drive Northeast, Suite A, Lot 2, in the City of Lacey within Thurston County. The proposed facility would serve the residents of Thurston County. [Source: RCGNW Application, Page 8 and October 31, 2007; Supplemental Information, Page 1]

¹ This facility is not yet operational

²QualiCenter Walla Walla

The capital expenditure associated with the establishment of the new 10-station dialysis center is \$860,662, of which approximately 66% is related to architect, engineering and leasehold improvements at the site; 26% is related to fixed and moveable equipment and the remaining 8% is related to application, taxes and fees. [Source: Application, Page 26]

RCGNW anticipates that all 10-stations would become operational by the end of March 2009. Under this timeline, year 2010 would be the facility’s first full calendar year of operation and 2012 would be year three. [Source: RCGNW Application, Page 10 and October 31, 2007; Supplemental Information, Page 2]

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

CRITERIA EVALUATION

To obtain Certificate of Need approval, each applicant 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). Additionally, each applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 288.³

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted both applications under the Kidney Disease Treatment Centers-Concurrent Review Cycle #3. A chronological summary of the review is shown below.

Action	DaVita	RCGNW
Letter of Intent Submitted	July 31, 2007	July 31, 2007
Application Submitted	August 31, 2007	August 31, 2007
Department’s Pre-Review Activities including Screenings and Responses	September 4, 2007 through October 30, 2007	
Beginning of Review	November 16, 2007	
Public Hearing /End of Public Comment	November 16, 2007 thorough January 15, 2008	
Rebuttal Comments Received	February 14, 2008	
Department's Anticipated Decision Date	March 31, 2008	
Department's Actual Decision Date	March 31, 2008	

CONCURRENT REVIEW AND AFFECTED PERSONS

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); and WAC 246-310-287.

The concurrent review process promotes the expressed public policy goal of RCW 70.38 that the development or expansion of health care facilities is accomplished in a planned, orderly fashion and without unnecessary duplication. For this projects, concurrent review allows the department to review dialysis applications proposing to serve the same planning area or an adjacent planning area where there is no existing facility [as defined in WAC 246-310-280(9) and WAC 246-310-284 (a) simultaneously to reach a decision that serves the best interests of the planning area's residents.

In the case of the applications submitted by DaVita and RCGNW, the department will issue one single evaluation regarding whether both, any or none of the applicant's should be issued a Certificate of Need.

For each application, the other competing applicant sought and received affected person status under WAC 246-310-010. No other entity sought or received affected person status related to the two projects.

SOURCE INFORMATION REVIEWED

- DaVita, Inc. Certificate of Need application submitted August 31, 2007
- RCGNW Certificate of Need application submitted August, 2007
- DaVita, Inc. supplemental information dated October 31, 2007
- RCGNW supplemental information dated October 31, 2007
- DaVita, Inc. public comments received on January 15, 2008
- RCGNW public comments received on January 15, 2008
- DaVita, Inc. rebuttal comments received February 14, 2008
- Community letters of support received by the department on January 15, 2008
- Evergreen Nursing and Rehabilitation Center public comments dated January 15, 2008
- Providence Health and Services Washington/Montana public comments dated January 15, 2008
- Memorial Nephrology Associates public comments dated January 15, 2008
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2006 Northwest Renal Network 4th 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
- Certificate of Need historical files
- Data obtained from the Washington Secretary of State website
- Medical Quality Assurance compliance data

CONCLUSIONS

DaVita Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a new 6-station dialysis center in the City of Olympia to serve the residents of Thurston County is consistent with applicable criteria.

If approved, the Department would include terms that DaVita would be required to comply with prior to the issuing of CN. Provided that DaVita agrees to the terms identified below, a Certificate of Need would be issued for the establishment of the 6-station DaVita Olympia Dialysis Center to be located in the city of Olympia within Thurston County. The approved capital expenditure associated with the establishment of the dialysis center is \$1,308,804.

Terms

1. Prior to providing services, DaVita, Inc. must provide to the department for review and approval copy of the executed Medical Director's agreement. The executed agreements shall be consistent with the draft agreements and information provided within the application and must identify the compensation.
2. Prior to providing services at the DaVita Olympia Dialysis Center, DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval.
3. Prior to commencing this project, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located at 335 Cooper Point Road NW, Olympia, WA 98502.

Renal Care Group Northwest, Inc.

For the reasons stated in this evaluation, the application submitted on behalf of RCGNW proposing to establish a new 10-station dialysis center in the City of Lacey within Thurston County is not consistent with the 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 both applicants have met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280.

(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.

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 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)]

DaVita's Application of the Numeric Methodology

DaVita proposes to establish a 6-station kidney dialysis facility in Olympia to serve the residents of Thurston County. Based on the calculations of the annual growth rate in the planning areas as described above, DaVita used linear regression to project need. Given that the

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]

facility would be located in Thurston County, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area.

Tables 1 below summarize DaVita’s application of the kidney dialysis numeric methodology for Thurston County. [Source: Application page 18]

**Table 1
Summary of DaVita’s Thurston County Numeric Methodology**

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	121.6	129.2	136.8	144.4
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	25.33	26.92	28.50	30.08
Total Station Need Rounded Up	26	27	29	31
Minus # CN Approved Stations	25	25	25	25
Net Station Need / (Surplus)	1	2	4	6

As shown in Table 1 above, DaVita projected need for 6 dialysis stations in Thurston County in year 2010. Based on the results of its methodology, DaVita requested a 6-station dialysis facility.

RCGNW Application of the Numeric Methodology

RCGNW proposes to establish a new 10-station kidney dialysis facility in Lacey to serve the residents of Thurston County. In its application, RCGNW states that five of the 10-stations requested are existing dialysis stations currently located at its Fresenius Lacey Dialysis Facility. The Fresenius Lacey Dialysis Facility is a 25-station facility that is being downsized to a 20-station facility. [Source: RCGNW Application, Page 3] Based on the calculation of the annual growth rate in the planning area as described above, RCGNW also used a linear regression to project need. Given that the facility would be located in Thurston County, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area.

Summarized in Table 2 below, is a summary of RCGNW application of the kidney dialysis numeric methodology for Thurston County. [Source: Application, Pages 15 and 16]

**Table 2
Summary of RCGNW Thurston County Numeric Methodology**

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	121	129	136	144
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	25.33	26.92	28.50	30.08
Total Station Need Rounded Up	26	27	29	31
Minus # CN Approved Stations	25	25	25	25
Net Station Need / (Surplus)	1	2	4	6

RCGNW application of the numeric methodology in the table above shows that in year 2010, 6-stations are need in Thurston County. RCGNW in its application chose to apply for only 5 new dialysis stations.

Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning areas as described above, the department used linear regression to project need in the planning area. For Thurston County, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. Table 3 below is a summary of the department's application of the numeric methodology for Thurston County. [Source: Appendix A attached to this evaluation]

Based on the numeric methodology, Table 3 below depicts a summary of the projected net need provided by each applicant and the department's projected net need for Thurston County. The department's numeric methodology for Thurston County is attached to this evaluation as Appendix A.

Table 3
Summary of Thurston County Numeric Methodology

4.8 in-center patients per station				
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
DaVita	30.08	25	5.08	6
RCGNW	30.08	25	5.08	6
DOH	30.08	25	5.08	6

When comparing the results of the three numeric methodology tables, it is noted that both DaVita, Inc. and RCGNW numeric methodology matched the department. In summary, the department's numeric needs methodology for Thurston County results in need for new 6-stations.

WAC 246-310-284(5) requires that all CN approved stations in the planning area must 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 31, 2007. [Source: WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2006 which became available on January 20, 2007. Currently, Fresenius Lacey Dialysis Facility is the only dialysis provider operational in Thurston County and according to data available to the department; Fresenius Lacey Dialysis is currently operating at 4.84 utilization rate. This criterion is met.

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For Thurston County, the requirement is 4.8 in-center patients per approved station. Both DaVita and RCGNW propose new dialysis stations to be located in Thurston County as a result; each applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station. DaVita states that year 2011 would be its third year of operation and RCGNW stated that year 2012 is its third full year of operation. A summary of each applicant's projected utilization for year's 2011 and 2012 is shown in Table 4 below.

Table 4
Third Year of Operation Projected Facility Utilization

Facility Name	Year 3	#of Stations	# of Pts	Pts/Station
DaVita Olympia Center	2011	6	33	5.50
Fresenius Hawks Prairie	2012	10	52	5.20

As shown in Table 4 above, both DaVita’s and RCGNW’s projections meet this standard. [Source: DaVita Application, Appendix 9 and RCGNW Supplemental Information October 31, 2007, Attachment 6]

Based on the information contained in Table 4 the department’s conclusions regarding this sub-criterion are as follows:

DaVita, Inc.

DaVita’s proposes to establish a 6-station dialysis center in Olympia to serve the residents of Thurston County. Based on the above standard and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. This sub-criterion is met

RCGNW.

RCGNW proposes to establish a new 10-station dialysis facility in Lacey within Thurston County. To accomplish this, RCGNW is requesting for 5 new dialysis stations and would combine this with an additional 5-station that is being relocated from its existing facility in the same planning area to build a new 10-station facility to serve the residents of Thurston County. As noted in Table 3, the department’s numeric methodology shows a need for 6-stations in Thurston County. Based on the standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. 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, both applicants currently provide 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 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.

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current admission and indigent care policies that would also be used at the proposed DaVita Olympia Dialysis Center. The Admission policy outlines the process and criteria the new facility would use to admit patients for treatment and ensures that patients receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the dialysis center without regard to race, color, national origin, sex, age, religion, or disability. [Source: Application, Appendix 14]

A review of the Admission and Charity Care policies for the proposed DaVita Olympia Dialysis Center identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. [Source: Application, Appendix 14]

Additionally, DaVita demonstrated its intent to provide charity care to residents by submitting its charity care policy that outlines the process a patient would use to access service. Further, DaVita's pro-forma financial statement included a charity care line item as a deduction from revenue within the pro-forma. [Source: Application, Appendix 9]

Based on the above information, the department concludes that all residents of the service areas would have reasonable access to health services at the proposed DaVita Olympia Dialysis Center. This sub-criterion is met.

RCGNW

To demonstrate compliance with this sub-criterion, RCGNW provided a copy of its current admission and indigent care policies that would be used at the proposed Fresenius Hawks Prairie Facility. The document provided by RCGNW outlines the process and criteria the proposed new facility would use to admit patients for treatment. 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 7]

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 Charity Care policies for the proposed Fresenius Hawks Prairie Facility identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. [Source: Application, Appendix 14]

RCGNW provided documentation in its application that suggested that charity care would be available to residents in Thurston County. However, the revised supplemental information pro-forma financial statement provided to the department did not include a charity care line item within the pro-forma. [Source: RCGNW Supplemental Information October 31, 2007, Exhibit 9]

The department received public comments from DaVita, Inc. regarding the proposed new facility. DaVita states, "*The lack of charity care line item in RCGNW revised pro-forma prevents the program from assuring that the project will meet charity care requirements*". [Source: DaVita, Inc. public comments dated January 15, 2008] RCGNW did not provide rebuttal comments to DaVita's concerns.

During the screening process, the department requested any necessary updates to the proposed facility pro-forma financial statements. The department requested updated pro-forma financial income statement because RCGNW anticipates the project will commence in March 2009, as stated in its application page 8, but the pro-forma income statement provided did not include partial year 2009 data. [Source: September 27, 2007, Supplemental Information #8] In response to the screening question, RCGNW provided a revised pro-forma income statement that included the partial year data and listed bad debt as a line item, but the revised pro-forma income statement did not include charity care as a line item. On the last day of public comment period, RCGNW provided a revised pro-forma income statement showing charity care as a line item and states, “*Finally, the revised pro-forma contained in RCGNW October 31, 2007, screening response did not separately break out charity care from bad debit line item*” [Source: RCGNW public comments received January 15, 2008]

The department notes that the October 31, 2007, revised pro-forma financial statement provided by RCGNW in response to the screening questions listed bad debt, but did not show charity care as a line item. The department notes that the revised pro-forma income statement provided to the department on January 15, 2008, during public comments shows that charity care will be available to the residents of the planning area. Based on the above information, the department concludes that all residents of the service area would have reasonable access to health services at the proposed Fresenius Hawks Prairie Facility. This sub-criterion is met

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.’s project has met the financial feasibility criteria in WAC 246-310-220; and
- Renal Care Group Northwest project 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.

DaVita Inc.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates all 6-station would become operational by the end of November 2008. Under this timeline, year 2009 would be the proposed DaVita Olympia Dialysis Center first full calendar year of operation and 2011 would be year three. [Source: DaVita Application, Page11]

Summarized in Table 5, is DaVita’s year one through year four projected financial revenue, expenses, and net income for the DaVita Olympia Dialysis Center as a 6-station dialysis facility [Source: Application, Appendix 9]

**Table 5
DaVita Olympia Dialysis Center
Projected Revenue and Expenses Years (1 through 4)**

	Partial Year 2008	Full Year 2009	Full Year 2010	Full Year 2011	Full Year 2012
# of Stations	6	6	6	6	6
# of Treatments [1]	1,498	2,995	4,493	4,942	5,391
# of Patients [2]	10	20	30	33	36
Utilization Rate [2]	1.67	3.33	5.00	5.50	6.00
Net Patient Revenue[1]	\$538,800	\$1,091,054	\$1,819,330	\$2,336,124	\$2,669,362
Total Operating Expenses [1, 3]	\$844,183	\$1,047,131	\$1,491,327	\$1,804,531	\$2,019,233
Net Profit or (Loss)[1]	(\$305,383)	\$43,923	\$328,003	\$531,593	\$650,129
Operating Revenue / Treatment [1]	\$298.67	\$302.48	\$336.29	\$378.93	\$385.75
Operating Exp./ Treatment [1]	\$467.95	\$290.31	\$275.66	\$292.71	\$291.80
Net Profit per Treatment [1]	(\$169.28)	\$12.18	\$60.63	\$86.23	\$93.95

[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 above in Table 5, at the projected volumes identified, the DaVita Olympia facility would be operating the 6-station dialysis center at a loss in partial year 2008 and a profit in years 2009 through 2012. DaVita states that the proposed facility will be operated at utilization levels consistent with other facilities. In order to clarify that DaVita has site control, it provided a draft lease agreement between EDG-DV Olympia, LLC (Tenant) and Total Renal Care, Inc. its parent company as the Landlord. Rent costs data identified in the draft lease are consistent with the pro-forma financial projections used to prepare Table 5 above

During the review of this application, Fresenius Medical Care Holdings, Inc. the parent company of Renal Care Group Northwest, Inc. provided comments to the department regarding DaVita's project. Those comments are summarized below.

Fresenius Medical Care Holding comments regarding DaVita's projected patient volume

- CN guidelines require the applicant provide a pro-forma balance sheet for the project.
- DaVita assumed a payer mix and revenue stream that is not consistent with Fresenius experience in Thurston County.
- DaVita's projected treatment volumes increase 50% between years 2-3, but total revenues increase 67%.
- DaVita's EBIT increases by 74% between years 3 and 4, while patient volume is only projected to increase by 14%. [Source: Fresenius, Inc. public comments received January 15, 2008]

Summarized below is the rebuttal comments provide by DaVita to the concerns raised by FMC regarding DaVita's proposed project.

DaVita's Response

- The department does not require a facility specific balance sheet and this point have been previously raised in connection with other applications and the Program has adhered to its consistent position.
- FMC makes apples to oranges comparison that DaVita payer mix projections are incorrect. DaVita accurately projected its payers mix as stated on its application. Previous DaVita applications uses 10-K and internal company reports for year 2005 and earlier and DaVita Olympia application uses data from the 2006 10-K which becomes available in 2007. DaVita serves a category of patients who have assigned their Medicare and Medicaid benefits to HMO and have become HMO enrollees.
- FMC argues that 22% of its revenue will come from commercial payers. If DaVita labeled its revenue in the same manner, it would project 20% commercial payer revenue.
- DaVita is not able to predict with accuracy the actual payor mix experience at a new facility and it relies on company-wide performance data as a starting point.
- FMC criticism of DaVita's projected treatment volumes and revenues in years 2 and 3 has no merit. The Program has not asked DaVita to explain its treatment volumes or revenues estimates for this project and there is no discrepancy to volume in a new facility. DaVita model is based upon and reflects actual experience at DaVita's new facilities.
- DaVita EBIT values are derived from a highly complex interplay among Total Treatment counts, Total Revenue values, Total Expenses values, and G&A allocations. Facilities operate at a different level of profitability (EBIT) depending on a variety of factors, one of which is wages, salary and benefits. Between years 3 and 4, projections will increase by 29%, but wages, salary and benefits expense will increase by only 22%. Capturing other efficiencies at greater volumes, total operating expenses projections will increase by only 20%. [Source: DaVita, Inc. rebuttal comments received February 14, 2008]

The Department Response

The department notes that as directed by the application guidelines, a balance sheet would be required, but the provision of a facility specific balance sheet is optional hence, the department places an emphasis upon the submission of a pro-forma financial income statement for the proposed facility. The department notes that the only reasonable method available in which an applicant can verify its patient's volume assumption is to refer to the applicant's company-wide performance data regarding payer-mix. The department concludes that DaVita's responses are reasonable regarding its market share expectations and agrees with the assertions that it cannot predict with accuracy the actual payer mix it will experience in a new facility. The department would expect DaVita to rely on its company-wide performance data as a starting point for estimating future payer mix for its new facilities.

If approved, the Department would include a term that DaVita provide for review and approval an executed lease agreement contract which includes the relevant terms and compensation as identified in the draft agreement.

Term

- *Prior to commencing this project, DaVita, Inc. must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located at 335 Cooper Point Road NW, Olympia, WA 98502.*

Based on the information presented the department concludes that the proposed project is financially feasible. This sub-criterion is met.

RCGNW

As stated in the project description portion of this evaluation, if this project is approved; RCGNW anticipates all 10-stations would become operational by the end of March 2009. Under this timeline, year 2010 would be the facility's first full calendar year of operation and 2012 would be year three. [Source: RCGNW Application, Page 10 and October 31, 2007; Supplemental Information, Page 2]

Summarized in Table 6, is RCGNW's year one through year three projected financial revenue, expenses, and net income for the Hawks Prairie Dialysis Center as a 10-station dialysis facility. [Source: October 31, 2007; Supplemental Information, Attachment 6]

Table 6
RCGNW Hawks Prairie Dialysis Center
Projected Revenue and Expenses Years (1 through 3)

	Partial Year 2009	Full Year 2010	Full Year 2011	Full Year 2012
# of Stations	10	10	10	10
# of Treatments [1]	3,564	5,184	6,264	7,200
# of Patients [2]	33	39	48	52
Utilization Rate [2]	3.30	3.90	4.80	5.20
Net Patient Revenue[1]	\$1,167,139	\$1,697,656	\$2,051,335	\$2,357,762
Total Operating Expenses [1, 3]	\$1,075,916	\$1,462,116	\$1,721,002	\$1,945,919
Net Profit or (Loss)[1]	\$91,223	\$235,540	\$330,333	\$411,843
Operating Revenue / Treatment [1]	\$327.48	\$327.48	\$327.48	\$327.47
Operating Exp./ Treatment [1]	\$301.88	\$282.04	\$274.74	\$270.27
Net Profit per Treatment [1]	\$25.60	\$45.44	\$52.74	\$57.20

[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 6 above, at the projected volumes identified above, the Hawks Prairie Dialysis Center would be operating the 10-station dialysis center at profit from partial year 2008 though year 2012. RCGNW provided a draft lease agreement for the proposed site between Renal Care Group Northwest, Inc. (RCGNW)/Inland Northwest Renal Care Group, LLC. (Tenant) its parent company and Summit Corporate Park, LLC (Landlord). The costs identified in the lease are consistent with the pro-forma financial projections used to prepare Table 6 above.

Summarized below are DaVita's public comments regarding RCGNW (Fresenius, Inc.) proposed project.

DaVita's Comments regarding RCGNW unexplained Pro-forma Income Statement changes

- FMC screening response indicates that only changes in the revised pro-forma reflected the addition of a partial year and changes in rental expenses, lease related costs and medical director fees. This statement obviously is not correct and misrepresents and conceals other

material changes FMC made to its pro-forma. While treatment volume remains unchanged between the original and revised pro-forma operating statements there are large and totally unexplained fluctuations in revenue and expenses between the two operating statements.

- FMC has misrepresented the revised pro-forma income statement it has submitted to the program. FMC describes its revised pro-forma as containing changes only in rent –related items, medical director compensation and first partial year of operation. In fact, the revised pro-forma contains extensive changes on both the revenue and expenses side that go far beyond FMC’s description. Most of the discrepancies between the original and the revised pro-forma are unexplained, making the two pro-forma’s irreconcilable and confusing.
- There are a number of expense categories presented in the original pro-forma that do not appear in the revised pro-forma.
- The revised pro-forma indicates substantial changes in the operation of the proposed unit but FMC has provided no documentation or explanation as to what those changes are. [Source: DaVita, Inc. Public Comments received January 15, 2008]

The Department Response

The department agrees that FMC misrepresented the scope of changes made to the revised pro-forma income statements provided on October 31, 2007. In response to screening question #8, dated September 27, 2007, FMC states “*The pro-forma financials have been revised to reflect the following:*”

- *Addition of partial year;*
 - *Adjustment of rental expense to reflect draft lease agreement*
 - *Adjustment of other operating expenses to reflect lease related costs; and*
 - *Adjustment of the medical director fees to reflect the draft medical director agreement.*
- [Source: RCGNW supplemental information #8, received October 31, 2007]

The department review of the changes made to the pro-forma income statement indicated that the statements made by FMC above are not true. Assertions by FMC that changes in the revised Pro-forma income statements were limited to a partial year data, adjustments to operating expense to reflect lease related costs and adjustments to medical director fees and agreement are misleading statements that do not reflect changes in other line items. The department notes that FMC made several changes to the revised pro-forma income statements that is more than what is being acknowledged.

The department agrees with DaVita’s assertions that changes made by FMC “*shows wide variance from the original in several expense categories other than the rent-related items and medical director compensation.*” [Source: DaVita’s public comment received January 15, 2008]

The department concludes that the revised pro-forma income statement shows inconsistent revenue’s and expense’s statement that are different from the original pro-forma Income statement.

Based on the above information, because of the unexplained changes in RCGNW pro-forma income statements, the department is unable to conclude that the proposed project is financially feasible. 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.

DaVita Inc.

The costs and charges per dialysis for the proposed DaVita Olympia Dialysis Center can be compared to recent kidney dialysis proposals submitted to the department. The estimated capital expenditure associated with the establishment of 6-station dialysis facility is \$1,308,804. [Source: Application page 1] Summarized in Table 7 below, is the capital expenditure.

**Table 7
DaVita Olympia Dialysis Center Capital Cost**

Item	Cost	% of Total
Leasehold Improvements	\$720,000	55%
Fixed & Moveable Equipment	\$449,395	34.3%
Architect/Engineering and CN fees	\$139,409	10.7%
Total Project Cost	\$1,308,804	100%

The department recognizes that the majority of reimbursements for dialysis services are thorough Medicare ESRD entitlement. To further, demonstrate compliance with this sub-criterion, DaVita provided the sources of its patient revenue shown in the table 8 below. [Source: Application, Page 9]

**Table 8
DaVita Olympia Dialysis Center Revenue and Payor Source**

Source of Revenue	% of Revenue	% of Patients per Payor
Medicare	58%	78%
Medicaid /State	7%	9%
Insurance / HMO	35%	13%
Total	100%	100%

As shown in Table 8 above, Medicare and state (Medicaid) entitlements as stated by DaVita are projected to equal 65% of revenue and 87% patients per payor source. The projected Medicare and Medicaid revenue sources are not cost based reimbursement. The department concludes that costs associated with this project will not have an unreasonable impact on the remaining 35% of revenue and 13% of patients per payor source.

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

RCGNW

Renal Care Group Northwest, Inc. identified the capital expenditure associated with the establishment of 10-station dialysis to be \$860,662. [Source: Application, Page 26] The capital expenditure is summarized in Table 10 below.

**Table 10
RCGNW Capital Cost**

Item	Cost	% of Total
Building Construction*	\$570,283	66%
Fixed & Moveable Equipment	\$220,766	26%
Sales Tax and Fees	\$69,613	8%
Total Project Cost	\$860,662	100%

* includes Architectural and Engineering Fees

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, RCGNW also provided the sources of its patient revenue shown in Table 11 below. [Source: Application, Page 27]

**Table 11
RCGNW Source of Revenue**

Source of Revenue	% of Revenue
Medicare	73%
State (Medicaid)	5%
Other	22%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 78% of the revenue at the proposed Hawks Prairie Dialysis Center. 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. However, because of the unexplained changes in the pro-forma income statement, the department is unable to conclude that the remaining 22% of the charges would not have an unreasonable impact. The costs and charges per dialysis for the proposed facility cannot be compared to recent kidney dialysis proposals submitted to the department. The department is not able to calculate the average cost per dialysis with any certainty due to in-consistent pro-forma data. This sub-criterion is not met

(3) The project can be appropriately financed.

DaVita Inc.

The source of financing for the proposed DaVita Olympia Dialysis Center is the facility parent company cash reserves. A review of DaVita's historical financial statements for years 2004 through 2006, demonstrates that the funds necessary to finance the project are available. [Source: Application, Exhibit 10]

DaVita's financial reserves as documented by Exhibit 10 are more than adequate to fund the new 6-station dialysis facility. Based on the information provided, the department concludes that DaVita has demonstrated that the establishment of a new Dialysis Center in Thurston County will not adversely affect DaVita's financial stability. Further, the department concludes that DaVita's application proposing to establish a new facility in Olympia to serve the residents Thurston County can be appropriately financed. This sub-criterion is met.

RCGNW

RCGNW source of financing for the proposed Hawks Prairie Dialysis Center is RCGNW cash reserves. The department reviewed RCGNW's parent company historical financial statements for years 2005 through 2006, to determine if the funds necessary to finance the project are available. [Source: Application, Appendix 2] That review shows that RCGNW's parent company financial reserves are more than adequate to fund the establishment of the new 10-station Hawks Prairie Dialysis Center in Thurston County. The department concludes that RCGNW's application proposing to establish a new facility in Lacey to serve the residents of Thurston County can be appropriately financed. 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:

- DaVita, Inc.'s project has met the structure and process (quality) of care criteria in WAC 246-310-230; and
- Renal Care Group, Inc. project 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.

DaVita Inc.

To implement this project DaVita proposes to hire the equivalent of 2.60 new staff during the first partial year of operation and thereafter, increase the number of new staff to 8.30 by the end of the fourth full year of operation. The proposed project staff increase is summarized in Table 11 below.

Table 11
DaVita Olympia Dialysis Center Proposed FTE's 2008 – 2012

Category	Partial Year 2008	Year 1. 2009 Increase	Year 2. 2010 Increase	Year 3. 2011 Increase	Year 4. 2012 Increase	Total FTE's
Medical Director	<i>Professional Services Contract</i>					
Administrator	0.20	0.10	0.70	-	-	1.00
Registered Nurses	0.80	0.60	0.30	0.50	0.30	2.50
Patient care Tech	0.90	0.60	0.70	0.40	0.20	2.80
Biomedical Tech	0.20	-	-	-	-	0.20
Re-Use Tech	0.10	0.10	0.10	-	-	0.30
Administrative Asst	-	-	-	0.20	0.30	0.50
Social Worker	0.20	0.10	0.10	0.10	-	0.50
Dietician	0.20	0.10	0.10	0.10	-	0.50
Number of FTE'S	2.60	1.60	2.00	1.30	0.80	8.30

As shown in Table 11 above, after the initial recruitment of FTE's, DaVita expects a steady increase in FTE's for its Olympia Dialysis Center through year 2012. DaVita states it expects no difficulty in recruiting staff for the new facility because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. In addition, DaVita states that several employees have already expressed interest in working at its proposed facility. [Source: Application, Page 24]

DaVita identified Catherine Richardson, MD as the Medical Director for the proposed Olympia Dialysis Center and provided a draft medical director’s agreement between Pacific Nephrology Associates, PS (“Group”), Dr. Richardson and DaVita. The draft medical director agreement outlines the roles and responsibilities of the Group and Dr. Richardson. Additionally, the draft agreement also identifies the annual compensation for the medical director. [Source: DaVita Inc, Supplemental Information received October 31, 2007, Attachment 4]

If approved, the Department would include a term that DaVita provide for review and approval an executed medical director contract which includes the relevant terms and compensation as identified in the draft agreement prior to project completion.

Term

- *Prior to providing services DaVita, Inc. must provide to the department for review and approval an executed copy of the Medical Director’s agreement. The executed agreements shall be consistent with the draft agreement provided within the application.*

Base on information provided by DaVita, the department concludes that staffing is expected to be available for recruitment by the applicant when the dialysis center commences services in November 2008. This sub-criterion is met provided DaVita agrees to the term identified above.

RCGNW

To implement this project RCGNW proposes to hire the equivalent of 7.35 new FTE’s during the first partial year of operation and thereafter, increase the number of new staff to 35.45 by the end of the fourth full year of operation. The proposed project staff increase is summarized in Table 12 below.

**Table 12
RCGNW Hawks Prairie Dialysis Center Proposed FTE’s 2008 – 2011**

Category	Partial Year 2009	Year 1. 2010 Total	Year 2. 2011 Total	Year 3. 2012 Total
Medical Director	Professional Services Contract			
Nurse Manager	0.5	0.5	0.6	0.7
Out-Patient Nurse	1.5	1.5	2	3
Patient Care Tech	4	4	5	6
Social Worker	0.6	0.6	0.6	0.6
Dietician	0.25	0.25	0.4	0.4
Secretary	0.25	0.25	0.4	0.4
Bio-Med	0.25	0.25	0.25	0.4
Total FTE’s	7.35	7.35	9.25	11.5

As shown in Table 12 above, RCGNW expects a steady increase in FTEs for the Hawks Prairie Dialysis Center through year 2012.

RCGNW states it does not anticipate any unusual difficulty in recruiting and retaining staff for Fresenius Hawks Prairie. The applicant states that Thurston County continues to be one of the fastest growing counties in Washington State and the population influx has resulted in relatively large numbers of health care professionals moving to the area. Further, RCGNW states, in order

to be effective in staff recruitment and retention, training of staff would be done at Fresenius Lacey. RCGNW owns the Fresenius Lacey facility and states that the proposed facility is within a relatively short distance to Fresenius Lacey and this would help to realize some economies of scale by sharing administrative as well as various support staff. [Source: Application, Page 29]

RCGNW identified Seth Thaler, MD as the Medical Director for the proposed Hawks Prairie Dialysis Center and provided a draft medical director's agreement between RCGNW and RVS, LLC (the "Consultant"). The draft medical director agreement outlines the roles and responsibilities of both RCGNW and the Rockwood Clinic and identifies the annual compensation for the position. [Source: RCGNW Supplemental Information, Attachment 4, received October 31, 2007]

If approved, the Department would include a term that RCGNW provide for review and approval an executed medical director contract which includes the relevant terms and compensation as identified in the draft agreement prior to project completion.

Term

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

Base on information provided by RCGNW, the department concludes that staffing is expected to be available for recruitment by the applicant when the dialysis center commences services in March 2009. 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.*

DaVita, Inc.

Information provided by DaVita states that ancillary and support services such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site upon the commencement of services at the proposed facility. The applicant states that services would be coordinated through DaVita's corporate office in El Segundo, California and support offices in Washington. [Source: Application, Page 24] To further demonstrate compliance with this sub-criterion, DaVita provided draft transfer agreement. [Application, Appendix 12]

If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed transfer agreement with a local hospital in Thurston County.

Term

- *Prior to providing services at the DaVita Olympia Dialysis Center, DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval*

Based on this information and with agreement to the term above, the department concludes that DaVita currently has appropriate relationships with ancillary and support services. This sub-criterion would be met.

RCGNW

Information provided by RCGNW states that ancillary services such as social and nutrition services would be provided on site while support services such as pharmacy, laboratory and radiology will be available through working relationship with local providers. [Source: Application, Page 29]

To further demonstrate compliance with this sub-criterion, RCGNW states that a formal transfer agreement would be established with providence St. Peter a local hospital in Thurston County. [Source: Application, page 30]

If this project is approvable, the department would include a term requiring RCGNW to provide a copy of the executed transfer agreement with a local hospital in Thurston County.

Term

- *Prior to providing services at the Hawks Prairie Dialysis Center, Renal Care Group Northwest, Inc. will provide an executed copy of the Patient Transfer Agreement for the department's review and approval*

Based on the evaluation of supporting documents provided, and with agreement to the term above, the department concludes that there is reasonable assurance that the Hawks Prairie Dialysis Center will have appropriate ancillary and support services with a healthcare provider in Thurston County. 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.*
DaVita, Inc.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,300 outpatient centers located in 42 states (including Washington State) and the District of Columbia. [Source: DaVita Webpage] Prior to the October 1, 2005, acquisition of the dialysis operations of Gambro Healthcare US, DaVita operated 665 centers in 37 states and the District of Columbia. Currently within Washington State, DaVita owns and operates fourteen 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 public⁵. To accomplish this task, in January 2007 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the 42 states and the District of Columbia where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Of the 43 entities, the department received responses from 28 states or 66% of the 42 states.⁶ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁷

Ten of the 28 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Delaware, one in New York and one in Texas, none of the deficiencies were reported to have resulted in fines or enforcement action All other facilities

⁵ WAC 246-310-230(5).

⁶ Alabama, Arizona, Connecticut, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New York, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

⁷ Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2006 due to several condition-level citations, but was operating in compliance at the time of survey. The New York facility was cited with condition-level deficiencies. This facility was voluntarily de-certified and closed by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005. No further fines were identified for this facility.

The department concludes that considering the 1,300 facilities owned/managed by DaVita, few out-of-state facilities listed above demonstrated substantial non-compliance issues, with only three reported as subject to fines or actually decertified. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 32 compliance surveys for the operational facilities that DaVita either owns or manages.⁸ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [Source: facility survey data provided by the Office of Health Care Survey]

Compliance history review of the proposed medical director Dr. Catherine Richardson did not reveal any recorded sanctions. DaVita provided a draft medical director agreement with Dr. Richardson. The agreement outlines the roles and responsibilities of the medical director. Given the compliance history of DaVita and that of the proposed facility medical director, the department concludes that there is reasonable assurance that the proposed DaVita Olympia Dialysis Center would be operated in conformance with state and federal regulation. This sub-criterion is met.

RCGNW

Renal Care Group Northwest, Inc (RCGNW) is owned by Renal Care Group (RCG). On March 31, 2006, Fresenius Medical Care Holdings, Inc (FMCHI) became the sole owner of RCG through stock acquisition. RCG is an indirect subsidiary of Fresenius Medical Care—AG (FMCAG) a German corporation.

In Washington State, RCGNW currently owns, operates and/or manages thirteen kidney dialysis treatment facilities in ten separate counties. The FMC-owned or operated facilities in Washington have collectively been surveyed 33⁹ times in the last six years. Of the 33 surveys, one survey revealed 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

⁸ DaVita's Ellensburg Dialysis Center and Tacoma Dialysis Center are not yet operational. Olympic View Dialysis Center is owned by Group Health and managed by DaVita.

⁹ 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-North Pointe 2005, 2002 no def, 1999 no def; RCGNW-Chehalis 2002 no def, 2005, RCGNW-Moses Lake 2000 (condition-level deficiency regarding equipment and electrical—corrections submitted, 2003 no def; 2006 no def .

allowable response time. [Source: compliance survey data provided by Office of Health Care Survey (OHCS)]

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 FMC facilities. [Source: Licensing and/or survey data provided by out of state health care survey programs] In summary, in those states that license and/or survey dialysis facilities, FMC 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]

On the basis of recent surveys of RCGNW's facilities in the State of Washington, it is reasonable to expect that the proposed Hawks Prairie Dialysis Center would be operated in compliance with the applicable standards and regulations of Washington State.

RCGNW identified Seth Thaler, MD, as its medical director under a draft contract provided in the application. A review of Dr. Thaler's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

Based on RCGNW's compliance history and the compliance history of the Dr. Thaler as medical director, the department concludes that there is reasonable assurance that the proposed Hawks Prairie Dialysis Center would be operated 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.*

DaVita, Inc

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [Source: Application, Page 24, Appendices 17 & 18]

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

Additionally, the department must consider the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology by the department shows a need for 6 new dialysis stations in Thurston County. Within its application, DaVita proposes to establish a 6-station dialysis center in the city of Olympia within Thurston County. Therefore, the department concludes that the approval of DaVita's application for 6-stations in Olympia to serve the residents of Thurston County would

not causing fragmentation of dialysis services. Based on this information, the department concludes that approval of this project would promote continuity in the provision of healthcare for the planning area, and would not result in an unwarranted fragmentation of services.

RCGNW

The applicant stated that it has a close working relationship with all area nursing homes and that the establishment of a second facility in Thurston County owned and operated by RCGNW will allow for maximum efficiency, coordination and continuity of care through shared staff. RCGNW stated that it will establish transfer agreement with St. Peter Hospital and provided a copy of its Fresenius Lacey Facility agreement with that hospital. [Source: Application, Page 3. and Exhibit 9]

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

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 by the department shows need for a new 6 dialysis stations facility in the Thurston County.

Based on this information, the department concludes that approval of this project would promote continuity in the provision of healthcare for the planning area, and would not result in an unwarranted fragmentation of services. Further, RCGNW demonstrated it has, and will continue to have, appropriate relationships to the service area's existing health care system within the planning area. This sub-criterion is met.

- (5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

For both projects, this sub-criterion is addressed in sub-section (3) above and is considered met.

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.'s application has met the cost containment criteria in WAC 246-310-240; and
- Renal Care Group Northwest, Inc. application 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.

DaVita, Inc.

To comply with this sub-criterion, DaVita stated that it considered the three alternatives listed below.

- Establish a 6-station dialysis center at the site in Olympia.
- Establish a robust 6-station center with isolation and training capabilities with a permanent bed station.
- Pursue joint ventures with existing providers.

DaVita states that after rejecting two of the three alternatives it considered the choice to establish a 6-station center at the site in Olympia was the best because the need methodology indicates that a 6-station facility is required to serve the residents of Thurston County. DaVita intends to provide a full service dialysis center with all dialysis modalities on site including on-site training and a permanent bed station that would maintain high utilization levels. Base on this alternative and with the rejections of the other two alternatives considered, DaVita submitted its application proposing to establish a new 6-station facility in Thurston County [Source: Application pages 26 and 27]

The department concludes that the proposed DaVita Olympia project is the best available alternative. Therefore, this criterion is met.

RCGNW

To comply with this sub-criterion, RCGNW considered the three alternatives listed below.

- Expand the existing Lacey facility
- Establish a new 5 station facility

RCGNW states that after rejecting the expansion of the Lacey unit because of various site issues relating to lack of improved access for patients, it then explored various five and ten station configuration thought the county. RCGNW stated that it considered establishing a unit in Tumwater and Yelm, but rejected these options due to patients travel time.

Based on RCGNW's discussion of the alternatives considered and rejected above, an application was submitted proposing to establish a new 10-station facility in Lacey to serve Thurston County.

The Department Response

In determining the best available alternative, the department considered its findings on the other applicable review criteria and concludes that RCGNW's application did not meet all other review criteria. RCGNW's application failed to meet the review criteria of financial feasibility. Base on these factors, the department concludes that RCGNW's application is not the best available alternative. The department cannot conclude that the proposed Hawks Prairie project is the best available alternative. While the department determined that need was demonstrated, the project as proposed failed to meet financial feasibility. 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;

DaVita, Inc.

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.

RCGNW

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.

DaVita, Inc.

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.

RCGNW

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.

E. Kidney Disease Treatment Centers—Tie-breakers (WAC 246-310-288)

This criterion is applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. Once the department evaluates the applications for compliance with the other applicable review criterion, only then can it determine if this criterion is to be applied.

To determine if this criterion applies to the two applications under review, the department considered its findings on the other review criteria. The department previously concluded that RCGNW's application did not meet all the applicable review criteria; and DaVita's application met the applicable review criteria. As a result, approval of DaVita's application addresses the need in Thurston County planning area. Therefore, tie-breaker criterion is not applicable.

APPENDIX A