EXECUTIVE SUMMARY

EVALUATIONS OF THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD NEW DIALYSIS CENTERS IN SPOKANE COUNTY ESRD PLANNING AREA #2.

- **DAVITA, INC. IS PROPOSING TO ESTABLISH A FIVE-STATION DIALYSIS CENTER IN THE CITY OF SPOKANE TO SERVE THE RESIDENTS OF SPOKANE COUNTY IN SPOKANE ESRD PLANNING AREA #2.**
- **INLAND NORTHWEST RENAL CARE GROUP (IN-RCG)[1] IS PROPOSING TO ESTABLISH A FIVE-STATION DIALYSIS CENTER IN THE CITY OF DEER PARK TO SERVE THE RESIDENTS OF SPOKANE ESRD PLANNIG AREA #2.**

BRIEF PROJECT DESCRIPTIONS

DaVita Inc.

This project proposes to establish a new five-station kidney dialysis center to be located at 1823 North Division Street in Spokane within Spokane ESRD planning area #2. The new kidney dialysis center would serve the residents of the planning area. [Source: DaVita Application, Page 4]

The capital expenditure associated for the five-station kidney dialysis center is $1,376,516. [Source: Application, Page 9] If approved, DaVita anticipates all five-stations to become operational by the end of May 2010. Under this timeline, year 2011 would be the dialysis center's first full calendar year of operation and 2013 would be year three. [Source: DaVita Application, Page 10]

Inland Northwest Renal Care Group, LLC (IN-RCG)

This project proposes to establish a new five-station kidney dialysis center to be located at 830 South Main, Building #3 in the city of Deer Park in Spokane ESRD planning area #2. The new kidney dialysis center would serve the residents of the planning area. [Source: Application, Page 10]

The capital expenditure associated for the 5-station kidney dialysis center is $940,695. [Source: Application, Page 30] If approved, IN-RCG anticipates all five-stations would become operational by the end of September 2010. Under this timeline, year 2011 would be the dialysis center's first calendar full year of operation and 2013 would be year three. [Source: Application, Page 1]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both DaVita and IN-RCG 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).

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[1] IN-RCG is owned 80% by Renal Care Group and 20% by Sacred Health Medical Center

CONCLUSIONS

DaVita Inc.
For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a new 5-station kidney dialysis center in Spokane ESRD planning area #2 to serve the residents of that planning area is not consistent with applicable criteria of the Certificate of Need Program and a Certificate of Need is denied.

Inland Northwest Renal Care Group, LLC.
For the reasons stated in this evaluation, the application submitted on behalf of IN-RCG proposing to establish a new 5-station kidney dialysis center in Spokane ESRD planning area # 2 to serve the residents of that planning area is consistent with applicable criteria. With agreement to the terms identified below, a Certificate of Need would be issued for the establishment of the 5-station North Spokane Dialysis Center to be located in Spokane ESRD planning area #2 within Spokane County. The approved capital expenditure associated with the establishment of the dialysis center is $940,695.

Terms:

1. Prior to commencement of the project, Inland Northwest Renal Care Group, LLC must provide to the Certificate of Need Program a copy of the adopted charity care policy for the North Spokane Dialysis Center for review and approval. The adopted policy must be consistent with the draft provided within the application.

2. Prior to the project commencement, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located on the southwest 830 S. Main, Building #3, Deer Park, WA 99006. The proposed facility site parcel tax identification is #28101.0087. The executed lease must be consistent with the draft provided within the application.

3. Prior to providing services, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval copy of the executed Medical Director's amended agreement. The executed agreement must be consistent with the draft agreement provided within the application.

4. Prior to providing services at the North Spokane Dialysis Center, Inland Northwest Renal Care Group, LLC must provide an executed copy of the Patient Transfer Agreement for the department review and approval. The executed agreement must be consistent with the draft provided within the application.

EVALUATIONS OF THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD NEW DIALYSIS CENTERS IN SPOKANE COUNTY ESRD PLANNING AREA #2.

- **DAVITA, INC. IS PROPOSING TO ESTABLISH A FIVE-STATION DIALYSIS CENTER IN THE CITY OF SPOKANE TO SERVE THE RESIDENTS OF SPOKANE COUNTY IN SPOKANE ESRD PLANNING AREA #2.**

- **INLAND NORTHWEST RENAL CARE GROUP (IN-RCG)[2] IS PROPOSING TO ESTABLISH A FIVE-STATION DIALYSIS CENTER IN THE CITY OF DEER PARK TO SERVE THE RESIDENTS OF SPOKANE ESRD PLANNIG AREA #2.**

Applicant and Project Descriptions

DaVita Inc.

DaVita Inc. (DaVita) is a for-profit corporation that provides kidney dialysis services in over 1,400 outpatient centers located in 43 states and the District of Columbia. DaVita also provides acute inpatient kidney dialysis services in over 700 hospitals throughout the country. [Source: DaVita Application, Page 4]

In Washington State, DaVita owns or operates 24 kidney dialysis facilities in 12 separate counties. Below is a listing of the 24 DaVita facilities in Washington. [Source: CN historical files & Application, Page 1]

Benton
Chinook Kidney Dialysis Center
Kennewick Dialysis Center

Clark
Vancouver Dialysis Center

Franklin
Mid-Columbia Kidney Center

Island
Whidbey Island Dialysis Center

King
Bellevue Dialysis Center
Federal Way Community Dialysis Center
Kent Community Dialysis Center (Management only)
Olympic View Dialysis Center
Westwood Dialysis Center

Kittitas
Ellensburg Dialysis Center

Klickitat
Goldendale Dialysis Center

Pacific
Seaview Dialysis Center

Pierce
Lakewood Community Dialysis Center
Puyallup Community Dialysis Centre
Parkland Dialysis Centre
Tacoma Dialysis Center
Graham Dialysis Center

Snohomish
Mill Creek Dialysis Center
Everett Dialysis Center

Thurston
Olympia Dialysis Center

Yakima
Mt. Adams Dialysis Center
Union Gap Dialysis Center
Yakima Dialysis Center

[2] IN-RCG is owned 80% by Renal Care Group and 20% by Sacred Health Medical Center

DaVita's application proposes to establish a new five-station kidney dialysis center in Spokane ESRD planning area #2. The new facility to be known as DaVita North Spokane Dialysis Center would be located at 1823 North Division Street in the city of Spokane. The proposed kidney dialysis center would serve the residents of the planning area. [Source: DaVita Application, Page 4] The capital expenditure associated with the five-station kidney dialysis center is $1,376,516. Approximately 64% of these costs is related to leasehold improvements at the site; 27% is related to both fixed and moveable equipment; and the remaining 9% is related to architect, engineering, application and consulting fees. [Source: Application, Page 9]

If approved, DaVita anticipates all five-stations would become operational by the end of May 2010. Under this timeline, calendar year 2011 would be the kidney dialysis center first full year of operation and 2013 would be year three. [Source: DaVita Application, Page 10]

Inland Northwest Renal Care Group, LLC

The applicant Inland Northwest Renal Care Group (IN-RCG) is a subsidiary of Renal Care Group, LLC (RCG). On March 31, 2006, Fresenius Medical Care Holdings, Inc (FMCHI) became the sole owner of RCG through stock acquisition. Under the FMCHI umbrella there are three entities Pacific Northwest Renal Services (PNRS), Renal Care Group of the Northwest, Inc. (RCGNW) and IN-RCG. PNRS is jointly owned by RCG and Oregon Health Sciences University. In Washington PNRS owns or operates facilities in Clark County and RCGNW owns or operates facilities in Thurston, Lewis and Grays Harbor Counties. In Washington, IN-RCG owns and operates facilities in Adams, Grant, Okanogan, Stevens, and Spokane Counties and is jointly owned by RCG and Sacred Heart Medical Center. [Source: CN historical files; & Application, Page 2] In Washington under the FMCHI business name, there are 19 dialysis facilities operating in 14 separate counties that are wholly owned by FMCHI or one of its subsidiaries, or jointly operated. Below is a listing of the 19 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
Cowlitz
Fresenius Longview Dialysis Facility
Grant
Fresenius Ephrata Dialysis Facility
Fresenius Moses Lake Dialysis Facility
Grays Harbor
Fresenius Aberdeen Dialysis Facility
Spokane
Fresenius Northpointe Dialysis Facility
Fresenius Spokane Kidney Center
Fresenius North Pines Dialysis Facility
Pend Oreille[3]
Fresenius Pend Oreille Dialysis Facility
Stevens
Colville Dialysis Center
Lewis
Fresenius Chehalis Facility
Mason
Fresenius Shelton Dialysis Facility
Adams
Fresenius Othello Dialysis Facility
Okanogan
Fresenius Omak Dialysis Facility
Thurston
Fresenius Lacey Dialysis Facility
Fresenius Hawks Prairie Facility
Walla Walla
QualiCenters Walla Walla

[3] This facility is not yet operational

FMCHI the parent company of RCG also conducts its operations through the 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: QualiCenters Inland Holdings, Inc and QualiCenters, Inc. These two entities serve as the corporate parents of QualiCenters Northwest, LLC. This entity provides kidney dialysis services in one Washington State facility[4].

IN-RCG proposes to establish a new 5-station kidney dialysis center in Spokane ESRD planning area #2. The new facility to be called North Spokane Dialysis Center would be located at 830 South Main, Building #3 in the city of Deer Park. The proposed facility would serve the residents of the planning area. [Source: IN-RCG Application, Page 8 and May 29, 2009; Supplemental Information, Page 1]

The capital expenditure associated with the new 5-station kidney dialysis center is $940,665. Approximately 62% of these costs is related to architect, engineering, and leasehold improvements at the site; 26% is related to fixed and moveable equipment, and the remaining 12% is related to application, taxes and fees. [Source: Application, Page 30]

IN-RCG anticipates that all 5-stations would become operational by the end of September 2010. Under this timeline, calendar year 2011 would be the kidney dialysis first full year of operation and 2013 would be year three. [Source: IN-RCG Application, Page 13]

During the review of the two applications' DaVita questioned whether IN-RCG's application was valid. DaVita's comments are below.

<u>DaVita Inc</u>.
DaVita states that *"FMC and Sacred Heart Medical Center ("Sacred Heart") both are the "Applicants" under the definition set forth in WAC 246-310-010(6) but the FMC application does not identify Sacred Heart as an applicant or provide required applicant information for Sacred Heart. FMC declares in a footnote: "IN-RCG is owned 80% by Renal Care Group and 20% by Sacred Heart Medical Center." Department rules define the term "Applicant" as:*

- *Any person or individual with a ten percent or greater financial interest in a partnership or corporation or other comparable legal entity engaging in any undertaking subject to review under chapter 70.38 RCW.*

WAC 246-310-010(6)(b). FMC admits Sacred Heart has a "ten percent or greater financial interest in" IN-RCG, which is a corporation engaging in an undertaking subject to CN review. With a 20 percent interest in IN-RCG, Sacred Heart unquestionable is an applicant. ...The failure to identify Sacred Heart as an applicant, standing alone is fatal to the application.

[4] QualiCenter Walla Walla

A change in the applicant constitutes an amendment of the application." [Source: Public comments received August 14, 2009, Page 2] Below are the rebuttal provided to the department by IN-RCG.

IN-RCG

IN-RCG rebuttal comments states, *"DaVita states that both Fresenius Medical Care (Fresenius) and Sacred Heart Medical Center (Sacred Heart) are the "applicants" per the definition contained in WAC. The legal applicant for the proposed North Spokane Dialysis Center (NSDC) is IN-RCG. In-RCG is not a new applicant to the Washington Certificate of Need (CN) process. Table #1*[5] *provides details each of the CN applications submitted by IN-RCG since the new dialysis rules were adopted in January of 2007. Table #1 also includes a verbatim restatement of our description of the legal applicant and the Department of Health's (Department) summary (from the CN decision) of the legal applicant. At no time has the Department asked Fresenius or IN-RCG for any additional information regarding ownership, or for any further information about Sacred Heart. Further, each of the applications identified in Table 1 was found by the Department to be fully consistent with applicable CN requirements, and the applications were approved".* [Source: Rebuttal comments received September 16, 2009, Page 1]

Department Response

The department reviewed its CN historical documents. Since at least 2007, IN-RCG has stated within its applications that Sacred Heart Medical Center is a part owner. That disclosure is also made in this application. Therefore, the department agrees with IN-RCG that its ownership structure has been known to the department. The department concludes the IN-RCG application is valid.

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both DaVita and IN-RCG 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

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determinations. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

(a) In the use of criteria for making the required determinations, the department shall consider:

- *(i) The consistency of the proposed project with service or facility standards contained in this chapter;*
- *(ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
- *(iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."*

[5] The department did not reproduce table #1 provided by IN-RCG.

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

"The department may consider any of the following in its use of criteria for making the required determinations:
(i) Nationally recognized standards from professional organizations;
(ii) Standards developed by professional organizations in Washington State;
(iii) Federal Medicare and Medicaid certification requirements;
(iv) State licensing requirements;
(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application."

To obtain Certificate of Need approval, each applicant must demonstrate compliance for their project with the applicable criteria found in WAC 246-310-210 (need) and 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.[6]

APPLICATION CHRONOLOGY

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

Action	DaVita	IN-RCG
Letter of Intent Submitted	January 30, 2009	January 30, 2009
Application Submitted	February 27, 2009	February 27, 2009
Amended Application Submitted	March 27, 2009	None submitted
Department's Pre-Review Activities including Screenings and Responses	March 2, 2009 through June 15, 2009	
Beginning of Review	June 16, 2009	
Public Hearing /End of Public Comment	August 17, 2009	
Rebuttal Comments Received	September 16, 2009	
Department's Anticipated Decision Date	November 2, 2009	
Department's Actual Decision Date	March 3, 2010	

[6] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-287.

CONCURRENT REVIEW AND AFFECTED PERSONS

The purpose of the concurrent review process is to comparatively analyze and evaluate competing or similar projects to determine which of the projects may best meet the identified need. For these 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 IN-RCG, the department will issue one evaluation regarding whether both, one 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 February 27, 2009
- DaVita, Inc. Certificate of Need amended application received March 27, 2009
- IN-RCG Certificate of Need application submitted February 27, 2009
- DaVita, Inc. supplemental information dated May 8, 2009
- IN-RCG supplemental information dated May 29, 2009
- DaVita, Inc. public comments received on August 14, 2009
- IN-RCG public comments received on August 17, 2009
- DaVita, Inc. rebuttal comments received September 16, 2009
- IN-RCG rebuttal comments received September 16, 2009
- Years 2003 through 2008 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2008 Northwest Renal Network 4th Quarter Data
- Licensing and/or survey data provided by the Department of Health's Office of Investigation and Inspections
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- 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 5-station kidney dialysis center in Spokane ESRD planning area #2 is not consistent with the applicable criteria of the Certificate of Need Program and a Certificate of Need is denied.

Inland Northwest Renal Care Group, Inc.

For the reasons stated in this evaluation, the application submitted on behalf of IN-RCG proposing to establish a new 5-station kidney dialysis center in Spokane ESRD planning area # 2 to serve the residents of that planning area is consistent with applicable criteria. With agreement to the terms identified below, a Certificate of Need would be issued for the establishment of the 5-station North Spokane Dialysis Center to be located in Spokane ESRD planning area #2 within Spokane County. The approved capital expenditure associated with the establishment of the dialysis center is $940,695.

Terms:

1. Prior to commencement of the project, Inland Northwest Renal Care Group, LLC must provide to the Certificate of Need Program a copy of the adopted charity care policy for the North Spokane Dialysis Center for review and approval. The adopted policy must be consistent with the draft provided within the application.

2. Prior to the project commencement, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located on the southwest 830 S. Main, Building #3, Deer Park, WA 99006. The proposed facility site parcel tax identification is #28101.0087. The executed lease must be consistent with the draft provided within the application.

3. Prior to providing services, Inland Northwest Renal Care Group, LLC must provide to the department for review and approval copy of the executed Medical Director's amended agreement. The executed agreement must be consistent with the draft agreement provided within the application.

4. Prior to providing services at the North Spokane Dialysis Center, Inland Northwest Renal Care Group, LLC must provide an executed copy of the Patient Transfer Agreement for the department review and approval. The executed agreement must be consistent with the draft provided within the application.

1. **A. Need (WAC 246-310-210) and Need Forecasting Methodology (WAC 246-310-284)**
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 246-310-284.

(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.[7]

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 5-station kidney dialysis facility in Spokane ESRD planning area #2. Based on the calculations of the annual growth rate in the planning area as described above, DaVita used linear regression in step one. The number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. Table 1 below summarizes DaVita's application of the kidney dialysis numeric methodology for Spokane ESRD planning area #2. [Source: Application page 21]

[7] 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]

Table 1
Summary of DaVita's Spokane ESRD Planning Area #2 Numeric Methodology

	Year 2009	Year 2010	Year 2011	Year 2012
In-center Patients	170.7	178.6	186.5	194.4
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	35.56	37.21	38.85	40.50
Total Station Need Rounded Up	36	38	39	41
Minus # CN Approved Stations	36	36	36	36
Net Station Need / (Surplus)	0	2	3	5

As shown in Table 1 above, DaVita projected need for five dialysis stations in Spokane ESRD planning area #2 in year 2012. Based on the results of its methodology, DaVita requested a 5-station dialysis facility.

IN-RCG Application of the Numeric Methodology

IN-RCG also proposes to establish a new 5-station kidney dialysis facility in Spokane ESRD planning area #2. Based on the calculation of the annual growth rate in the planning area IN-RCG also used a linear regression to project need. IN-RCG provided a summary of its application of the need methodology for year 2012 shown in the tables below. [Source: Application, Pages 19-20]

Table 2A
IN-RCG Projected Year-End Resident In-Center Patients

	Year 2009	Year 2010	Year 2011	Year 2012
Number of Patients	171	179	187	194

Table 2B
IN-RCG Analysis of Current Supply Vs. Net Need

	Stations
Current Supply	36
Total Supply	**36**
2012 Projected Need	41
Need Station Need	5

As shown in Tables 2A and 2B, above IN-RCG projected need for five dialysis stations in planning area in 2012. Based on the result above, IN-RCG requested a 5-station dialysis facility.

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 Spokane ESRD planning area #2. 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 the planning area. The department's full numeric methodology is attached to this evaluation as Appendix A.

Table 3
Summary of Department's Spokane ESRD Planning Area # 2 Numeric Methodology

	Year 2009	Year 2010	Year 2011	Year 2012
In-center Patients	170.70	178.60	186.50	194.90
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	35.56	37.21	38.85	40.5
Total Station Need Rounded Up	36	38	39	41
Minus # CN Approved Stations	36	36	36	36
Net Station Need / (Surplus)	0	2	3	5

As shown in Table 3 above, the department's projected net need for Spokane ESRD Planning Area #2 is 5 new stations.

Comparing the results of the three tables above, all three identify the same number of stations needed. The comparison of the department's and DaVita numeric methodologies and IN-RCG need summary is presented in Table 4 below.

Table 4
Comparison of Spokane County ESRD planning area #2 Numeric Methodologies

	4.8 in-center patients per station			
	2012 Projected # of stations	**Minus Current # of stations**	**2012 Net Need**	**2012 Net Need (Rounded)**
DaVita	40.50	36	4.5	5
IN-RCG/FRESENIUS	41	36	5	5
DOH	40.50	36	4.50	5

In its comments to the department about the IN-RCG application, DaVita states that the IN-RCG application is proposing to establish a 6-staion dialysis center rather than the five as stated in the project description and elsewhere in the application. The comments provided by DaVita are summarized below.

<u>DaVita</u>
DaVita comments states, *"FMC's line drawing shows five numbered stations, numbered 1-5, including a bed station. In a separate area, the line drawing shows an "isolation" room, with an unnumbered chair and dialysis machine indicated. FMC's narrative explains, "Please note that IN-RCG intends to purchase 6 machines" (one machine [sic] will serve as a back up [sic]. At no time will NSDC operate more than 5 stations without further CN approval. The drawing taken with narrative mistakenly shows FMC intends to install and operate six machines, not five".* [Source: Public comments received August 14, 2009, Page 6 and 7] Below is the response provided by IN-RCG regarding DaVita's concern.

IN-RCG Response

IN-RCG rebuttal comment states, *"There is no station switching. IN-RCG is proposing to establish a 5-station facility that—on any given shift—can accommodate 5 patients needing any combination of general chairs, bed, and private room/isolation or training. This is consistent with the CN requirements and past Department decisions. In fact, DaVita's application, which also requests only 5-stations, includes a line drawing that depicts a total of 12 stations. Yet, DaVita in an attempt to disqualify us on tiebreakers accuses us of some concocted "stations switching ploy" simply because we, like them have proposed a 6th station...to serve as back up".* [Source: Rebuttal comments received September 16, 2009, Page 6]

Department Response

The line drawings submitted by IN-RCG do show five numbered stations (inclusive of the permanent bed station) and an un-numbered isolation room. On that fact, the department agrees with DaVita. It is not unusual for applicants to submit line drawings showing spaces for future station expansion. The line drawings submitted by DaVita show that there is space at the proposed site for an additional seven stations. On that fact, the department agrees with IN-RCG. From a construction standpoint, this approach is more cost effective. What is at issue is the number of stations authorized to equip, certify and use following CN approval. A facility may not equip, certify, or use more stations than its CN is approved for. Table 5 below is an illustration of a correct and incorrect configuration.

Table 5
Illustration of 10-Station CN Approved Facility Configuration

	Correct	Incorrect
Permanent bed station	1	1
Isolation station	1	1
Training station	1	1
Other in-center stations	7	10
Total set-up stations	**10**	**13** Only 10 stations in use at any given time.

Each applicant's line drawings show a permanent bed station, an isolation room, and a number of other dialysis stations. If either or both of these projects are approved, the maximum number of dialysis stations that may be set-up and ready for use is the number approved by its issued CN.

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 February 2, 2009. [Source: WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2008, which became available on January 26, 2009. Currently, Fresenius Northpointe and DSI North Spokane are the dialysis providers operational in Spokane ESRD planning area #2. According to data available to the department, Fresenius Northpointe is currently operating at 4.96 utilization rate and DSI North Spokane is currently operating at 5.08 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 Spokane ESRD planning area #2, the requirement is 4.8 in-center patients per approved station. Both DaVita and IN-RCG propose new dialysis stations to be located in Spokane ESRD planning area# 2. Each applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Both DaVita and IN-RCG state that year 2013 would be their third year of operation. A summary of each applicant's projected utilization for years 2010 and 2013 is shown in Table 6 below.

Table 6
Projected Third Year of Operation Facility Utilization

Facility Name	Year 3	#of Stations	# of Pts	Pts/Station
DaVita North Spokane	2013	5	28	5.6
North Spokane Dialysis Center	2013	5	27	5.4

As shown in Table 6 above, DaVita is projecting to be operating at 5.6 patients per station by year 3. IN-RCG projects to be operating at 5.4 patients per station by year 3. [Source: DaVita Application, Appendix 9 and IN-RCG Supplemental Information May 29, 2009, Attachment 5] Based on the standards and criterion, and the information contained in Table 6, the department concludes both projects meet this sub-criterion.

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

To determine whether all residents of the service areas would have access to an applicant's proposed project, the department looks at three key variables to make this determination. These variables are admission policies, Medicare/Medicaid certification, and provision of charity care.

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 it uses at its facilities. These are the same policies that would be used at the proposed DaVita North Spokane 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]

To determine whether the elderly would have access to the proposed services, the department uses Medicare certification as the measure to make that determination. The proposed DaVita North Spokane Dialysis Center would be Medicare certified upon CN approval and the department's review of the application shows that revenue is expected from Medicare.

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. Review of the application shows that DaVita expects revenue from Medicaid**.** [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 North Spokane Dialysis Center. This sub-criterion is met.

IN-RCG

To demonstrate compliance with this sub-criterion, IN-RCG provided a copy of its current admission and indigent care policies it uses at its facilities. These are the same policies that would be used at the proposed North Spokane Dialysis Center. The document provided by IN-RCG 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 6]

To determine whether the elderly would have access to the proposed services, the department uses Medicare certification as the measure to make that determination. The proposed Fresenius North Spokane Dialysis Center would be Medicare certified upon CN approval and the department's review of the application shows that revenue is expected from Medicare.

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. Review of the application shows North Spokane Dialysis Center expects revenue from Medicaid**.** [Source: Application, page 8] Additionally, IN-RCG demonstrated its intent to provide charity care to residents by submitting a draft Indigent Policy.

The policy outlines the process a patient would use to access service. Further, North Spokane Dialysis Center's pro-forma financial statement included a charity care line item as a deduction from revenue within the pro-forma. [Source: Supplemental Information received February 27, 2009, Attachment 5] If approved the department would include a term that IN-RCG provide for review and approval an adopted charity care policy for the proposed North Spokane Dialysis Center.

Term

Prior to commencement of the project, Inland Northwest Renal Care Group, LLC must provide to the Certificate of Need Program a copy of the adopted charity care policy for the North Spokane Dialysis Center for review and approval. The adopted policy must be consistent with the draft provided within the application.

Based on the information and with agreement to the term above, the department concludes that all residents of the service area would have reasonable access to health services at the proposed North Spokane Dialysis Center. 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 not met the financial feasibility criteria in WAC 246-310-220; and
- Inland Northwest Renal Care Group project 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.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

DaVita Inc.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates all 5-station would become operational by the end of May 2010. Under this timeline, year 2011 would DaVita's North Spokane Dialysis Center first full year of operation and 2013 would be year three. [Source: DaVita Application, Page14]

Table 7 summarizes DaVita's year one through year four projected revenues, expenses, and net income for the 5-station dialysis facility [Source: Application, Appendix 9]

Table 7
DaVita North Spokane Dialysis Center
Projected Revenue and Expenses Years (1 through 4)

	Partial Year 2010	Full Year 2011	Full Year 2012	Full Year 2013	Full Year 2014
# of Stations	5	5	5	5	5
# of Treatments [1]	1,668	3,184	4,700	5,460	6,068
# of Patients [2]	9	17	25	28	30
Utilization Rate [2]	1.8	3.4	5.2	5.6	6.0
Net Patient Revenue[1]	$437,528	$897,277	$1,289,707	$1,666,445	$1,939,499
Total Operating Expenses [1, 3]	$825,780	$993,746	$1,342,694	$1,608,376	$1,770,263
Net Profit or (Loss)[1]	($388,252)	($96,469)	($52,987)	$58,069	$169,236
Operating Revenue / Treatment [1]	$262.31	$281.81	$274.11	$305.21	$319.63
Operating Exp./ Treatment [1]	$495.07	$312.11	$285.68	$294.57	$291.74
Net Profit per Treatment [1]	($232.76)	($30.30)	($11.27)	$10.64	$27.89

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

Department's Evaluation

As shown above in Table 7, at the projected volumes identified, DaVita's North Spokane facility would be operating at a loss starting from partial year 2010 through 2012, the second full year of operation. The facility is projected to make a profit in years 2013 through 2014. DaVita states that the proposed facility will be operated at utilization levels consistent with other facilities.

DaVita provided a draft lease agreement to demonstrate site control. The draft lease is between Total Renal Care, Inc. or its related entity as (Tenant) and Delay Limited Partnership as the lessor (landlord), Inc. The lease agreement identifies the size of the facility to be 5,500 square feet and rent is based on the facility's square feet. The annual base rent for years 1-4 is $18.50 per square foot or $101,750 annually. In addition, the lease requires that DaVita pay an additional amount of $3.50 per square foot per year as its proportionate share of initial operating costs. With this additional $3.50 per square foot, the annual rent is $22 per square foot or $121,000 per year. While the draft lease also includes a 3% annual rate adjustment, that adjustment does not begin until year 5, which is outside of the department's review period. [Source: Draft lease agreement Appendix 15]

A closer look at the financials reveals the financial information provided in the pro forma revenue and expense statements are not consistent with the lease agreement. Table 8, is a comparison of the amounts.

Table 8
Lease Costs and Pro Forma Comparison

	Lease Amounts	Pro Forma Amounts	Differences
Year 1	$121,000	$192,500	$71,500
Year 2	$121,000	$158,620	$37,620
Year 3	$121,000	$163,379	$42,379
Year 4	$121,000	$158,280	$37,280
Year 5	$121,000	$173,328	$52,328
Total	$605,000	$846,107	$241,107

During the review of this application, IN-RCG provided comments to the department regarding DaVita's financial statements for this project. IN-RCG's comments are summarized below.

<u>DaVita's lease cost cannot be confirmed (an "Exact Match" is not provided)</u>
Comments provided to the department by IN-RCG states, *"The department has an exact match requirement between the draft lease and the pro-forma financials, yet DaVita's application does not provide such. DaVita draft lease indicates that its lease will not increase during the first five years of operation (or the projected CN timeframe). Specifically, the lease agreement (see section 3 titled "Rent Adjustments") states, "Beginning on the 5th anniversary of the Commencement Date...rent shall be increased by three percent (3%) per rentable square foot annually over the Rent for the prior Lease Year". The pro-forma therefore should include no such increase...The discrepancy between DaVita's lease agreement for its proposed Spokane 2 dialysis center and its pro-forma financial renders the application inconsistent with WAC 246-310-220."* [Source: IN-RCG public comments received August 17, 2009, Pages 8 and 9] Summarized below, are the rebuttal comments provided by DaVita.

<u>DaVita's Response</u>
Rebuttal comments provided by DaVita states, *"In its public comments, FMC points to a discrepancy between DaVita's draft lease and pro-forma DaVita submitted with its amended application. Attached as Exhibit 1, to this rebuttal is a pro-forma that conforms to the draft lease and confirms the facility's financial feasibility using the more favorable lease expense. The pro-forma accurately reports the rental rate of $18.50 per square foot for an estimated 5,500 square feet, and includes the lessee's Proportionate Share of initial Operating Expenses, estimated at $3.50 per square foot.*

The program has consistently allowed applicants to submit clarifying information in response to public comments. The attached pro-forma clarifies the effect of the more favorable lease expense on financial feasibility. FMC agrees with DaVita's right to submit the pro-forma and argues for an even more expansive right. It declares in another matter. "The CON regulations explicitly contemplate that information may be submitted by an applicant after the Program gives notice of the beginning of review and until the public comments period ends. FMC pretends it does not understand DaVita's longstanding practice of including additional months of rent expense during the first partial year of operation (here 2010).

As DaVita has explained many times and the Program has accepted equally as many times, DaVita routinely includes additional months of rent expense as proxy for one-time facility opening expense not otherwise reflected in the pro forma. In this application, DaVita added three months of rent expense to 2010. DaVita's expense-reporting approach is conservative and designed to accurately reflect actual operating expenses, including one-time startup expenses other applicants (including FMC) generally omit." [Source: DaVita, Inc. rebuttal comments received September 16, 2009, Page 2 and 3]

Department Response

The pro forma operating statement provided by DaVita in its amended application is not consistent with the draft lease provided in that same submission. When public comments pointed out that error to the department, DaVita responded by submitting a revised pro forma operating statement as part of its rebuttal responses. In submitting the revised operating statement, DaVita attempts to portray the changes as merely clarifying the information already contained in the application materials. The department disagrees. Had the rebuttal pro forma operating statement merely been clarifying information already contained in the application, the EBIT line on the operating statement would not have changed.

The rebuttal submission appears to amend/correct information contained in the application. Therefore, the department considers the revised/corrected pro forma operating statements improper rebuttal. Additionally the time for an application undergoing concurrent review to be amended has passed. Therefore, the revised/corrected pro forma operating statements with the DaVita's rebuttal comments will not be considered[8]. The department notes that DaVita usually includes additional three or four months rent in its first year pro-forma. The department does not find the inclusion of those costs to be improper. However, the rent amounts those costs are based on and the rent amounts themselves cannot be substantiated in the pro forma operating statements provided in the application.

DaVita identified Henry Mroch, MD as the medical director for the proposed DaVita North Spokane Dialysis Center and provided a draft medical director agreement between DaVita and Dr. Mroch. The draft medical director's agreement identifies the terms of the agreement, role and responsibilities of both parties. Additionally, the draft medical director agreement and the pro-forma income statement identified the compensation to be paid to the medical director. The project cannot be fully evaluated on its long-range capital and operating costs because the department could not substantiate the lease costs in the pro-forma as discussed earlier. Therefore, this sub-criterion not is met.

IN-RCG

As stated in the project description portion of this evaluation, if this project is approved IN-RCG anticipates all 5-stations would become operational by the end of September 2010. Under this timeline, year 2011 would be the facility's first full calendar year of operation and 2013 would be year three. [Source: IN-RCG Application, Page 13]

Summarized in Table 9, is IN-RCG year one through year three projected financial revenue, expenses, and net income for the North Spokane Dialysis Center as a 5-station dialysis facility. [Source: May 29, 2009; Supplemental Information, Attachment 4]

[8]In its rebuttal submission, DaVita provides a copy of QualiCenters' opening brief for a 2007 QualiCenters Benton County judicial appeal to support its submission of corrected/revised financial statements during the rebuttal period. The department did not accept corrected/revised financial statements in that review.

Table 9
IN-RCG North Spokane Dialysis Center
Projected Revenue and Expenses Years (1 through 3)

	Partial Year 2010	Full Year 2011	Full Year 2012	Full Year 2013
# of Stations	5	5	5	5
# of Treatments [1]	864	3,024	3,600	3,888
# of Patients [2]	17	20	23	27
Utilization Rate [2]	3.4	4.0	4.6	5.4
Net Patient Revenue[1]	$316,813	$1,105,523	$1,332,238	$1,435,627
Total Operating Expenses [1, 3]	$283,357	$994,204	$1,141,751	$1,214,536
Net Profit or (Loss)[1]	$33,456	$111,319	$190,487	$221,091
Operating Revenue / Treatment [1]	$366.68	$365.58	$370.07	$369.25
Operating Exp./ Treatment [1]	$327.96	$328.77	$317.15	$312.38
Net Profit per Treatment [1]	$38.72	$36.81	$52.91	$56.86

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

Department's Evaluation

As shown in Table 9 above, at the projected volumes identified, the North Spokane Dialysis Center would be operating at a profit beginning in partial year 2010 though year 2013. IN-RCG provided a draft lease agreement for the proposed site between Inland Northwest Renal Care Group, LLC (Tenant) and Eon, Inc. (Landlord). Information within IN-RCG application states that tenant improvement will be borne by the landlord and then added to its annual lease expense. Additional information provided states, "*Although IN-RCG will not provide the initial capital outlay for the tenant improvements (these will be paid for initially by the developer), IN-RCG will pay for these, over time, with higher lease expense*". [Source: Application, Page 30] The department received comments from DaVita regarding IN-RCG proposed project. Summarized below are the comments provided by DaVita regarding IN-RCG project.

DaVita's Comments regarding IN-RCG Construction cost and Depreciation expenses

- *"FMC's financial disclosures are so incomplete and contradictory, it is impossible to determine what its actual capital expenditure and construction costs will be.*
- *FMC slightly reduced the area to 4,280 square feet, leading to a reduced total tenant allowance of construction costs, falling short by $119,782. FMC claimed it treated the $119,782 cost as depreciable capital cost. Its financial disclosures show otherwise and cannot be reconciled with the construction costs FMC admits it will incur. FMC's original pro-forma shows an annual depreciation expense of $48,614. The revised pro-forma submitted with its screening response shows an annual depreciation expense of $49,391, a difference of $777 per year. FMC claims the difference represents $119,782 in construction costs.*
- *This claim is obviously false. The $777 difference falls short of the annual depreciation expense of $119,782 in construction costs. …Using a 10-year schedule, the annual depreciation expense should have increased by $11,978 instead of $777. The $777 difference in depreciation expense FMC reports would cover only $7,770 in construction costs not the $119, 782 FMC claims.*

- *FMC may be hiding some equipment costs in undisclosed leases or other arrangement. The small amount FMC claims for its Spokane application ($246,308) compares to the equipments budget in FMC's 6-station Goldendale application ($228, 82). In Goldendale, however, FMC stated the dialysis machines would be leased and were not included in the equipment budget."* [Source: DaVita, Inc. public comments received August 14, 2009, Pages 4-6]

<u>IN-RCG Response</u>

- *"DaVita argues, in error, that IN-RCG's construction cost estimate and depreciation expenses are both incomplete and contradictory. The reality is that IN-RCG's capital cost estimate and depreciation have been fully disclosed, and are both complete and accurate.*

- *Accordingly, and as the Department will concur, the updated pro-forma financial replaces the original pro-forma. The pro-formas cannot and should not be compared. The original pro-forma was prepared prior to final site selection and contained IN-RCG's best assumptions (at application submittal) regarding the capital and construction costs. These assumptions were later refined to reflect the selected site and were appropriately modified and revised during the screening response.*

- *All necessary information, in the required CN format, is included in the screening submittal. Contrary to what DaVita has said, IN-RCG has accurately reported both its construction costs and depreciation expense. In fact, IN-RCG, in its screening submittal included Table 1 to specifically account for and explain the additional depreciation expense. Table 1 includes the incremental depreciation expenses associated with the construction costs that IN-RCG will incur (above and beyond the $120/square foot tenant improvement allowance).*

- *In the Goldendale application (which was QualiCenters not an IN-RCG application), the equipment budget included a more costly TV system than we are proposing for NSDC. The Goldendale budget also included a generator, which was not included in the NSDC budget because we have determined that NSDC does not need a generator because we are so close to four other Washington IN-RCG facilities (North Pointe, Spokane Dialysis Center, North Pines Valley and Colville) that can serve as back ups in the case of emergency. These two modifications, in and of themselves, account for about $100,000."* [Source: IN-RCG Rebuttal Comments received September 16, 2009, Pages 3 and 4]

<u>Department Response</u>

The department review of IN-RCG depreciation expenses stated in the revised pro-forma provided as supplemental information to screening questions, did not show a confirmable assertion regarding DaVita's comments. Further, the department cannot confirm DaVita's assertions regarding IN-RCG's equipment cost. To show that it has funds that would cover cost not accounted for by the tenant improvement allowance in the draft lease, IN-RCG application states, "*Please note that the lease agreement includes a tenant improvement allowance of $120 per square foot ($513,600). This is less than the building construction line item ($633,382) included in the capital expenditure breakout contained on page 30 of the application. The difference in costs ($119,782) will be born by IN-RCG and have been included in our depreciation expense. Table 1 details how the tenant improvement costs have been allocated between the lease agreement and the depreciation expense line item*". [Source: Supplemental information received on May 29, 2009, Page 2] Reproduced by the department in the next page, is the table referenced above by IN-RCG.

Allocation of Tenant Improvement Costs

(From IN-RCG Application)

Line Item	**Cost**
Building Construction/Tenant Improvement (P.30 of application[9])	$633,382
	Allocation
Tenant Improvement allowance per lease ($120/sf)	$513,600
Additional depreciation/ capital expense to be incurred by IN-RCG[10]	$119,782

To further show, that its parent company has funds available to cover cost for fixed and moveable equipments, taxes, and fees IN-RCG provided a letter from its corporate office. The letter from IN-RCG corporate office states, *"Please accept this letter that the funds necessary for the establishment of the North Spokane Dialysis Center will be provided by IN-RCG's cash reserves. The reserves are more than adequate to fund the project (estimated capital expenditure to be incurred by IN-RCG of ($427,095) as proposed".* [Source: Supplemental Information received May 29, 2009, Page 137]

The department review of the draft lease agreement between EON, Inc, (landlord) and IN-RCG, LLC. (Lessee) shows that rent costs identified in the draft lease are consistent with the pro-forma financial projections used to prepare the information in Table 9. If approved the department would include a term that IN-RCG provide for review and approval an executed lease agreement contract which includes the relevant terms and compensation as identified in the draft agreement.

<u>Term</u>

Prior to the project commencement, In-land Northwest Renal Care Group, LLC must provide to the department for review and approval an executed copy of the lease agreement to the proposed site located on the southwest 830 S. Main, Building #3, Deer Park, WA 99006. The proposed facility site parcel tax identification is #28101.0087. The executed lease must be consistent with the draft provided within the application.

Within the application, IN-RCG provided a pro-forma financial statement that identifies the annual compensation for the proposed facility medical director. A review of the draft amended medical director's contract shows that it is consistent with the pro-forma financial statements. Based on the information and with agreement to the term above, the department concludes that the proposed project is financially feasible. This sub-criterion is met.

(2) *<u>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.</u>*

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2) (a) (i). There are also no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

[9] Includes sales tax

[10] Since this amount is also included in the capital costs to be incurred by IN-RCG, it is included in the financing letter in Attachment 5. (Attachment 5 is revised pro-forma)

DaVita Inc.

To comply with this sub-criterion, DaVita states it has constructed and expanded or managed over 1,400 Medicare certified dialysis community centers throughout the US. However, given the inconsistency in DaVita's pro-forma income statement relating to lease agreement cost, the proposed DaVita North Spokane Dialysis Center charges per dialysis cannot be compared to recent kidney dialysis proposals submitted to the department. The estimated capital expenditure associated with the establishment of the 5-station dialysis facility is $1,376,516. [Source: Application page 9] Summarized in Table 10 below, is the capital expenditure.

Table 10
DaVita North Spokane Dialysis Center Capital Cost

Item	**Cost**	**% of Total**
Leasehold Improvements	$885,00	64%
Fixed & Moveable Equipment	$370,429	27%
Architect/Engineering and CN fees	$121,087	9%
Total Project Cost	**$1,376,516**	**100%**

To further, demonstrate compliance with this sub-criterion, DaVita stated the source of its patient revenue and payor source shown in Table 11 below. [Source: Application, Page 11] As shown in Table 11 below, DaVita expected that the majority of its revenue and patients per payor source would be Medicare and Medicaid.

Table 11
DaVita North Spokane 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%**

In summary, the proposed DaVita North Spokane Dialysis Center is expected to have 65% of its revenue and 87% of its patients payor source come from Medicare and Medicaid entitlement programs. These programs are not cost based reimbursement and therefore this project is not expected to have an unreasonable impact on the charges for these Medicare and Medicaid patients. However, this same conclusion cannot be made for those with insurance or HMO patients. Due to inconsistencies between the pro-forma statements and the reported lease costs, the department cannot evaluate with any certainty, the impact for insurance and HMO patients. Therefore, the department cannot conclude that the cost of this project would probably not result in an unreasonable impact on the costs and charges for health services. This sub-criterion is not met.

IN-RCG

On page 30 of the application, IN-RCG identified the capital expenditure cost associated with the establishment of the 5-station facility to be $940,695. Additional information provided to the department by IN-RCG disclosed that it would only incur cost for fixed and moveable plus taxes and the property owner is responsible for construction and tenement improvement cost. Summarized in Table 12 below is the project capital expenditure as stated within the application.

Table 12
IN-RCG North Spokane Dialysis Center Capital Cost

Item	Cost	% of Total
Building Construction	$582,688	62%
Fixed & Moveable Equipment	$246,308	26%
Sales Tax and Fees*	$111,699	12%
Total Project Cost	**$940,695**	**100%**

* includes Architectural and Engineering Fees

To further demonstrate compliance with this sub-criterion, IN-RCG provided the sources of its patient revenue shown in Table 13 below. [Source: Application, Page 11]

Table 13
IN-RCG/Fresenius Source of Revenue

Source of Revenue	% of Revenue
Medicare	85.7%
State (Medicaid)	2.8%
Other	11.5%
Total	100%

In summary, the proposed North Spokane Dialysis Center is expected to have 88.5% of its revenue from Medicare and Medicaid entitlement programs. These programs are not cost based reimbursement and therefore this project is not expected to have an unreasonable impact on the charges for these Medicare and Medicaid patients. Based on the department's review of the application materials this same conclusion can be made for those with insurance or HMO patients that make up 11% of the project's revenue. Therefore, the department concludes that this project would probably not result in an unreasonable impact on the costs and charges for health services. This sub-criterion is met

(3) *<u>The project can be appropriately financed.</u>*
WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2) (a) (i). There are also no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

<u>DaVita Inc.</u>
Within the application, DaVita stated that funding source for the proposed DaVita North Spokane Dialysis Center is the parent company capital expenditure budget. To show that financing would be available, DaVita provided a letter of financial commitment from its chief operating officer. The letter states, *"The DaVita, Inc. Board of Directors has authorized management to make strategic investments in operations throughout the United States...each project will be funded with cash on hand that has been generated through operation. The capital expenditure is not an advance or loan and none of the parent company debt will be assigned to the facility at any point after the project is complete".* [Source: Application, Appendix 6]
In addition, the department reviewed DaVita historical financial statements for years 2005 through 2008, and that review shows that the funds necessary to finance the project are available. [Source: Application, Appendix 6 and 10] DaVita's financial reserves as documented by Exhibit 10 are

adequate to fund the new 5-station dialysis facility. Based on the source information reviewed, the department concludes that DaVita has demonstrated that this project can be financed. This sub-criterion is met.

IN-RCG

IN-RCG source of financing for the proposed North Spokane Dialysis Center is IN-RCG/Fresenius Medical Holding Inc. cash reserves. The department received a letter from IN-RCG Group Vice President Pacific stating that the sum of $427,095 is available to fund the project. This amount represents fixed and moveable equipment cost plus fees and taxes. The department notes that the available cash reserve is less than the entire project declared capital cost ($940, 695). [Source: Application, Page 30 and Supplemental information received May 29, 2009, Page 137]

Within the application and additional documentation provided by IN-RCG, states that the sum of $513, 600 would be borne by the property owner as tenant allowance and construction cost, and then added to IN-RCG annual lease expense. [Source: Supplemental information received May 29, 2009] Base on the information provided, the department concludes that IN-RCG's application, proposing to establish a new 5-station kidney dialysis facility in Spokane ESRD planning area #2; 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 concludes that:

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

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size.

DaVita Inc.

To implement this project, DaVita proposes to hire the equivalent of 2.4 FTEs staff during the first partial year of operation and thereafter, increase the number of new staff to 7.6 FTEs by the end of the fourth full year of operation. The proposed staffing is summarized in Table 14.

Table 14
DaVita North Spokane Dialysis Center Proposed FTE's 2010 – 2014

Category	Partial Year 2010	Year 1 2011 Increase	Year 2 2012 Increase	Year 3 2013 Increase	Year 4 2014 Increase	Total FTE's
Medical Director	*Professional Services Contract*					
Administrator	0.2	0.2	0.4	0.2	-	1.00
Registered Nurses	0.6	0.5	0.2	0.3	0.2	1.8
Patient care Tech	0.8	0.4	1	0.4	0.2	2.8
Biomedical Tech	0.3	-	-	-	-	0.3
Re-Use Tech	0.1	0.1	0.1	-	0.1	0.4
Administrative Asst	0.2	0.1	0.2	0.1	-	0.6
Social Worker	0.2	0.1	0.1	0.1	-	0.5
Dietician	-	-	0.1	0.1	-	0.2
Number of FTE'S	**2.4**	**1.4**	**2.1**	**1.2**	**0.5**	**7.6**

As shown in Table 14 above, after the initial recruitment of FTE's, DaVita expects a steady increase in FTE's for its North Spokane Dialysis Center through year 2014. DaVita states it expects no difficulty in recruiting staff for the new facility because of its competitive wage and benefit package offered to employees. DaVita states that job openings are posted nationally and internally. DaVita also states that several of its current employees have already expressed interest in working at the proposed facility. [Source: Application, Page 27]

Department's Evaluation

The department notes that DaVita owns and operates many dialysis facilities in Washington. Within the application DaVita stated it offers competitive wages, post job openings nationally and that many current employee have already expressed interest in working at the proposed facility. Therefore, the department concludes the proposed staffing plan can reasonably be expected to be accomplished.

DaVita identified Henry Mroch, MD as the medical director for the proposed North Spokane Dialysis Center and provided a draft medical director's agreement between Kidney Care of Spokane ("Group"), and Total Renal Care, Inc. ("Company"). According to the draft medical director agreement recitals, Dr. Mroch is a physician employee of Group. [Source: Application, Appendix 3] The draft medical director agreement outlines the roles and responsibilities of the Group and Company. Additionally, the draft agreement also identifies the annual compensation for the medical director. [Source: Application Page 7, and Appendix 3]

A review of Dr. Mroch's compliance history shows that in year 2002, the physician was placed on probation and his license to practice medicine in Washington was suspended for two years by an adjudicative law judge. Additional review of Dr Mroch's compliance history shows that the physician medical license has since been reinstated. As of the time of writing this evaluation, staff is not aware of any additional recorded sanctions against Dr. Mroch. Further, a review of the medical director's agreement between DaVita and Dr. Mroch shows that the agreement outlines the roles and responsibilities of both parties involved.

If the project is approved, the department would include a term that DaVita provide for review and approval the executed medical director's 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 Agreement. The executed agreement must be consistent with the draft agreement provided within the application.

Base on information reviewed, the department concludes that staffing is expected to be available for this project. Provided DaVita agrees to the term identified above, this sub-criterion is met.

IN-RCG
To implement this project IN-RCG proposes to hire the equivalent of 5.02 FTE's during the first partial year of operation and thereafter, increase the number of new staff to 7.08 FTEs by the end of the third full year of operation. The proposed staffing is summarized in Table 15.

Table 15
IN-RCG North Spokane Dialysis Center Proposed FTE's 2010 – 2013

Category	Partial 2010	Year 1 2011 Increase	Year 2 2012 Increase	Year 3 2013 Increase
Medical Director	Professional Services Contract			
Nurse Manager	1.0	0	0	0
Out-Patient Nurse	1.2	0.3	0.2	0.2
Patient Care Tech	2.2	0	0.3	0
Social Worker	0.16	0.04	0	0.05
Dietician	0.16	0.04	0	0.05
Secretary	-	-	0.5	0
Bio-Med	0.3	0.2	0	0
Total FTE's	**5.2**	**0.58**	**1.0**	**0.3**

As shown in Table 15 above, IN-RCG expects a steady increase in FTEs for the North Spokane Dialysis Center through year 2013.

IN-RCG states it offers competitive wage and benefits packages and has never experienced difficulty in recruiting and retaining staff. The applicant states that several months prior to opening, staff will be recruited and trained at its Northpointe facility. IN-RCG also stated training staff at its Northpointe facility has the added benefit of allowing any patients that might transfer to NSDC the opportunity to become acquainted with the staff prior to the formal opening. In addition, having another center within the same general geographic area will allow IN-RCG to realize additional economies of scale by sharing administrative staff. [Source: Application, Page 34]

Department's Evaluation
The department notes that Fresenius, the parent company of IN-RCG owns or operates many dialysis facilities in Washington and has demonstrated that it has the resources to recruit trained staffs to its facilities. Within the application, IN-RCG states that several months prior to opening, staff will be recruited and trained at Fresenius Northpointe Dialysis Facility. Therefore, the department concludes that the proposed staffing plan can reasonably be expected to be accomplished.

IN-RCG identified John Musa, MD as the medical director for the proposed North Spokane Dialysis Center and provided a draft amendment to medical director service agreement by the applicant parent company RCG referred to as the ("Company") and Rockwood Clinic, PS referred to as (the "Consultant") a Washington professional corporation which includes several physicians collectively known as (Member Physicians). In November 2000, RCG the parent company of IN-RCG and its affiliates signed a management services agreement with Rockwood Clinic, PS to provide medical director services in facilities and acute programs owned and operated by IN-RCG. Dr. John Musa is a member physician with Consultant. [Source: Application, Appendix 3] The draft amendment to the medical director services agreement outlines the roles and responsibilities of Company and Consultant. In addition, the agreement also identifies the annual compensation for the medical director position. [Source: Application, Page 8 and Exhibit 3]

The department reviewed Dr. Musa's compliance history and that review did not reveal any recorded sanctions. If this project is approved, the Department would include a term that IN-RCG provide for review and approval an executed medical director's amended contract consistent with the draft agreement.

Term

Prior to providing services, Inland Northwest Renal Care Group must provide to the department for review and approval copy of the executed Medical Director's Amended agreement. The executed agreement must be consistent with the draft agreement provided within the application.

Base on information reviewed by the department concludes that staffing is expected to be available for this project. Provided IN-RCG agrees to the term identified above, 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.

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

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 28] To further demonstrate compliance with this sub-criterion, DaVita provided a 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 Spokane County.

Term

Prior to providing services at the DaVita North Spokane Dialysis Center, DaVita, Inc. must provide an executed copy of the Patient Transfer Agreement for the department review and approval. The executed copy must be consistent with the draft provided within the application.

Based on this information and with agreement to the term above, the department concludes that it expects that DaVita will have appropriate relationships with ancillary and support services in the planning area. This sub-criterion is met.

<u>IN-RCG</u>
IN-RCG states, as with its existing facilities, NSDC will provide the required social and nutrition services for all patients. Other ancillary support services utilized by a dialysis program include pharmacy, laboratory and radiology and blood administration will be available through working relationship with local providers. Further, IN-RCG states, that it does not anticipate any difficulty in meeting the clinical service demands of the propose facility. [Source: Application, Page 35] To further demonstrate compliance with this sub-criterion, IN-RCG states that a formal transfer agreement would be established with Holy Family Hospital a local healthcare provider in Spokane County and provided a draft. [Source: Application, page 35] If this project is approved, the department would include a term requiring IN-RCG to provide a copy of the executed transfer agreement with a local hospital in Spokane County.

Term

Prior to providing services at the North Spokane Dialysis Center, Inland Northwest Renal Care Group must provide an executed copy of the Patient Transfer Agreement for the department review and approval. The executed copy must be consistent with the draft provided within the application.

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 North Spokane Dialysis Center will have appropriate ancillary and support services with a healthcare provider in Spokane County. This sub-criterion is met.

(3) <u>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.</u>

Department's Evaluation
WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2) (a) (i). There are known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

<u>DaVita, Inc.</u>
To comply with this sub-criterion within the application, DaVita provided a contact list of the regulatory agencies responsible for surveying its facilities in Washington and the United States. [Source: Application, Appendix 13] As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,400 outpatient centers located in 43 states (including Washington State), the District of Columbia, and San Juan Puerto Rico. [Source: DaVita Webpage] Currently within Washington State, DaVita owns and operates 24 kidney dialysis treatment centers in 12 separate counties.

As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.[11] To accomplish this task, in March 2008 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the states, District of Columbia, and San Juan Puerto Rico where DaVita, Inc. or any subsidiaries have health care facilities.

Of the 45 entities, the department received responses from 24 states or 60% of the 43 states.[12] The compliance history of the remaining 19 states and the District of Columbia is unknown.[13]

Ten of the 27 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 Iowa, none of the deficiencies were reported to have resulted in fines or enforcement action all other facilities were reported as currently in compliance with applicable regulations. The Iowa facility chose voluntarily termination in August 2007 due to its inability to remain in compliance with Medicare Conditions for Coverage rather than undergo the termination process with Medicare. This facility is currently operating as a private ESRD facility. [Source: compliance history from state licensing and/or surveying entities]

The department concludes that considering the more than 1,400 facilities owned/managed by DaVita, one out-of-state facility listed above demonstrated substantial non-compliance issues; therefore, the department concludes the out-of-state compliance surveys are acceptable. For Washington State, since January 2008, the Department of Health's Investigations and Inspections Office has completed more than 30 compliance surveys for the operational facilities that DaVita either owns or manages.[14] 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 Investigations and Inspections Office]

Compliance history review of the proposed medical director Dr. Henry Mroch revealed a recorded sanction. A Stipulated Findings of Fact, Conclusion of Law and Agreed Order dated October 2002 sanctioned and suspended Dr. Mroch's license to practice medicine in Washington for two year starting from the date the order was signed. Accordingly, Dr. Mroch's license has been reinstated. As of the time of writing this evaluation, staff is not aware of any additional recorded sanctions against Dr. Mroch. DaVita provided a draft medical director agreement with Dr. Mroch. The agreement outlines the roles and responsibilities of the medical director.

[11] WAC 246-310-230(5).

[12] States that provided responses are: Arizona, California, Colorado, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, Washington, and Wisconsin. San Juan Puerto Rico also provided a response.

[13] States that did not provide responses are: Alabama, Arkansas, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maine, New Mexico, New Jersey, New York, North Carolina, Ohio, South Carolina, South Dakota, Tennessee, and West Virginia. The District of Columbia also did not respond to the survey.

[14] As of the writing of this evaluation, nine of DaVita's facilities are not yet operational. Those facilities are Everett Dialysis Center, Goldendale Dialysis Center, Kennewick Dialysis Center, Mill Creek Dialysis Center, Olympia Dialysis Center, Parkland Dialysis Center, Richland Dialysis Center, Seaview Dialysis Center, and Whidbey Dialysis Center. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita.

Given the compliance history of DaVita and that of the proposed medical director, the department concludes that there is reasonable assurance that the proposed DaVita North Spokane Dialysis Center would be operated in conformance with state and federal regulations. This sub-criterion is met.

IN-RCG

To comply with this sub-criterion, within the application IN-RCG provided a contact list of the regulatory agencies responsible for surveying its facilities in Washington and the United States. [Source: Application, Exhibit 2] As stated earlier in this evaluation, Fresenius is the parent company of IN-RCG. Information available at Fresenius Medical Care North America website stated that Fresenius is a provider of dialysis and related renal services in the United States with more than 1,700 outpatient centers located in 45 states (including Washington State), the District of Columbia, and Puerto Rico. [Source: http://www.fmcna.com/company.html]

As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.[15] To accomplish this task in March 2008, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for conducting surveys where Fresenius or any of its subsidiaries have healthcare facilities. Of the 45 and the 2 non-state entities surveyed, the department received responses from 41 states or 91% of the 45 states and from Puerto Rico.[16] The compliance history of the remaining 4 states and the other non-state entity is unknown.[17]

Twelve of the 41 states responding to the survey indicated that non-compliance deficiencies were cited at Fresenius facilities in the past three years, but none of the deficiencies were reported to have resulted in fines or enforcement action. Fresenius submitted and implemented acceptable plans of correction. Given the results of the out of state compliance history of the facilities own or operated by Fresenius, the department concludes that considering that it own or operates more than 1,700 facilities; the number of out-of-state non-compliance surveys is acceptable. [Source: Licensing and/or survey data provided by out of state health care survey programs]

Within the application, IN-RCG stated that it is jointly own by RCG and Providence Sacred Heart Medical Center. In Washington State, Fresenius and its subsidiary IN-RCG currently owns, operates and/or manages nineteen kidney dialysis treatment facilities in ten separate counties. The IN-RCG/Fresenius owned or operated facilities in Washington have collectively been surveyed 33 times within 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 allowable response time. [Source: compliance survey data provided by Office of Health Care Survey (OHCS)]

According to the applicant, IN-RCG is 80% owned by RCG and 20% by Providence Sacred Heart Medical Center a major healthcare provider. [Source: Application, Page 2] To ascertain that the applicant proposed services would meet standards, the department reviewed Providence Sacred Heart Medical Center's quality of care compliance history. That review shows that two compliance surveys were completed for Providence Sacred Heart Medical Center between 1999 and 2008. The compliance survey revealed deficiencies typical for the type of facility and

[15] WAC 246-310-230(5).

[16] The District of Columbia did not respond to the survey.

[17] States that did not provide responses are: Arkansas, Arizona, Minnesota and Oklahoma.

Providence Sacred Heart Medical Center submitted plan of corrections and implemented the required corrections. [Compliance survey data provided by Investigation and Inspection's Office]

Based on recent surveys of Fresenius and its affiliates and Providence Sacred Heart Medical Center, it is reasonable to expect that the proposed North Spokane Dialysis Center would be operated in compliance with the applicable standards and regulations of Washington State.

IN-RCG identified John Musa, MD, as its medical director under a draft contract provided in the application. A review of Dr. Musa'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 IN-RCG's, Providence Sacred Heart Medical Center, and FMC's compliance history and the compliance history of Dr. Musa as medical director, the department concludes there is reasonable assurance that the proposed North Spokane 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.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

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. DaVita did not provide documentation to show a relationship with an existing health care provider in the planning area, but submitted a patient transfer draft agreement and stated that without an operating facility, actual agreements with specifics cannot be executed. [Source: Application, Page 28, Appendices 17 & 18]

Department's Evaluation

The department considered DaVita's history of providing care to residents in Washington State and concludes it has provided dialysis services for several years and has appropriately participated in relationships with community facilities to provide a variety of medical services. Therefore, the department expects that if this application is approvable and with an operational facility in the planning area, DaVita would establish relationship with an existing local healthcare provider. [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 five new dialysis stations in Spokane ESRD planning area #2. Within its application, DaVita proposes to establish a 5-station dialysis center in Spokane ESRD planning area #2.

Based on this information, the department concludes the applicant would have appropriate relationships with local healthcare providers within the planning area. However, given the inconsistency in DaVita's lease cost, the department is not able to conclude that this project will not have an unreasonable fragmentation of services in the planning area. This sub-criterion is not met.

<u>IN-RCG</u>
The applicant stated that customary to its practices at existing facilities, NSDC would provide support services needed by a dialysis facility. Further, IN-RCG states all other services will be available through existing working relationships that FMC Northpointe already has with local providers. In addition, IN-RCG stated that it will establish a transfer agreement with Holy Family Hospital and provided a draft copy of its transfer agreement. [Source: Application, Page 35 and Exhibit 9]

<u>Department's Evaluation</u>
The department considered IN-RCG's history of providing care and concludes that given it has been providing dialysis services to the residents of Washington for several years and have appropriately participated in relationships with community providers, the department expects the relationship established by applicant and its affiliates would be extended to the proposed project if it's approvable. As stated before, IN-RCG is partly owned by Providence Sacred Heart Medical Center a major healthcare provider located within the planning area therefore; the department expects that relationship established by the applicant affiliates would be extended to the proposed project if approvable. [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 five dialysis stations facility in the Spokane ESRD planning area #2.

Based on this information, the department concludes the applicant has 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) *<u>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.</u>*
For both projects, this sub-criterion is addressed in sub-section (3) above and is considered met.

D. Cost Containment (WAC 246-310-240) and WAC 246-310-288 (Tie Breakers)

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

- DaVita, Inc.'s application did not meet the cost containment criteria in WAC 246-310-240; and
- Inland Northwest Renal Care Group applications 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.

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met WAC 246-310-210 thru 230 criteria, the department would move to step two in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific criteria (tiebreaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects, which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2) (a) (i), then the department would look to WAC 246-310-240(2) (a) (ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

DaVita, Inc.

Before discussing the alternatives considered, DaVita stated that it agrees with recent department's observations that in a certificate of need context, delaying the implementation of a project is not really an option because there is no action required by the applicant. Additionally, DaVita states that in this case, there is a need for a 5-station facility by year 2012 and no viable argument exists for delaying action. To comply with this sub-criterion, DaVita stated that it considered the alternatives listed and summarized below.

- Establish a 5-ststion dialysis center at the Spokane 2 site
- Pursue joint ventures with existing providers.

Alternative 1: Establish a 5-station dialysis center at the Spokane site

The applicant stated, *"Under this alternative DaVita would establish a dialysis center without some supporting services and additional modalities such as isolation and training to minimize the capital expenditure. Such an alternative by necessity would have shifts starting after 5:00 p.m. to achieve the required 80% utilization at a 3-shift level as required by rule. Reducing isolation and permanent bed capacity and eliminating training would minimally reduce capital expenditure.*

Currently, training services are not provided with the planning area so there is an outright need for a more robust facility to provide access and choice for services such as training and a permanent bed station". Therefore, this alternative was rejected**.** [Source: Application pages 30]

Alternative 2: Purse joint ventures with existing providers
The applicant stated it reviewed this alternative during a technical assistance meeting with the department, but since it did not have sufficient time to know whether there is need within the planning area before application submission timeline deadline; this option was rejected. [Source: Application page 31]

Step One
For this project, the department determined that DaVita did not meet all review criteria under WAC 246-310-210, 220, and 230. Since DaVita did not meet all the review criteria, the department determines that it also failed to meet the review criteria under cost containment WAC 246-310-240. The department concludes that DaVita's proposal to establish a new 5-station dialysis facility in Spokane ESRD planning area #2 is not the best available alternative. Therefore, step two and step three are not necessary.

IN-RCG
To comply with this sub-criterion, IN-RCG stated it considered several options before electing to proceed with the establishment of the 5-station facility in Spokane ESRD planning area#2. The options considered by IN-RCG are listed and summarized below.

- Do nothing
- Expand the FMC Northpointe facility

Option #1: Do nothing.
IN-RCG asserted that option # 1, which is do nothing was rule out and stated, "*FMC Northpointe facility is now operating above the 4.8 patient standards, making it increasingly challenging to accommodate all new patients that choose to be cared for within the IN-RCG/Fresenius system. In addition, the other facility in the planning area is also above the standard. Therefore, both facilities have limited capacity to accommodate new patients needing dialysis."* For this reason, this option was rejected. [Source: Application, Page 37]

Option #2: Expand the Northpointe Facility.
IN-RCG states that expanding the FMC Northpointe was ruled out because it was not cost effective and adding stations to the existing facility would be disruptive to patients and staff due to the impact of construction. For the reason stated, IN-RCG decided to reject this option**.**

Step One
For this project, IN-RCG has met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two
IN-RCG stated this project is directed at meeting future need for Spokane ESRD planning area #2 patients because the establishment of the facility would lead to overall systems efficiencies. Further, IN-RCG stated that it would use its organizational structure to maximize economies of scale by sharing administrative and support staff.

Given that the only other option to this project is do nothing, taking into account that the existing facilities in the planning area exceeds 4.8 patients per station as of the end of year report December 31, 2008, and the results of the numeric need methodology. Therefore, the department concludes that the project described is IN-RCG best available alternative.

Step Three

This step is used to determine the best available alternative between two or more approvable projects. For the ESRD Concurrent Review Cycle #1, DaVita also submitted an application to add 5-stations in Spokane ESRD planning area #2, but the department determined that DaVita's application did not met the applicable review criteria. Therefore, step three is not necessary.

(2) In the case of a project involving construction:
(a) The costs, scope, and methods of construction and energy conservation are reasonable;

DaVita, Inc.

DaVita's proposes to lease a "built to suit" facility from a real estate developer. DaVita states that the scope and methods of the facility will meet Medicare certification and the local authority construction and energy conservation code. The cost the developer incurs to construct the building is reflected in the negotiated lease costs. The lease costs were evaluated in the financial feasibility section of this analysis. The department concluded the overall project did not meet the financial feasibility criterion because of inconsistencies between the submitted draft lease and pro forma financial statements. Therefore, the department could not conclude that this criterion that is tied directly to the lease agreement has been met. Based on the information, the department concludes that this sub-criterion is not met.

IN-RCG

IN-RCG also proposes to lease a "built to suit" facility from a real estate developer. Within the application, IN-RCG states, *"The new construction will be designed and built to meet or exceed all applicable state and local codes and CMS conditions of coverage".* [Source: Application, Page 38] The cost the developer incurs to construct the building is reflected in the negotiated lease costs. These costs were evaluated in the financial feasibility section of this analysis. The department concluded the overall project met the financial feasibility criterion. Based on the information, 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

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.

IN-RCG

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.

APPENDIX A