STATE OF WASHINGTON
DEPARTMENT OF HEALTH

October 3, 2013

CERTIFIED MAIL # 7011 200 0000 5081 8593

Anthony Halbeisen
Director Business Development
DaVita HealthCare Partners, Inc.
North Star Division
3227 32nd Avenue South
Federal Way, Washington 98001

CN: 13-15A2

Dear Mr. Halbeisen:

We have completed review of the Certificate of Need application submitted by DaVita HealthCare Partners, Inc. proposing to establish a 6-station facility in Stevens County. For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners, Inc. agrees to the following in its entirety.

Project Description:
This certificate approves the establishment of a six-station dialysis center in Colville within Stevens County. At project completion, Colville Dialysis Center will be approved to certify and operate six dialysis stations. Services provided include home hemodialysis, in-center hemodialysis, peritoneal dialysis, training/support for dialysis patients and shifts beginning after 5:00 pm. The six dialysis stations include a permanent bed station and an isolation station. A breakdown of all six stations is below:

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	3
Total	6

Conditions:
1. Approval of the project description as stated above. DaVita HealthCare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

2. Prior to providing services at Colville Dialysis Center, DaVita HealthCare Partners, Inc. will provide an executed copy of the facility's Patient Transfer Agreement for the department's review and approval. The executed patient transfer agreement must be consistent with the draft provided in the application.
3. Prior to providing services at Colville Dialysis Center, DaVita HealthCare Partners, Inc. will provide a copy of the adopted Accepting Patients for Treatment Policy for the department's review and approval. The adopted Accepting Patients for Treatment Policy must be consistent with the draft provided in the application.
4. Prior to providing services at Colville Dialysis Center, DaVita HealthCare Partners, Inc. will provide an executed copy of the dialysis center ancillary and support services agreement for the department's review and approval. The executed ancillary and support services agreement must be consistent with the draft provided in the application

Approved Capital Costs

The approved capital expenditure associated with this project is $1,312,865. This amount represents the total capital expenditure of $1,652,466, minus the landlord's project costs of $339,601.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:	Other Than By Mail:
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerely,

Steven M. Saxe, FACHE
Director

Enclosure

EVALUATION DATED OCTOBER 3, 2013, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ESTABLISH A SIX STATION KIDNEY DIALYSIS FACILITY IN STEVENS COUNTY

APPLICANT DESCRIPTION

In 2012, HealthCare Partners Holding, Inc. and DaVita, Inc. merged and changed its name to DaVita HealthCare Partners, Inc.[1]. Information available at DaVita HealthCare Partners, Inc. website states DaVita, Inc.[2] is the dialysis division of DaVita HealthCare Partners Inc. DaVita HealthCare Partners, Inc. is a for-profit end stage renal care provider.

DaVita HealthCare Partners, Inc. currently provides administrative services to approximately 1,912 dialysis facilities located in 43 states and the District of Columbia. Additionally, DaVita HealthCare Partners, Inc. also provides acute inpatient kidney dialysis services in over 720 hospitals located throughout the United Sates. [Source Application Page 5] In Washington State, DaVita HealthCare Partners, Inc. owns or operates 31[3] kidney dialysis facilities in 14 separate counties. Below is a listing of the facilities. [Source: Amended application received January 15, 2013, Pages 5-6]

Benton	**Pacific**
Chinook Dialysis Center	Seaview Dialysis Center
Kennewick Dialysis Center	
	Pierce
Clark	Graham Dialysis Center
Battleground Dialysis Center	Lakewood Dialysis Center
Vancouver Dialysis Center	Parkland Dialysis Center
	Puyallup Dialysis Center
Chelan	Tacoma Dialysis Center
Wenatchee Valley Dialysis Center[4]	
	Snohomish
Douglas	Everett Dialysis Center[5]
East Wenatchee Dialysis Center	Mill Creek Dialysis Center
Franklin	**Spokane**
Mid-Columbia Kidney Center	Downtown Spokane Renal Center
	North Spokane Renal Center
Island	Spokane Valley Renal Center
Whidbey Island Dialysis Center	
	Thurston
	Olympia Dialysis Center

[1] Supplemental information received March 14, 2013
[2] http://www.davita.com/about
[3] Battle Ground Dialysis Center, Kennewick Dialysis Center, Renton Dialysis Center and Zillah Dialysis Center are CN approved but not yet operational.
[4] This facility was recently purchased from Central Washington Hospital
[5] Refuge Dialysis, LLC is 80% owned by DaVita, Inc. and 20% by The Everett Clinic.

King	
Bellevue Dialysis Center	
Renton Dialysis Center	**Yakima**
Federal Way Dialysis Center	Mt. Adams Dialysis Center
Kent Dialysis Center	Union Gap Dialysis Center
Olympic View Dialysis Center (management only)	Yakima Dialysis Center
Westwood Dialysis Center	Zillah Dialysis Center
Kittitas	
Ellensburg Dialysis Center	

PROJECT DESCRIPTION

DaVita HealthCare Partners, Inc. proposes to establish a 6-station facility in Stevens County to be known as the Colville Dialysis Center. The new facility would be located at 198 Ponderosa Road #A within the city of Colville in Stevens County. [Source: Application Page 8] Services provided at the Colville Dialysis Center would include home hemodialysis, in-center hemodialysis, peritoneal dialysis, training/support for dialysis patients, and shifts beginning after 5:00 pm. The new six dialysis stations would include a permanent bed station and an isolation station. [Source: Application Page 9]

The capital expenditure associated with the new 6-station kidney dialysis facility is $1,652,466. Of this amount, approximately 52% is related to leasehold improvements, 23% is related to fixed and moveable equipment, 21% is related to building owner expenses, permit, taxes, financing and commission costs, and the remaining 4% is related to professional service fees. [Source: Amended application received January 15, 2013, Page 8 and Appendix 7]

If this project is approved, DaVita HealthCare Partners, Inc. anticipates the new 6-station facility would become operational by January 2014. Under this timeline, year 2015 would be the second year of operation and 2016 would be year three. [Source: Application Page 12] For ease of reference, the department would refer to DaVita HealthCare Partners, Inc. throughout this evaluation as 'DaVita'.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need (CN) 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).

EVALUATION CRITERIA

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."

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."

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations. To obtain Certificate of Need approval, DaVita must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment)[6]. Additionally, DaVita must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Concurrent Review Cycle #4 for year 2012. No other kidney disease treatment center application was received for Stevens County ESRD planning area during Cycle #4. The review was converted to a regular review. A chronological summary of the review activities is shown in the table on page 3.

[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), (6); and WAC 246-310-240(3); WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

APPLICATION CHRONOLOGY

Action	Dates
Letter of Intent Submitted	October 31, 2012
Initial Application Submitted	November 30, 2012
1st Amended Application Submitted	December 31, 2012
2nd Amended Application Submitted	January 15, 2013[7]
Department's pre-review activities including screening and responses	December 1,2012 through March 19, 2013
Beginning of Review	March 20, 2013
End of Public Comment/No Public Hearing Requested or Conducted	March 23, 2013
Rebuttal Comments	May 8, 2013
Department Declares Pivotal Unresolved Issue (PUI)	July 24, 2013
Applicant Submits PUI Documents	July 24, 2013
Public Comments on PUI Documents	August 9, 2013
Rebuttal Comments Submitted for PUI Documents	September 4, 2013[8]
Department's Anticipated Decision Date	October 21, 2013
Department's Actual Decision Date	October 3, 2013

AFFECTED AND INTERESTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person" as:

"...an "interested person" who:

(a) Is located or resides in the applicant's health service area;

(b) Testified at a public hearing or submitted written evidence; and

(c) Requested in writing to be informed of the department's decision."

For this project, Inland Northwest Renal Care Group (INRCG), a subsidiary of Fresenius Medical Care (FMC) sought and received affected person status under WAC 246-310-010.

SOURCE INFORMATION REVIEWED

- DaVita HealthCare Partners, Inc. Certificate of Need application received January 15, 2013
- DaVita HealthCare Partners, Inc. supplemental information received March 12, 2013
- Years 2006 through 2011 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2012 Northwest Renal Network 3rd Quarter Data available on October 29, 2012
- Public comments received from Inland Northwest Renal Care Group on April 23, 2013
- Rebuttal comments received from DaVita HealthCare Partners, Inc. on May 8, 2013
- DaVita HealthCare Partners Inc. pivotal unresolved issue (PUI) documentation received July on 24, 2013

[7] DaVita HealthCare Partners, Inc. submitted an initial Certificate of Need application on November 30, 2012 and that application was amended twice. The first amended application was received on December 31, 2012 and on January 15, 2013; the applicant again amended this application. Given that the applicant amended its initial application twice, only the second amended application received by the department on January 15, 2013, would be reviewed.

[8] The applicant requested an extension to the rebuttal comment due date until September 5, 2013.

- Inland Northwest Renal Care Group public comments on PUI documents received August 9, 2013
- Rebuttal comments on PUI documents received from DaVita HealthCare Partner, Inc. September 4, 2013
- http://www.medicare.gov–Medicare Coverage of Kidney Dialysis and Kidney Transplant Services
- Licensing and/or survey data provided by the Department of Health's Inspections and Investigation Office (IIO)
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- Quality Assurance compliance data. http://www.doh.wa.gov/LicensesPermitsandCertificates
- Data obtain from the Washington Secretary of State. http://www.sos.wa.gov

CONCLUSION

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to establish a new 6-station kidney dialysis center in Stevens County is consistent with the applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners, Inc. agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a six-station dialysis center in Colville within Stevens County. At project completion, Colville Dialysis Center will be approved to certify and operate six dialysis stations. Services provided include home hemodialysis, in-center hemodialysis, peritoneal dialysis, training/support for dialysis patients and shifts beginning after 5:00 pm. The six dialysis stations include a permanent bed station and an isolation station. A breakdown of all six stations is below:

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CRITERIA DETERMINATIONS

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

Based on the source information reviewed and the applicant's agreement to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-289.

(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 requires the department to evaluate kidney disease treatment center applications based on the population's need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed in WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

Kidney Disease Treatment Center Methodology WAC 246-310-284

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology 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.[9]

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.[10] 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)]

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[9] 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]

[10] WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report."

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

To determine the type of regression analysis to be used to project station need, DaVita stated that it used 2006 through 2011 historical data for the planning area. Based on that data DaVita used linear regression. The table below shows DaVita's application of the numeric methodology for Stevens County ESRD Planning area. [Source: Application Pages 16-19]

Table 1
Summary of DaVita's Stevens County ESRD Planning Area Numeric Methodology

	Year 2012	Year 2013	Year 2014	Year 2015
Hemodialysis Patients	33.1	36.6	40.1	43.6
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	10.34	11.44	12.53	13.63
Existing Stations	8	8	8	8
Net Station Need/(Surplus)	-3	-4	-5	-6

*Negative number indicates need for additional stations

As shown in the table above, DaVita projected need for six stations in year 2015, and submitted an application requesting to establish a new six-station facility in the planning area.

Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning area as described above, the department used linear regression to project need. The number of projected patients (un-rounded) was divided by 3.2 to determine the number of new stations needed in the planning area. The net station need for Stevens County ESRD planning area is six stations. The table below summarizes the department's application of the numeric methodology for the planning area

Table 2
Summary of Department's Numeric Methodology
Stevens County ESRD Planning Area

	Year 2012	Year 2013	Year 2014	Year 2015
In-center Patients	32.30	35.60	38.90	42.20
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need Rounded Up	11	12	13	14
Minus # CN Approved Stations	8	8	8	8
Net Station Need / (Surplus)	-3	-4	-5	-6

When comparing the results of Tables 1 and 2 above, both DaVita and the department projected a numeric need for additional six stations within the planning area in year 2015. The department's numeric methodology for Stevens County ESRD planning area is attached to this evaluation as Appendix A.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 3.2 in-center patients per station before new stations can be added. Fresenius Medical Center Colville Dialysis operated by INRCG (a subsidiary of Fresenius Medical Center) is the only dialysis facility located in the planning area. 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 for this project is November 1, 2012. [WAC 246-310-282] The quarterly modality report from NRN available at that time was September 2012, which became available on October 29, 2012. The table below shows Fresenius Medical Center Colville Dialysis Center (FMC Colville) utilization as of September 30, 2012.

Table 3
NWRN Facility Utilization Data

Facility Name	#of Stations	# of Pts	Pts/Station
FMC Colville	8	28	3.5

As shown in the table above, FMC Colville is operating above the required 3.2 standard. **This standard is met.**

WAC 246-310-284(6)

WAC 246-310-284(6) requires by the third full year of operation, new in-center kidney dialysis stations must reasonably project to be operating at the required number of in-center patients per approved station by end of the third full year of operation. DaVita Colville Dialysis Center would be located in Stevens County; therefore, the standard for this criterion is 3.2 in-center patients per approved station. DaVita stated year 2016 would be the third year of operation with six stations. Below is DaVita's third year projected utilization.

Table 4
DaVita Colville Dialysis Center
Third Full Year Projected (2016) Facility Utilization

Facility Name	# of Stations	# of Pts	Pts/Station
DaVita Colville Dialysis Center	6	25	4.17

As shown in the table above, DaVita Colville Dialysis Center would meet this standard in year 2016 with all 6 stations operational. [Source: Application Appendix 9] **This sub-criterion is met.**

The department received many comments from INRCG related to DaVita's application of the need methodology. Below is a summary of INRCG's comments.

INRCG [Source: Public Comments, April 23, 2013]

- DaVita projected that it would serve 18 in-center hemodialysis patients in 2015 and that volume is 15% greater than the number of patients forecasted in the need methodology. DaVita's estimates are nearly 31% above what the need methodology projects as net need. It is highly unlikely that DaVita's projections would meet its volume estimates. DaVita can only meet its volume estimates by having a significant and unreasonable impact on the volume of FMC Colville.

- DaVita overestimated its projected patient population. It projected 11 in-center patients in 2014 and in year 2016, it projected 25 patients. The need methodology projected only 12 new patients in 2014 and 16 year 2016. Given that FMC Colville is the only dialysis facility in the planning area, it is highly unlikely that DaVita would receive 11 of 12 new patients projected for year 2014.

- DaVita has previously testified that it is not reasonable to assume that 100% of patients will relocate to a new facility.[11] DaVita also stated in its previous applications that it is an unreasonable and unrealistic assumption that its facility would serve every patients in a planning area.

- DaVita overstated its dialysis patient volumes. In order for DaVita to achieve its projected number of patients, it would have to convince 20% of our existing patients to transfer to its facility. DaVita did not provide any documentation to justify or explain how it will achieve its census projections. DaVita's projections rely on faulty patient volume, payer mix and reimbursement assumptions. Some of the comments made by DaVita in its past CN applications do not support the assertions presented in this application. Example of instances where DaVita's facilities has not met the projected volume are DaVita Richland, DaVita Everett, and DaVita Mill Creek. These facilities are operating below the projections DaVita used in its CN projections.

[11] INRCG provided citations of public comments where DaVita previously has taken this position.

In response to the comments submitted to the department by INRCG, DaVita provided the rebuttal comments summarized below.

DaVita's Rebuttal Comments [Source: Rebuttal comments received May8, 2013]

- DaVita projected its census for Stevens County using the same approach it has used successfully in many of its applications. DaVita projected the Colville facility will treat 25 patients in 2016, the facility's third full year of operation. This is in line with WAC 246-310-284(6) requirement to treat at least 19.2 patients in that year using 3.2 patients per station standard.

- DaVita's projections reflect the unique nature of Stevens County because the planning area draws patients from a large surrounding area. When Fresenius Medical Care expanded its existing Colville facility in 2009, it claimed approximately 40 percent of the patients that would use the facility reside outside Stevens County, and the Program allowed it.

- FMC assumed it's entitled to serve 28 patients (Colville current census) indefinitely into the future. The dialysis need methodology does not include an assumption about future census at an existing facility. For Stevens County, the methodology assumed existing stations would operate at 3.2 patients per station. The need methodology assumes that the existing FMC facility would serve 25.6 patients and not 28 patients.

- FMC referenced comments DaVita made six years ago regarding the unique circumstances of a Port Townsend facility and those comments have no relevance to our Colville facility application. At the time of this application, DaVita operates 27 dialysis facilities in Washington. However, FMC can only point to three facilities as the only example of DaVita's facilities that have fallen short of projections. By implication, FMC's argument implies that DaVita's remaining 24 facilities have met projections. The performance of facilities in Richland, Everett, or Mill Creek says nothing about the accuracy of our projections for a Colville facility.

The Department's Response

The department's need methodology shows that in 2016, there is an additional net need of 6 stations Stevens County. DaVita appropriately applied the methodology under WAC 246-310-284 to project that 6 stations are needed in Stevens County. The department disagrees with INRCG's assertions that DaVita overestimated its patient's census and volume since INRCG did not provide documentation to collaborate its assertions. The department acknowledges that it allowed INRCG to include patient projections from adjacent planning areas in its need calculation when INRCG submit an application to expand its Colville facility.

DaVita asserts Stevens County is unique and patients residing outside the county may use a facility located within the county is true. However, DaVita did not provide the number of such residents located outside the planning area that would use the proposed facility. Therefore, the department concludes that DaVita's patient projections are not necessarily unrealistic, but optimistic.

INRCG provided documentation to show three instances where DaVita's projected patient census and assumptions have been wrong, but INRCG did not provide documentation directly related to a facility to be located in Stevens County. As shown in Table 4, based on DaVita's projections with all 6 stations operational, the proposed facility would be operating over 3.2 patients per in-center station by the third year of operation (year 2016). Based on the information, the department concludes DaVita's proposal to establish a new 6-station dialysis facility in Stevens County **met 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.*

DaVita is currently a provider of health care services to the residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of Stevens County would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of Accepting Patients for Treatment Policy used at dialysis centers owned or operated by DaVita or its subsidiaries. The policy outlines the process and guidelines that DaVita uses to admit patients for treatment at Colville Dialysis Center. The policy asserted that any patient needing treatment would be accepted at the dialysis facility without regard to race, creed, color, age, sex, or national origin. [Source: Application Appendix 14]

The admission policy document provided by the applicant shows that it was last updated in September 2012, therefore the department would require that the applicant provide an updated admission policy for review and approval. With the applicant's agreement to the conditions related to the Admission Policy, the department expects that dialysis patients within the planning are would have access to DaVita's services.

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. DaVita currently provides services to Medicaid eligible patients at it existing dialysis centers in Washington. A review of the anticipated revenue sources indicates that the facility expects to receive Medicaid reimbursements. [Source: Application Page 10]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. DaVita currently provides services to Medicare eligible patients at its existing dialysis centers. A review of DaVita's anticipated revenue sources indicates that it expects to receive Medicare reimbursements. [Source: Application Page 10]

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 demonstrated its intent to provide charity care to patients receiving treatment at the facility by submitting an Administrative Policy Colville Dialysis Center/Indigent Care Policy that outlines the process one would use to access charity care at the facility. A review of DaVita's projected pro-forma operating statement shows that it included a 'charity care' line item as a deduction from revenue. [Source: Application Appendix 9] The department concludes that all residents of the planning area would have access to the health services at the facility. **This sub-criterion is met.**

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s 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.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates that the new stations would become operational by January 2014. Under this timeline, year 2015 would be the second calendar year of operation and year 2016 would be year three. [Source: Application Page 12]

DaVita provided its projected revenue and expense statement for the DaVita Colville Dialysis Center as a six-station facility. Table 5 summarizes that information. [Source: Application, Appendix 9]

Table 5
DaVita Colville Dialysis Center
Projected Revenue and Expenses for Full Years 2014-2017

	Year 1 2014	Year 2 2015	Year 3 2016	Year 4 2017
# of Stations	6	6	6	6
# of Treatments [1]	963	2,594	3,927	5,261
# of Patients [2]	11	18	25	32
Utilization Rate [2]	1.83	3.00	4.14	5.33
Net Patient Revenue[1]	$380,503	$1,044,921	$1,613,955	$2,205,333
Total Operating Expenses [1, 3]	$874,735	$1,168,490	$1,527,063	$1,933,797
Net Profit or (Loss)[1]	(-$494,232)	(-$123,569)	$86,892	$271,536

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

The 'Net Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for DaVita Colville Dialysis Center. As shown in the table above, DaVita Colville Dialysis Center would be operating at a loss in calendar years 2014 and 2015. In year 2016, the facility is expected to operate at a profit. DaVita provided an executed purchase agreement between EDG-DV Colville, LLC as the ("Lessor") and Total Renal Care, Inc. as the ("Lessee"). [Source: Application Appendix 15] The department's review of the purchase/ lease agreement shows that those costs are consistent with the pro-forma financial projections.

DaVita provided an executed copy of the medical director's agreement between Providence Physician Services Co d/b/a Providence Medical Group Eastern Washington ("Group") and Petru Groza, MD ("Physician") and Total Renal Care Inc., ("Company"). The medical director's agreement identified the annual compensation for the medical director position. Additionally, DaVita's pro-forma financial statement identified the annual compensation for the medical director. [Source: Application, Appendix 3]

INRCG's comments related to DaVita's site control are summarized below.

INRCG [Source: Public Comments submitted by Inland Northwest Renal Care Group April 23, 2013]

- To demonstrate site control, the applicant's documentation must establish a link between the applicant and the legal owner of the proposed site. DaVita submitted a lease agreement between two of its affiliates, one as the lessee and the other as lessor. Neither of the two affiliates owns the selected site. The 'Rider' to the 'Preferred Developer Agreement' clearly recognizes that DaVita is aware that it needs a purchase agreement.

- According to Stevens County assessor's webpage, Hudesman Colville, LLC, owns the identified site. DaVita has not provided documentation to explain the relationship between the property owner (Hudesman Colville, LLC) and the property owner (EDG-DV Colville) therefore; it has failed to establish it has an enforceable agreement.

In response to the comments submitted by INRCG, DaVita provided the rebuttal comments summarized below.

DaVita's Rebuttal Comments [Source: Rebuttal comments received May8, 2013, Page 3]

- FMC criticized the absence of a Purchase and Sale Agreement with the current landowner it argues that DaVita has not provided documentation to explain the relationship between the site's property owner and developer. We submitted a 'Rider to the Preferred Developer Agreement Colville, WA. The rider provides a detailed description of the arrangement between the property owner and the developer. DaVita site control is solid and well documented

- The independent developer for this project EDG Commercial Real Estate, Inc. formed a limited liability company for the purpose of the project with the name of EDG-DV Colville, LLC (EDG-DV Colville). EDG-DV Colville then entered into a binding purchase and sale agreement with the current site owner.

- If DaVita obtains a CN to establish a new facility, EDG-DV Colville would then purchase the site from Hudesman Colville and will lease the site to DaVita for the Stevens County facility. The entire site control arrangement is for EDG-DV Colville to the purchase site and lease it to DaVita. The details related to the arrangement are explained in the rider.

The Department's Response

The department reviews of the purchase and sales agreement provided by DaVita shows that EDG-DV Colville intends to lease landed parcel #0043255 located at 198A Ponderosa Road, Colville 99114 to DaVita. The Rider to the Preferred Developer Agreement shows a relationship between DaVita and EDG-DV Colville. Restated below is an excerpted pertinent part of the rider agreement:

"Concurrently herewith, EDG though its affiliates, Lessor, and DaVita, through its affiliates Lessee, are entering into a Lease Agreement (the Colville Lease), with respect to the Colville site. However, neither Lessor nor Lessee wishes to be bound to the clinic lease unless and until Lessee receives a Certificate of Need to operate a dialysis clinic on the Colville site". [Source: Amended application received January 15, 2013, Appendix 15, Exhibit I]

The above statement implies that EDG-DV owns the property and it planned to lease the site to DaVita. Public comments submitted by INRCG asserted that DaVita does not own the proposed site, as demonstrated by the purchase and lease documentation it provided. INRCG also stated DaVita did not show by way of documentation that it has a relationship with EDG-DV, Colville, LLC or Hudesman Colville, LLC. In order to ascertain ownership of the proposed facility site, the department searched the Stevens County Assessors webpage and the search revealed that Hudesman Colville, LLC, owns the proposed site. Therefore, the department agrees with INRCG's assertions that DaVita has not provided documentation to show that it has site control or explained the relationship between the property owner Hudesman Colville, LLC and EDG-DV Colville. Given the confusion related to who owns the proposed facility site, the department agrees with INRCG's assertions that DaVita failed to establish it has an enforceable lease agreement.

On July 24, 2013, because of the lack of clarity related to ownership of the proposed facility site, the department declared a pivotal unresolved issue (PUI). The PUI gives DaVita the opportunity to provide clarification and documentation related to the ownership of the proposed site. Summarized below are the comments provided by DaVita related to the PUI.

DaVita PUI Comments [Source: Response to PUI Comments received July 24, 2013]
On July 24, 2013, as requested in the PUI notice, DaVita provided documentation to show that it has demonstrated it has site control. Listed below are the documents provided by DaVita that shows it has site control.

- Purchase and Sales Agreement between EDG-DV Colville, LLC and Hudesman Colville, LLC
- Promissory note between EDG-DV and Hudesman Colville, LLC

INRCG's Comments [Source: Responses to PUI comments received August 9, 2013]

- DaVita did not demonstrate that is has site control when it submitted its application in November 2012 or when it amended the application in December 2012. There is no indication that DaVita's draft lease documentation is real or that Hudesman Colville, LLC ever intended to develop the property for DaVita. The lease documentation submitted makes it clear EDG-DV does not own the property.

- The purchase and sales agreement DaVita provided is questionable because it is not clear if EDG-DV is committed to doing anything. The purchase and sales documentation includes a rider that stipulates DaVita agreed to earnest money down payment for the property, but it did not document it paid any earnest money as agreed.

- The preferred development agreement identified use restrictions related to the site that needed to be resolved. The rider to the preferred developer agreement stated lessor and leasee acknowledge that the property is encumbered by certain covenants, conditions and restrictions. DaVita did not provide any data indicating how or if these restrictions have been addressed and if the required waivers has been obtained.

- DaVita's application did not disclose all capital expenditures associated with the project. The rider to the preferred developer agreement shows a cost compensation payment that was not disclosed by DaVita. According to the purchase and sales agreement, this payment is to be made by the lessee (Total Renal Care/DaVita) to the lessor (EDG-DV Colville).

Below are the comments provided by DaVita in response to the issues raised by INRCG.

DaVita Rebuttal Comments [Source: Rebuttal comment received on September 4, 2013]

- FMC stated DaVita's initial and amended applications did not document site control, but this statement is not correct because DaVita's initial and amended applications satisfied all site control documentation. The changes DaVita made in its capital and rent costs when it amended its application is not evidence of error or cost understatement rather it reflects changes in negotiations with the site owner and DaVita's developer.
  The purchase and lease agreement submitted by DaVita is clear on all essential contract terms. The definition and basic terms of the agreement such as site control, purchase

price, earnest money, due diligence period, closing date, title insurance company, escrow agent, and real estate brokers commission are all presented in section one of the sales and purchase agreement DaVita submitted.

- In section two of the sales and purchase agreement, the seller (Hudesman Colville, LLC) agreed to sell and convey to the buy or (EDG DV Colville, LLC) title to the property and any interest or improvement to the site. The sales and purchase agreement was executed by representatives of both buyer and seller. The buyer paid earnest money in the form of a legally enforceable promissory note which is a common and valid method of payment.

- The proposed site lessor agreed that DaVita may occupy the site for purposes of operating a dialysis clinic. The September 1, 2013 deadline noted in the agreement has been extended because DaVita still has concerns related to any conflict with the permitted use of the site. Due to DaVita's concerns related to permit use of the site, the lessor agreed to pay substantial sums to secure the site for DaVita after it obtains a CN.

- FMC states the proposed project would incur a capital cost undisclosed by DaVita. This is not true because the undisclosed capital cost that FMC references is an agreed provision that both the seller and lessee agree to use in event of an unforeseen changes in circumstances that is beyond the lessors and lessee's control during the CN process. This provision establishes a formula for a potential compensation that one party or the other would use for an unforeseen cost changes during the CN process. The possible payment is essentially an adjustment to the base rent and it should be treated as a possible future operating expense and not a reportable capital expense.

Department's Evaluation

A review of the executed purchase and sales agreement provided by DaVita in response to the PUI show the agreement is between EDG-DV, Colville and Hudesman Colville. According to the agreement, EDG-DV would buy the site and developed it, then lease it to DaVita. A promissory note dated January 9, 2013, between EDG-DV Colville and Hudesman Colville, LLC identifies the purchase price, earnest money, due diligence period, and closing date. Amongst others, when reviewed together the promissory note and the executed sales and purchase agreement demonstrates site control by DaVita through EDG-DV.

Therefore, the department disagrees with INRCG assertions that DaVita did not demonstrate site control. DaVita has used this process in past projects. Given that DaVita has used similar entities in previous applications reviewed by the department, it is reasonable to conclude that EDG DV would operate similar to other entities established by DaVita for CN purposes.

FMC alleges that DaVita's preferred development agreement identified land use restrictions related to the site that needed to be resolved, but it did not provide specifics related to the restrictions. A review of the application shows that communications between EDG-DV and the city of Colville officials addressed issues related to site zoning and restrictions.

Other comments by INRCG stated DaVita's application did not disclose all capital expenditures associated with the project because the rider to the preferred developer agreement shows a cost compensation payment that was not disclosed by DaVita.

In response to FMC's comment, DaVita stated the capital expenditure FMC alleges is merely a provision within the sales and purchase agreement that provides for compensation for either party should an unforeseen change in circumstances arises that is beyond either lessor or lessee control during the CN process. The department concludes this approach is reasonable.

The department declared a PUI and requested DaVita to provide clarifying documentation demonstrating that its affiliate EDG-DV has site control. The documents provided by DaVita shows EDG-DV have a sales and purchase agreement with Hudesman Colville, LLC. The rider to the purchase and sales agreement shows that EDG-DV would buy the site and develop it then lease back to DaVita. Based on the information, the department concludes DaVita has demonstrated site control, and the projected revenue and expenses are reasonable and can be substantiated. **This sub-criterion is met.**

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

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.

DaVita identified the capital expenditure associated with establish of the new 6-station DaVita Colville Dialysis Center. The costs are broken down in the table below. [Source: Application, Appendix 7]

Table 6
DaVita Colville Dialysis Center Capital Cost

Item	Cost	% of Total
Leasehold Improvement	$860,000	52%
Fixed and Moveable Equipment	$384,865	23%
Landlords Costs	$339,601	21%
Professional Services Fees	$68,000	4%
Total Project Cost	**$1,652,466**	**100%**

The above table shows DaVita's and the landlord costs. To further demonstrate compliance with this sub-criterion, DaVita provided the sources of its patient revenue shown in the table below. [Source: Application, Page 10]

Table 7
DaVita Colville Dialysis Center Source by Payer

Source of Revenue	% of Revenue
Medicare	61%
Medicaid / State	9%
Insurance/HMO	30%
Total	100%

According to the information presented in the table above, the proposed DaVita Colville Dialysis Center is expected to have 70% of its revenue from Medicare and Medicaid entitlement programs. The department received comments from INRCG related to DaVita's payer mix and revenue. The comments received from INRCG are summarized below.

INRCG [Source: Public Comments, April 23, 2013]

- The application contains unrealistic and unachievable payer mix. DaVita assumed a payer mix and revenue stream that is different from our actual experience serving Stevens County patients. Of our 28 patients, we have only one patient whose payer is other than Medicare or Medicaid. DaVita assumed that 12% of patients and 30% of revenue would come from commercial payers.

- DaVita's projections rely on faulty patient volume, payer mix, and reimbursement assumptions. Some of the comments made by DaVita in its past CN applications do not support the assertions presented in this application. For example, DaVita Richland, DaVita Everett, and DaVita Mill Creek are all operating below DaVita's CN projections.

In response to INRCG's comments, DaVita submitted rebuttal comments to the department summarized below.

DaVita's Rebuttal Comments [Source: Rebuttal comments received May 8, 2013]

- FMC asserts a false assumption to support its payer mix argument that DaVita expects 12% of its Colville patients would have insurance/HMO coverage. DaVita does not use a company-wide payer mix to project revenues. DaVita's revenue is projected using a blended revenue-per-treatment factor that was developed internally by referencing actual performances at other DaVita facilities.

- FMC argues that DaVita's projected revenue assumes a greater revenue-per-treatment amount than FMC obtains in Colville. FMC fails to provide any supporting information to support its assertions.

The Department's Response

INRCG did not provide documentation to show that DaVita's application contains unrealistic and unachievable payer mix. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. Under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment. That rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary. Even if two different dialysis providers billed the same commercial payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services.

Given the department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by DaVita may not have an unreasonable impact on charges for services within the planning area. Based on the review of the application materials, the department concludes t**his sub-criterion is met.**

(3) The project can be appropriately financed.

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.

DaVita's capital expenditure associated with the establishment of the six stations DaVita Colville Dialysis Center is $1,312,865. DaVita stated the project will be funded from its own reserves and a letter from the applicant's chief operating officer was provided confirming that corporate funding is available to fund the project. [Source: Application, Appendix 6] Further, a review of DaVita's audited financial statements shows the funds necessary to finance the project are available. [Source: Application, Appendix 6 and 10] Based on the information provided, the department concludes that the project 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 and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc. project has met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

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 (full time equivalents) that should be employed for projects of this type or size.

Since DaVita Colville Dialysis Center would be a new facility, DaVita provided a breakdown of the proposed staff for years 2014 through 2016. [Source: Application, Page 23] A breakdown of the proposed staff is summarized in the Table 8.

Table 8
DaVita Colville Dialysis Center proposed FTE's Years 2014 – 2016

Staff/FTEs	Year 1 2014	Year 2 2015	Year 3 2016	Total FTEs
Medical Director	Professional Services Contract			
Administrator	1.0	0.0	0.0	1.0
Registered Nurses	1.3	0.3	0.5	2.1
Patient Care Tech	1.0	0.3	0.5	1.8
Biomedical Tech	0.2	0.0	0.0	0.2
Admin Assistant	0.5	0.3	0.2	1.0
Social Worker	0.5	0.0	0.3	0.8
Dietician	0.5	0.0	0.3	0.8
LVN	0	0.0	0.0	0.0
Number of FTE'S	**5.0**	**0.9**	**1.8**	**7.7**

As shown above, DaVita expects to open with 5.0 FTE's and it would add FTEs as volume grow. DaVita stated it does not anticipate any difficulty recruiting staff because it offers competitive wage and benefit package to employees. Additionally, DaVita states that job openings are posted nationally and internally and it has extensive employee travelling program that guarantee it will maintain staffing at its facilities. [Source: Application, Page 23]

DaVita identified Petru Groza, MD as the medical director for DaVita Colville Dialysis Center and provided an executed medical director's agreement between Total Renal, Inc. ("Company"), and Providence Physician Services Co., d/b/a Providence Medical Group Eastern Washington ("Group"), and Petru Groza, MD, ("Physician"). [Source: Application, Page 7 and Appendix 3] The medical director agreement outlines the roles and responsibilities of the Company, Group, and Physician. The agreement also identifies the annual compensation for the medical director and the applicant's pro-forma financial statement shows the medical director compensation.

Based on the information provided the department concludes that sufficient staffing is available or can be recruited. **This sub-criterion is met.**

(2) *The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.*

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.

As a provider of dialysis services in Washington State, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers.

For the proposed DaVita Colville Dialysis Center, 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. Additional services are coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [Source: Application, Page 23]

DaVita stated because the Colville dialysis center would be a new facility in Stevens County, transfer agreements will be established with a local healthcare provider before the facility becomes operational. To further demonstrate compliance with this sub-criterion, DaVita provided a sample transfer agreement and stated, *"Without an operating facility, actual transfer agreement with specifics cannot be executed"*. [Source: Application Page 24, and Appendix 12]

Based on this information, the department concludes DaVita currently has access to the necessary ancillary and support services that could support the proposed facility. If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed transfer agreement with a local hospital that is consistent with the example presented in the application. **With the condition, this sub-criterion is met.**

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

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.

As stated within this evaluation, DaVita is a provider of dialysis services in approximately 1,912 facilities located in 43 states (including Washington State) and the District of Columbia. DaVita also provides acute inpatient kidney dialysis services in over 720 hospitals throughout the country. [Source: Application, Page 1] In Washington State, DaVita owns or operates 31 kidney dialysis facilities in 14 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.[12] To comply with this sub-criterion, DaVita provided a contact list of the regulatory agencies responsible for surveying its out-of-state facilities and the District of Columbia. [Source: Application, Appendix 2] In February 2010, the department requested quality of care compliance history from out-of-state licensing and/or surveying entities and the District of Columbia where DaVita or any subsidiaries have health care facilities.

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

Of the 42 states and entities, the department received responses from 21 states or 50% of the 42 states.[13] The compliance history of the remaining 21 states and the District of Columbia is unknown.[14] Five of the 21 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 that decertified and later reopened, none of the deficiencies is reported to have resulted in fines or enforcement action.[15] All other facilities are reported to be currently in compliance with applicable regulations. [Source: compliance history from state licensing and/or surveying entities] The department concludes that considering the more than 1,642 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 2010, the Department of Health's Investigations and Inspections Office has completed 26 compliance surveys for the operational facilities that DaVita either owns or manages.[16] Of the compliance surveys completed, there were minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues are 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]

For medical director services, DaVita provided an executed copy of its medical director agreement with Petru Groza, MD, who is part of Providence Physician Services Co., d/b/a Providence Medical Group Eastern Washington. Four other physicians are part of the practice and according to the medical director agreement, may provide backup services if necessary. The department's review of the compliance history for Dr. Petru Groza, Dr. Henry Mrock, Dr. Nelson Chow, Dr. Vijayakkumar Reddy and Dr. Krishna Malireddi revealed no recorded sanctions or license restrictions.

Based on the compliance history of DaVita and the five physicians, the department concludes that there is reasonable assurance the proposed DaVita Colville Dialysis Center would operate in conformance with state and federal regulations. **This sub-criterion is met.**

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[13] States that provided responses are: California, Colorado, Connecticut, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nevada, New Mexico, North Dakota, Ohio, Oregon, South Carolina, Tennessee, South Dakota and West Virginia

[14] States that did not provide responses are Alabama, Arizona, Arkansas, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Texas, Utah, Virginia and Wisconsin. The department did not send survey to itself. The District of Columbia did not respond to the survey.

[15] 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.

[16] At the time of writing this evaluation, Battle Ground, Kennewick, Renton, and Zillah dialysis centers are CN approved, but not yet operational.

(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.

In its response to this sub-criterion, DaVita provided a summary of the quality and continuity of care indicators used by its quality improvement program. DaVita's quality of care program shows it incorporates all areas of its dialysis program by monitoring and evaluating all activities related to clinical outcomes, operations management and process flow.

Further, DaVita also provided examples of its quality index data and its physician, community, and patient services program known as 'Empower'. Additionally, DaVita also provided a sample draft transfer agreement and stated, *"Without an operating facility, actual transfer agreement with specifics cannot be executed"*. [Source: Application, Page 24, and Appendix 12] If this project is approved, the department would include a condition requiring DaVita to provide a copy of its ancillary and support services agreement with a local healthcare provider.

Based on the information, the department concludes the applicant has demonstrated it will have appropriate relationships with a health care provider in the planning area. **With the condition, this sub-criterion is met**

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

For this project, 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 and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s project has met the cost containment criteria in WAC 246-310-240

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

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 assess 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.

Step One
DaVita's proposal to establish a new 6-station dialysis facility in Stevens County has met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two.

Step Two
Before submitting this project, DaVita considered the option of establishing a new 7 or 8 station facility in Stevens County using stations from adjacent county. Summarized below is the option DaVita considered and rejected. [Source: Application, Pages 26 and 27]

Establish a new 7 or 8 station facility
DaVita considered establishing either a 7 or 8 station facility in Colville to serve patients in Stevens and Ferry counties two separate planning areas, but it rejected this option because it anticipated this would lead to delays in approval and implementation of the proposed project. Having rejected this option, DaVita submitted application to establish a new 6-station facility Stevens County.

Given that FMC Colville the existing facility current utilization exceeds 3.2 patients per station, and the result of the numeric methodology show a need for 6 stations in Stevens County, the department concludes the application submitted by DaVita is the best available alternative for the planning area. **This sub-criterion is met.**

Step Three
This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted to add dialysis stations in Stevens County ESRD planning area during the Kidney Disease Treatment Centers Review Cycle #4. This step is not applicable to the project.

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

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

WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable. However, the department, through its experience knows that construction projects are usually built to exceed these minimum standards. Therefore, the department considered information in the applications that addressed the reasonableness of their construction projects that exceeded the minimum standards.

DaVita proposes to lease a "built to suit" facility from a real estate developer. DaVita stated the scope and methods of the facility would meet Medicare certification and the local authority construction and energy conservation code. The cost the developer would incur to construct the proposed dialysis facility is reflected in the negotiated sale and purchase lease agreement provided by DaVita. The proposed property lease costs were evaluated in the financial feasibility section of this analysis. Within this evaluation, the department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes **this sub-criterion is met**.

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

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes **this sub-criterion is met.**

APPENDIX A

Washington State Department of Health

2012
Stevens County
ESRD Need Projection Methodology

	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	Stevens	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
	Stevens	11	15	21	21	26	29
	TOTALS	11	15	21	21	26	29
246-310-284(4)(a)	**Rate of Change**		36.36%	40.00%	0.00%	23.81%	11.54%
	6% Growth or Greater?		TRUE	TRUE	FALSE	TRUE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2012	Year 2 2013	Year 3 2014	**Year 4 2015**
Projected Resident Incenter Patients	from 246-310-284(4)(b)			32.30	35.60	38.90	42.20
Station Need for Patients	**Divide Resident Incenter Patients by 3.2**			10.0937	11.1250	12.1562	13.1875
	Rounded to next whole number			**11**	**12**	**13**	**14**
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				8	8	8	8
Results of (4)(c) above			-	11	12	13	14
Net Station Need				-3	-4	-5	-6
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	**# of Stations**	**Patients**	**Utilization (Patients per Station)**				
FMC Colville	8	28	3.50				
Total	8	28					

Source: Northwest Renal Network data 2006-2011
Most recent year-end data: 2011 year-end data as of 02/13/2012
Most recent quarterly data as of the 1st day of application submission period: 3rd quarter 2012 as of 10/29/2012

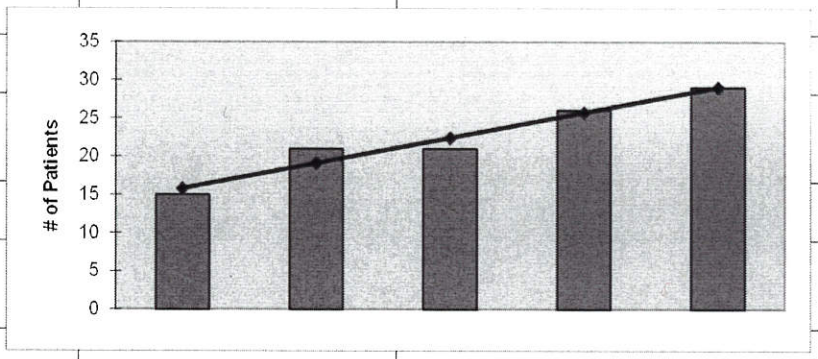
Prepared by Mark Thomas

246-310-284(4)(a),(c),(d),(5)

Washington State Department of Health

2012
Stevens County
ESRD Need Projection Methodology

x	y	Linear
2007	15	**16**
2008	21	**19**
2009	21	**22**
2010	26	**26**
2011	29	**29**
2012		**32.300**
2013		**35.600**
2014		**38.900**
2015		**42.200**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.972271824
R Square	0.9453125
Adjusted R Square	0.927083333
Standard Error	1.449137675
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	108.9	108.9	51.85714286	0.005519519
Residual	3	6.3	2.1		
Total	4	115.2			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-6607.3	920.6396852	-7.176857685	0.005573357	-9537.186364	-3677.41364	-9537.186364	-3677.41364
X Variable 1	3.3	0.458257569	7.201190378	0.005519519	1.841619891	4.758380109	1.841619891	4.758380109

RESIDUAL OUTPUT

Observation	*Predicted Y*	*Residuals*
1	11.6	-0.6
2	15.2	-0.2
3	18.8	2.2
4	22.4	-1.4
5	26	0

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246-310-284(4)(a),(c),(d),(5)