State of Washington
Department of Health

June 3, 2015

CERTIFIED MAIL # 7011 1570 0002 7808 8188

Ann Sullivan, MHA, BSN, RN
Area Manager-Washington Capital
Fresenius Medical Care
719 Sleater Kinney Road, Suite 152
Lacey, WA 98503

RE: CN15-03A

Dear Ms. Sullivan:

We have completed review of the Certificate of Need (CN) application submitted by Fresenius Medical Care proposing to construct a new 6-station facility in Lewis County. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the application proposing to construct 6 station facility in Lewis submitted by Fresenius Medical Care is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

Cost Containment	WAC 246-310-240

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:
You or any interested person, or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560.

A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

Mailing Address:	Physical Address
Janis Sigman, Manager	Department of Health
Certificate of Need Program	Certificate of Need Program
Department of Health	111 Israel Road SE
Mail Stop 47852	Tumwater, WA 98501
Olympia, WA 98504-7852	

Appeal Option 2:
You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:	Physical Address
Adjudicative Service Unit	Adjudicative Clerk Office
Mail Stop 47879	311 Israel Road SE, Building 6
Olympia, WA 98504-7879	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, Community Health Systems

Enclosure

EXECUTIVE SUMMARY

EVALUATION DATED JUNE 3, 2015 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO LEWIS COUNTY:

- **FRESENIUS MEDICAL CARE HOLDINGS INC. ON BEHALF OF RENAL CARE GROUP NORTHWEST, INC. PROPOSING TO ESTABLISH A SIX STATION KIDNEY DIALYSIS FACILITY IN MORTON**
- **DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ESTABLISH A SIX STATION DIALYSIS CENTER IN CENTRALIA**

BRIEF PROJECT DESCRIPTIONS

Fresenius Medical Care Holdings, Inc.

Fresenius Medical Care Holding, Inc. (FMC) currently operates the only dialysis facility operating in the Lewis County Dialysis Planning Area. FMC Chehalis has 12 stations and is located in the city of Chehalis within Lewis County. FMC is seeking to relocate its twelve dialysis stations to an updated facility with improved technology. This facility will continue to be located in city of Chehalis.

This current application from Fresenius Medical Care Holdings, Inc.[1] (Fresenius) on behalf of Renal Care Group Northwest, Inc. (RCGNW) proposes to establish a new six station facility in the city of Morton to serve resident of Lewis County. Services proposed to be provided at the Fresenius Morton Dialysis Center include in-center hemodialysis, backup dialysis service, isolation station, home hemodialysis and home peritoneal training, and permanent bed station. [Source: Application, p14]

If this project is approved, Fresenius anticipates the stations would be available by July 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation with six stations and 2019 would be year three. [Source: Application, Face Page & p15]

The total capital expenditure associated with this project is $3,113,056. The applicant's approved capital expenditure will be $436,916. Of that total amount 12.1% is related to equipment; 0.9% for sales tax. The remaining 87.0% ($2,707,985) is related to the landlord's portion of the costs. [Source: Application, p27 & 28]

DaVita HealthCare Partners, Inc.

DaVita HealthCare Partners, Inc. (DaVita) proposes to establish a new six station dialysis facility in the Lewis County dialysis planning area. The DaVita Centralia Dialysis Center would be located at 1821 Cooks Hill Road in the city of Centralia within Lewis County. This dialysis center would provide in-center dialysis, peritoneal dialysis training, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station, hemodialysis patients requiring treatment shifts that begin after 5:00 pm, back-up dialysis services for home dialysis patients, home hemodialysis and home peritoneal training, support for patients for all forms of home dialysis, and visiting patient hemodialysis. [Source: Application: p2 & 3]

If this project is approved, DaVita anticipates the station would be available by April 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation and 2019 would be year three. [Source: Application, p13]

---

[1] Throughout this analysis, Fresenius will be used interchangeably with Fresenius Medical Care Holdings, Inc. and RCGNW.

The total capital expenditure associated with this project is $2,323,087. The applicant's approved capital expenditure will be $1,394,299. Of that total amount 37% is related to construction; 20% for moveable equipment; 3% for professional fees. The remaining 40% ($1,928,788) is related to the landlord's portion of the costs. [Source: Application, p9]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they either establish 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) or they increase the number of dialysis stations in a kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

CONCLUSIONS

Fresenius Medical Care Holdings, Inc. on behalf of Renal Care Group Northwest

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care Holdings, Inc. on behalf of Renal Care Group Northwest proposing to establish six station dialysis facility in Morton within Lewis County is not consistent with applicable criteria and a Certificate of Need is denied.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita Health Care Partners, Inc. proposing to establish six station dialysis facility in Centralia within Lewis County is not consistent with applicable criteria and a Certificate of Need is denied.

EVALUATION DATED JUNE 3, 2015 OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO LEWIS COUNTY:

- **FRESENIUS MEDICAL CARE HOLDINGS INC. ON BEHALF OF RENAL CARE GROUP NORTHWEST, INC. PROPOSING TO ESTABLISH A SIX STATION KIDN EY DIALYSIS FACILITY IN MORTON**
- **DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ESTABLISH A SIX STATION DIALYSIS CENTER IN CENTRALIA**

APPLICANT DESCRIPTION

Fresenius Medical Holdings, Inc. (Fresenius)[2]

Renal Care Group Northwest is one of three entities owned by Renal Care Group, Inc. (RCG). RCGNW is responsible for the operation of facilities under four separate legal entities. These four entities are Pacific Northwest Renal Services, Renal Care Group of the Northwest, Inland Northwest Renal Care Group and Renal Care Group of Alaska. On March 31, 2006, thorough stock acquisition, Fresenius Medical Care Holdings, Inc. (FMC) became the sole owner of Renal Care Group, Inc., and its subsidiaries. Listed below are the five entities owned by FMC. [Source: Amended Application, page 3; CN Historical files]

QualiCenters Inc.
Inland Northwest Renal Care Group, LLC
National Medical Care, Inc.
Pacific Northwest Renal Services
Renal Care Group Northwest, Inc.

In Washington State, Fresenius or one of its four subsidiaries owns, operates or manages 19 kidney dialysis facilities in 14 separate counties. Below is a listing of the 19 facilities in Washington. [Application: p3-6]

Adams County
Fresenius Leah Layne Dialysis Center

Benton County
Columbia Basin Dialysis Center

Clark County
Battleground Dialysis Facility
Fresenius Fort Vancouver Dialysis Facility
FreseniusSalmon Creek Dialysis Facility

Lewis County
Fresenius Chehalis Dialysis Facility

Grant County
Fresenius Moses Lake Dialysis Facility

Spokane County
Fresenius Northpointe Dialysis Facility
Fresenius Spokane Kidney Center
Fresenius North Pines Dialysis Facility
Fresenius Panorama Dialysis Facility

Mason County
Fresenius Shelton Dialysis Center

Okanogan County
Fresenius Omak Dialysis Facility

Stevens County
Fresenius Colville Dialysis Facility

Thurston County
Fresenius Lacey Dialysis Center
Thurston County Dialysis Center

[2] Throughout this analysis, Fresenius will be used interchangeably with Fresenius Medical Care Holdings, Inc. and RCGNW.

Cowlitz County
Fresenius Longview Dialysis Facility

Grays Harbor County
Fresenius Aberdeen Dialysis Facility

Walla Walla County
QualiCenters Walla Walla

DaVita

In late 2010, DaVita, Inc. a for-profit end stage renal care provider was acquired by HealthCare Partners Holding, Inc. To reflect the combination of the two companies, DaVita, Inc. changed its name to DaVita HealthCare Partners Inc. Throughout this evaluation, DaVita HealthCare Partners Inc. will be referenced as 'DaVita.' [Source: CN historical files]

DaVita Healthcare Partners, Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 2,119 outpatient centers located in the United States. [Source: 2nd Amendment Application, p6-7; CN historical files]

In Washington State, DaVita owns or operates a total of 38 kidney dialysis facilities in 18 separate counties. Below is a listing of the DaVita facilities in Washington. [Source: 2nd Amendment Application & CN historical files]

Benton
Chinook Dialysis Center
Kennewick Dialysis Center

Chelan
Wenatchee Valley Dialysis Center

Clark
Vancouver Dialysis Center
Battle Ground Dialysis Center

Douglas
East Wenatchee Dialysis Center

Franklin
Mid-Columbia Kidney Center

Island
Whidbey Island Dialysis Center

King
Bellevue Dialysis Center
Federal Way Dialysis Center
Federal Way Dialysis Center

Pacific
Seaview Dialysis Center

Pierce
Graham Dialysis Center
Lakewood Dialysis Center
Parkland Dialysis Center
Puyallup Dialysis Center
Rainer View Dialysis Center
Tacoma Dialysis Center

Skagit
Cascade Dialysis Center

Snohomish
Everett Dialysis Center[3][4]
Mill Creek Dialysis Center
Pilchuck Dialysis Center

Spokane
Downtown Spokane Renal Center
North Spokane Renal Center
Spokane Valley Renal Center

[3] Refuge Dialysis, LLC, whose ownership is 80% DaVita and 20% The Everett Clinic, owns this facility.
[4] Pilchuck Dialysis Center is also owned by Refuge Dialysis, LLC and managed by DaVita

Kent Dialysis Center
Olympic View Dialysis Center (management only)
Redondo Heights Dialysis Center
Westwood Dialysis Center

Kittitas
Ellensburg Dialysis Center

Mason
Belfair Dialysis Center

Stevens
Echo Valley Dialysis Center

Thurston
Olympia Dialysis Center
Tumwater Dialysis Center

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

PROJECT DESCRIPTION

Fresenius

Fresenius Medical Care Holding, Inc. (FMC) currently operates the only dialysis facility operating in the Lewis County Dialysis Planning Area. FMC Chehalis has 12 stations and is located in the city of Chehalis within Lewis County. FMC is seeking to relocate its twelve dialysis stations to an updated facility with improved technology. This facility will continue to be located in city of Chehalis.

This current application from Fresenius Medical Care Holdings, Inc.[5] (Fresenius) on behalf of Renal Care Group Northwest, Inc. (RCGNW) proposes to establish a new six station facility in the city of Morton to serve resident of Lewis County. Services proposed to be provided at the Fresenius Morton Dialysis Center include in-center hemodialysis, backup dialysis service, isolation station, home hemodialysis and home peritoneal training, and permanent bed station. [Source: Application, p14]

If this project is approved, Fresenius anticipates the stations would be available by July 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation with six stations and 2019 would be year three. [Source: Application, Face Page & p15]

The total capital expenditure associated with this project is $3,113,056. The applicant's approved capital expenditure will be $436,916. Of that total amount 12.1% is related to equipment; 0.9% for sales tax. The remaining 87.0% ($2,707,985) is related to the landlord's portion of the costs. [Source: Application, p27 & 28]

DaVita

DaVita HealthCare Partners, Inc. (DaVita) proposes to establish a new six station dialysis facility in the Lewis County dialysis planning area. The DaVita Centralia Dialysis Center would be located at 1821 Cooks Hill Road in the city of Centralia within Lewis County. This dialysis center would provide in-center dialysis, peritoneal dialysis training, hemodialysis for patients requiring isolation, hemodialysis for patients requiring a permanent bed station, hemodialysis patients requiring treatment shifts that begin after 5:00 pm, back-up dialysis services for home dialysis patients, home hemodialysis and home peritoneal training, support for patients for all forms of home dialysis, and visiting patient hemodialysis. [Application: p2 & 3]

[5] Throughout this analysis, Fresenius will be used interchangeably with Fresenius Medical Care Holdings, Inc. and RCGNW.

If this project is approved, DaVita anticipates the station would be available by April 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation and 2019 would be year three. [Source: Application, p13]

The total capital expenditure associated with this project is $2,323,087. The applicant's approved capital expenditure will be $1,394,299. Of that total amount 37% is related to construction; 20% for moveable equipment; 3% for professional fees. The remaining 40% ($1,928,788) is related to the landlord's portion of the costs. [Source: Application, p9]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they either establish 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) or they increase the number of dialysis stations in a kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for the application. WAC 246-310-200(2) provides additional direction in 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 the 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 CN approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment) and any service/facility specific criteria and standards linked to these four criteria. WAC 246-310 contains specific kidney dialysis specific criteria and standards. These are contained in WAC 246-310-280 through 289. These facility specific criteria and standards must be used to make the required determinations.[6]

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted these two projects under the year 2014 Kidney Disease Treatment Centers-Concurrent Review Cycle #3.

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. In the case of the projects submitted by Fresenius and DaVita, the department will issue one single evaluation regarding whether one, all, or neither of the projects should be issued a CN.

APPLICATION CHRONOLOGY

Below is a chronologic summary of the projects.

Action	Fresenius	DaVita Inc.
Letter of Intent Submitted	July 31, 2014	July 31, 2014
Amended Application Submitted	October 16, 2014	October 15, 2014
Department's pre-review Activities		
• Department screening letter sent	October 31, 2014	
• Fresenius Screening responses received	November 26, 2014	
• DaVita HealthCare Partners screening responses received	November 26, 2014	
Beginning of Review	December 16, 2014	
End of Public Comment • No public hearing conducted • Public comments accepted through end of public comment	February 17, 2015	
Rebuttal Comments Received	March 19, 2015	
Department's Anticipated Decision Date	May 4, 2015	
Department's Actual Decision Date	June 3, 2015	

[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); WAC 246-310-240(3), and WAC 246-310-287, and 289.

AFFECTED 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 each application, the other applicant sought and received affected person status under WAC 246-310-010. No other entities sought and received affected person status for the other project.

SOURCE INFORMATION REVIEWED

- Fresenius's Amended Certificate of Need application submitted October 16, 2014
- DaVita HealthCare Partners Inc.'s Amended Certificate of Need application submitted October 15, 2014
- Fresenius's supplemental information November 26, 2014
- DaVita HealthCare Partners Inc.'s supplemental information submitted November 26,2014
- Public comment submitted prior to end of public comment period
- Fresenius's rebuttal submitted March 19, 2015
- DaVita HealthCare Partners Inc.'s Rebuttal submitted March 19, 2015
- Years 2008 through 2013 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2014 Northwest Renal Network 3rd Quarter Utilization Data available July 31, 2014
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Data obtained from Fresenius's webpage
- Data obtained from DaVita, Inc.'s webpage
- Data obtained from Medicare webpage (www.medicare.gov)
- Certificate of Need historical files

CONCLUSIONS

Fresenius Medical Care Holdings, Inc. on behalf of Renal Care Group Northwest

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care Holdings, Inc. on behalf of Renal Care Group Northwest proposing to establish six station dialysis facility in Morton within Lewis County is not consistent with applicable criteria and a Certificate of Need is denied.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita Health Care Partners, Inc. proposing to establish six station dialysis facility in Centralia within Lewis County is not consistent with applicable criteria and a Certificate of Need is denied.

CRITERIA DETERMINATION

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

Based on the source information provided and reviewed, the department concludes:

- Fresenius'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 246-310-284; and
- DaVita, 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 246-310-284.

(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 requires the department to evaluate kidney disease treatment centers applications based on the populations 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 under 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.[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.[8] 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,

[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]

[8] 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." For this project, the base year is 2013.

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)]

Fresenius's Application of the Numeric Methodology

Fresenius proposes to establish a new six station dialysis facility to be located in Morton. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was applied to project need. Given that the Morton dialysis center is located in Lewis County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, p20]

DaVita's Application of the Numeric Methodology

DaVita proposes to establish a six station dialysis facility located in the city Centralia within Lewis County. Based on the calculation of the annual growth rate in the planning area as described above, DaVita used the same linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, pp17-19]

Department's Application of the Numeric Methodology

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

The table below shows a summary of the projected net need provided by the applicants and the department for Lewis County. The complete methodology is attached as appendix A.

Table 1
Summary of Lewis County Projected 2017 Station Need

	Projected # of Stations	Current # of Stations	Net Need
Fresenius	18	12	6
DaVita	18	12	6
DOH	18	12	6

The table above demonstrates the projections of the two applicants match the department's figures. As a result, the net station need for Lewis County is six.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations are 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 for these projects was August 1, 2014. [WAC 246-310-282] The quarterly modality report from NRN available at that time was June 30, 2014, which was available July 31, 2014. For Lewis County there are 12 stations located in the Chehalis facility. The table below shows the reported utilization of the stations in Lewis County.

Table 2
June 30, 2014 - Facility Utilization Data

Facility Name	# of Stations	# of Pts.	Pts./Station
Fresenius-Chehalis Dialysis Facility	12	59	4.92

The table above demonstrates that the current facility satisfies this utilization requirement. **This sub-criterion is met.**

WAC 246-310-284(6)
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 Lewis County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, the applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Fresenius anticipates their six new stations would become operational by July 2016 and DaVita anticipates their six new stations would become operational by April 2016. Under this timeline, year 2017 would be the first full calendar year of operation for Fresenius and DaVita and 2019 would be the third full year of operation. A summary of the two applicants' projected utilization for their respective third year of operation is shown in the table below. [Source: Fresenius Application, p24; & DaVita Application, p17]

Table 3
Third Year (2019) Projected Facility Utilization[9]

Facility Name	# of Stations	# of Pts.	Pts./Station
FMC Morton	6	34	5.67
DaVita Centralia	6	29	4.83

Public Comment
DaVita states that FMC proposes an extremely remote and isolated site. DaVita asserts that the Fresenius project will place 100 percent of the new Lewis County stations in a location that lacks convenient access for more than 90% of Lewis County dialysis patients. DaVita asserts that Fresenius has substantially overstated it projected patient census, revenues, and expenses.

Rebuttal
Fresenius states that the Morton facility will serve patients not currently served by their Chehalis dialysis facility. They would serve patients living more than 10 miles from the I-5 corridor and would improve accessibility of dialysis services to residents of Lewis County.

Department Evaluation

[9] Fractional numbers for patients per station are not rounded up.

Fresenius provided a table listing the zip codes located within a 10 mile radius of Morton. The applicant stated that four dialysis patients are located within these zip codes. The table below shows this data with the city located in the zip code added by the department.

Table 4
Current Lewis County Dialysis Patients

Zip Codes	City	HD	IPD
98336	Glenona	1	0
98356	Morton	1	0
98564	Mossy Rock	2	0
98585	Silver Creek	0	0
Total		**4**	**0**

Source: Application, p4 & Washington State County Code Listing

The table above based on 3rd quarter data from Northwest Renal Network shows that 4 of 59 or 7% of the current patients live within 10 miles of Morton. The applicant is proposing to have 24 dialysis patients at the Morton facility by 2017 and 34 patients by 2019. While the projections support this number of patients, it is reasonable to assume only 7% of the new patients would be within 10, miles of Morton, less than 2 patients in 2017 and less than 3 patients in 2019. The rest of the patient growth would be expected to occur along the I-5 corridor as shown in Table 5.

Table 5
Current Lewis County Dialysis Patients

Zip Codes	City	HD	IPD
98531	Centralia	23	0
98532	Chehalis	13	0
98591	Toledo	3	0
98570	Winlock	5	0
98565	Napavine	1	0
Total		**45**	**0**

The table above also uses 3rd quarter data from Northwest Renal Network to allow comparison with the applicant's data in Table 4. The Chehalis facility reports 59 patients for the 2nd and 3rd quarter of 2014. The table above is based on 3rd quarter data indicates that 45 of the 59 patients or 76 % of the dialysis patients reside on the I-5 corridor. These patients are at least 20 miles or more from the Morton facility. In order for the Morton facility to reach its projected utilization the department concludes that some of these patients, possibly as many as 20 patients, would have to commute to the Morton facility to receive dialysis services. This does not improve accessibility for dialysis patients in Lewis County and could create a hardship and additional personal expense for these patients. It appears from this that for the first year the Morton facility will need to absorb all the new dialysis patients and draw some patients from the existing facility in Chehalis. The department concludes that since Fresenius is the only dialysis provider in Lewis County, they will be able to direct the dialysis patients to which ever facility needs to improve their patient census.
As shown in the table above the department concludes this sub-criterion **is met for both Fresenius and DaVita.**

(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.

Fresenius

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of Lewis County planning area 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, Fresenius provided a copy of its current Admission Criteria that will be used at the facility. The Admission Criteria outlines the process/criteria that the Lewis County dialysis center will use to admit patients for treatment, and ensure that patients will receive appropriate care at the dialysis center. The Admission Criteria also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, religion, sex, national origin, or age. [Source: Application, pp16 & 25, Exhibit 14]

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. Fresenius currently provides services to Medicare eligible patients in their existing Chehalis dialysis center. Details provided in the application demonstrate that Fresenius intends to maintain this status the proposed new facility. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [Source: Application, p25 & Exhibit 12]

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. Fresenius currently provides services to Medicaid eligible patients in their Chehalis dialysis center. Details provided in the application demonstrate that Fresenius intends to maintain this status at the new dialysis facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Application, pp 16, 25 & Exhibit 14]

Fresenius demonstrated its intent to provide charity care by submitting the Charity Care policy currently used by their existing dialysis facilities. It outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. Fresenius also included a 'charity' line item as a deduction from revenue within the pro forma income statements for proposed facility. [Source: Application, pg. 25 and Exhibit 13] The department concludes, **this sub-criterion is met**.

DaVita

As previously stated, DaVita currently provides health care services to residents of Washington State. To determine whether all residents of Lewis County dialysis planning area 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 its proposed Admission Criteria that would be used at the facility. The Admission Criteria outlines the process/criteria that DaVita Centralia dialysis facility would use to admit patients for treatment, and ensure that patients will receive appropriate care at the dialysis center. The Admission Criteria also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, religion, sex, national origin, or age. [Source: Application, p20 & Appendix 14]

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 in their dialysis centers. Details provided in the application demonstrate that DaVita intends to be Medicare certified at its proposed new facility. A review of the anticipated revenues indicates that the facility expects to receive Medicare reimbursements. [Source: Application, p20 & Appendix 14]

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 in their dialysis centers. Details provided in the application demonstrate that DaVita intends to be Medicaid certified at the new facility. A review of the anticipated revenue indicates that the facility expects Medicaid reimbursement at the proposed new facility. [Source: Application, p20 & Appendix 14]

DaVita demonstrated its intent to provide charity care by submitting the Charity Care policy proposed for the new facility. It outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. DaVita also included a 'charity' line item as a deduction from revenue within the pro forma income statements for their proposed facility. [Source: Application, p20 & Appendix 14] The department concludes **this sub-criterion is met.**

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

Based on the source information provided and reviewed the department concludes:

- Fresenius's project has met the financial feasibility criteria in WAC 246-310-220; and
- DaVita, Inc.'s project has not met the financial feasibility criteria in WAC 246-310-220.

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

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.

Fresenius

Fresenius anticipates the new six station Morton Dialysis Center will become operational by July 2016. Based on this timeline, fiscal year (FY) 2017 would be the facility's first full year of operation. Using the financial information provided as part of the completed application, the table below illustrates the projected revenue, expenses, and net income for FY 2017 through 2019 for the Fresenius Morton Dialysis Center. [Source: November 28, 2014 Supplemental Material, Revised Exhibit 14]

Table 6
Fresenius-Morton Dialysis Center
Projected Revenue and Expenses Fiscal Years 2017 - 2019[10]

	FY 1 - 2017	FY 2 - 2018	FY 3 - 2019
# of Stations	6	6	6
# of Treatments [1]	3,456	4,608	4,896
# of Patients [1]	24	32	34
Utilization Rate [1]	4.0	5.33	5.67
Net Patient Revenue [3]	$2,096,530	$2,583,426	$2,705,150
Total Operating Expense [2,3]	$1,637,757	$1,937,181	$2,013,461
Net Profit or (Loss)	$458,773	$646,245	$691,689

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

As shown in the table above, at the projected volumes identified in the application, Fresenius anticipates that the Fresenius Morton Dialysis Center would be operating at a profit in all three years.

Public Comment

DaVita states that FMC proposes an extremely remote and isolated site. DaVita asserts that the Fresenius project will place 100 percent of the New Lewis County stations in a location that lacks convenient access for more than 90% of Lewis County dialysis patients. DaVita asserts that Fresenius has substantially overstated it projected patient census, revenues, and expenses.

[10] Whole numbers may not add due to rounding.

Rebuttal

Fresenius states that their patient count projections are reasonable and reliable. They commented that "DVA claims FMC patient count projections also are unrealistic in comparison with our projections for a new Lewis County facility." [Source: March 19, 2015 Fresenius Rebuttal, p11 DVA Position Paper p7] Fresenius states that examination of this statement reveals that DVA's only evidence to critique FMC's patient count are its own unsubstantiated patient count projections. Fresenius stated in their supplemental materials that the a key reason for selecting the city of Morton is to provide improved dialysis access to a growing population of residents over the age of 65, the age cohort with the highest prevalence of dialysis. According to Fresenius this age group is growing by 2.88% per year over the period 2010 to 2020. Fresenius provided a table showing the current number of dialysis patients within a 10 mile commute radius of Morton. They reported a total of four in-center patients in the zip codes composing the area around Morton.

Department' Evaluation

The department has taken the same concept using a 10 mile and 20 mile radius with the population identified by green dots as shown in the map in Appendix B. This illustrates that the population density for the county is in excess of 20 miles from Morton. It further shows that even the population within the 10 to 20 mile range may actually be closer to dialysis services than if they were provided in Chehalis. The applicant notes that there are currently four in-center dialysis patients within 10 miles of Morton. Since Fresenius is the only dialysis provider in Lewis County the department concludes they will be able to coordinate which facility the patients will use to balance utilization. Based on the previous discussion the department also concluded that this has the potential to not improve access for the majority of dialysis patients in Lewis County. If patients have to come from the I-5 corridor to Morton for dialysis services it will not improve access to dialysis services. With a total of 77 dialysis patients projected for 2016 and the available capacity being 83 or greater there will be some impact on the Chehalis facility and patients.

The executed lease provided in the application is for 221 Knittles Way in the city of Morton. The lease provided in the supplemental materials outlines the initial terms and the annual rent for the space. The annual lease costs are substantiated in the pro forma financial documents presented. [Source: November 28, 2014 Supplemental Material, Revised Exhibit 7]

The draft medical director's agreement provided in the application is one that includes is consistent with the amount identified in the applicant's pro-forma income statement. If this project were approved, the department will include conditions requiring Fresenius to provide an executed medical director's agreement consistent with the draft agreement provided in the application.

Based on the source documents evaluated, the department concludes that Fresenius's projected revenues and expenses are reasonable. The department concludes that the patient projections are achievable, but patients will have to come from the I-5 corridor to achieve the utilization projections for the Morton facility. **This sub-criterion is met.**

DaVita

DaVita anticipates the new stations at DaVita Centralia will become operational by April 2016. Based on this timeline, fiscal year (FY) 2017 would be the facility's first full year of operation. Using the financial information provided in the application, the table below illustrates the projected

revenue, expenses, and net income for FY 2017 through 2019 for DaVita Centralia. [Source: Application: P11 & Screening Responses Appendix 9]

Table 7
DaVita's Centralia Dialysis Center
Projected Revenue and Expenses Fiscal Year 2015-2017

	FY1-2017	FY2-2018	FY3-2019
# of Stations	6	6	6
# of Treatments [1]	2890	3853	4520
# of Patients [1]	23	29	32
Utilization Rate [1]	3.83	4.83	5.33
Net Patient Revenue [3]	$1,501,965	$2,031,572	$2,445,879
Total Operating Expense [2,3]	$1,393,740	$1,658,700	$1,850,114
Net Profit or (Loss)	$108,225	$372,872	$595,765

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

As shown in the table above, at the projected volumes identified in the application, DaVita anticipates that the DaVita Centralia Dialysis Center will be operating at a profit for the first three years of operations.

The proposed DaVita Centralia Dialysis Center will be located at 1821 Cooks Hill Road in the city of Centralia, within Lewis County. The draft lease agreement provided in the application outlines the terms and the annual rent for the space for ten years after executing the lease. The annual lease costs are substantiated in the pro forma financial documents and the supporting least cost worksheet. [Source: Application Appendix 9 & 15]
The executed medical director's agreement is consistent with the amount identified in the applicant's pro-forma income statement. [Source: Application, Appendix 3 & 9]

Based on the source documents evaluated, the department concludes that DaVita's projected revenues and expenses are reasonable and can be substantiated. **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 WAC 246-310-220(2) 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 an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

<u>Fresenius</u>
The total capital expenditure for this project is $3,357,786. The CN approvable portion of the capital expenditure stated for the new six station Morton Dialysis Center is $436,916 of which 93% is related to moveable equipment and 7% for fixed equipment. The capital cost breakdown is shown in the table below. [Source: Application, p29]

Table 8
Estimated Capital Costs of Fresenius Morton Dialysis Center

Item	Cost	% of Total
Moveable Equipment	$405,302	93%
Sales Tax Moveable Equipment	$31,614	7%
Fresenius Total Capital Costs	**$436,916**	**100%**
Plus Landlord Project Costs	2,920,871	
Total Estimated Project Costs	**3,357,786**	

The landlord will incur costs of $2,920,871 for this project. These costs will be included in the lease expense for the facility.

Department's Evaluation

Fresenius's project will be the most costly project of the two projects being reviewed in this analysis. The applicant is proposing expansion space for three additional stations. Previously in this evaluation, the department concluded that the revenue and expenses proposed by the applicant probably can't be achieved without adversely affecting the patients at the existing Chehalis dialysis facility. Also meeting patient projections will place a hardship on patients required to make the long commute to the Morton facility.

The department recognizes that the majority of reimbursements for dialysis services are through Medicare End Stage Renal Disease (ESRD) entitlements. To further demonstrate compliance with this sub-criterion, Fresenius provided the following information to show the sources of revenue and the anticipated percentage of revenue from each source. [Source: Application, p16]

Table 9
Fresenius-Morton Dialysis Center

Projected Treatments by Payor			Percent of Total Revenue Calculated by the Department Using Revenue Projections in Pro Forma Income/Expense Statement
Payor	**% of Total Treatments**		
Medicare	64.0%		43.0%
Medicaid	4.2%		3.1%
Commercial	12.6%		33.4%
Other	19.2%		20.6%
Total	**100%**		**100%**[11]

As shown above, the Medicare and Medicaid treatments are projected to equal 68.2%. The payor mix supplied by the applicant indicates that these treatments produce 46.1% of the revenue. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS has recently implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, 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.

[11] Whole numbers may not add due to rounding

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 quality for Medicare payments, the department concludes that the information presented by Fresenius about its revenue may not have an unreasonable impact on charges for services within the planning area.

Based on the source documents evaluated, the department concludes the costs of this project will probably not result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is met.**

DaVita

The total capital expenditure associated with the new six station DaVita Centralia facility is $2,323,087. DaVita's share of the cost is $1,394,299 and the landlord's portion is $928,788. The capital cost breakdown is shown in the table below. [Source: Application, p9]

Table 10
Estimated Capitals Costs of DaVita Centralia Dialysis Center

Item	Cost	% of Total
Leasehold Improvements	$855,000	61.3%
Professional Service Fees	$72,250	5.2%
Movable and Fixed Equipment	$467,049	33.5%
DaVita Total Costs	**$1,394,299**	**100%**
Plus Landlord Project Costs	$928,788	
Total Estimated Capital Costs	**$2,323,087**	

Public Comment

Fresenius commented that DaVita is proposing a new six station dialysis facility for the Lewis County Dialysis planning area. Fresenius states that the proposed lease indicates that the center would be 6,000 sq. ft. and would require a total capital expenditure of $2,323,087. They state that while DaVita requests approval for only six stations the majority of the treatment area is reserved for future expansion space for an additional seven stations. Fresenius provided the following concerns regarding the project.

- DaVita does not indicate what space is allocated to its requested stations and what space is allocated for future expansion.
- The department can't evaluate the cost of the project since this is essentially construction of a 13 station facility.
- The cost per station is over $387,181 because of the lack of capital cost break-out.

Rebuttal

DaVita states that the cost of the project is not unreasonable and it is cost effective to construct the larger facility to anticipate growth. They state that the size of the facility will not have any impact on rates for insurance providers.

Department's Evaluation

DaVita intends to finance the project entirely from the DaVita capital expenditures budget. A review of the financial statement provided in the application indicates that DaVita had sufficient cash assets in both 2012 and 2013 to fund the project. [Source: Application, Appendix 10]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in the table below. [Source: Application, p11]

Table 11
Estimated Sources of Revenue and Patients by Payor
Based on DaVita "Company Wide"

Sources of Revenue By Payor Type	% of Revenue		Percentage of Patients by Payor	% of Patients
Medicare	56.7%		Medicare	78.9%
Medicaid/State	4.5%		Medicaid/State	7.7%
Insurance/HMO	38.8%		Insurance/HMO	13.4%
Total	**100%**		**Total**	**100%**

As shown above, the Medicare and Medicaid are projected to equal 61.2% of the revenue at the DaVita Centralia facility. DaVita use company-wide averages in projecting the payor mix for the new facility. This is a reasonable approach for a new facility. It however would not be appropriate for an expansion project. The department would expect the applicant to use a facility's actual breakdown.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the DaVita Centralia facility it's estimated that 86.6% of the patients will have either Medicare or Medicaid. CMS has recently implemented an ESRD PPS. Under the new ESRD PPS, 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.

In reviewing the line drawing supplied by DaVita, the project is a 13 station dialysis facility rather than a six station facility. The department has historically approved dialysis projects containing some shelled-in space for reasonable future expansion. This space has been intended to allow for cost effective expansions when a small number of stations become needed in a planning area. In this case the number of stations for expansion exceeds the needed stations by over two times. Also this expansion space is integral to the treatment space proposed for this project. The department generally views expansion space as a separate unfinished space that could be finished in the future for expansion. This project does not seem to fit this concept. It appears from the line drawing that the expansion space would need to be finished as part of this project. This expansion space will

need to be paid for by the costs and charges for dialysis treatments provided in the six stations until such time as an expansion would be approved. It does not seem cost effective to over build a project to this extent. The department concludes this project is overbuilt for the projected need in this dialysis planning area. As previously shown in Table 9, 13.4% of the treatments from non-Medicare/Medicaid patients generate 38.8% of the total revenue. This revenue is generated through negotiated rates with insurance providers or private patients. It is reasonable to expect these rates are higher than necessary to support the unnecessary capital and operating costs of this over built facility.

Based on the source documents evaluated, the department concludes the costs of this project will probably result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is not 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.

Fresenius

As previously stated, the capital expenditure associated with the expansion of Fresenius's Morton facility is $436,916. The project will be financed through the parent company, Fresenius. Fresenius provided a letter of financial commitment to the project. [Source: Application Exhibit 7] This source of financing is appropriate. Based on the source documents evaluated, the department concludes **this sub-criterion is met**.

DaVita

As previously stated, the capital expenditure associated with the expansion of DaVita's Centralia Dialysis Center is $1,394,299. DaVita states that the project will be funded from DaVita's capital expenditures budget. DaVita provided a letter of financial commitment to the project. [Source: Application, Appendix 6] This source of financing is appropriate. Based on source documents evaluated, the department concludes **this sub-criterion is met**.

Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information provided and reviewed, the department concludes:

- Fresenius's project has met the structure and process of care criteria in WAC 246-310-230; and
- DaVita, Inc.'s project has met the structure and process 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. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

Fresenius

Fresenius's Morton Dialysis Center is not operational at this time. To accommodate the additional patients associated with the additional station, Fresenius intends to start with 6.05 staff in 2016 and add 1.20 FTEs by the end of 2018. This will result in a total staff of 7.25 FTEs. A breakdown of the proposed FTEs is shown in the table below. [Source: Application p31]

Table 10
Fresenius Morton Dialysis Center 2016 – 2018 Projected Total FTEs

Staff/FTEs	Projected 2016	2017 Increase	2018 Increase	Total
Nurse Manager	1.20	0.05	0.00	1.25
RNs	1.80	0.10	0.10	2.00
Patient Care Tech	1.80	0.40	0.20	2.40
Equipment Tech.[12]	0.20	0.00	0.00	0.20
Social Worker	0.40	0.05	0.00	0.45
Dietitian	0.40	0.05	0.00	0.45
Clerical	0.25	0.25	0.00	0.50
Total FTE's	**6.05**	**0.90**	**0.30**	**7.25**

Fresenius expects to recruit staff from Lewis County as well as adjacent counties. Adjacent counties have relatively large numbers of health care professionals and RCG offers competitive wage and benefit packages. If necessary, they can relocate staff from FMC Chehalis or one of their other existing dialysis centers in Washington to staff on a temporary basis. [Source: Application: p32]

Based on source documents evaluated, the department concludes adequate staffing for the new six station Morton Dialysis Center is available or can be recruited. **This sub criterion is met.**

DaVita

DaVita's Centralia dialysis facility is not operational at this time. To accommodate the patients in the new facility, DaVita intends to start with 5.70 FTEs in 2017 and add 2.00 FTEs by 2019. This

[12] Includes BioMed

will result in a total staff of 7.70 FTEs. A breakdown of the proposed FTEs is shown in the table below. [Source: Application, p23 & 24]

Table 11
DaVita Tumwater Dialysis Center 2017 – 2017 Projected FTEs

Staff/FTEs	Start 7/1/2017	2018 Increase	2019 Increase	Total
Medical Director	Professional Services Contract			
Administrator	1.00	0.00	0.00	1.00
RNs	1.60	0.40	0.40	2.40
Patient Care Tech	1.30	0.60	0.50	2.40
Biomedical Tech	0.30	0.00	0.00	0.30
Clerical	0.50	0.00	0.10	0.60
MSW	0.50	0.00	0.00	0.50
Dietician	0.50	0.00	0.00	0.50
Total FTEs	**5.70**	**1.00**	**1.00**	**7.70**

DaVita does not anticipate any difficulty in recruiting staff for the new Centralia Dialysis Center. DaVita offers a competitive wage and benefit package to employees and advertises both locally and nation ally. Specific to the DaVita Centralia Dialysis Center, DaVita claims it is located in a desirable geographical location and since it is adjacent to urban areas recruitment of new staff should not be difficult. [Source: Application, p23 & 24]

Based on source documents evaluated, the department concludes adequate staffing for the new ten-station Tumwater Dialysis Center is available or can be recruited. The department concludes, t**his 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) 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.

Fresenius
As a provider of dialysis services in Washington State, Fresenius currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For its proposed FMC Fife center, social and dietary services would be provided on site. Ancillary and support services, such as pharmacy, laboratory, and radiology will be established in advance of opening. FMC states it has successfully established ancillary and support relationships in the past and does not anticipate any difficulties in meeting the clinical service demands of patients that will be cared for in the proposed facility. [Source: Application, p32]

Based on this information, the department concludes Fresenius has internal access to some ancillary and support services to support the new facility and has the ability to establish other ancillary and support services for the proposed facility. One typical agreement is a patient transfer

agreement with a local hospital. FMC did not provide an executed transfer agreement because they are generally established within a few months of opening a new dialysis center.

If this project is approved, the department would include a condition requiring Fresenius to provide a copy of the executed transfer agreement with a local hospital consistent with the draft agreement provided in the application. Based on source documents evaluated, the department concludes FMC will have the appropriate relationships with ancillary and support services. The department concludes **this sub-criterion is met.**

DaVita

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 its Centralia 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 will 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, p24] DaVita provided a template of their proposed transfer agreement, therefore if approved prior to providing services; DaVita will need to submit a final transfer agreement with a local hospital consistent with the draft agreement. [Source: Application p24 & Appendix 12]

If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed transfer agreement consistent with the draft agreement provided in the application. Based source documents evaluated, the department concludes DaVita will have the appropriate relationships with ancillary and support services. The department concludes **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.

Fresenius

Information available at Fresenius Medical Care North America's website states that Fresenius Medical Care is the largest provider of dialysis products and services in the United States with over 1,800 kidney dialysis clinics. FMC provides care for nearly 138,000 patients. [Source: FMC website]

As previously stated, Fresenius is currently a provider of dialysis services within Washington State, and operates 17 kidney dialysis treatment centers in several 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.[13] Historically, the department has requested quality of care compliance history from the licensing and/or surveying entities in each state where Fresenius

[13] WAC 246-310-230(5)

Medical Care or any of its subsidiaries have healthcare facilities. The most recent quality of care survey for FMC was completed in February 2010. For this application, the department reviewed information on the Center for Medicare & Medicaid Services website.

On January 22, 2015, the Centers for Medicare & Medicaid Services (CMS) released a media statement with the following information related to its dialysis facility compare website.

> *"Today, the Centers for Medicare & Medicaid Services (CMS) added star ratings to the Dialysis Facility Compare (DFC) website. These ratings summarize performance data, making it easier for consumers to use the information on the website. These ratings also spotlight excellence in health care quality. In addition to posting the star ratings, CMS updated data on individual DFC quality measures to reflect the most recent data for the existing measures.*
>
> *"Star ratings are simple to understand and are an excellent resource for patients, their families, and caregivers to use when talking to doctors about health care choices," said CMS Administrator Marilyn Tavenner. "CMS has taken another step in its continuous commitment to improve quality measures and transparency."*
>
> *DFC joined Nursing Home Compare and Physician Compare in expanding the use of star ratings on CMS websites. The DFC rating gives a one to five-star rating based on information about the quality of care and services that a dialysis facility provides. Currently, nine DFC quality measures are being used collectively to comprise the DFC star ratings. In the future, CMS will add more measures.*
>
> *In related news, CMS plans to add the Standardized Readmission Ratio (SRR) for dialysis facilities to the publicly reported quality outcome measures available on the Compare website. SRR is a measure of care coordination. SRR is not included in DFC's star rating at this time.*
>
> *DFC quality measure data is either updated quarterly or annually. CMS plans to update the DFC's star rating on an annual basis beginning in October 2015."*

CMS assigns a one to five 'star rating' in two separate categories: best treatment practices and hospitalizations and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

- <u>Best Treatment Practices</u>
  This is a measure of the facility's treatment practices in the areas of anemia management; dialysis adequacy, vascular access, and mineral & bone disorder. This category reviews both adult and child dialysis patients.
- <u>Hospitalization and Deaths</u>
  This measure takes a facility's expected total number of hospital admissions and compares it to the actual total number of hospital admissions among its Medicare dialysis patients. It also takes a facility's expected patient death ratio and compares it to the actual patient death ratio taking into consideration the patient's age, race, sex, diabetes, years on dialysis, and any co-morbidities.

Based on the star rating in each of the two categories, CMS then compiles an 'overall rating' for the facility. As with the separate categories: the more stars, the better the rating. The star rating is based on data collected from January 1, 2010 through December 31, 2013.[14]

For Washington State, FMS owns, operates, or manages 19 facilities. Two of the 19 facilities did not have a CMS star rating because they were not open for the entire reporting period.[15] Below is the overview of the CMS star rating for the remaining 17 FMS facilities.

FMS Facility	City/County	Star Rating
Aberdeen Dialysis Center	Aberdeen/Grays Harbor	3
Chehalis Dialysis Facility	Chehalis/Lewis	4
Colville Dialysis Facility	Colville/Stevens	5
Columbia Basin Dialysis Center	Kennewick/Benton	3
Fort Vancouver Dialysis Facility	Vancouver/Clark	2
Lacey Dialysis Facility	Lacey/Thurston	3
Leah Layne Dialysis Facility	Othello/Adams	3
Longview Dialysis Facility	Longview/Cowlitz	2
Moses Lake Dialysis Facility	Moses Lake/Grant	3
Northpointe Dialysis Facility	Spokane/Spokane	3
North Pines Dialysis Facility	Spokane/Spokane	2
Omak Dialysis Facility	Omak/Okanogan	4
Panorama Dialysis Facility	Deer Park/Spokane	3
Salmon Creek Dialysis Facility	Vancouver/Clark	3

[14] The information or data on Dialysis Facility Compare comes from two key sources: **1)** National Claims History Standard Analytical Files (NCH SAFs); and **2)** Consolidated Renal Operations in a Web-enabled Network (CROWN).

NCH SAFs –Medicare claims data are made available quarterly in the DESY system for CMS and its contractors. The Standard Analytical Files (SAFs) contain information collected by Medicare to pay for health care services provided to a Medicare beneficiary. SAFs are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers) claim type. The record unit of SAFs is the claim (some episodes of care may have more than one claim).

CROWN includes REMIS data from Medicare and SIMS data (now derived from CROWNWeb) from the ESRD Networks. CROWNWeb is a web-based data collection system that allows authorized users to securely submit, update, and verify data provided to Medicare on a monthly basis. This system was rolled out nationally in May 2012. It includes information like the facility name, address, and phone number, and information about people with Medicare who have ESRD. While CROWNWeb replaces the functionality of **Standard Information Management Systems (**SIMS), it also provides new data to support calculation of clinical measures. **Standard Information Management Systems (SIMS)** CROWNWeb data are now extracted to feed the SIMS tables that are then used by **Renal Management Information System (REMIS)**. SIMS includes information like the facility name, address, and phone number, and information about people with Medicare who have ESRD. It also includes information to track patient movement in and out of ESRD facilities, and transition from one treatment modality to another. **Renal Management Information System (REMIS) / Program Management and Medical Information System (PMMIS)** - This is a database maintained by Medicare with data about dialysis facilities. It includes: **1)** Demographic information (like age, race, and sex), medical claims, and payment and entitlement data on people with Medicare who have ESRD; 2**)** Certification and other information for Medicare-approved ESRD providers; and 3**)** Aggregate ESRD patient information.

[15] FMC Thurston County Dialysis Center and PNRS Clark County.

Shelton Dialysis Facility	Shelton/Mason	3
Spokane Kidney Center	Spokane/Spokane	3
Walla Walla Dialysis Facility	Walla Walla/Walla Walla	5

As shown above, with the exception of three facilities, all FMC dialysis centers received 3 stars or better. Information provided in the application shows that FMC operates in 44 of the 50 states, plus the District of Columbia and Puerto Rico.[16] [Source: FMC Application, Exhibit 2]

For FMC's out-of-state facilities, the department reviewed information on the Center for Medicare & Medicaid Services website comparing two or three FMC facilities in each of the states. The review revealed that typically FMC's dialysis centers scored 3 stars or better.

For medical director services, FMC provided a copy of the Medical Director Agreement between itself and the professional services corporation of RVS, PLLC. Nephrologist Seth Thaler, MD is the identified medical director; however, the agreement also states that any one of the physicians associated with RVS, PLLC, could act in the medical director capacity. A review of the compliance history for the following five physicians associated with RVS, PLLC revealed no recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission and corporation information provided by Washington State Secretary of State website]

Name	Credential Status	RVS, PLLC Corporation Status
Julia P. Anuras	Active	Member
Christopher Burtner	Active	Member
Michael G. Mondress	Active	Member
Vo Dang Nguyen	Active	Member
Seth M. Thaler	Active	Member

Given the compliance history of FMC, the current medical director, and all physicians associated with the nephrology group of RVS, PLLC, department concludes that there is reasonable assurance that the FMC Fife dialysis center would operate in compliance with state and federal regulations. **This sub-criterion is met.**

DaVita

DaVita, Inc. is a provider of dialysis services in over 2,098 outpatient centers located in 43 states (including Washington State), the District of Columbia. [Source: DaVita website at www.davita.com] Currently within Washington State, DaVita owns and operates 37 kidney dialysis treatment centers in 15 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.[17]

For Washington State, DaVita owns, operates, or manages 38 facilities. Nine of the 38 are CN approved, but not yet operational. For the remaining 29 operational dialysis centers, two did not

[16] Forty-four states are: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

[17] WAC 246-310-230(5)

have a CMS star rating.[18] Below is the overview of the CMS star rating for the remaining 27 DaVita facilities.

DaVita Facility	City/County	Star Rating
Bellevue Dialysis Center	Bellevue/King	4
Chinook Dialysis Center	Richland/Benton	3
Downtown Spokane Renal Center	Spokane/Spokane	3
East Wenatchee Dialysis Center	East Wenatchee/Douglas	3
Ellensburg Dialysis Center	Ellensburg/Kittitas	4
Everett Dialysis Center	Everett/Snohomish	5
Federal Way Dialysis Center	Federal Way/King	4
Graham Dialysis Center	Graham/Pierce	5
Kent Dialysis Center	Kent/King	5
Lakewood Dialysis Center	Lakewood/Pierce	4
Mid-Columbia Dialysis Center	Pasco/Franklin	4
Mill Creek Dialysis Center	Mill Creek/Snohomish	3
Mount Adams Dialysis Center	Sunnyside/Yakima	4
North Spokane Renal Center	Spokane/Spokane	4
Olympia Dialysis Center	Olympia/Thurston	4
Olympic View Dialysis Center	Seattle/King	3
Parkland Dialysis Center	Parkland/Pierce	4
Puyallup Dialysis Center	Puyallup/Pierce	4
Seaview Dialysis Center	Seaview/Pacific	3
Spokane Valley Dialysis Center	Spokane/Spokane	3
Tacoma Dialysis Center	Tacoma/Pierce	4
Union Gap Dialysis Center	Union Gap/Yakima	5
Vancouver Dialysis Center	Vancouver/Clark	4
Wenatchee Valley Dialysis Center	Wenatchee/Chelan	4
Westwood Dialysis Center	Seattle/King	4
Whidbey Island Dialysis Center	Oak Harbor/Island	3
Yakima Dialysis Center	Yakima/Yakima	4

As shown above, all 27 DaVita's Washington State dialysis centers received three stars or better. Information provided in the application shows that DaVita operates in 47 of the 50 states, plus the District of Columbia.[19] [Source: DaVita Applications, Appendix 2]

For DaVita's out-of-state facilities, the department reviewed information on the Center for Medicare & Medicaid Services website comparing two or three DaVita facilities in each of the states. The review revealed that these DaVita dialysis centers scored three stars or better.

[18] Kennewick Dialysis Center was not open for the entire reporting period; Zillah Dialysis Center did not have enough quality measure data to calculate a star rating.

[19] Forty-seven states are: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oregon, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

For medical director services, DaVita provided a copy of the executed Medical Director Agreement proposed between itself and Di Zhao M.D. A review of Dr. Zhao's compliance history with the Department of Health's Medical Quality Assurance Commission did not revealed any recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed Medical Director agreement consistent with the draft agreement provided in the application. Based on the source documents evaluated, the department concludes **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.

Fresenius

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

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 shows a need for six dialysis stations in the Lewis County dialysis planning area. This project proposes to add six dialysis stations to the Lewis County Dialysis Center.

Approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. Further, Fresenius demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area

Fresenius demonstrated that it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. **This sub-criterion is met.**

DaVita

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

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 shows a need for ten dialysis stations in Lewis County dialysis planning area. This project proposes to establish a six station Dialysis Center in Centralia.

Approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. Further, DaVita demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area

Based on the source documents evaluated, DaVita demonstrated that it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. **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.*

Fresenius
This sub-criterion is addressed in sub-section (3) above. **This sub-criterion is met.**

DaVita
This sub-criterion is addressed in sub-section (3) above. **This sub-criterion is met.**

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

Based on the source information provided and reviewed, the department concludes:

- Fresenius's project has not met the cost containment criteria in WAC 246-310-240; and
- DaVita, Inc.'s project has not met the cost containment criteria in WAC 246-310-240.

A determination that a proposed project will foster cost containment shall be based on the following criteria.

(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 through 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 (tie-breaker) criteria contained in WAC 246-310. The tie-breaker 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.

Step One

Fresenius

The department concluded Fresenius's proposed project meet the review criteria under WAC 245-310-210, 220, and 230. Therefore, the department has provided further analysis of the Fresenius project in step two.

DaVita

The department concluded under the financial feasibility criteria of WAC 246-310-220 that DaVita's proposed project did not meet the review criteria. This alone would be grounds for concluding this sub-criterion is not met. However, the department has provided further analysis of the Fresenius project in step two.

Step Two

Fresenius

Within the application, Fresenius identified four alternatives before submitting this application. A summary of each and Fresenius's rationale for rejection is below. [Source: Application, pp 34-38]

1. Build a new facility for six stations
   Fresenius compared this alternative to the project and determined that it would be more costly in terms of capital expenditure.

2. Expand existing facility by six stations
   Fresenius has requested to move their existing facility in Chehalis to a new location, but the new facility is not large enough to accommodate a six station expansion. The line drawing submitted with their Determination of Reviewability showed future expansion space for five stations.

3. Shared services/contract arrangement
   Based on the department's numeric methodology, there is a need for six additional stations in the planning area in year 2017 and there are no other existing dialysis providers in Lewis County.

4. Do nothing
   Based on the department's numeric methodology, there is a need for six additional stations in the planning area in year 2017. This option also does not improve patient access to additional stations in the planning area.

DaVita

Within the application, DaVita identified one alternative before submitting this application. A summary of this alternative and DaVita's rationale for rejection is below. [Source: Application, pp 26]

1. Do Nothing
   Based on the department's numeric methodology, there is a need for six additional stations in the planning area in year 2017. This option also does not improve patient access to additional stations in the planning area.

Department Evaluation

In reviewing the materials submitted by the applicants, the department determined that Fresenius had the greatest capital cost for their facility. The department also determined that the location chosen by Fresenius currently only has 4 dialysis patients within a 10 mile radius of the proposed location. Fresenius is the only dialysis provider in Lewis County and has the potential to consider expansion of an existing facility. They consider Morton as the best location to improve accessibility of dialysis services for the residents of Lewis County. The data indicates the majority of the patients reside in zip codes along the I-5 corridor. The department concluded Fresenius would have to divert patients from the closer Chehalis facility to the Morton facility to achieve the patient projections. The department concluded this would place undue hardship on patients required to make the long commute to the Morton facility. The department does not consider this project the best alternative for providing additional dialysis services for residents of Lewis County.

DaVita proposed a new dialysis facility in Centralia that would be substantially overbuilt and very costly compared to building the right size. The department does not consider this project the best alternative for providing additional dialysis services for residents of Lewis County.

The department concludes that Fresenius's proposal to establish a six station dialysis facility in Morton within Lewis County is not the best available alternative. **This sub-criterion is not met.**

The department concludes that DaVita's proposal to establish a six station in Centralia within Lewis County is not the best available alternative. **This sub-criterion is not met.**

Step Three

WAC 246-310-288 identifies specific tie-breaker criteria that must be applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. Under these tie-breaker criteria, the department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.

This step is used to determine the best available alternative between two or more approvable projects. Because Fresenius's and DaVita's project failed to meet all Certificate of Need criterion of WAC 246-310-210, 220, 230, and 240, this step 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;*

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.

Fresenius

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

DaVita

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). **This sub-criterion is not 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.

Fresenius

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

DaVita

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

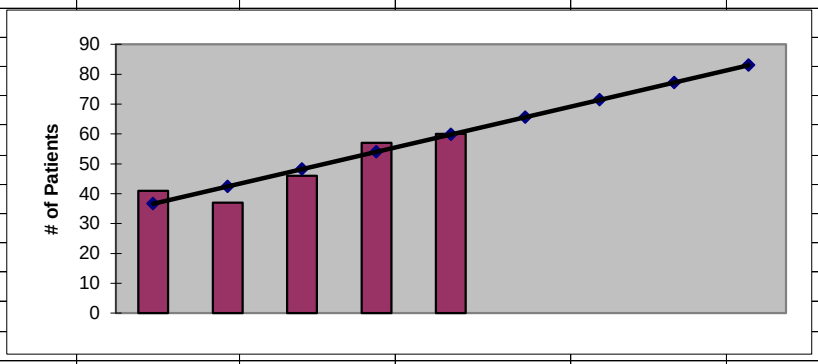
APPENDIX A

2014
Lewis County
ESRD Need Projection Methodology

	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	Lewis	2008	2009	2010	2011	2012	2013
	Lewis County	43	41	37	46	57	60
	TOTALS	43	41	37	46	57	60
246-310-284(4)(a)	Rate of Change		-4.65%	-9.76%	24.32%	23.91%	5.26%
	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	**Year 4**
				2014	2015	2016	**2017**
Projected Resident Incenter Patients	from 246-310-284(4)(b)			65.60	71.40	77.20	**83.00**
Station Need for Patients	**Divide Resident Incenter Patients by 4.8**			13.6667	14.8750	16.0833	**17.2917**
	Rounded to next whole number			**14**	**15**	**17**	**18**
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				12	12	12	**12**
Results of (4)(c) above			-	14	15	17	**18**
Net Station Need				-2	-3	-5	**-6**
Negative number indicates need for stations							
Planning Area Facilities							
Name of Center	**# of Stations**						
FMC Chehalis	**12**						
Total	**12**						
Source: Northwest Renal Network data 2008-2013							
Most recent year-end data**:** 2013 posted 01/29/14							

2014
Lewis County
ESRD Need Projection Methodology

x	y	Linear
2009	41	**37**
2010	37	**42**
2011	46	**48**
2012	57	**54**
2013	60	**60**
2014		**65.600**
2015		**71.400**
2016		**77.200**
2017		**83.000**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.918439215
R Square	0.843530592
Adjusted R Square	0.791374122
Standard Error	4.5607017
Observations	5

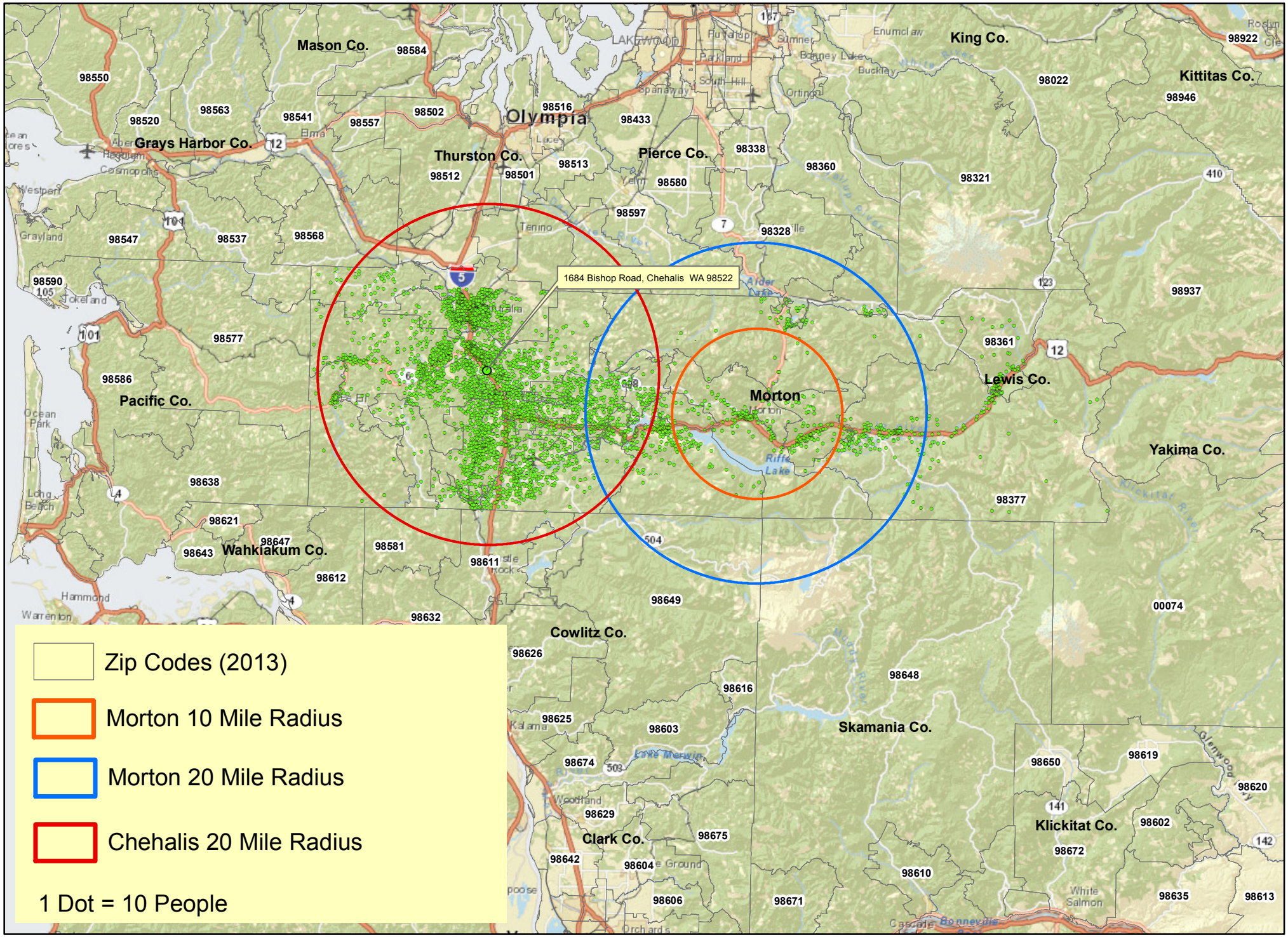
ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	336.4	336.4	16.17307692	0.027616597
Residual	3	62.4	20.8		
Total	4	398.8			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-11615.6	2900.306163	-4.004956493	0.027917809	-20845.66863	-2385.53137	-20845.66863	-2385.53137
X Variable 1	5.8	1.44222051	4.021576423	0.027616597	1.210210666	10.38978933	1.210210666	10.38978933

RESIDUAL OUTPUT

Observation	*Predicted Y*	*Residuals*
1	36.6	4.4
2	42.4	-5.4
3	48.2	-2.2
4	54	3
5	59.8	0.2

APPENDIX B

Lewis County Population