STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

December 23, 2015

CERTIFIED MAIL # 7009 0960 0000 5565 0161

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

RE: CN 15-24A

Dear Ms. Sullivan:

We have completed review of the Certificate of Need (CN) application submitted by Renal Care Group Northwest proposing to build a 29-nine station dialysis facility in south Tacoma, within the Pierce County ESRD planning area #5. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Washington Administrative Code 246-310-220	Financial Feasibility
Washington Administrative Code 246-310-240	Cost Containment

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

Appeal Option 1:
You or any person with standing 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
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

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
Department of Health	Department of Health
Adjudicative Service Unit	Adjudicative Clerk Office
Mail Stop 47879	111 Israel Road SE
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,

For Steven M. Saxe, FACHE
Director, Community Health Services

Enclosure

EVALUATION DATED DECEMBER 23, 2015 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY FRESENIUS MEDICAL CARE/RENAL CARE GROUP NORTHWEST, INC. PROPOSING TO ESTABLISH TWENTY NINE STATION KIDNEY DIALYSIS FACILITY IN PIERCE COUNTY END STAGE RENAL DIALYSIS PLANNING AREA #5

APPLICANT DESCRIPTION

Renal Care Group Northwest (RCGNW) 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, In-land Northwest Renal Care Group and Renal Care Group of Alaska. On March 31, 2006, thorough stock acquisition, Fresenius Medical Care Holdings, Inc. became the sole owner of Renal Care Group, Inc., and its subsidiaries. Information within the amended application indicates that Sacred Heart Medical Center a healthcare provider located in Spokane County and Renal Care Group, Inc. jointly owns Renal Care Group Northwest. Listed below are the five entities owned and operated by Fresenius Medical Care Holdings, Inc. [Source: Department's historical record and Amended Application, page 8]

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

Under four of the five subsidiaries listed above, Fresenius Medical Care Holdings, Inc. (FMC) operates outpatient dialysis centers in 45 states and the District of Columbia.[1] [Source: CN historical files]

In Washington State, Fresenius Medical Care Holdings, Inc. or one of its 4 subsidiaries owns, operates or manages 19 kidney dialysis facilities in 13 separate counties. Below is a listing of the 19 facilities in Washington. [Source: Amended Application: Page 3-6]

Adams County
FMC Leah Layne Dialysis Center

Benton County
Columbia Basin Dialysis Center

Clark County
Battleground Dialysis Facility
FMC Fort Vancouver Dialysis Facility
FMC Salmon Creek Dialysis Facility

Lewis County
Chehalis Dialysis Facility

Grant County
FMC Moses Lake Dialysis Facility

Cowlitz County
FMC Longview Dialysis Facility

Grays Harbor County
FMC Aberdeen Dialysis Facility

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

Mason County
FMC Shelton Dialysis Center

Okanogan County
FMC Omak Dialysis Facility

Stevens County
FMC Colville Dialysis Facility

Thurston County
FMC Lacey Dialysis Center
Thurston County Dialysis Center

Walla Walla County
QualiCenters Walla Walla

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

PROJECT DESCRIPTION

This application was submitted by Fresenius Medical Care Holdings, Inc. (FMC)[2] on behalf of Renal Care Group Northwest, Inc. FMC proposes to establish a new twenty nine station facility in the city of Tacoma to serve the resident of Pierce County end stage renal disease (ESRD) planning area #5. The new facility would be known as South Tacoma Dialysis Center and services to be provided include in-center hemodialysis, home hemodialysis and home peritoneal training, an isolation station, and a permanent bed station. [Source: Amended Application, Pages 13 and 14]

If this project is approved, FMC anticipates the 29 station facility would be operational by April 2017. Under this timeline, year 2018 would be the facility's first full calendar year of operation and year 2020 would be the facility third year of operation. [Source: Amended Application, Page 14]

The total capital expenditure associated with this project is $6,954,025 and FMC's portion of the capital expenditure is $633,732 or 9.1%, which is for equipment and associated sales tax. The remaining 90.9% or $6,320,293 is the landlord's portion, which is related to land purchase, building improvements, fees and taxes. [Source: Amended Application, Page 13]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need (CN) review as the construction, development or other establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for 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."*

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

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.[3]

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Concurrent Review Cycle #1 for year 2015. No other kidney disease treatment center application was received for Pierce County ESRD planning area #5 during the review cycle. Therefore, the review was converted to a regular review.

APPLICATION CHRONOLOGY

A chronological summary of the review activities is shown in the table below.

Action	FMC
Letter of Intent Submitted	January 30, 2015
Application Submitted	February 27, 2015
Amended Application submitted	March 31, 2015
Department's Pre-review Activities including	
• DOH 1st Screening Letter	April 21, 2015
• Applicant's Screening Responses Received	June 4, 2015
• DOH 2nd Screening Letter	June 26, 2015
• Applicant's 2nd Screening Responses Received	August 11, 2015
Beginning of Review	August 20, 2015

[3] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(3), and WAC 246-310-288, and 289.

Action	FMC
End of Public Comment • No public hearing conducted • Public comments accepted through the end of public comment	September 23, 2015
Rebuttal Comments Received	October 8, 2015
Department's Anticipated Decision Date	November 23, 2015
Department's Actual Decision Date	December 23, 2015

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."

Washington Administrative Code 246-310-010(34) defines "interested persons" means:

(a) The applicant;

(b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;

(c) Third-party payers reimbursing health care facilities in the health service area;

(d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;

(e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;

(f) Any person residing within the geographic area to be served by the applicant; and

(g) Any person regularly using health care facilities within the geographic area to be served by the applicant. (Emphasis added)

Throughout the review of this project, two entities sought affected person status under 246-310-010(2).

CHI-Franciscan Health

CHI-Franciscan Health provides acute care and end stage renal disease services in Pierce County. For ease of reference, the department would refer to CHI-Franciscan Health as 'Franciscan'. Franciscan has dialysis facilities located in ESRD planning areas: Pierce 1, Pierce 3, and Pierce 4. Franciscan does not have a facility located in Pierce 5[4]. During the twelve months prior to submission of this application, Franciscan submitted a letter of intent to provide similar services in Pierce 5 planning area. Additionally, Franciscan provided public comments on this proposed project and requested to be notified of the department's decision. Because Franciscan does not provide ESRD services in the Pierce 5 health services area they do not qualify as an affected person.

DaVita Healthcare Partner, Inc.

DaVita Healthcare Partners, Inc. provides end stage renal disease services in Pierce County. For ease of reference, the department would refer to DaVita Healthcare Partners, Inc. as 'DaVita'. DaVita has

[4] WAC 246-310-280(12) "Service area" means an individual geographic area designated by the department for which kidney dialysis station need projections are calculated. For purposes of kidney dialysis projects, service area and planning area have the same meaning.

dialysis facilities located in ESRD Pierce 5. Additionally, DaVita provided public comments on this proposed project and requested to be notified of the department's decision; therefore DaVita qualifies as an affected person.

SOURCE INFORMATION REVIEWED

- Fresenius Medical Care Amended Certificate of Need application submitted March 31, 2015
- Fresenius Medical Care supplemental information June 4, 2015, and August 11, 2015
- Public comment submitted by CHI Franciscan Health received on September 23, 2015
- Public comment submitted by DaVita Healthcare Partners, Inc. received on September 22, 2015
- Fresenius Medical Care rebuttal received October 8, 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 October 30, 2014
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Data obtained from Fresenius Medical Care webpage (www.FMC.com)
- Data obtained from Medicare webpage (www.medicare.gov)
- Certificate of Need historical files

CONCLUSIONS

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 a twenty-nine station kidney dialysis facility in Tacoma within Pierce County kidney dialysis planning area #5 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 reviewed the department concludes that Fresenius Medical Care did not 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 center 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 (NWRN).[5]

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.[6] 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 NWRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

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

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[5] Northwest Renal Network (NWRN) 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]

[6] 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.

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)]

FMC's Application of the Numeric Methodology
FMC proposes to establish a new 29-station dialysis facility to be located in Tacoma. 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 FMC South Tacoma dialysis center would be located in Pierce County ESRD planning area #5, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Amended Application, Pages 20-22]

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 Pierce County ESRD planning area #5. 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). Table 1 below shows a summary of the projected net need by the applicant and the department for the Pierce County planning area #5.

Table 1
Pierce County Planning Area #5 Numeric Methodology Summary

	2017 Projected # of stations	Minus Current # of stations	2017 Net Need
FMC	71	42	29
DOH	72	42	30

As shown in Table 1, FMC's projections did not match the department's figures. In evaluating FMC's projection method submitted in the application, it's noted that the number in-center patients in 2008, 2009, and 2010 are slightly different than those identified by the department. The difference results in the department projecting need for one additional station.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area to be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NWRN) 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 is February 1, 2015. [WAC 246-310-282] The quarterly modality report from NWRN available at that time was the September 30, 2014, which became available on October 30, 2014. In Pierce County planning area #5, there are 42 stations located in two separate centers owned or operated by DaVita, Inc. The table below shows the utilization of the two facilities.

Table 2
NWRN Facility Utilization Data September 30, 2014

Facility Name	# of Stations	# of Pts.	Pts./Station
DaVita Lakewood Dialysis Center	21	117	5.57
DaVita Parkland Dialysis Center	21	97	4.62

As shown in Table 2 above, DaVita Lakewood is operating at 5.57 patient per station which above the required standard. However, DaVita Parkland Dialysis Center is operating below the required 4.80 standard. The standard states that all CN approved stations within the planning area must be at the applicable utilization standard before new stations are added in the planning area.

Within the application, FMC stated that, *"As of September 30, 2014, both existing facilities in the planning area were operating at or close to 4.8 patients per station. As called out in other sections of the WAC, we have rounded DVA Parkland up to 4.8 which is very reasonable; given the Pierce Five Dialysis Planning area has a net need figure of 29 stations"*. [Source: Amended Application, page 18]

FMC further stated that since 2012, DaVita Parkland consistently grew its patient volumes until it neared the patient require standard in 2013, when its patient volume growth effectively stopped. Since then, DaVita Parkland's patient census has been flat, just short of the required 4.8 threshold. DaVita Parkland has managed to keep its patient census flat. If DaVita accepts just two more patients at DaVita Parkland, it would be operating above 4.8 patients per station.

The department received comments from DaVita and Franciscan related to this sub-criterion. Summarized below are the comments received by the department.

DaVita's Comments [Source: Public comments received September 22, 2015]

- DaVita Parkland facility is operating below the 4.8 in-center patient per station threshold. Pursuant to WAC 246-310-284(5), a kidney dialysis facility must demonstrate that existing providers in the planning area are operating at or above 4.8 in-center patients per station. When FMC submitted its application, all of the CN approved stations operated by DaVita Parkland were below the 4.8 required standards.

- There is no exception permitting approval of a project that does not satisfy the requirement of WAC 246-310-284(5). FMC argues that the Program should make an exception in this case, but this is not permissible. The regulation provides that the existing provider utilization threshold must be satisfied before the Program approves new stations. There is no exception set forth that permits rounding up of utilization from 4.62 to 4.8.

- DaVita is not artificially suppressing its patient census to prevent other providers into the Pierce 5 planning area. It is not usual for two facilities within the same planning area to have different utilization levels. DaVita Lakewood has been opened for about 20 years while the DaVita Parkland opened in 2011.

- FMC claimed that DaVita is manipulating its patient's census at the Parkland facility to prevent new provider this assertion is merely an attempt by FMC to circumvent a mandatory requirement that requires all existing providers be operating at or above 4.8 in-center patients per station, there is no exception to this requirement.

Franciscan's Comment [Source: Public comments received September 23, 2015]

- In its application, FMC attempts to argue that DaVita Parkland 4.71 utilization should round up to 4.8. Clearly, the Program does not round up utilization and there are no mechanisms for this in the existing dialysis rule. In fact, because there is no mechanism in WAC for rounding up facility utilization, FMC was unable to provide any relevant citations.

- In 2013, when Franciscan sought guidance it was told that all certificate of need approved stations in the planning area must be operating at 4.8 in-center patients per station before new station can be added.

- Franciscan has been planning to establish a new facility in Pierce 5 planning area for more than 18 months. Relying on written guidance of the CN Program Franciscan concluded that the outcome was predictable and therefore opted not to submit an application until the required data is available showing all station are meeting the 4.8 standards.

In response to the comments provided by DaVita and Franciscan, the applicant provided rebuttal comments, which are summarized below.

FMC Rebuttal Comment [Source: Rebuttal comments received October 8, 2015]

- Franciscan and DaVita public comment letters raised objections to FMC's request for special consideration because of the significant unmet need in Pierce 5 ESRD planning area. Franciscan discloses that it has been planning to submit an application for a new facility and is taking issue with the fact that Fresenius applied first. DaVita states it recently opened its Rainer facility in August 2015, a relocation of 10 stations from its Lakewood facility. Regarding DaVita's approved project to relocate stations, Fresenius noted that DaVita stated the 10 relocated stations would be operational in November 2014, but DaVita delayed this opening by 10 months.

- FMC submitted its CON application because of the significant net need for dialysis stations in the planning area that is well beyond the capacity of existing providers. Historical and current data shows that this net need is increasing. FMC's proposal was submitted to address this unmet need and out-migration. This is the basis for FMC's application and its request for an exception under WAC 246-310-287, which in FMC's opinion; the Department has authority to grant.

- The department's decision approving DaVita's relocation application determined the planning area needed 21 new dialysis stations, and the decision anticipated that it would grow to 27 new stations by the year 2016. FMC has demonstrated within its application that there are now 139 patients out-migrating from the planning area. While the growth in ESRD patients and out-migration has continued, DaVita Parkland has maintained a patient volume just below the 4.8 patient effectively preventing new facilities from opening to address net need.

- FMC requests that the department approve its application for new stations notwithstanding DaVita Parkland's operating at 4.71 patients per station because the department is authorized under the exception provision in WAC 246-310-287 to grant such stations if an applicant meets the stated criteria. This exception was clearly added to the rules to give the

department the flexibility to approve stations when exceptional circumstances warrant such approval.

Department Evaluation

WAC 246-310-284(5) states *"Before the department approves new in-center kidney dialysis stations, all certificate of need approved stations in the planning area must be operating at 4.8 in-center patients per station for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties. For these exception .... Data used to make this calculation must be from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period."* [Emphasis Added]

WAC 246-310-284(4)(c) states *"Determine the number of dialysis stations needed to serve resident in-center patients in the planning area in the projection year by dividing the result of (b) of this subsection by the appropriate resident in-center patient per station number from subsection (3) of this section. In order to assure access, fractional numbers are rounded up to the nearest whole number. For example, 5.1 would be rounded to 6. Rounding to a whole number is only allowed for determining the number of stations needed.* [Emphasis Added].

Based on the language of WAC 246-310-284(4)(c), the department rejects FMC's arguments that the department should round up the patients per station use rate from 4.62 to 4.8. The department notes that in its September 22, 2015 comments DaVita stated its Parkland facility was operating below the 4.8 in-center patient per station threshold. The department finds this statement is inconsistent with the statement made in DaVita's own application submitted August 31, 2015 that stated the Parkland facility was operating above utilization. [Source: CN16-08, pg 16] Regardless of data that became available after the first day of the application submission period for FMC's application the rules are clear about the data to be used for this calculation. As a result, the department concludes FMC's application is not consistent with WAC 246-310-284(5). This sub criterion **is not 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. FMC South Tacoma Dialysis Center would be located in Pierce County ESRD planning area #5; therefore, the standard for this criterion is 4.8 in-center patients per approved station. Table 3 below shows dialysis center projected utilization in the third year of operation. [Source: Supplemental information received June 4, 2015, Exhibit 14]

Table 3
FMC South Tacoma Dialysis Center
Third Full Year Projected (2020) Facility Utilization

Facility Name	#of Stations	# of Pts.	Pts./Station
FMC South Tacoma Dialysis Center	29	140	4.83

Table 3 above shows that South Tacoma Dialysis Center satisfies this utilization requirement. **This sub-criterion is met.**

WAC 246-310-287
Kidney disease treatment centers—Exceptions states,
The department shall not approve new stations in a planning area if the projections in WAC 246-310-284(4) show no net need, and shall not approve more than the number of stations projected as needed unless:

(1) All other applicable review criteria and standards have been met; *and*

(2) One or more of the following have been met:

(a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or

(b) Existing dialysis stations in the dialysis facility are operating at six patients per station. Data used to make this calculation must be from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period; or

(c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and

(3) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing. [Emphasis Added]

Within the supplemental information FMC provided statements why it qualifies for an exception. Summarized below are some of the reasons FMC provided to justify that its application qualifies for an exception. [Source: Supplemental information received August 11, 2015, Pages 2-4]

- DaVita Parkland has managed to keep its volume relatively flat, despite planning area residents travelling outside for dialysis. If DaVita Parkland would just accept just two more patients, it would be operating above 4.8 patients per station.

- We stated on pages 18 and 23 of the application that WAC 246-310-287 provides the department opportunity to approve stations in exceptional circumstances. We have shown net need is 29 stations and in our opinion, this is surely an instance where an exception exists.

- The applicant believe its application meets all other applicable review criteria and its proposed new facility is needed to locate stations reasonably close to planning area residents. In addition to satisfying the location element of the exception, we believe that DaVita's action to suppress volume at its Parkland facility is a significant change in treatment practice that is affecting dialysis stations use.

- Based upon Network data for year-end 2014, DaVita Parkland has 99 patients, which calculates to 300 treatments per week. FMC knows there is tremendous net need within the planning area and it is hard to fathom why patient's volume at DaVita Parkland has not grown, yet there is large need for additional stations within the planning area. The discrepancy between patient need and facility utilization means that patients residing in the planning area are seeking treatments outside the planning area. This is the basis for FMC request that the department exercise its discretion and approve its application

Department Evaluation

WAC 246-310-287 state the department shall not approve new stations in a planning area if the projections in WAC 246-310-284(4) show no net need, and shall not approve more than the number of stations projected as needed unless the project meets 246-310-287(1) and (3) and one or more under (2).

WAC 246-310-287(1) is the first criterion under the exception that must be met. This criterion requires that all other review criteria and standards have been met. As noted earlier, FMC's project failed to meet WAC 246-310-284(5). Because this criterion must be met in addition to one or more criteria under (2), and (3) the department need not evaluate the remaining criteria under the exception.

Therefore, **this sub-criterion is not met.**

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

As previously stated, the FMC currently provides health care services to residents of Washington State. To determine whether all residents of Pierce County ESRD planning area #5 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, FMC provided a copy of its current Admission Criteria that would be used at the facility. The Admission Criteria outlines the process/criteria that the Pierce County ESRD planning area #5 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: Amended Application, Page 25 and Exhibit 13]

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. FMC currently provides services to Medicare eligible patients in their existing Washington dialysis centers. Details provided in the application demonstrate that FMC 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: Amended Application, Page 25 & 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. FMC currently provides services to Medicaid eligible patients in their Washington dialysis centers. Details provided in the application demonstrate that FMC 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: Amended Application, Pages 15 and 25 and Exhibit 13, Supplemental information received June 4, 2015 and Exhibit 14]

FMC 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. FMC also included a 'charity' line item as a deduction from revenue within the pro forma income statements for the proposed facility[7]. [Source: Amended Application, Page 2525 and Exhibit 13] The department concludes, **this sub-criterion is met**.

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

Based on the source information reviewed the department concludes that Fresenius Medical Care 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.

FMC anticipates the new 29 station South Tacoma Dialysis Center will become operational by April 2017. Based on this timeline, year 2018 would be the facility's first full year of operation and year 2020 would be year three. Using the financial information provided within the application, the table below summarizes the projected revenue, expenses, and net income for the project for years 2017 through 2020. [Source: Supplemental information received June 24, 2015, Exhibit 14]

Table 4
Fresenius-South Tacoma Dialysis Center
Projected Revenue and Expenses Fiscal Years 2017 - 2020[8]

	Partial Year - 2017	Year 1 – 2018	Year 2 – 2019	Year 3 – 2020
# of Stations	29	29	29	29
# of Treatments [1]	81,00	13,680	19,152	23,040
# of Patients [1]	60	80	116	140
Utilization Rate [1]	2.06	2.75	4.00	4.83
Net Patient Revenue [3]	$4,037,990	$6,635,071	$9,112,025	$10,941,864
Total Operating Expense [2,3]	$2,822,090	$4,315,934	$5,749,017	$6,793,893
Net Profit or (Loss)	$1,215,900	$2,319,137	$3,363,009	$4,147,971

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

[7] The department acknowledges that the Affordable Care Act will likely have a long-term impact on the amount charity care provided by facilities. The regional average used to measure an applicant's compliance with the charity care standard is a self-correcting three-year rolling average. The department expects the applicant to make documented reasonable efforts to meet that level of charity care.

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

The 'Net Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Operating Expenses' line item includes salaries and wages, depreciation, and allocated costs for FMC South Tacoma Dialysis Center. As shown in Table 4, at the projected volumes identified in the application, FMC anticipates that the 29-station facility would be operating at a profit in each of the forecast years. [Source: Supplement Information Received June 4, 2015, Exhibit 14]

The applicant provided a copy of the executed lease agreement between Tacoma Renal Construction LLC, [landlord] and Renal Care Group Northwest, Inc. [tenant]. The executed lease agreement was notarized on May 22, 2015, with an initial term for 15 year. The lease agreement provided in the application outlines the initial terms and the annual rent for the space. The annual lease costs are substantiated in the pro forma financial statement documents presented. [Source: Supplement Information Received June 4, 2015, Exhibit 11]

Additionally, FMC also provided an executed copy of the proposed facility medical director agreement. The executed agreement between Renal Care Group Northwest, Inc. ("Company") and FMC Medical Care Holdings, Inc. ("Company") and RVS PLLC ('The Consultant") and Seth Thaler, MD, identified the medical director service costs. The medical director costs were also substantiated in the pro forma financial statement document submitted by Fresenius. The executed agreement also identified Julia Anuras, MD, Chris Burtner, MD., Lana Bur, MD., and Vo Nyugen, MD., as member ("Physicians") of affiliated with the consultant. [Source: Supplement Information Received June 4, 2015, Exhibit 5]

Summarized below are the comments received by the department related to this sub-criterion.

DaVita's Comment [Source: Public comments received September 22, 2015]

- FMC failed to provide an executed lease and a purchase sale agreement. The unexecuted lease in FMC's amended application indicated that Tacoma Renal Construction, LLC is the owner of the property, but the applicant failed to provide an executed agreement and purchase sales agreement showing that Tacoma Renal Construction, LLC owns the land or had bought the property. FMC has failed to demonstrate site control. The proposed facility would be located in a flood plain.

FMC Rebuttal Comment [Source: Rebuttal comments received October 8, 2015]

- DaVita asserts that FMC did not provide an executed lease nor did it provide an executed purchase and sale agreement. DaVita is wrong because FMC's first set of screening responses to the department shows that it provided these documents. Regarding DaVita's concerns because of FMC's proposed site, FMC fully anticipates the landlord is well apprised about zoning and other matters related to the proposed location.

Department' Evaluation

The department does not agree with DaVita that FMC failed to provide an executed lease and sales/purchase agreement. The executed lease agreement and the purchase/sales agreement provided with supplemental materials outlines the initial terms and annual rent cost for the proposed site. The executed lease agreement shows that lease costs are substantiated in the pro forma financial documentation. [Source: Supplement Information Received June 4, 2015, Exhibit 14]

FMC financial projections summarized in table 7 are based on the applicant's projections for 29-station approval. As shown in table 7 the facility's revenue is exceeding its expenses beginning in partial year 2017 through the third complete year of operation.

Typically, if the department fails an applicant under WAC 246-310-210 (Need) the application would also fail under WAC 246-310-220(1). If there is no projected need then the financial projections cannot be substantiated. However, in this particular case, the department failed FMC under need because of WAC 246-310-284(5) which requires all CN approved dialysis stations in a planning area to be at 4.8 patients per station before new stations are added. The numeric need for Pierce 5 showed a 30 station need by 2017. Therefore, it is reasonable to conclude FMC could reach the projected number of patients identified in the projected financial statements. Based on the information presented, the department concludes that the proposed project is financially feasible. **This sub-criterion is met.**

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

WAC 246-310 does not contain specific 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.

The total capital expenditure for the new 29 station FMC South Tacoma Dialysis Center is $6,954,025. FMC's portion of the capital expenditure is $633,732, or 9.1% of the overall capital costs for the project. The capital expenditure breakdown is shown in table 5 below. [Source: Amended Application, page 27]

Table 5
Estimated Capital Costs of FMC South Tacoma Dialysis Center

Item	Cost	% of Total
Moveable Equipment (Includes sales tax)	$633,732	9.1%
Landlord Projected Costs (Includes sales tax)	$6,320,293	90.9%
Total Estimated Project Costs	**$6,954,025**	**100.0%**

The landlord is responsible for $6,320,292 or 90.9% of the overall capital expenditure cost for this project. The department reviewed the floor plans for the proposed project. According to those plans, there enough space to house a total of 32 in-center dialysis stations or 3 additional stations for future expansion. These costs will be included in the lease expenses for the 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, FMC provided the following information to show the sources of its anticipated revenue and the percentage of revenue from each source. [Source: Amended Application, page 15]

Table 6
FMC South Tacoma Dialysis Center

Projected Treatments by Payer		Projected Revenue by Payer	
Payer	**% of Total**	**Payer**	**% of Total**
Medicare	81.3%	Medicare	52.5%
Medicaid	7.8%	Medicaid	3.1%
Commercial	6.3%	Commercial	39.7%
Other	4.6%	Other	4.7%
Total	**100%**	**Total**	**100%**

As shown in Table 6 above, Medicare and Medicaid treatments are projected to equal 89.1% and revenue from these payment sources would be 55.6%. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS recently implemented a Prospective Payment System (PPS) for kidney dialysis services. Under the PPS Medicare pays dialysis facilities a bundled rate per treatment, that rate is not the same for each facility because within a given geographic area, a facility of the same size as other facilities around, may not receive the same base rate.

There are a number of adjustments factors both at the facility and at patient-specific level that affects the final reimbursement rate each facility receives what a dialysis facility receives from its commercial payors varies. 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.

Within the application, FMC projected that 10.87 % of its projected non-Medicare/Medicaid patients would generate 44.4% of its total revenue. However, the department knows that for the 44.4%, revenue the applicant anticipates it would be generated would be realized through negotiated rates from insurance providers or private patients.

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

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

As previously stated, FMC's portion of the capital expenditure associated with the establishment of the proposed 29-station FMC South Tacoma facility is $633,732. FMC stated that the establishment of the project would be financed by the parent company, FMC. The applicant provided a letter of acknowledging the parent entity financial commitment to the project. [Source: Amended Application Exhibit 7] Based on the resource documentation reviewed, the departments agree that this source of financing is appropriate the department concludes **this sub-criterion is met.**

Structure and Process (Quality) of Care (WAC 246-310-230)
Based on the source information reviewed, the department concludes Fresenius Medical Care project has met the structure and process of care criteria in WAC 246-310-230.

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

To meet this sub criterion, FMC proposes to staff the facility with 13.45 FTE in 2017 and by the end of year 2020; the number of staff would increase to 32.86 FTE. A breakdown summary of the proposed FTEs is shown in table 7 below. [Source: Amended Application Page 30]

Table 7
FMC South Tacoma Dialysis Center 2017 – 2020 Projected Total FTEs

Production FTEs	Projected 2017	2018 Increase	2019 Increase	2020 Increase	Total
Nurse Manager	1.00	0.00	0.00	0.00	1.00
Outpatient RNs	2.95	1.50	1.05	3.36	8.86
Charge Nurse	0.00	0.00	1.00	0.00	1.00
Patient Care Tech	6.00	2.50	4.50	2.50	15.50
Equipment Tech	0.60	0.00	0.00	0.00	0.60
Social Worker	0.50	0.25	0.25	0.15	1.15
Dietician	0.50	0.25	0.25	0.15	1.15
Secretary	0.50	0.00	1.00	0.00	1.50
Sub Total	**12.05**	**4.50**	**8.05**	**6.16**	**30.76**
Home Dialysis FTE's					
Home Manager	0.20	0.00	0.00	0.00	0.20
RN	1.00	0.00	0.25	0.25	1.50
Social Worker	0.10	0.05	0.05	0.00	0.20
Dietician	0.10	0.05	0.05	0.00	0.20
Sub Total	**1.40**	**0.10**	**0.35**	**0.25**	**2.10**
Total FTE's	**13.44**	**4.60**	**8.40**	**6.41**	**32.86**

FMC expects to recruit staff from Pierce County as well as adjacent counties. The proposed facility would be located within a populous metropolitan area and adjacent counties have relatively large numbers of health care professionals and FMC offers competitive wage and benefit packages. If necessary, the applicant stated it could relocate staff from other nearby FMC facilities or one of their other existing dialysis centers in Washington to staff on a temporary basis. [Source: Amended Application, Page 30]

Based on source documents evaluated, the department concludes adequate staffing for the new 29-station FMC South Tacoma Dialysis Center is available or can be recruited. **This sub criterion is met.**

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

WAC 246-310 does not contain specific WAC 246-310-230(2) 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.

As a provider of dialysis services in Washington State, FMC currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For its proposed FMC South Tacoma facility, 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 stated 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: Amended Application, Page 31]

Based on this information, the department concludes FMC 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 FMC to provide a copy of the executed transfer agreement with a local hospital. Based on source documents evaluated, the department concludes FMC would 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.

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, FMC is currently a provider of dialysis services within Washington State, and operates 19 kidney dialysis treatment centers in 13 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.[9] Historically, the department has requested quality of care compliance history from the licensing and/or surveying entities in each state where FMC or any of its subsidiaries have healthcare facilities.

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

In April 2013, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for conducting surveys where FMC or any of its subsidiaries have healthcare facilities. Of the 48 states[10] and the non-state entities surveyed, the department received 32 responses or 67% of those surveyed.

One of the states responding to the survey indicated significant compliance and the rest reported non-compliance deficiencies were cited at FMC facilities in the past three years. FMC submitted and implemented acceptable plans of correction. Given the results of the out-of-state compliance history of the facilities owned or operated by Fresenius, the department concludes that considering that it owns or operates more than 1,800 facilities the number of out-of-state non-compliance surveys is acceptable. [Source: Licensing and/or survey data provided by out of state health care survey programs]

For this application, the department reviewed information on the Center for Medicare & Medicaid Services (CMS) website related to dialysis facilities star ratings. CMS assigns a one to five 'star rating' in two separate categories: best treatment practices, hospitalizations, and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

- Best Treatment Practices
  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.

- Hospitalization and Deaths
  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-morbidity.

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

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.[11] Below is the overview of the CMS star rating for the remaining 17 FMS facilities.

Table 8
FMC Centers for Medicare and Medicaid Star Rating

Facility	City/County	Star Rating
Aberdeen Dialysis Center	Aberdeen/Grays Harbor	4
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

[10] This figure excludes Washington. The department did not send a survey to itself for compliance.
[11] FMC Thurston County Dialysis Center and PNRS Clark County.

Facility	City/County	Star Rating
Leah Layne Dialysis Facility	Othello/Adams	4
Longview Dialysis Facility	Longview/Cowlitz	2
Moses Lake Dialysis Facility	Moses Lake/Grant	3
Northpointe Dialysis Facility	Spokane/Spokane	4
North Pines Dialysis Facility	Spokane/Spokane	3
Omak Dialysis Facility	Omak/Okanogan	3
Panorama Dialysis Facility	Deer Park/Spokane	3
PNRS Salmon Creek	Vancouver/Clark	3
Salmon Creek Dialysis Facility	Vancouver/Clark	4
Shelton Dialysis Facility	Shelton/Mason	3
Spokane Kidney Center	Spokane/Spokane	3
Walla Walla Dialysis Facility	Walla Walla/Walla Walla	5

As shown in Table 8 above, with the exception of two facilities, all FMC dialysis centers received three stars or better. [Source: Amended Application, Exhibit 2]

For medical director services, FMC provided an executed copy of a medical director agreement between itself and the professional services corporation of RVS, PLLC. Nephrologist Seth Thaler, MD is identified by the agreement as the medical director designee for the proposed dialysis facility. Additionally, 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	Corporation Status
Julia P. Anuras	Active	Member
Christopher Burtner	Active	Member
Lana Bur	Active	Member
Vo Dang Nguyen	Active	Member
Seth M. Thaler	Active	Member

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

(4) <u>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.</u>

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.

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. The department notes that nothing in the materials reviewed by staff suggests that these relationships would change.

Based on the source information reviewed, the department conclude that FMC demonstrated that it has, and will continue to have, appropriate relationships to the service area existing health care system within the county but it cannot conclude that this project would not results in unwarranted fragmentation of services. **This sub-criterion is met.**

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

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 reviewed, the department concludes Fresenius Medical Care project did not met the cost containment criteria in WAC 246-310-240 (1) and (2).

(1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>.

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

Within the application, FMC identified three alternatives before submitting this application. A summary of each and the rationale considered and rejected is below. [Source: Amended Application, Pages 33- 37]

Lease space for a 29-station facility
FMC stated that if this option is rejected, residents of the planning area will not be able to access needed dialysis services and will be forced to out-migrate to other facilities outside the planning area. Leasing space to build a facility is appealing because FMC would leverage its experience for better economy of scale that this option presents. Therefore, FMC choose this option because it improves access in the planning area.

Build a New Facility for 29-stations
This option is similar to option #1 however, FMC stated it would be costly in terms of capital expenditure and it does not improve the economy of scale. For this reason, this option was rejected.

Shared services/contract arrangement
FMC stated that this option would not provide sufficient additional capacity in the planning area because it would not improve access. FMC asserted that it operates numerous facilities in Washington and is confident that it can provide quality low cost services in the planning area. FMC noted there is a very significant net need for additional stations within the planning area and this option is costly because it would increase the cost of providing services. For these reasons, FMC rejected this option.

Do nothing
Planning area residents would continue to out-migrate and it would have a negative impact on quality of care in the planning area. FMC stated this option does not address out-migration of residents in the planning area therefore, it was rejected.

Step One
For this project, the department determined that FMC did not meet all review criteria under WAC 246-310-210. Given that FMC did not meet all the review criteria, the department also determined that FMC failed to meet the review criteria under cost containment WAC 246-310-240. The department does not consider this project the best available alternative for providing additional dialysis services for the residents of Pierce County ESRD planning area #5 therefore, step two and step three are not necessary. The department concludes that FMC's proposal to establish a 29-station dialysis facility in south Tacoma within Peirce County ESRD planning area #5 is not the best available alternative. **This sub-criterion is not met.**

(2) <u>In the case of a project involving construction:</u>
(a) *<u>The costs, scope, and methods of construction and energy conservation are reasonable;</u>*
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.

FMC proposes to lease a "built to suit" facility from a real estate developer. FMC states the scope and methods of the facility will meet Medicare certification and the local authority construction and energy conservation code. The cost the developer incurs to construct the building is reflected in the negotiated lease costs. The lease costs were evaluated in the financial feasibility section of this analysis. The department concluded the overall project met the financial feasibility criterion. Based on the information, the department concludes **this sub-criterion is met.**

(b) <u>The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.</u>
This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concluded **this sub-criterion is met.**

2014
Pierce County 5
ESRD Need Projection Methodology

Planning Area	6 Year Utilization Data - Resident Incenter Patients					
Pierce Five	2008	2009	2010	2011	2012	2013
98303	0	0	0	0	1	1
98327	3	2	3	4	2	0
98387	33	29	38	42	39	44
98388	5	5	5	6	8	7
98430	0	0	0	0	0	0
98433	2	1	1	2	1	2
98438	0	0	0	0	0	0
98439	3	8	6	5	6	7
98444	37	49	58	55	62	68
98445	29	32	28	28	34	34
98446	3	7	6	7	15	12
98447	1	0	0	0	0	0
98467	11	18	20	19	19	19
98498	31	28	30	23	25	32
98499	46	48	54	55	54	54
98580	7	5	6	5	5	12
TOTALS	211	232	255	251	271	292

246-310-284(4)(a)	Rate of Change		9.95%	9.91%	-1.57%	7.97%	7.75%
	6% Growth or Greater?		TRUE	TRUE	FALSE	TRUE	TRUE
	Regression Method:	Linear					

			Year 1	Year 2	Year 3	Year 4
246-310-284(4)(c)			2014	2015	2016	2017
Projected Resident Incenter Patients	from 246-310-284(4)(b)		301.00	314.60	328.20	341.80
Station Need for Patients	Divide Resident Incenter Patients by 4.8		62.7083	65.5417	68.3750	71.2083
	Rounded to next whole number		63	66	69	72

246-310-284(4)(d)	subtract (4)(c) from approved stations					
Existing CN Approved Stations			42	42	42	42
Results of (4)(c) above		-	63	66	69	72
Net Station Need			-21	-24	-27	-30

Negative number indicates need for stations

Planning Area Facilities

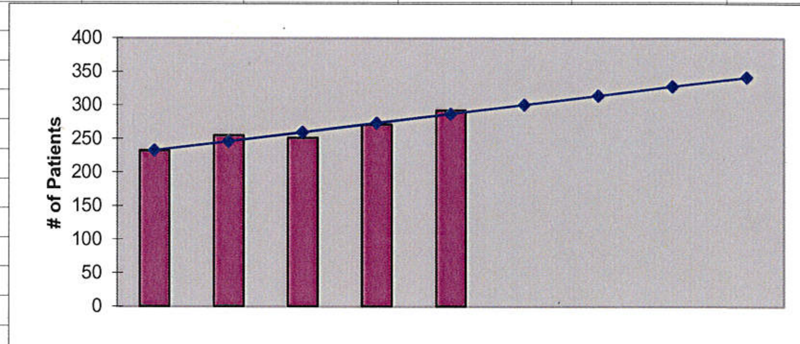
Name of Center	# of Stations
DaVita Lakewood Comn	21
DaVita Parkland	21
Total	42

Source: Northwest Renal Network data 2008-2013
Most recent year-end data: 2013 posted 01/29/14

Washington State Department of Health

2014
Pierce County 5
ESRD Need Projection Methodology

x	y	Linear
2009	232	**233**
2010	255	**247**
2011	251	**260**
2012	271	**274**
2013	292	**287**
2014		**301.000**
2015		**314.600**
2016		**328.200**
2017		**341.800**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.953406358
R Square	0.908983684
Adjusted R Square	0.878644912
Standard Error	7.857056277
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	1849.6	1849.6	29.96112311	0.011988506
Residual	3	185.2	61.73333333		
Total	4	2034.8			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-27089.4	4996.570756	-5.421598397	0.012311197	-42990.71814	-11188.0819	-42990.71814	-11188.0819
X Variable 1	13.6	2.484619354	5.473675466	0.011988506	5.692832317	21.50716768	5.692832317	21.50716768

RESIDUAL OUTPUT

Observation	*Predicted Y*	*Residuals*
1	233	-1
2	246.6	8.4
3	260.2	-9.2
4	273.8	-2.8
5	287.4	4.6