STATE OF WASHINGTON
DEPARTMENT OF HEALTH

February 20, 2015

Certified Mail 7009 0960 0000 5564 6560

Ann Sullivan, Area Manager
Fresenius Medical Care
Washington Capital Area Office
719 Sleater Kinney Rd SE Suite 152
Lacey, Washington 98503

RE: CN14-33A2

Dear Ms. Sullivan:

We have completed the review of the Certificate of Need application submitted by Fresenius Medical Care proposing to establish a six station dialysis facility in Milton within Pierce County ESRD planning area #1. 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.

Financial Feasibility	WAC[1] 246-310-220
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 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:

[1] Washington Administrative Code

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

Appeal Option 2:
You or any affected 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:	Other Than By Mail
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,

Steven M. Saxe, FACHE
Director, Health Professions and Facilities

Enclosure

EXECUTIVE SUMMARY

EVALUATIONS DATED FEBRUARY 20, 2015, FOR THE FOLLOWING CERITICATE OF NEED APPLICATIONS PROPROSING TO ADD DIALYSIS STATIONS IN PIERCE COUNTY ESRD PLANNING AREA #1:

- **FRESENIUS MEDICAL CARE PROPOSING TO ESTABLISH A SIX STATION DIALYSIS CENTER IN MILTON**
- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH A SIX STATION DIALYSIS CENTER IN BONNEY LAKE**
- **DAVITA, HEALTHCARE PARTNERS, INC. PROPOSING TO ADD SIX STATION TO DAVITA PUYALLUP DIALYSIS CENTER IN PUYALLUP**

BRIEF PROJECT DESCRIPTIONS

Fresenius Medical Care

Renal Care Group, Inc. (RCG) is a publicly held, for profit corporation, incorporated in the state of Washington that provides dialysis services through its facilities across the nation. Fresenius Medical Care (FMC) on the behalf of (RCG) proposes to establish a new six station dialysis facility in Milton within the Pierce County Dialysis Planning Area #1. This facility will be known as FMC Milton and will provide in-center hemodialysis, home hemodialysis, home peritoneal dialysis training, a dedicated isolation area, and a permanent bed station. To best meet patient needs, this facility will also provide evening treatments (after 5 PM). [Source: Second Amendment Application, p12]

The capital expenditure associated with this project is $2,896,891. If this project is approved, FMC anticipates all six stations would become operational in December 2015. Under this timeline, 2016 would be the facility's first full calendar year of operation and 2018 would be year three. [Source: Second Amendment Application, p14]

FHS

Franciscan Health System is a healthcare provider based in Tacoma, within Pierce County and is an affiliate of Catholic Health Initiatives. Franciscan Health System (FHS) provides healthcare services to the residents of Pierce and King Counties through its seven healthcare facilities. FHS proposes to establish a new six station dialysis facility in Bonney Lake within the Pierce County Dialysis Planning Area #1. This facility will be known as Franciscan Bonney Lake and will provide in-center hemodialysis, home hemodialysis, home peritoneal dialysis training, a dedicated isolation area, and a permanent bed station. To best meet patient needs, this facility will also provide evening treatments (after 5 PM). [Source: Amendment Application p7 and Supplement information p2]

The capital expenditure associated with this project is $2,356,175. FHS's share of these costs is $2,172,481. If this project is approved, FHS anticipates all six stations would become operational in December 2015. Under this timeline, 2016 would be the facility's first full calendar year of operation and 2018 would be year three. [Source: Amendment Application p8]

DaVita HealthCare Partners, Inc.

DaVita Health Care Partners, Inc. (DaVita) proposes to expand their existing 16 station facility by adding six stations in the Pierce County planning area #1. The DaVita Puyallup Dialysis Center facility is located at 716 C South Hill Park Drive, Puyallup, WA.

DaVita Puyallup Dialysis Center proposes to provide hemodialysis, backup dialysis service, a dedicated isolation station, home hemodialysis training, a permanent bed station, and shifts beginning after 5 PM. [Source: Amendment Application p11]

The capital expenditure associated with this project is $212,140. If this project is approved, DaVita anticipates all six stations would become operational in May 2015. Under this timeline, 2016 would be the facility's first full calendar year of operation and 2018 would be year three. [Source: Amendment Application p14]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need (CN) review because they either are 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

DaVita

For the reasons stated in this evaluation, the application submitted on behalf of DaVita HealthCare Partners, Inc. proposing to add six stations to the DaVita Puyallup Dialysis Center, within Pierce County ESRD planning area #1, is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

DaVita is approved to add six stations to the 16 stations DaVita Puyallup Dialysis Center for a total of 22 kidney dialysis stations. The DaVita Puyallup Dialysis Center will serve residents of Pierce County dialysis planning area #1. The DaVita Puyallup Dialysis Center is approved to provide hemodialysis, backup dialysis service, isolation station, home hemodialysis training, permanent bed station, and shifts beginning after 5pm at the DaVita Puyallup Dialysis Center.

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	19
Total	**22**

Condition:

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

2. Prior to the project commencement, DaVita HealthCare Partners, Inc. must provide to the department for review and approval an executed copy of the lease agreement to DaVita Puyallup Dialysis Center located at 716 C South Hill Park Drive, Puyallup, Washington. The executed lease must be consistent with the draft provided within the application.

Approved Cost:

The approved capital expenditure associated with this project is $212,140.

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care proposing to establish a six station dialysis center in Pierce County planning area #1 is not consistent with the applicable criterion and a Certificate of Need is denied.

Franciscan Health System

For the reasons stated in this evaluation, the application submitted by Franciscan Health System proposing to establish a six station dialysis center in Pierce County planning area #1 is not consistent with the applicable criterion and a Certificate of Need is denied.

EVALUATIONS DATED FEBRUARY 20, 2015, FOR THE FOLLOWING CERITICATE OF NEED APPLICATIONS PROPROSING TO ADD DIALYSIS STATIONS IN PIERCE COUNTY ESRD PLANNING AREA #1:

- **FRESENIUS MEDICAL CARE PROPOSING TO ESTABLISH A NEW SIX STATION DIALYSIS CENTER IN MILTON**
- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH A NEW SIX STATION DIALYSIS CENTER IN BONNEY LAKE**
- **DAVITA HEALTHCARE PARTNERS, INC PROPOSING TO ADD SIX STATION TO THE DAVITA PUYALLUP COMMUNITY DIALYSIS CENTER**

APPLICANT DESCRIPTIONS

Fresenius Medical Care, Inc. (FMC)

Renal Care Group Northwest, INC (RCG) is one of three entities owned by Renal Care Group, Inc. RCG is responsible for the operations 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 Holding, Inc. (FMC) became the sole owner of Renal Care Group, Inc. and its subsidiaries. Listed below are the five entities owned by FMC. [Source: Department's historical record and Second Amended Application p6]

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

In Washington State, Fresenius Medical Care or one of its four subsidiaries owns, operates, or manages 18 kidney dialysis facilities in 13 separate counties. Below is a listing of the 18 facilities in Washington. [Source: Second Amended Application pp7-9]

Adams County
Fresenius Leah Layne Dialysis Center

Clark County
Battleground Dialysis Facility

Cowlitz County
Fresenius Longview Dialysis Center

Benton County
Columbia Basin Dialysis Center

Fort Vancouver Dialysis Facility
Salmon Creek Dialysis Facility

Grant County
Moses Lake Dialysis Facility

Grays Harbor County
Aberdeen Dialysis Facility

Lewis County
Chehalis Facility

Mason County
Shelton Dialysis Center

Okanogan County
Omak Dialysis Facility

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

Stevens County
Colville Dialysis Center

Thurston County
Fresenius Lacey Dialysis Center

Walla Walla County
QualiCenters Walla Walla

Franciscan Health System (FHS)

FHS is part of the Catholic Health Initiatives (CHI), one of the largest non-for-profit health care systems in the United States. FHS is proposing to establish a six station dialysis facility in Bonney Lake, which is in Pierce 1 Dialysis Planning Area. This facility will be known as Franciscan Dialysis Center Bonney Lake (Franciscan Bonney Lake). [Source: Amended Application p1]

In Washington State, Franciscan Health System owns, operates, or manages five dialysis facilities. Below is a listing of the five facilities in Washington. [Source: Amended Application p3]

Pierce County Planning Area 1
Greater Puyallup Dialysis Center

Pierce County Planning Area 3
St. Joseph Dialysis Center Gig Harbor

Pierce County Planning Area 4
Franciscan Eastside Dialysis Center
St. Joseph Medical Center
Franciscan South Tacoma Dialysis

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. For ease of reference, DaVita Healthcare Partners, Inc. will be referred to as 'DaVita'. Currently DaVita operates or provides administrative services in approximately 2,098 outpatient dialysis centers located in the United States. [Source: Amendment Application, Page 1] In Washington State, DaVita owns or operates 37[1] kidney dialysis facilities in 17 separate counties. Listed below are the names of the facilities owned or operated by DaVita in Washington State. [Source: CN historical files & Application, p2]

[1] Battle Ground Dialysis Center, Renton Dialysis Center, North Federal Way, Marysville Dialysis Center, Zillah Dialysis Center, Tumwater Dialysis Center, Belfair Dialysis Center and Colville Dialysis Center are Certificate of Need approved but not yet operational.

Benton
Chinook Dialysis Center
Kennewick Dialysis Center

Clark
Vancouver Dialysis Center
Battle Ground Dialysis Center

Chelan
Wenatchee Valley Dialysis Center

Douglas
East Wenatchee Dialysis Center

Franklin
Mid-Columbia Kidney Center

Island
Whidbey Island Dialysis Center

King
Bellevue Dialysis Center
Renton Dialysis Center
Federal Way Dialysis Center
North Federal Way Dialysis Center
Kent Dialysis Center
Olympic View Dialysis Center (management only)
Westwood Dialysis Center

Kittitas
Ellensburg Dialysis Center

Mason
Belfair Dialysis Center

Pacific
Seaview Dialysis Center

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

Snohomish
Everett Dialysis Center[2]
Mill Creek Dialysis Center
Marysville Dialysis Center[3]

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

Stevens
Colville Dialysis Center

Thurston
Olympia Dialysis Center
Tumwater Dialysis Center

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

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both Fresenius Medical Care and Franciscan Health System projects is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

[2] Refuge Dialysis, LLC, is owned 80% by DaVita, Inc. and 20% by The Everett Clinic and managed by DaVita.
[3] Ibid

DaVita HealthCare Partners, Inc.'s project is subject to Certificate of Need review as an increase in dialysis stations capacity at an existing center 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."

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, 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); and 246-310-240 (cost containment).

Additionally, the applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.[4]

TYPE OF REVIEW

As directed under WAC 246-310-282(1), the department accepted all three projects under the year 2014 Kidney Disease Treatment Centers-Concurrent Review Cycle #2. A chronologic summary of both projects is shown below.

Action	Fresenius	Franciscan	DaVita
Letter of Intent Submitted	April 30, 2014	April 30, 2014	April 30, 2014
Application Submitted	May 30, 2014	May 30, 2014	May 30, 2014
1st Amendment Application Submitted	June 30, 2014	July 15, 2014	June 30, 2014
2nd Amendment Application Submitted	July 15, 2014	N/A	N/A
Department's pre-review Activities			
• Department screening letter sent	July 31, 2014	July 31, 2014	July 31, 2014
• Screening responses received	August 29, 2014	August 29, 2014	August 29, 2014
Beginning of Review	September 16, 2014		
End of Public Comment • No public hearing conducted • Public comments accepted through end of public comment	November 17, 2014		
Rebuttal Comments Received	December 17, 2014		
Department's Anticipated Decision Date	February 2, 2015		
Department's Actual Decision Date	February 20, 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."

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 project.

[4] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-286, 287, and 289.

SOURCE INFORMATION REVIEWED

- Fresenius Medical Care's second amended Certificate of Need application submitted July 15, 2014[5]
- Franciscan Health System's first amended Certificate of Need application submitted July 15, 2014
- DaVita HealthCare Partners, Inc.'s first amended Certificate of Need application submitted June 30, 2014
- Fresenius Medical Care public comment received November 17, 2014
- Franciscan Health System public comment received November 17, 2014
- DaVita HealthCare Partners, Inc. public comment received November 17, 2014
- Fresenius Medical Care rebuttal comments received December 17, 2014
- Franciscan Health System rebuttal comments received December 17, 2014
- DaVita HealthCare Partners, Inc. rebuttal comments received December 17, 2014
- United States Department of Veteran Affairs – Space requirement for dialysis stations – https://www.wbdg.org/ccb/VA/VASPACE/SPchapter316.pdf
- Years 2008 through 2013 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2013 Northwest Renal Network 2nd Quarter Utilization Data
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Certificate of Need historical files

[5] Fresenius Medical Care submitted its initial application on May 30, 2014, consistent with the ESRD concurrent review cycle #2. On June 30, 2014, Fresenius Medical Care submitted its first amendment application consistent with WAC 246-310-100(6). On July 15, 2014, Fresenius Medical Care submitted its second amendment application consistent with WAC 246-310-100(6). Once the second amendment application was received, the initial and first amendment applications are no longer considered in this review. As a result, neither of these two applications will be further discussed in this evaluation, including Franciscan Health System and DaVita HealthCare Partners, Inc. initial application.

CONCLUSIONS

DaVita

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to add six station to the DaVita Puyallup Community Dialysis Center in Pierce County dialysis planning area #1 is consistent with applicable criteria and a Certificate of Need Program, provided DaVita HealthCare Partners, Inc. agree to the following in its entirety.

Project Description:

DaVita HealthCare Partners, Inc. proposes to add six station to its 16 station dialysis facility in the Pierce County ESRD planning area #1. DaVita Puyallup Dialysis is located at 716 C South Hill Park Drive, Puyallup, WA 98373 within Pierce County. This dialysis center would provide in-center hemodialysis, home hemodialysis, home peritoneal dialysis training, a dedicated isolation area, after 5 p.m. evening treatments, and a dedicated bed station. The station breakdown for the facility at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	19
Total	**22**

Conditions:

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

2. Prior to the project commencement, DaVita HealthCare Partners, Inc. must provide to the department for review and approval an executed copy of the lease agreement to DaVita Puyallup Dialysis Center located at 716 C South Hill Park Drive, Puyallup, Washington. The executed lease must be consistent with the draft provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is $212,140.

FMC

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care Holdings, Inc. proposing to establish a six-station dialysis center in Pierce County planning area #1 is not consistent with applicable criterion and a Certificate of Need is denied.

FHS

For the reasons stated in this evaluation, the application submitted by Franciscan Health System proposing to establish a six-station dialysis center in Pierce County planning area #1 is not consistent with applicable criterion and a Certificate of Need is denied.

CRITERIA DETERMINATION

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes:

- Fresenius Medical Care'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.
- Franciscan Health System's Care'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.
- DaVita HealthCare Partners, Inc.'s project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284.

(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.[6]

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.[7] 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.

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[6] 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]

[7] 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 these projects, the base year is 2010.

In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

WAC 246-310-280(9) identifies the ESRD planning areas for the state. All three applicants Fresenius, Franciscan and DaVita propose to add dialysis station capacity to Pierce County planning area #1. The following zip codes are included in this planning area.

Zip	City
98354	Milton
98371	Puyallup
98372	Puyallup
98373	Puyallup
98374	Puyallup
98375	Puyallup
98390	Sumner
98391	Bonney Lake

FMC's Application of Numeric Methodology

FMC propose to establish a new six station dialysis facility located in the Milton zip code of 98354. Based on the calculation of the annual growth rate in the planning area as described above, FMC used a linear regression to project need. Given that Milton is located in Pierce County planning area #1, the number of projected patients was divided by 4.8 to determine the number stations needed in the planning area. FMC projected need for six new stations. [Source: Second Amended Application pp18-21]

FHS Application of Numeric Methodology

FHS proposes to establish six stations dialysis center in Bonney Lake zip code of 98391 within Pierce County planning area #1. FHS projected need for six new stations. [Source: Amended Application p18]

DaVita Application of Numeric Methodology

DaVita proposes to add six stations to the DaVita Puyallup Dialysis Center located within Pierce County planning area #1. 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. DaVita projected need for six new stations [Source: Amended Application p20]

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 the need for Pierce County dialysis planning area #1. 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 1 below shows a summary of the projected net need provided by all applicants and the department for the Pierce County planning area #1.

Table 1
Pierce County Planning Area #1
Numeric Methodology Summary

	4.8 in-center patients per station		
	2017 Projected # of stations	**Minus Current # of stations**	**2017 Net Need**
Fresenius	34	28	6
Franciscan	34	28	6
DaVita	34	28	6
DOH	34	28	6

Table1demonstrates the projections of the three applicants match the department's figures. As a result, the net station need for Pierce County planning area #1 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 May 30, 2014. [WAC 246-310-282]

The quarterly modality report from NRN available at that time was March 31, 2014 available on April 30, 2014. For Pierce County planning area #1, there are 28 dialysis stations located in Puyallup at two facilities. Table 2 shows the reported utilization of the stations in Pierce County planning area #1.

Table 2
March 31, 2014 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
FHS St Joseph Dialysis Center	12	59	4.92
DaVita Puyallup Community	16	94	5.88

Table 2 demonstrates that the two current facilities satisfy 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 approval station by the end of the third full year of operation. For Pierce County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, the applicants must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Fresenius and Franciscan anticipate their new six stations dialysis centers would become operational by December 2015. For DaVita their addition of six stations would become operational by May 2015. Under this timeline, year 2016 would be all the facilities first full calendar year of operation and 2018 would be year three. A summary of the three applicant's projected utilization for the third year of operation is shown in the table below. [Source: FMC Second Amended Application p14, FHS Amended Application p8, DaVita Amended Application p19]

Table 3
Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of In-Center Patients	Patients/Station
FMC Milton Kidney Center	2018	6	34	5.6
Franciscan Bonney Lake Dialysis Center	2018	6	31	5.2
DaVita Puyallup Dialysis Center	2018	22	110	5.0

As shown in Table 3 the department concludes **this sub-criterion is met for Fresenius, Franciscan, 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.*

FMC

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of Pierce County planning area #1 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 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 and 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 Admission Criteria for FMC Milton Dialysis Center that would continue to be used at the facility. The Admission Criteria outlines the process/criteria that the facility will use to admit patients for treatment, and ensures 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: Second Amended Application, 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 at their existing dialysis center. Details provided in the application demonstrate that FMC intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Second Amended Application, Exhibit 12]

FMC demonstrated its intent to provide charity care to Pierce County planning area #1 residents by submitting the Charity policy currently used within the facility. It outlines the process one 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 each proposed facility. [Source: Second Amended Application, Exhibit 12 and Supplement information]

The department concludes that all residents of the service area would have adequate access to the health services at Milton Dialysis Center. **This sub-criterion is met.**

FHS

FHS is currently a provider of health care services to the residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of Pierce County planning area #1 would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy.

To demonstrate compliance with this sub-criterion, FHS provided a copy of its current Admission policy. The policy outlines the process and guidelines that FHS uses to admit patients for treatment at the dialysis center. The policy states the dialysis center will continue to admit and treat patients meeting physiologic criteria for end stage renal disease and will not discriminate as to age, sex, race, religion or sexual preference, physical disability, financial status, or disease. [Source: Amended Application, Exhibit 9]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to additional services. FHS currently provides services to Medicare eligible patients at its existing dialysis centers. A review of the application shows FHS anticipates it would continue to receive Medicare reimbursements. [Source: Amended Application, p9 and Exhibit 9]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

FHS demonstrated its intent to continue to provide charity care to patients receiving treatment by submitting its current Uninsured/Underinsured Patient Discount Policy (Charity Care). [Source: Supplement Information Exhibit 9] The charity care policy outlines the process one would use to access services provided at FHS facilities. FHS also include a 'charity care' line item as a deduction from revenue within its pro forma income statement. [Source: Amended Application, Exhibit 11] Based on the above information and standards, 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 Pierce County dialysis planning area #1 would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current admission policy. The admission policy provides the overall guiding principles of the facility as to the type 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 continue to 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 current Admission Criteria that is being used at the DaVita Puyallup facility. The Admission Criteria outlines the process/criteria that the DaVita Puyallup Dialysis Center would use to admit patients for treatment, and ensure that patients will receive appropriate care. 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, national origin, gender, sexual orientation, age, religion, or disability. [Source: Amended Application, Exhibit 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 this dialysis center. Details provided in the application demonstrate that DaVita will continue to maintain this status. A review of the anticipated revenue source indicates that the facility expects to continue to receive Medicaid reimbursements. [Source: Amended Application, Exhibit 14]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial, and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

DaVita demonstrated its intent to continue to provide charity care to patients receiving treatment by submitting its current Charity Care policy. [Source: Amended Application, Exhibit 14] 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 include a 'charity care' line item as a deduction from revenue within the pro forma income statements for their current facility. [Source: Amended Application, Exhibit 9] Based on the source documents evaluated, the department concludes **this sub-criterion is met.**

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

Based on the source information reviewed and the applicant's agreement to the conditions identified in the conclusion section of this evaluation, the department determines:

- Fresenius Medical Care's project has not met the financial feasibility criteria in WAC 246-310-220;
- Franciscan Health System's project has not met the financial feasibility criteria in WAC 246-310-220; and
- DaVita, HealthCare Partners Inc.'s project has met the financial feasibility criteria in WAC 246-310-220

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

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

Department Evaluation

FMC

FMC anticipates the new six stations would become operational in December 2015. Using the fiscal years provided in the application, FY 2016 would be FMC Milton Dialysis Center's first full 12 months of operations with six dialysis stations. The table on the following page illustrates the projected revenue, expenses, and net income for fiscal years 2016 through 2018 for FMC Milton Dialysis Center. [Source: Supplement Information Revised Exhibit 14]

Table 4
FMC Milton Dialysis Center
Projected Revenue and Expenses Fiscal Year 2015-2018[8]

	Dec- 2015	FY 1 - 2016	FY 2 - 2017	FY 3- 2018
# of Stations	*6*	6	6	6
# of Treatments [1]	*168*	3,168	4,320	4,896
# of Patients [2]	14	22	30	34
Utilization Rate [2]	2.33	3.67	5.00	5.67
Net Revenue [1]	$ 83,779	$ 1,670,598	$ 2,333,987	$ 2,563,201
Total Expense [1,3]	$ 214,488	$ 1,487,200	$ 1,863,319	$ 2,009,351
Net Profit or (Loss) [1]	$ (130,709)	$ 183,399	$ 470,668	$ 553,851

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

[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 Expenses' line item includes salaries and wages, depreciation, and allocated costs for FMC Milton Dialysis Center. As shown in Table 4, at the projected volumes identified in the application, FMC anticipates that the six-station facility would be operating at a profit in each of the forecast years. [Source: Supplement Information Revised Exhibit 14]

The lease provided in the application outlines the initial terms and the annual rent for the space and includes a copy of the lease for the premises between WRP Meridian LLC, [landlord] and Renal Care Group Northwest, Inc. [tenant]. The lease was executed and notarized on May 20, 2014 and extends for five years and nine months. The annual lease costs are substantiated in the pro forma financial documents presented. [Source: Supplement Information Revised Exhibit 11]

Additionally, FMC provided a copy of the Medical Director Agreement and compensation amendment currently in effect between itself and Seth Thaler, MD. The medical director service costs are also substantiated in the pro forma documents. [Source: Supplement Information Revised Exhibit 14]

FHS

As stated in the project description portion of this evaluation, if this project is approved, FHS anticipates the six new stations would become operational by December 2015. Under this timeline, calendar year 2016 would Franciscan Bonney Lake year one with 2017 and 2018 would be second and third year of operation. The table on below illustrates the projected utilization for fiscal years 2015 through 2018 for Franciscan Bonney Lake. [Source: Amended Application pp 8-9]

Table 5
Franciscan Bonney Lake Dialysis Center Estimated Number Of In-Center Patients, Treatments and Patients per Station

Year	Full or Partial Year	Estimated In-Center Patients	Estimated In-Center Dialyses	Patients per Station
2015	Partial	10	130	1.7
2016	Full	20	3,120	3.3
2017	Full	27	4,212	4.5
2018	Full	31	4,836	5.2

Table 6 shows Franciscan Bonney Lake would be operating at a loss in year 2015 and 2016 profit beginning in year 2017. The 'Net Patient 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 Franciscan Bonney Lake. [Source: Amended Application Exhibit 11]

Table 6
Franciscan Bonney Lake Dialysis Center
Projected Revenue and Expenses Fiscal Year 2015-2018[9]

	Dec- 2015	FY 1 - 2016	FY 2 - 2017	FY 3- 2018
# of Stations	*6*	6	6	6
# of Treatments [1]	*130*	3,120	4,212	4,836
# of Patients [2]	10	20	27	31
Utilization Rate [2]	1.7	3.3	4.5	5.2
Net Revenue [1]	$ 72,218	$ 1,663,095	$ 2,171,547	$ 2,532,216
Total Expense [1,3]	$ 181,663	$ 1,472,973	$ 1,719,409	$ 1,898,231
Net Profit or (Loss) [1]	$ (131,776)	$ (77,850)	$ 184,166	$ 366,013

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

The applicant provided a lease agreement with addendum for portions of office spaces and new spaces to be used for future expansion. Information within the application and supplemental information provided by the applicant shows establishing six stations with seven stations for future expansion. [Source: Supplement Information Revised Attachment 3]

The lease agreement provided in the application outlines the initial terms and the annual rent for the space and includes a copy of the lease for the premises between Lake Tapps Equities, LLC [landlord] and Franciscan Health System [tenant]. The lease was executed and notarized on July 1, 2014 and extends for two additional five years. The annual lease costs are substantiated in the pro forma financial documents presented. [source: Amended Application Exhibit 8]

DaVita

DaVita anticipates the six additional stations at the DaVita Puyallup Dialysis Center will become operational by May 1, 2015. Based on this timeline, 2016 is the facility's first full Calendar year of operation with 22 stations. Using the financial information provided as part of the completed application, Table 7 illustrates the projected revenue, expenses, and net income for 2016 through 2018 for the DaVita Puyallup Dialysis Center. [Source: Amended Application p19 and Exhibit 9]

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

Table 7
DaVita Puyallup Dialysis Center
Projected Revenue and Expenses Fiscal Year 2016-2018[10]

	FY 1 - 2016	FY 2 – 2017	FY 1 - 2018
# of Stations	22	22	22
# of Treatments [1]	17,295	17,732	18,621
# of Patients [2]	101	105	110
Utilization Rate [2]	4.59	4.77	5.00
Net Revenue [1]	$ 7,557,889	$ 7,903,920	$ 8,466,277
Total Expense [1,3]	$ 2,122,145	$ 2,237,036	$ 2,403,132
Net Profit or (Loss) [1]	$ 5,435,744	$ 5,666,884	$ 6,063,145

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

DaVita provided a copy of the existing Medical Director Agreement currently being used at the DaVita Puyallup Dialysis Center. Costs identified in the agreement are consistent with the amount identified in the pro-forma income statement.

The lease agreement provided in the application outlines the initial terms and the annual rent for the space and includes a copy of the lease for the premises between East-West Investment Co., Inc. [landlord] and Walker Family Trust and South Hill Associates, LLC and Total Renal Care, Inc. successor to DaVita Inc. [tenant]. The executed lease has been previously extended however, a review of the lease shows that extended term expires on September 30, 2015. Therefore, the department considers the lease provided in the application a draft and would require that DaVita submit a finalized lease agreement for at least the first three full years of operation for the add stations. With DaVita's agreement to this condition, the department concludes that DaVita met the sub criterion. [Source: Amend Application Appendix 15]

Additionally, DaVita provided a copy of the Medical Director Agreement and compensation currently in effect between DaVita and Zhuowei Wang, MD. The medical director service costs are also substantiated in the pro forma documents. [Source: Amend Application Appendix 3 and 9 and Supplement Information p3] 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.**

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

(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.

FMC

The capital expenditure associated with the establishment of a new six stations facility in Milton is $2,896,891. Of that amount 37% is related to leasehold improvements, 14% for fixed/moveable equipment, 7% is related to professional fees, and 37% in construction. [Source: Second Amended Application p27] The capital cost breakdown is shown in the table below.

Table 8
FMC Estimated Capital Costs

Item	Cost	% of Total
Construction	$ 1,084,845	37%
Fixed & Moveable Equipment	$ 401,300	14%
Architect & Engineering fees	$ 109,020	4%
Permits & Legal fees	$ 80,000	3%
Taxes	$ 155,222	6%
Lease/Landlord Improvement fees	$ 1,066,504	37%
Total Estimated Capital Costs	**$ 1,786,383**	**100%**

FMC intends to finance its portion of the project, which is $1,803,387, entirely from existing reserves from Renal Care Group. A review of the historical financial statements provided in the application indicates that FMC has sufficient cash assets and board approval to fund the project. [Source: Second Amended Application p15 and historical files] To further support compliance with this criteria FMC also provided the following source of its revenue projections.

Table 9
FMC Milton Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	45%
Medicaid	3%
Commercial	31%
Other [1]	21%
Total	**100%**

[1] Other sources include miscellaneous insurance and self-pay patients

The department received public comments from DaVita related to FMC proposed project. Summarized below are the comments received by the department.

DaVita [Comments received from DaVita on November 17, 2014]

- FMC fails to document site control and it has not documented accurate capital expenditure
- FMC's site control documentation provided an executed lease agreement which is mot consistent with the proposed facility physical address
- FMC has substantially underreported the value of its expansion equipment's by more than $100,000. It is unclear if FMC would house 12 or 13 stations and FMC has estimated constructions costs for only 12 stations. FMC's confusion and inconsistency regarding its project costs leads to erroneous calculation of its cost per station for the purposes of the Economies of Scale tiebreaker.

The department received rebuttal comments in response to the public comments submitted by DaVita. Summarized below are the comments.

FMC [Rebuttal comments received December 17, 2014]

FMC's capital expenditures are correct. FMC has extensive experience owning and operating dialysis facilities. Additionally, FMC's financial projections are based on its extensive experience. FMC used its actual operations information and disclosure of all assumptions.

Department Evaluation

Given that FMC is a major provider of dialysis services in Washington and the United States, the department expects FMC to rely on its experience when making projections for its applications. DaVita assertions that FMC's assumptions were incorrect, however since it did not provide documentation to show why FMS's projections are wrong, the department cannot verify the assertions. 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.

Fresenius' project has the highest capital expenditure of the three projects. In reviewing, the line drawing supplied by Fresenius the project appears to show a 12-station dialysis facility rather than a six-station facility. The department has historically approved dialysis projects containing shelled-in space for reasonable future expansion. This space has been intended to allow for cost effective expansions when a small number of addition stations become needed in a planning area. In this case, the number of stations for future expansion exceeds the needed stations by two times. In addition, 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 when 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. Within the application, the applicant projected that 21% treatments from non- Medicare/Medicaid patients would generate 52% 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 information provided, the department concludes that the costs of this project would result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is not met.**

FHS

The capital expenditure associated with the establishment of a new six stations facility in Bonney Lake is $2,356,175. Of that amount 7.8% is related to leasehold improvements, 40.5% for fixed/moveable equipment, 7.6% is related to professional fees, and 36.6% in construction. [Source: Amended Application p27] The capital cost breakdown is shown in the table below.

Table 10
FHS Estimated Capital Costs

Item	Cost	% of Total
Construction	$ 863,203	36.6%
Fixed/Moveable Equipment	$ 954,208	40.5%
Architect & Engineering fees	$ 151,164	6.4%
Permits & Legal fees	$ 28,815	1.2%
Taxes	$ 175,091	7.4%
Lease/Landlord Improvement fees	$ 183,694	7.8%
Total Estimated Capital Costs	**$ 2,356,175**	**100%**

FHS intends to finance its portion of the project, which is $2,172,481, entirely from existing reserves. A review of the historical financial statements provided in the application indicates that FHS has sufficient cash assets and board approval to fund the project. [Source: Amended Application p9, Exhibit 10 and 11]

The department recognizes that the majority of reimbursements typically for dialysis services are through Medicare ESRD reimbursements. To further demonstrate compliance with this sub-criterion, FHS also provided the sources of patient revenue shown in the table below. [Source: Amended Application p9]

Table 11
Franciscan Bonney Lake Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	75.5%
Medicaid	5.5%
Other	19.0%
Total	**100%**

[1] Other sources include miscellaneous insurance and self-pay patients

As shown above, the Medicare and Medicaid reimbursements are projected to equal 81% of the revenue at the Franciscan Bonney Lake dialysis center. The department concludes that since the majority of revenue is dependent upon sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining 19% will be derived through a variety of reimbursement sources. Below are summary of public comments received by the department related to FHS's proposed project.

FMC [Public comments received on November 17, 2014, p4]

- The project cost for the proposed six-station facility is unknown. The total capital expenditure is for twelve stations, but only six stations can be CN approve at this time
- FHS does not provide any explanation for its financials. There are no disclosure of assumption or sources used to calculate the projected revenue and expenses. FHS did not disclose its expenses associated with FTE salaries, wages and benefits.
- FHS did not disclose its expenses associated with FTE salaries, wages and benefits

DaVita [Public comments received November 17, 2014, p12]

Because of the fundamentally different assumptions used in calculating gross revenue and net revenue, FHS financial reporting does not allow us to calculate its actual payer mix using net revenue. FHS use of fictional gross revenue for its payer mix means it has failed to document the percentages of revenue it anticipated from each payer source. FHS failed to document actual revenue it expects from Medicare, Medicaid and commercial sources. In repose to DaVita and FMC comments, FHS provided rebuttal comments summarized below.

FHS [Rebuttal comments received December 17, 2014, p4]

FHS has been fully compliant and transparent in its payer mix. FHS proposed Bonney Lake payer mix is based on FHS's actual experience at its Puyallup unit. The payer mix is consistent with the payer mix information provided within the application and the most recent application submitted to the department.

Department Evaluation

The department agrees with FHS that an applicant payer mix should be based on the applicant's experience. Given that FHS is a major provider of healthcare services in Peirce County, the department expects that FHS would use it experience to predict its payer sources and payer mix at it healthcare facilities. 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.

FHS's project has the second highest capital expenditure of the three projects. In reviewing, the line drawing supplied by Fresenius the project appears to show a 12-station dialysis facility rather than a six-station facility. The department has historically approved dialysis projects containing 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 future expansion exceeds the needed stations by two times. In addition, 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 when 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. Within the application, the applicant projected that 19 % of its projected patients would come from non-Medicare/Medicaid patients and it did disclosed what the total revenue from that would be. However, the department knows that for the 19%, revenue would be generated through negotiated rates with insurance providers or private patients.

It is reasonable to expect these rates for the 19% are higher than necessary to support the unnecessary capital and operating costs of this over built facility. Based on the information provided, the department concludes that the costs of this project would result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is not met.**

DaVita

The capital expenditure associated with this project is $212,140. Of that amount 53% is related to lease improvements, 37% is new movable equipment's and 6% is related to professional fees, and 5% to taxes. The capital cost breakdown is shown in the table below. [Source: Amended Application p10 and Supplemental Information Appendix 7]

Table 12
DaVita Estimated Capital Costs

Item	Cost	% of Total
Lease/Landlord Improvement fees	$ 112,054	52.8%
Fixed/Moveable Equipment	$ 77,940	36.7%
Professional Services fees	$ 12,500	5.9%
Taxes	$ 9,646	4.5%
Total Estimated Capital Costs	**$ 211,140**	**100%**

DaVita intends to finance the project, which is $212,140, entirely from existing reserves from DaVita capital expenditures budget. A review of the historical financial statements provided in the application indicates that DaVita has sufficient cash assets and board approval to fund the project. [Source: Amended Application p12 and historical files]

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

Table 13
DaVita Puyallup Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	84%
Medicaid	1%
Insurance/HMO	15%
Total	**100%**

As shown in Table 13, the Medicare and Medicaid reimbursements are projected to equal 85% of the revenue at the DaVita Puyallup Dialysis Center. The department concludes that since the majority of revenue is dependent upon cost based reimbursement, they are not expected to have unreasonable impact on charges for services. The remaining 15% will be derived through a variety of reimbursement sources such as private insurance. [Source: Amended Application p12] The department received public comments related to DaVita's proposal summarized in the next page.

FHS [Public comments received on November 17, 2014, p11]
At 22 stations, DaVita Puyallup would have 290 square feet per station. In comparison, the FHS location in Gig Harbor with 12-stations has approximately 433 square feet per station. FMC's proposed facility will contain 699 square feet per station. The space for DaVita's project is critically deficient. DaVita line drawing shows:

- Only I patient restroom
- A lack of visibility (patient sight line) from other applicants for not providing sufficient space for the proposed number of stations or a bed station
- DaVita's equipment list for clinical equipment's only list dialysis machines and no other equipment's such as TV's. FHS assumes that DaVita does not presently have a bed in its Puyallup unit.

In response to the comments provided above, the department received rebuttal comments summarized below.

DaVita [Rebuttal comments received on December 17, 2014]
FHS comments raise no issue of concern about our application, Rather, FHS argues for a landlord construction cost allocation that has been rejected by the department. FHS application remains fundamentally incomplete and deficient. FHS argues that DaVita's proposal provides the least amount of space for patients care at the facility, but this contention has no basis in facts. FHS points to three of DaVita's recent applications, but in the example used, FHS failed to consult any of the relevant applications because its argument ignores the patient's treatment spaces in those projects. In each of the projects, which FHS used as example, the patient's spaces were detailed and labelled as 'Chronic Dialysis Stations". For example, DaVita Puyallup has 104 square feet of treatment space per stations. The guideline for Design and Construction of Hospital and Outpatients Facilities, 2014 Edition requires 80 feet for a dialysis stations. The Puyallup project that FHS criticizes would exceed the treatment guidelines by 30 percent.

Department's Evaluation (Summary)
FHS stated in its comments that at 22 stations, DaVita Puyallup would have 290 square feet per station but it did not specifically document why DaVita's stations addition using existing space is an issue. In response to FHS comments and DaVita's rebuttal comments, the information reviewed by the department showed that the 290 square feet per station that FHS attributed to DaVita Puyallup facility, is sufficient. Since FHS did not provide any documentation that would show that DaVita Puyallup allocated space per space is insufficient, the department agrees with DaVita's comments that it has sufficient space at the existing DaVita Puyallup facility to accommodate the six stations if this project is approvable.

The department noted that Fresenius project has the highest capital expenditure of the three projects and FHS has the second highest and DaVita the lowest. In reviewing the facility line drawings supplied by both Fresenius and Franciscan, it appears both projects would be adding more than six dialysis stations. 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. However, in these cases the numbers of stations shown in the line drawings exceeds the needed stations by almost two times. In addition, these expansion spaces are integral to the treatment space proposed for both of these projects. The department generally views expansion space as a separate unfinished space that could be finished in the future for expansion.

Fresenius and Franciscan projects do not seem to fit this concept. It appears from the line drawings that the expansion space would need to be finished as part of these projects. These expansion spaces will 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 these extents. The department concludes both FMC and FHS are overbuilt for the projected need in the dialysis planning area. As previously shown in Tables 9 and Table 11 typically the majority of revenue comes from non-Medicare/Medicaid patients. 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 these two over built facilities. Based on the source documents evaluated, the department concludes the costs of Fresenius and Franciscan dialysis centers will result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion is not met for Fresenius and Franciscan. This sub-criterion is met for DaVita.**

(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.

FMC

As previously stated, the capital expenditure associated with the establishment of the six-station FMC Milton dialysis center is $2,896,891, and FMC's portion of the costs is $1,830,387. FMC states that the project will be financed through existing reserves from RCG's parent company. A review of FMC's historical financial statements show the funds necessary to finance the project are available. [Source: Second Amended Application p15 and historical files] Based on the information provided, the department concludes **this sub-criterion is met.**

FHS

The capital expenditure associated with the establishment of the six-station Franciscan Bonney Lake dialysis center is $2,356,175, and FHS's portion of the costs is $2,172,481. FHS states that the project will be financed through existing reserves as well. A review of FHS's historical financial statements show the funds necessary to finance the project are available. [Source: Amended Application p28 and historical files] Based on the information provided, the department concludes **this sub-criterion is met.**

DaVita

As previously stated, the capital expenditure associated with the expansion of DaVita Puyallup Dialysis Center is $212,140. DaVita states the project will be funded from DaVita's capital expenditures budget. 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: Amended Application p12 and historical files] DaVita provided a letter of financial commitment to the project. A review of DaVita's historical financial statements show the funds necessary to finance the project are available. [Source: Amended Application Appendix 6 and historical files] Based on the information provided, the department concludes **this sub-criterion is met.**

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

Based on the source information reviewed, the department concludes:

- Fresenius Medical Care's project has met the structure and process of care criteria in WAC 246-310-230;
- Franciscan Health System's project has met the structure and process of care criteria in WAC 246-310-230; and
- DaVita, HealthCare Partners 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 full time equivalents (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.

FMC

FMC Milton dialysis center would be a new facility, FMC provided a breakdown of all proposed staff beginning in December 2015, and the full year one (2016) through full year three (2018). [source: Second Amendment Application, p30] A breakdown of the FTEs is shown in Table 14.

Table 14
FMC Milton Dialysis Center Projected FTEs

Staff/FTEs	Start 12/1/2015	2016 Increase	2017 Increase	2018 Total	Total
Medical Director		Professional Services Contract			
Nurse Manager	1.20	1.20	1.25	1.25	4.90
Registered Nurse	1.25	1.80	1.90	2.00	6.95
Patient Care Techs	1.30	1.80	2.20	2.40	7.70
Biomedical Techs	0.20	0.20	0.20	0.20	0.80
Administrative	0.25	0.25	0.50	0.50	1.50
MSW	0.40	0.40	0.45	0.45	1.70
Dietician	0.40	0.40	0.45	0.45	1.70
Total FTEs	**5.00**	**6.05**	**6.95**	**7.25**	**25.25**

FMC states that it does not anticipate any difficulty in recruiting staff for the FMC Milton dialysis center due to its location and past success in attracting qualified health personnel. Further, FMC states this is aided by their competitive wage and benefit packages. [Source: Second Amendment Application, p31]

FMC has a contract with Seth Thaler, MD as the medical director for the proposed facility and provided a copy of the medical director's agreement that identified RVS PLLC (the Consultant), a Washington professional services corporation comprised of the following physicians: Julia Anuras, MD, Chris Burtner, MD, Michael Mondress MD, Vo Nyugen MD, and Seth Thaler, MD. [Source: Supplement Information Revised Exhibit 5, p1]

Based on the information reviewed, the department concludes adequate staffing for the six stations FMC Milton dialysis center is available or can be recruited. **This sub-criterion is met.**

FHS

Franciscan Bonney Lake dialysis center would be a new facility, FHS provided a breakdown of all proposed staff beginning in December 2015, and the full year one (2016) through full year three (2018). [Source: Amendment Application, p30] A breakdown of the FTEs is shown Table 14.

Table 15
FHS Bonney Lake Dialysis Center
Proposed Staffing

	2015	2016	2017	2018
HD Tech	2.40	2.40	2.40	2.40
RNs	1.40	1.40	1.40	1.40
Clinical Nurse Mgr	1.00	1.00	1.00	1.00
Unit Secretary			0.50	0.50
MSW	0.10	0.20	0.30	0.30
Dietician	0.10	0.20	0.30	0.30
Total	**5.00**	**5.20**	**5.90**	**5.90**

FHS stated they are aware that the staffing needs for the Table 15 are relatively small for their size of organization. FHS's efforts to assure that their staffing needs to support their existing and proposed new programs by offering competitive wage and benefit packages. FHS has listed eight different bullet points for specific strategies for clinical, ancillary and support staff recruitment and retention. [Source: Amendment Application, p31]

FHS has a confirmed that nephrologist, Dr. Amandeep Gill will serve as the medical director for the Franciscan Bonney Lake Dialysis Center. FHS has provided a copy of the medical director's agreement. [Source: Supplement Information Attachment 1]

Based on the information reviewed, the department concludes adequate staffing for the stations FHS Bonney Lake dialysis center is available or can be recruited. **This sub criterion is met.**

DaVita

DaVita Puyallup Dialysis Center is currently in operation with 16 dialysis stations. Table 16 shows the current and projected staffing for this facility if the project is approved.

Table 16
DaVita Puyallup Dialysis Center 2014-2018 FTEs

Staff/FTEs	Current FTE	Full Year 2016	Full Year 2017	Full Year 2018	Total FTEs
Medical Director	Professional Services Contract				
Administrator	1	1	0	0	1
Registered Nurses	4.2	4.2	0.3	0.2	4.7
Patient Care Tech	7.8	7.8	0.4	0.4	8.6
Biomedical Tech	0.3	0.4	0	0	0.4
Administrative Admin	1.2	1.2	0	0.1	1.3
Social Worker	1.1	1.1	0	0.1	1.2
Dietitian	1.1	1.1	0	0.1	1.2
Reuse Technician	1	1	0	0	1
Licensed Practice Nurse	1.6	1.6	0	0	1.6
Total FTE's	**19.3**	**19.4**	**0.7**	**0.9**	**21**

As shown in Table 16, DaVita expects a minimal increase over the three year period time. DaVita sated that is that it expects no difficulty in recruiting staff since they are located in an urban area and have a history of being able to recruit staff. [source: Amended Application p27] Based on the source documents evaluated, the department concludes adequate staffing for the six station increase for DaVita Puyallup 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 no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

FMC

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 Milton dialysis center, ancillary and support services, such as pharmacy, laboratory, and radiology will be secured well in advance of opening.

Based upon FMC past successes, FMC does not anticipate any difficulties in meeting the clinical service demands of patients that will be cared for in the proposed facility. [Source: Second Amendment Application, p31]

Based on this information, the department concludes FMC currently has access to necessary ancillary and support services that could support the proposed facility. 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. **With the condition, this sub-criterion is met.**

FHS

Franciscan understands, as Medicare requirements for dialysis certification there are special social services and dietary support services to be included with their program. As with all their existing facilities, FHS will continue to provide these special services and additional typical ancillary support services including pharmacy, laboratory, and blood administration will be available. [Source: Amendment Application, p 32]

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

DaVita

As a provider of dialysis services in the Pierce County planning area #1, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers within Washington State. For the DaVita Puyallup Dialysis Center, ancillary and support services such as social services, nutrition, financial counseling, pharmacy access, patient and staff education, human resources, material management, administration and biomedical technical services are provide 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: Amendment Application, p 28]

Based on this information, the department concludes DaVita will continue to 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 no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

FHS

As previously stated, FMC 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.[11]

Fresenius Medical Care is the parent company of RCGNW. Information available at Fresenius Medical Care North America's website stated, in the United States, Fresenius Medical Care is the largest provider of dialysis products and services with over 1,800 kidney dialysis clinics, and it provides care for nearly 138,000 patients. [Source:http://www.fmcna.com/fmcna/DialysisCompany/dialysis-company.html]

As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public. To accomplish this task, in February 2010 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for conducting surveys where Fresenius Medical Care or any of its subsidiaries have healthcare facilities. Of the 45 states[12] and the non-state entities surveyed, the department received 26 responses or 55% of those surveyed[13].

Six of the 26 states responding to the survey indicated that non-compliance deficiencies were cited at Fresenius facilities in the past three years, but none was reported to have resulted in fines or enforcement action. Fresenius submitted and implemented acceptable plans of correction. Given the results of the out-of-state compliance history of the facilities 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]

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

[12] This figure excludes Washington. The department did not send a survey to itself for compliance.

[13] Those not responding are Alabama, Arkansas, District of Columbia, Georgia, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, New Jersey, New York, Oklahoma, Pennsylvanian, Rhode Island, Texas, Vermont, Wisconsin, and Puerto Rico.

Fresenius is currently a provider of dialysis services within Washington State, and operates 18 kidney dialysis treatment centers in 14 separate counties. For medical director services, FMC provided a copy of the Medical Director Agreement and compensation agreement between itself and Seth Thaler, MD. A review of the compliance history for Dr. Thaler revealed no recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of FMC and that of the current medical director, the department concludes that there is reasonable assurance that the FMC Milton dialysis center would operate in compliance with state and federal regulations with the establishment of six-station dialysis center. **This sub-criterion is met.**

FHS

As previously stated, FHS is currently a provider of dialysis services within Pierce County planning area 1. 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.
For medical director services, FHS provided a copy of the Medical Director Agreement and compensation agreement between itself and Amandeep Gill, MD. A review of the compliance history for Dr. Gill revealed no recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of FHS and that of current medical director, the department concludes that there is reasonable assurance that the FHS Bonney Lake dialysis center would operate in compliance with state and federal regulations with the establishment of six-station dialysis center. **This sub-criterion is met.**

DaVita

DaVita currently within Washington State alone owns and operates 37 kidney dialysis treatment centers in 15 separate counties. DaVita operates or provide administrative services to approximately 2,098 outpatient dialysis centers located in the United States, serving approximately 165,000 patients. [Source: Amended Application pgs. 1-2]

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 and in conformance with applicable state licensing requirements and or Medicare/Medicaid certification.[14]

To accomplish this task, in February 2010 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the each of the states, the District of Columbia, and San Juan Puerto Rico, where DaVita or any subsidiaries have health care facilities. The department received responses from 21 states or 47% of the 45 entities.[15] The compliance history of the remaining 24 states, the District of Columbia, and San Juan Puerto Rico is unknown.[16]

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

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

Ten of the 24 states responding to the survey indicated that minor non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Iowa, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported to have no deficiencies and are currently in compliance with applicable regulations. The Iowa facility chose voluntarily termination in August 2007 due to its inability to remain in compliance with Medicare Conditions for Coverage, rather than undergo the termination process with Medicare. This facility is currently operating as a private ESRD facility.

The department concludes that considering the more than 1,912 facilities owned/managed by DaVita, one out-of-state facility listed above demonstrated substantial non-compliance issues; therefore, the department concludes the out-of-state compliance surveys are acceptable. For Washington State, since January 2010, the Department of Health's Office of Investigations and Inspections as the contractor for Medicare has completed more than 26 compliance surveys for the operational facilities that DaVita either owns or manages.[17] Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [Source: Facility survey data provided by the Investigations and Inspections Office]

For medical director services, DaVita provided a copy of the executed Medical Director Agreement proposed between itself, and Zhuowei Wang, M.D. A review of Dr. Wang'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] Based on the source documents evaluated, the department concludes **this sub-criterion is met.**

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

[17] As of the writing of this evaluation, five facilities—East Wenatchee Dialysis Center, Battle Ground Dialysis Center, Whidbey Dialysis Center, Everett Dialysis Center, and Kennewick Dialysis Center—were recently approved by the department and are not yet operational. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita.

(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.

FMC

The department considered FMC'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 Pierce County. This project proposes to establish six stations in Milton located in Pierce County planning area 1.

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, FMC demonstrated it is likely to have appropriate relationships to the service area's existing health care system within the planning area. **This sub-criterion is met**.

FHS

The department considered FHS's history of providing care to residents in Washington State. The department concludes that the applicant has been not only providing dialysis services to the residents of Washington State for several years but also been appropriately participating in relationships with the community 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 Pierce County. This project proposes to establish six stations in Milton located in Pierce County planning area #1.

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, FHS demonstrated it is likely to have appropriate relationships to the service area's existing health care system within the planning area. **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 the relationship with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this new facility would change these relationships and DaVita has submitted documentation that this facility will continue to cooperate with existing providers.

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 stations in Pierce County planning area #1. This project proposes to add six stations to the 16 stations DaVita Puyallup 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, DaVita demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area.

DaVita provided their patient transfer agreement currently used at DaVita Puyallup Dialysis Center used at the existing facilities in Washington. The transfer agreement between Good Samaritan Hospital and MultiCare Health Systems will continue to be used at the expanded DaVita Puyallup Dialysis Center. [Source: Amended Application, Appendix 12]

Based on the source documents evaluated, the department concludes approval of this project would promote continuity in provision of healthcare for the planning area, and would not result in an unwarranted fragmentation of services. **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.

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

FHS
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 reviewed, the department concludes that

- Fresenius Medical Care project has not met the cost containment criteria in WAC 246-310-240(1) and (2); and

- Franciscan Health System project has not met the cost containment criteria in WAC 246-310-240(1) and (2); and

- DaVita, Inc.'s project has met the cost containment criteria in WAC 246-310-240(1) and (2) provided the applicant agrees to the conditions identified in the 'conclusion' section of this evaluation.

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.

FMC

To comply with this sub-criterion, FMC stated that it considered the alternatives listed and summarized below.

- Lease space for a 6-station facility
- Build a new facility for 6-stations
- Shared services/ contract arrangements
- Do noting

The applicant chose to submit an application and rejected all other options. FMC stated it rejected other options because doing nothing, leasing space or sharing services with another provider would not improve access. [Source: Application, p34]

Step One

For this project, the department determined that FMC's did not meet all review criteria under WAC 246-310-210, 220, and 230. Since FMC did not meet all the review criteria, the department determines that it also failed to meet the review criteria under cost containment WAC 246-310-240. The department concludes that FMC's proposal to establish a new 6-station dialysis facility in Pierce County ESRD planning area #1 is not the best available alternative. Therefore, step two and step three are not necessary.

FHS

To comply with this sub-criterion, FHS stated it considered two options before electing to proceed with the establishment of the 6-station facility in Pierce County ESRD planning area#1. The options considered by FHS are listed and summarized below.

- Do nothing
- Expand the Puyallup facility

Option #1: Do nothing.

FHS asserted that doing nothing was rejected because providers in the planning area have been operating above the required 4.8 patients per station. For this reason, this option was rejected. [Source: Application, p35]

Option #2: Expand the Puyallup Facility.

FHS states that expanding its Puyallup facility was ruled out because it is the applicants desire to improve access to services for ESRD patients within the planning area. For the reason stated, IN-RCG decided to reject this option. [Source: Application, p35]

Step One

For this project, the department determined that FHS did not meet all review criteria under WAC 246-310-210, 220, and 230. Since FHS did not meet all the review criteria, the department determines that it also failed to meet the review criteria under cost containment WAC 246-310-240. The department concludes that FHS's proposal to establish a new 6-station dialysis facility in Pierce County ESRD planning area #1 is not the best available alternative. Therefore, step two and step three are not necessary

DaVita

To comply with this sub-criterion, DaVita stated it considered two options before submitting an application to expand it existing 16-station DaVita Puyallup Dialysis Center in Pierce County ESRD planning area#1. The options considered by DaVita are listed and summarized below.

- Add no additional stations
- Build a new 6-station dialysis center in Pierce one
- Expand the existing 16-station facility by 6-stations

Add no additional stations.
DaVita stated the existing Puyallup facility is operating in excess of 4.8 patients per station and therefore there is need for additional capacity. For these reason, DaVita rejected this option. Add no additional stations

Build a new 6-station dialysis center.
DaVita stated it looked but could not find a suitable location for new facility. DaVita asserted that a new facility located far away from patients in the planning area, would not be advantageous, but expensive when compared to adding stations to an existing facility. For the reasons given, DaVita rejected this option and decided to add 6-stations to the existing DaVita Puyallup Dialysis Center. [Source: Application, p30]

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

Step Two
Within the application, DaVita stated there are several advantages to the DaVita Puyallup Dialysis Center proposal that promote staff and systemic efficiency such as:

- Increase availability and flexibility of scheduling for all patients
- More efficient use of RN's, management and administrative assets
- Committed to continuous quality improvements that result in higher clinical outcomes, lower hospitalization rates and lower costs to payers

Given that the only other option to this project is to do nothing, taking into account that the existing facility in the planning area exceeds 4.8 patients per station as of the end of year report December 31, 2013, and the results of the numeric need methodology. Therefore, the department concludes that the project described is DaVita's best available alternative.

Step Three
This step is used to determine the best available alternative between two or more approvable projects. For the 2014 ESRD Concurrent Review Cycle #2, FMC, FHS and DaVita submitted applications to add 6-stations in Pierce County ESRD planning area #1, but the department determined that FMC and FHS applications did not met the applicable review criteria. Therefore, step three is not necessary.

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

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

FMC

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 did not meet the financial feasibility criterion because the facility would be over-built with dialysis stations not need for this project. Therefore, the department could not conclude that a criterion that is tied directly to the lease agreement has been met. Based on the information, the department concludes **this sub-criterion is not met.**

FHS

FHS also proposes to lease a "built to suit" facility from a real estate developer. These costs were evaluated in the financial feasibility section of this analysis. The department concluded the overall project did not meet the financial feasibility criterion because the facility would be over-built with dialysis stations not need for this project. Therefore, the department concluded the overall project did not meet the financial feasibility criterion. Based on the information, the department concludes this **sub-criterion is not met**

DaVita

DaVita's proposes to add 6-stations to an existing facility. DaVita's lease costs were evaluated in the financial feasibility section of this analysis. The department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes **this sub-criterion is met.**

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

FMC

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 not met**

FHS

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 not met**.

DaVita

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.**

APPENDIX A

Washington State Department of Health

2014
Pierce County 1
ESRD Need Projection Methodology

	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	Pierce One	2008	2009	2010	2011	2012	2013
	98354	9	5	4	4	4	4
	98371	15	12	10	11	15	17
	98372	21	19	13	17	17	29
	98373	10	13	14	15	21	23
	98374	13	17	15	16	16	20
	98375	2	11	17	11	9	20
	98390	12	7	8	5	7	9
	98391	10	14	23	21	20	15
	TOTALS	92	98	104	100	109	137
246-310-284(4)(a)	**Rate of Change**		**6.52%**	**6.12%**	**-3.85%**	**9.00%**	**25.69%**
	6% Growth or Greater?		**TRUE**	**TRUE**	**FALSE**	**TRUE**	**TRUE**
	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)			134.50	142.80	151.10	**159.40**
Station Need for Patients	**Divide Resident Incenter Patients by 4.8**			28.0208	29.7500	31.4792	**33.2083**
	Rounded to next whole number			**29**	**30**	**32**	**34**
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				28	28	28	**28**
Results of (4)(c) above			-	29	30	32	**34**
Net Station Need				-1	-2	-4	**-6**
Negative number indicates need for stations							

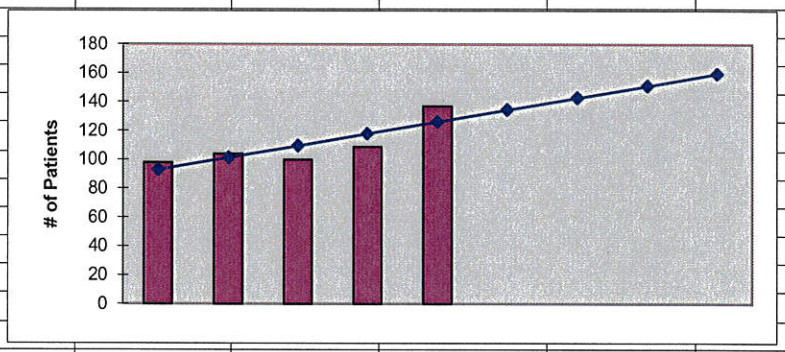
Planning Area Facilities

Name of Center	# of Stations
Greater Puyallup	**12**
DaVita Puyallup	**16**
Total	**28**

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

2014
Pierce County 1
ESRD Need Projection Methodology

x	y	Linear
2009	98	**93**
2010	104	**101**
2011	100	**110**
2012	109	**118**
2013	137	**126**
2014		**134.50**
2015		**142.80**
2016		**151.10**
2017		**159.40**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.826208144
R Square	0.682619897
Adjusted R Square	0.576826529
Standard Error	10.33279568
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	688.9	688.9	6.452388386	0.084668034
Residual	3	320.3	106.7666667		
Total	4	1009.2			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-16581.7	6570.978103	-2.523475157	0.085914293	-37493.48499	4330.084986	-37493.48499	4330.084986
X Variable 1	8.3	3.267516896	2.540155189	0.084668034	-2.098697074	18.69869707	-2.098697074	18.69869707

RESIDUAL OUTPUT

Observation	*Predicted Y*	*Residuals*
1	93	5
2	101.3	2.7
3	109.6	-9.6
4	117.9	-8.9
5	126.2	10.8