STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

May 22, 2015

CERTIFIED MAIL # 7009 0960 0000 5565 0451

David Natali, Regional Operations Director
DaVita Healthcare Partners, Inc.
32275 – 32nd Avenue South
Federal Way, Washington 98001

RE: CN Application #15-04A2

Dear Mr. Natali:

We have completed review of the Certificate of Need (CN) application submitted by DaVita Healthcare Partners, Inc. proposing to add nine dialysis stations to Tacoma Dialysis Center in Tacoma, within Pierce County End Stage Renal Disease (ESRD) planning area #4. Enclosed is a written evaluation of the application.

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

Washington Administrative Code 246-310-240 Cost Containment

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

Appeal Option 1:
You or any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

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

Mailing Address:	Physical Address
Department of Health	Department of Health
Adjudicative Service Unit	Adjudicative Clerk Office
Mail Stop 47879	111 Israel Road SE
Olympia, WA 98504-7879	Tumwater, WA 98501

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

Sincerely,

For Bart M. Eggen

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

Enclosure

EXECUTIVE SUMMARY

EVALUATIONS DATED MAY 22, 2015, FOR THE FOLLOWING CERITICATE OF NEED APPLICATIONS PROPROSING TO ADD DIALYSIS STATION CAPACITY IN PIERCE COUNTY END STAGE RENAL DISEASE PLANNING AREA #4

- **FRESENIUS MEDICAL CARE PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN FIFE**
- **DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ADD NINE STATIONS TO DAVITA TACOMA DIALYSIS CENTER IN TACOMA**
- **DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN FIFE**
- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ADD NINE STATIONS TO ST. JOSEPH DIALYSIS CENTER IN TACOMA**

BRIEF PROJECT DESCRIPTIONS

Fresenius Medical Care

Fresenius Medical Care (FMC) is the parent corporation for five subsidiaries. Renal Care Group, Inc. (RCG) is one of the five subsidiaries and is a publicly held, for-profit corporation, incorporated in the state of Washington. RCG provides dialysis services through its facilities across the nation. FMC submitted this application on the behalf of RCG. FMC proposes to establish a new nine-station dialysis facility in Fife within the Pierce County Dialysis Planning Area #4.

This facility will provide in-center hemodialysis, home hemodialysis, dialysis training services, 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: Application, p12]

The capital expenditure associated with this project is $1,764,119; and of that amount, FMC would be responsible for $1,623,324, or 92% of the total. [source: Application, p25]

If this project is approved, FMC anticipates the nine-station facility would become operational in September 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation and 2019 would be year three. [source: November 26, 2014, supplemental information, p1]

DaVita HealthCare Partners, Inc.

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

DaVita submitted two separate applications during this concurrent review cycle. One application proposes to expand an existing facility in Pierce County planning area #4 [DaVita-Tacoma] and the other proposes to establish a new dialysis center in the planning area [DaVita-Fife]. The two applications are summarized below.

DaVita-Tacoma

This application proposes to add nine stations to DaVita's Tacoma Dialysis Center located in Tacoma. This facility currently provides in-center hemodialysis, home hemodialysis, and dialysis training services. The facility currently has an isolation area and a permanent bed station. The dialysis facility also provides evening treatments (after 5 pm). [source: 2nd Amendment Application, p1 and pp10-11]

The capital expenditure associated with this project is $99,920. [source: 2nd Amendment Application, Appendix 7]

If this project is approved, DaVita anticipates the additional nine stations would become operational in August 2015. Under this timeline, 2016 would be the facility's first full calendar year of operation and 2018 would be year three. [source: 2nd Amendment Application, p14 and November 26, 2014, supplemental information, p2]

DaVita-Fife

This application proposes to establish a nine-station dialysis center located in Fife. The Fife dialysis center would provide in-center hemodialysis, backup dialysis service, dialysis training services, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: 1st Amendment Application, pp10-11]

The capital expenditure associated with this project is $2,049,810; and of that amount, DaVita would be responsible for $1,846,959 or 90% of the total. [source: 1st Amendment Application, Appendix 7]

If this project is approved, DaVita anticipates the nine-station dialysis center would become operational by the end of February 2016. Under this timeline, 2017 would be the facility's first full calendar year of operation and 2019 would be year three. [source: 1st Amendment Application, p4 and Appendix 7]

Franciscan Health System

Franciscan Health System (FHS) is a healthcare provider based in Tacoma, within Pierce County and is an affiliate of Catholic Health Initiatives. FHS provides healthcare services to the residents of Pierce and King Counties through its seven hospitals and a variety of other healthcare facilities.

For this project, FHS proposes to add nine dialysis stations to the existing 16-station center known as St. Joseph Medical Center dialysis center located in Tacoma. For reader ease, the facility will be referenced as St. Joseph Dialysis Center or "SJDC." This facility currently provides in-center hemodialysis, home hemodialysis, and dialysis training services. The facility currently has two dedicated isolation areas and nine permanent bed stations. The dialysis facility also provides evening treatments (after 5 pm). [source: Application, p11]

The capital expenditure associated with this project is $206,572. [source: Application, p11] If this project is approved, FHS anticipates the nine additional stations would be operational in September 2015. Under this timeline, 2016 would be the facility's first full calendar year of operation and 2018 would be year three. [source: November 25, 2014, supplemental information, p2]

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

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care proposing to establish a nine-station dialysis center in Fife, within Pierce County planning area #4 is not consistent with the applicable criterion and a Certificate of Need is denied.

DaVita-Tacoma

For the reasons stated in this evaluation, the application submitted by DaVita Healthcare Partners, Inc. proposing to add nine dialysis stations to Tacoma Dialysis Center located in Pierce County planning area #4 is not consistent with the applicable criterion and a Certificate of Need is denied.

DaVita-Fife

For the reasons stated in this evaluation, the application submitted by DaVita Healthcare Partners, Inc. proposing to establish a nine-station dialysis center in Fife, within Pierce County planning area #4 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 add nine dialysis stations to the existing 16-station dialysis center known as St. Joseph Dialysis Center located in Tacoma, within Pierce County planning area #4 is consistent with applicable criteria of the Certificate of Need Program, provided Franciscan Health System agrees to the following in its entirety.

Project Description:

This certificate approves the addition of nine dialysis stations to the existing 16-station dialysis center known as St. Joseph Dialysis Center located in Tacoma within Pierce County planning area #4. At project completion, the dialysis center is approved to certify and operate 25 dialysis stations. Services to be provided at St. Joseph Dialysis Center include hemodialysis with treatment shifts beginning after 5:00 pm, permanent bed stations, and an isolation station. Based on the information provided in the application, a breakdown of all 25 stations is below.

Franciscan Health System-St. Joseph Dialysis Center

Private Isolation Room	2
Permanent Bed Station	14
Other In-Center Stations	~~10~~ **9**
Total	25

Conditions:

1. Franciscan Health System agrees with the project description as stated above. Franciscan Health System 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.

Approved Capital Expenditure

The approved capital expenditure for this project is $206,572.

EVALUATIONS DATED MAY 22, 2015, FOR THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY IN PIERCE COUNTY END STAGE RENAL DISEASE PLANNING AREA #4

- **FRESENIUS MEDICAL CARE PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN FIFE**
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- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ADD NINE STATIONS TO ST. JOSEPH DIALYSIS CENTER IN TACOMA**

APPLICANT DESCRIPTIONS

Fresenius Medical Care, Inc.

Renal Care Group Northwest, Inc (RCG-NW) is one of three entities owned by Renal Care Group, Inc. (RCG). RCG is responsible for the operations of dialysis 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, through a 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: CN historical files and Application, pp7-10 and Exhibit 1]

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

In Washington State, Fresenius Medical Care or one of its subsidiaries owns, operates, or manages 19 kidney dialysis facilities in 13 separate counties. A listing of the 19 facilities in Washington is below and continues on the following page. [source: Application pp7-10]

Adams County
Fresenius Leah Layne Dialysis Center

Benton County
Columbia Basin Dialysis Center

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

Grant County
Moses Lake Dialysis Facility

Lewis County
Chehalis Facility

Cowlitz County
Fresenius Longview Dialysis Center

Okanogan County
Omak Dialysis Facility

Grays Harbor County
Aberdeen Dialysis Facility

Stevens County
Colville Dialysis Center

Mason County
Shelton Dialysis Center

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

Thurston County
Fresenius Lacey Dialysis Center
Thurston County Dialysis Center

Walla Walla County
QualiCenters Walla Walla

DaVita Healthcare Partners, Inc.

DaVita, Inc. is a for-profit end stage renal care provider that was acquired by HealthCare Partners Holding, Inc. in late 2010. To reflect the combination of the two companies, DaVita, Inc. changed its name to DaVita HealthCare Partners Inc. Throughout this evaluation, DaVita HealthCare Partners Inc. will be referenced as 'DaVita.'

Currently DaVita operates or provides administrative services in approximately 2,119 outpatient dialysis centers located in the United States. [source: 2nd Amendment Application, p6] In Washington State, DaVita owns or operates 38[1] kidney dialysis facilities in 18 separate counties. Listed below and continuing on the following page are the names of the facilities owned or operated by DaVita in Washington State. [source: CN historical files and 2nd Amendment Application, pp6-7]

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

Pacific
Seaview Dialysis Center

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

Skagit
Cascade Dialysis Center

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

[1] Nine of DaVita's dialysis facilities are CN approved, but not yet operational. The nine facilities are: Battle Ground Dialysis Center, Belfair Dialysis Center, Cascade Dialysis Center, Echo Valley Dialysis Center, Pilchuck Dialysis Center, Redondo Heights Dialysis Center, Rainier View Dialysis Center, Renton Dialysis Center, and Tumwater Dialysis Center.
[2] Everett Dialysis Center is owned by Refuge Dialysis, LLC, which is owned 80% by DaVita, Inc. and 20% by The Everett Clinic. The facility is managed DaVita.
[3] Marysville Dialysis Center is also owned by Refuge Dialysis, LLC and managed DaVita.

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

Kittitas
Ellensburg Dialysis Center

Mason
Belfair Dialysis Center

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

Stevens
Echo Valley Dialysis Center

Thurston
Olympia Dialysis Center
Tumwater Dialysis Center

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

Franciscan Health System

Franciscan Health System (FHS) is a healthcare provider based in Tacoma, within Pierce County and is an affiliate of Catholic Health Initiatives. FHS provides healthcare services to the residents of Pierce and King Counties through its seven hospitals and a variety of other healthcare facilities.

In Washington State, FHS owns, operates, or manages five dialysis facilities located in Pierce County. Below is a listing of the five facilities in Washington. [source: Application, pp5-7]

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 Dialysis Center
Franciscan South Tacoma Dialysis

PROJECT DESCRIPTIONS

Fresenius Medical Care, Inc.

FMC proposes to establish a new nine-station dialysis facility in Fife within Pierce County Dialysis Planning Area #4. The proposed center is to be located at 5113 Pacific Highway East, Suites 11 & 12 in Fife [98424]. The new center will provide in-center hemodialysis, home hemodialysis, dialysis training services, 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: Application, p12]

The capital expenditure associated with this project is $1,764,119; and of that amount, FMC would be responsible for $1,623,324 and the landlord would be responsible for $140,795. [source: Application, p25]

If this project is approved, FMC anticipates the nine-station facility would become operational in September 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation and 2019 would be year three. [source: November 26, 2014, supplemental information, p1]

Public Comments

DaVita provided comments on the FMC's application related to the number of stations proposed. A summary of the comments is below.

- FMC will be setting up and equipping more than the nine stations requested in its application.

Rebuttal

A summary of FMC's responses to the public comments is below.

- The additional dialysis machines and chairs listed in FMC's equipment list in Exhibit 8 of the application is back-up equipment used during repair and maintenance or if an operable machine fails. FMC does not state anywhere in the application or screening responses that the equipment is for '*expansion subject to CN approval*' as asserted by DaVita.

Department's Evaluation

Exhibit 8 in FMC's application identifies the equipment needed for the proposed nine-station facility in Fife. Ten stations are in the column identified as '*Initial Build-Out*' and three stations are in the column identified as '*Expansion Subject to CON*.' This exhibit does imply that FMC would be purchasing nine stations for this project and another five stations for future expansion. During the screening of FMS's application CN staff requested clarification of the line drawings provided in Exhibit 9 which showed more than nine stations set-up at the proposed center. In response FMC provided revised line drawings [Revised Exhibit 9] showing only 9 stations set up and reconfigured space for storage or offices. FMC stated that when future additional stations are approved at the Fife facility, the storage or office space could be easily converted to patient space. FMC states this approach of completing additional space, but using it for storage or offices, is more cost effective and less disruptive to patients than leaving the space incomplete and finishing it at a later date when the facility is operational.

The department accepted this explanation and the revised line drawings to demonstrate that the facility will be equipped to operate a total of nine stations. FMC states the additional three stations referenced in the column identified as '*Expansion Subject to CON'* will be used as back-up equipment. This approach is acceptable with the recognition that the costs for these three stations is included in this nine-station project as back-up stations; rather than additional stations to be used for a future expansion project.

DaVita-Tacoma

This application proposes to add nine stations to DaVita's Tacoma Dialysis Center located at 3401 South 19th Street in Tacoma [98405]. Currently, the Tacoma facility operates 13 dialysis stations. If this station addition is approved, the center would be operating 22 dialysis stations. [source: 2nd Amendment Application, p1]

DaVita's Tacoma Dialysis Center currently provides in-center hemodialysis, home hemodialysis, and dialysis training services. The facility has an isolation area and a permanent bed station. The dialysis facility also provides evening treatments (after 5 pm). [source: 2nd Amendment Application, p1 and pp10-11]

The capital expenditure associated with this project is $99,920; of that amount, 75% is related to equipment and the remaining 25% is for leasehold improvements and professional service fees. [source: 2nd Amendment Application, Appendix 7]

If this project is approved, DaVita anticipates the additional nine stations would become operational in August 2015. Under this timeline, 2016 would be the facility's first full calendar year of operation with 22 stations and 2018 would be year three. [Source: 2nd Amendment Application, p14 and November 26, 2014, supplemental information, p2]

Public Comments

FMC provided comments on DaVita's Tacoma application related to space for the number of stations proposed. A summary of the comments is below.

- DaVita's allocation of space for the addition of nine stations in Tacoma is much too low. The space per station figure is too low. [source: FMC public comments]

Rebuttal

Below is a summary of DaVita's responses to the public comments.

- The Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2010 Edition (FGI Guidelines) require at least 80 square feet for a dialysis station treatment area. Our 2nd amendment application shows approximately 1,800 square feet allocated for chronic dialysis stations. The space satisfies the minimum station area guidelines for 20 dialysis stations, one bed station, and one isolation station.

Department's Evaluation

Washington Administrative Code 246-310-200(2) allows the department to consider applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking. The FGI guidelines are one example of the program's use of an organization with expertise in a particular area. Another example is the Department of Health's Construction Review Services office (CRS) which reviews the construction for kidney dialysis facilities. CRS review of kidney dialysis facilities is voluntary, rather than mandatory.[4] The CRS website cites the guidelines used for review of kidney dialysis facilities [NFPA 101, 2000 Edition] which also cites the FGI Guidelines referenced by DaVita in its response to public comments. The FGI guidelines state that individual patient treatment areas must be at least 80 square feet. [source: FGI 3.10.3.2.1] DaVita's Tacoma application identifies the total square footage of the dialysis center at 7,695 and the chronic dialysis station space to be 1,800 square feet. [source: 2nd Amendment Application, p13] The proposed 22 station facility must have at least 1,760 square feet within the chronic dialysis station area. The 1,800 square feet identified by DaVita meets this FGI requirement.

DaVita-Fife

This application proposes to establish a nine-station dialysis center located at 5306 Pacific Highway East, #D in Fife [98424]. The Fife dialysis center would provide in-center hemodialysis, backup dialysis service, dialysis training services, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: 1st Amendment Application, pp10-11]

[4] An exception to the voluntary review is kidney dialysis facilities that will be licensed under a hospital's license. CRS review of these facilities is mandatory.

The capital expenditure associated with this project is $2,049,810; of that amount, DaVita would be responsible for $1,846,959 and the landlord would be responsible for $202,851. [source: 1st Amendment Application, Appendix 7]

If this project is approved, DaVita anticipates the nine-station dialysis center would become operational by the end of February 2016. Under this timeline, 2017 would be the facility's first full calendar year of operation and 2019 would be year three. [source: 1st Amendment Application, p4 and Exhibit 7]

Franciscan Health System

SJDC has been operating for many years and has been at the current site in in the North Pavilion since 1982. Over the years the dialysis center increased the number of stations. In 1991, St. Joseph Medical Center was approved for a total of 50 dialysis stations.[5] The dialysis center continued to operate 50 stations until year 2010, when FHS established a 12-station facility in east Tacoma by relocating 12 of the 50 stations at St. Joseph Medical Center.[6] In year 2012, FHS established a 22-station facility in at another site in Tacoma using 22 of the remaining 38 stations at SJDC, leaving 16 stations at the center.[7]

With this project, FHS proposes to add nine dialysis stations to the existing 16-station dialysis stations at SJDC located at 1717 South 'J' Street in Tacoma [98405]. This facility currently provides in-center hemodialysis, home hemodialysis, and dialysis training services. The facility currently has two dedicated isolation areas and nine permanent bed stations. The dialysis facility also provides evening treatments (after 5 pm). [source: Application, p11]

The capital expenditure associated with this project is $206,572 and is solely dedicated to moveable equipment and associated sales tax. [source: Application, p11 &p34]

If this project is approved, FHS anticipates the nine additional stations would be available by the end of September 2015. Under this timeline, 2016 would be the dialysis center's first full calendar year of operation with 25 dialysis stations and 2018 would be year three. [source: November 25, 2014, supplemental information, p2]

APPLICABILITY OF CERTIFICATE OF NEED LAW

The application submitted by FMC and one of the applications submitted by DaVita [DaVita-Fife] are subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

The application submitted by FHS and the other application submitted by DaVita [DaVita-Tacoma] are 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).

[5] CN #1051 issued on June 13, 1991. [source: CN historical files]
[6] CN #1421 issued on April 27, 2010. [source: CN historical files]
[7] CN #1488 issued on September 18, 2012. [source: CN historical files]

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.

As allowed under Revised Code of Washington 34.05.360, the department adopted the following 'emergency rule' related to training services as defined in WAC 246-310-280. The rule became effective on April 1, 2015, and will be used in this evaluation for training services.

(13) "Training services" means services provided by a kidney dialysis facility to train patients for home dialysis. Home training stations are not used to provide in-center dialysis treatments. Stations used for training are not included in the facility's station count for projecting future station need or utilization. Types of home dialysis include at least, but are not limited to, the following:

(a) Home peritoneal dialysis (HPD); and

(b) Home hemodialysis (HHD).

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.[8]

TYPE OF REVIEW

As directed under WAC 246-310-282(1), the department accepted all four projects under the year 2014 Kidney Disease Treatment Centers-Concurrent Review Cycle #3. A chronologic summary of all four projects is provided in Appendix A attached to this document.

Public Comments

FMC provided comments on DaVita's Tacoma application related to the costs identified in the letter of intent vs the costs identified in the 2nd amendment application. Below is a summary of the comments.

- DaVita included a letter of intent with is 2nd amendment application that was 45.6% greater than its capital costs in this amendment. Since the application cannot be held for the 30-day letter of intent period, DaVita must wait for the next review cycle [2014 cycle 4] to submit an application.

Rebuttal

A summary of DaVita's responses to the public comments is below.

- DaVita submitted a letter of intent to add 9 stations to the Tacoma facility on July 31, 2014. This letter of intent identified an estimated capital cost of $146,360. DaVita submitted an application on August 29, 2014, consistent with the letter of intent. On September 30, 2014, DaVita submitted its 1st amendment application; and on October 15, 2014, DaVita submitted its 2nd amendment application for this project. The 2nd amendment application reduced the capital costs to $99,920 from the initial costs of $146,360. FMC asserts that since we reduced our capital costs in the 2nd amendment application by approximately 32% of our initial letter of intent costs, our 2nd amendment application should have been held for the 30 day letter of intent period, which would take it out of the concurrent review cycle. This is a misread of the rule.

Department's Evaluation

On August 29, 2014, DaVita submitted an application consistent with the letter of intent filed on July 31, 2014. On September 30, 2014, and October 15, 2014, DaVita submitted amendment applications consistent with WAC 246-310-100(6). An increase, or decrease, in the capital costs beyond the 12% allowable is a reason to amend an application [WAC 246-310-100(1)(d)]. The initial application and both amendment applications were appropriately submitted to continue in this concurrent review cycle.

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

AFFECTED PERSONS

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

"…an "interested person" who:

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

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

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

Under concurrent review, each applicant is an affected person for the other application(s). Throughout the review of this project, no other entities sought or received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Fresenius Medical Care's Certificate of Need application submitted August 29, 2014
- DaVita Healthcare Partners, Inc. second amended Certificate of Need application submitted on September 30, 2014 for its Tacoma Dialysis Center project[9]
- DaVita Healthcare Partners, Inc. first amended Certificate of Need application submitted on October 15, 2014 for its Fife project[10]
- Franciscan Health System's Certificate of Need application submitted August 29, 2014
- Fresenius Medical Care's 1st screening responses received November 26, 2014
- DaVita Healthcare Partners, Inc. 1st screening responses received November 26, 2014 for its Tacoma project and its Fife project
- Franciscan Health System's 1st screening responses received November 26, 2014
- Fresenius Medical Care's public comment received February 17, 2015
- DaVita HealthCare Partners, Inc. public comment received February 17, 2015 for its Tacoma project
- DaVita HealthCare Partners, Inc. public comment received February 17, 2015 for its Fife project
- Franciscan Health System public comment received February 17, 2015
- Fresenius Medical Care rebuttal comments received March 19, 2015
- DaVita HealthCare Partners, Inc. rebuttal comments received March 19, 2015 for its Tacoma project and its Fife project
- Franciscan Health System rebuttal comments received March 19, 2015
- Years 2008 through 2013 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2014 Northwest Renal Network June 30, 2014, third quarter utilization data released July 30, 2014

[9] DaVita submitted its initial application on August 29, 2014, consistent with the ESRD concurrent review cycle #3. On September 30, 2014, DaVita submitted its first amendment application consistent with WAC 246-310-100(6). On October 15, 2014, DaVita 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 discussed further in this evaluation.

[10] DaVita submitted its initial application on August 29, 2014, consistent with the ESRD concurrent review cycle #3. On October 15, 2014, DaVita submitted its first amendment application consistent with WAC 246-310-100(6). Once the amendment application was received, the initial application is no longer considered in this review and will not be discussed further in this evaluation.

SOURCE INFORMATION REVIEWED (continued)

- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office [ILRS database]
- Medical Quality Assurance Commission compliance history for credentialed or licensed staff
- Fresenius Medical Care website at www.fmcna.com
- DaVita Healthcare Partners website at www.davita.com
- Franciscan Health Systems website at www.chifranciscan.org
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Washington State Secretary of State website at www.sos.wa.gov
- US Department of Health and Human Services Office of Inspector General website at https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp#d
- Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2010 Edition (FGI Guidelines) section 3.10.3.2.1
- Certificate of Need historical files

CONCLUSIONS

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care proposing to establish a nine-station dialysis center in Fife, within Pierce County planning area #4 is not consistent with the applicable criterion and a Certificate of Need is denied.

DaVita-Tacoma

For the reasons stated in this evaluation, the application submitted by DaVita Healthcare Partners, Inc. proposing to add nine dialysis stations to Tacoma Dialysis Center located in Pierce County planning area #4 is not consistent with the applicable criterion and a Certificate of Need is denied.

DaVita-Fife

For the reasons stated in this evaluation, the application submitted by DaVita Healthcare Partners, Inc. proposing to establish a nine-station dialysis center in Fife, within Pierce County planning area #4 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 add nine dialysis stations to the existing 16-station dialysis center known as St. Joseph Medical Center dialysis center located in Tacoma, within Pierce County planning area #4 is consistent with applicable criteria of the Certificate of Need Program, provided Franciscan Health System agrees to the following in its entirety.

Project Description:

This certificate approves the addition of nine dialysis stations to the existing 16-station dialysis center known as St. Joseph Dialysis Center located in Tacoma within Pierce County planning area #4. At project completion, the dialysis center is approved to certify and operate 25 dialysis stations. Services to be provided at St. Joseph Dialysis Center include hemodialysis with treatment shifts beginning after 5:00 pm, permanent bed stations, and an isolation station. Based on the information provided in the application, a breakdown of all 25 stations is below.

Franciscan Health System
St. Joseph Dialysis Center

Private Isolation Room	2
Permanent Bed Station	14
Other In-Center Stations	~~10~~ **9**
Total	25

Conditions:

1. Franciscan Health System agrees with the project description as stated above. Franciscan Health System 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.

Approved Capital Expenditure

The approved capital expenditure for this project is $206,572.

CRITERIA DETERMINATIONS

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.
- DaVita HealthCare Partners, Inc.'s Tacoma 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 Fife 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 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.[11]

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.[12] In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

[11] 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]

[12] 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 2013.

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 projection year, 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—FMC, DaVita, and FHS—propose to add dialysis station capacity to Pierce County planning area #4. The following 16 zip codes are included in this planning area.

Zip	City	Zip	City
98402	Tacoma	98416	Tacoma
98403	Tacoma	98418	Tacoma
98404	Tacoma	98421	Tacoma
98405	Tacoma	98422	Tacoma
98406	Tacoma	98424	Fife
98407	Ruston	98443	Tacoma
98408	Tacoma	98465	Tacoma
98409	Lakewood	98466	Fircrest

FMC's Application of Numeric Methodology

FMC proposes to establish a new nine-station dialysis facility located in the Fife zip code of 98424. 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 Fife is located in Pierce County planning area #4, the number of projected patients was divided by 4.8 to determine the number stations needed in the planning area. FMC projected need for nine new stations in year 2017. [source: Application, pp18-20]

DaVita's Application of Numeric Methodology

DaVita proposes to add nine dialysis stations to Pierce planning area #4. The nine stations would either be added to the Tacoma Dialysis Center located in zip code 98405 or would be new stations located in a facility in Fife within zip code 98424.

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 nine new stations in year 2017. [source: DaVita-Tacoma 2nd Amendment Application, pp18-19; DaVita-Fife 1st Amendment Application, pp19-21]

FHS's Application of Numeric Methodology

FHS proposes to add nine stations to the 16-station dialysis center in the Tacoma zip code of 98405 within Pierce County planning area #4. FHS also projected need for the nine new stations using the linear regression and divided the number of patients by 4.8 to determine the number of stations needed in the planning area. [source: Application, pp23-25]

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 #4. The department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

Table 1 below shows a summary of the projected net need provided by the three applicants and the department for the Pierce County planning area #4. The department's methodology is included in this evaluation as Attachment B.

Table 1
Pierce County Planning Area #4
Numeric Methodology Summary

	4.8 in-center patients per station		
	2017 Projected # of stations	**Minus Current # of stations**	**2017 Net Need or (Surplus)**
FMC	74	65	9
DaVita	74	65	9
FHS	74	65	9
DOH	74	65	9

Table 1 above shows that all three applicants and the department projected a need for nine stations in the planning area. As a result, the net station need for Pierce County planning area #4 is nine for year 2014.

Public Comments

During the review of these four projects, each applicant—FMC, DaVita, and FHS—provided comments on the other application(s) related to this sub-criterion. A summary of the comments is below.

- Locating additional dialysis stations in Tacoma does not improve patient access to quality services in the planning area. [source: FMC public comments]
- FMC and DaVita do not address why Fife is the best location for a new facility in Pierce planning area #4. [source: FHS public comments]
- FHS's project fails to meet patient need because not all patients need a bed station and FHS states it will serve patients outside the planning area. [source: DaVita public comments]

Rebuttal

Below is a summary of each applicant's responses to the public comments.

- FMC conducted extensive research in the Pierce #4 planning area to determine the ideal location for a new dialysis facility to best meet patient need. Fife is a convenient and practical site for a new facility for a variety of reasons. FMC provided an overview of its research referenced above. [source: FMC rebuttal comments]
- Adding nine stations to DaVita's Tacoma facility will improve scheduling access for patients. The nine new stations means that new schedule slots for 54 patients will open up; the patients will have access to scheduling to better fit their lives; new patients and existing patients will have more scheduling choices. [source: DaVita rebuttal comments]
- The new nine-station center in Fife will serve an underserved part of the planning area and be convenient to nearly half of the planning area patients. December 2014 NRN data identified 162 patients residing in the seven zip codes located east and south of Downtown Tacoma[13]. The 162 patients represent 47% of all Pierce #4 patients. Many of these patients may find a dialysis facility in Fife to be more convenient than a facility in Tacoma. [source: DaVita rebuttal comments]
- FHS proposes a nine-station addition to the St. Joseph Medical Center dialysis unit. The majority of the nine stations will be bed stations that are used for high acuity patients that cannot tolerate a chair for extended periods. In 2014, 13 patients were admitted to or transferred to the hospital's dialysis unit because they either needed a bed or because of their care needs. This includes 9 patients managed by the nephrologist that exclusively refers to DaVita as well as four Group Health patients. Because St. Joseph Medical Center's dialysis facility serves higher acuity patients, it draws patients from zip codes outside of the planning area. [source: FHS rebuttal comments]

Department's Evaluation

As previously stated, WAC 246-310-280(9) identifies the planning area for the state. Specific to these projects under review, the rule also identifies the 16 zip codes included in Pierce planning area #4. Since the need methodology identifies a need for nine additional stations, each application proposes to add nine stations within the planning area. Each of the three applicants provided rationale for adding stations within their chosen zip codes in the planning area. Two of the applicant's assert that Fife is the better area for the nine stations and two assert that Tacoma is the preferred area.

The numeric need methodology does not breakdown the zip codes within a planning area to determine the preferred zip code for a project. An applicant identifies a specific zip code to establish a dialysis center within the planning area and provides reasonable justification for the site. Both FMC and DaVita provided reasonable justification for establishing a facility in Fife, within Pierce planning area #4. Further, historical Northwest Renal Network data identifies 4 patients residing in the Fife zip code in year 2008, which increased to 10 in year 2010, and 7 in year 2013.

The methodology also does not take into account in- or out-migration for a planning area. Whether patients cross planning area boundaries to dialyze at a particular facility is not part of the numeric calculation of need for stations.

[13] Zip codes: 98404, 98408, 98418, 98421, 98422, 98424, and 98443.

Specific to the FHS project, FHS asserted throughout its application that its project would not only add station capacity in the planning area, but would also address a growing need for 'specialty dialysis services' within Pierce County. When SJDC was a 50-station facility, FHS established a goal of decentralizing dialysis care by relocating 34 of the 50 stations to two separate sites within Pierce planning area #4. At the time that the 34 stations were relocated, FHS anticipated that the remaining 16 stations would be enough capacity at SJDC. FHS states that over the past year, the demand for stations to serve a higher acuity/unstable dialysis patient population has outpaced the demand for other services. [source: Application, pp3-4]

FHS states that patients needing dialysis services at SJDC are generally sicker, more unstable, and have more co-morbidities than the average dialysis patients. The patients frequently dialyze in a bed and by virtue of their needs, require higher levels of staffing (bed patients have higher RN staffing) and require immediate access to the ancillary and support services that are available in a hospital setting. FHS states that as of August 2014, SJDC had 84 patients, and 51 of them (or 61%), are considered high acuity/unstable patients. These patients general fall into one of four categories. **1)** patients requiring a bed for dialysis; **2)** patients with other special medical equipment/medical management needs; **3)** patients with special isolation needs; or **4)** medical unstable patients. Finally, FHS states that it would be serving patients throughout the entire planning area; rather than just Pierce County planning area #4. [source: Application, pp3-4]

In summary, FHS provided documentation and information within its application intended to support its assertions that its project should be approved because it would service a higher acuity, or special dialysis patient, than the patients that would be served by the other two applicants.

The department does not concur with FHS that it should be awarded stations because it proposes to serve a different type of patient than other applicants. When FHS elected to relocate stations from SJDC in 2010 and again in 2012, the level of acuity for its patients was no different than it is now. In those applications, FHS vigorously asserted that relocating 34 stations from SJDC is the best choice for the patients and the community.[14] The department does not concur that SJDC's patient acuity/type has changed from those recent approvals. As a result, the assertions raised by FHS related to its patient acuity and SJDC's special need for additional stations should not outweigh the need of its competitors. The assertions by FHS related to special needs will not be considered as superior rationale for its project.

In summary, none of the issues raised by the applicants is grounds for denial of their competitor's project.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations are added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for these projects was August 1, 2014. [WAC 246-310-282] The quarterly modality report from NRN available at that time was June 30, 2014, data available on July 30, 2014. For Pierce County planning area #4, there are 65 dialysis stations located in four separate

[14] Application #09-33 and CN #1421 issued on April 27, 2010, and Application #12-18 and CN #1488 issued on September 18, 2012.

centers within the planning area. Table 2 below shows the reported utilization of the stations in Pierce County planning area #4 as of June 30, 2014.

Table 2
June 30, 2014 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
FHS St Joseph Dialysis Center	16	84	5.25
FHS St. Joseph East	14	82	5.86
FHS South Tacoma	22	120[15]	5.45
DaVita Tacoma Dialysis Center	13	71	5.56

Table 2 demonstrates that the four 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.

FMC projects the nine-station center in Fife would be operational by the end of September 2016. Using that timeline, year 2017 would be the first full year of operation and 2019 would be year three. [source: November 26, 2014, supplemental information, p1]

DaVita projects the nine additional stations would be operational at Tacoma Dialysis Center by the end of September 2015. Using that timeline, year 2016 would be the first full year of operation as a 22-station center and 2018 would be year three. [source: 2nd Amendment Application, p14 and November 26, 2014, supplemental information, p2]

DaVita projects the nine-station center in Fife would be operational by the end of February 2016. Using that timeline, year 2017 would be the first full year of operation and 2019 would be year three. [source: 1st Amendment Application, p14]

FHS projects the nine additional stations would be operational at St. Joseph Dialysis Center by the end of September 2015. Using that timeline, year 2016 would be the first full year of operation as a 25-station center and 2018 would be year three. [source: November 25, 2014, supplemental information, p2]

A summary of the projected utilization for the third year of operation for each of the four projects is shown in the table on the following page. [sources: FMC-November 26, 2014, supplemental information, p2; DaVita-Tacoma November 26, 2014, supplemental information, Exhibit B; DaVita-Fife 1st Amendment Application, Exhibit 9; and FHS-Application, p26]

[15] On August 5, 2014, FHS was approved to operate nine temporary stations at its South Tacoma facility during the final stages of completing the station addition project at its Gig Harbor Dialysis Center. The 120 patients identified in the June 30, 2014, utilization data does not include the additional patients dialyzing at the South Tacoma facility in the nine temporary stations.

Table 3
Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of In-Center Patients	Patients/Station
FMC Fife	2019	9	50	5.5
DaVita Tacoma Dialysis Center	2018	22	106	4.8
DaVita Fife	2019	9	44	4.8
FHS St. Joseph Dialysis Center	2018	25	125	5.0

As shown in Table 3 above, each facility is projected to operate at or above the 4.8 standard by the end of the third full year of operation. The department concludes **this sub-criterion is met for all four applications.**

(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.

Admission Policy

To determine whether all residents of the service area would have access to the 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 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.

Medicare and Medicaid Eligibility

The department uses the applicant's or facility's Medicare certification to determine whether the elderly would have access or continue to have access to additional services.

The department uses the applicant's or facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the services.

Charity Care

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.

Fresenius Medical Care

As previously stated, FMC currently provides health care services to residents of Washington State. To demonstrate compliance with this sub-criterion, FMC provided a copy of its FMC Admission Policy used for all dialysis patients admitted into an FMC facility for services. This is the same policy that would be used at the new Fife dialysis facility. The Admission Policy outlines the process/criteria that FMC uses to admit patients for treatment, and ensures that patients will receive appropriate care at a dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, creed or religion, color, age, sex, disability, national origin, marital status, diagnosis, and/or sexual orientation. [source: Application, Exhibit 12]

FMC currently provides services to Medicare and Medicaid eligible patients at its operational dialysis centers throughout the nation. Details provided in the application demonstrate that FMC intends to maintain this status and its new facility in Fife would also be Medicare and Medicaid certified. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare and Medicaid reimbursements. [source: November 26, 2014, supplemental information, Revised Exhibit 14]

FMC demonstrated its intent to provide charity care to Pierce County planning area #4 residents by submitting the Charity Care Policy used for all FMC dialysis centers. The policy outlines the process one would use to access charity care at an FMC dialysis center and provides the sliding fee schedule used to determine patient eligibility for charity care. FMC also included a 'charity care' line item as a deduction from revenue within the pro forma income statements for its proposed Fife center. [source: Application, Exhibit 13 and November 26, 2014, supplemental information, Revised Exhibit 14]

The department concludes that all residents of the service area would have access to the health services at FMC's dialysis center in Fife. **This sub-criterion is met.**

DaVita-Tacoma

DaVita currently provides health care services to residents of Washington State. To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current "Accepting End State Renal Disease Patients for Treatment" or admission policy, used for all dialysis patients admitted into a DaVita facility for services. This is the same policy that is used at the Tacoma Dialysis Center. The Admission Policy outlines the process/criteria that DaVita uses to admit patients for treatment, and ensures that patients will receive appropriate care at a dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, national origin, gender, sexual orientation, age, religion, provided that the patient is a candidate for dialysis services. [source: 2nd Amendment Application, Appendix 14]

DaVita currently provides services to Medicare and Medicaid eligible patients at its operational dialysis centers throughout the nation. Details provided in the application demonstrate that DaVita intends to maintain this status and its Tacoma facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare and Medicaid reimbursements. [source: November 26, 2014, supplemental information, Exhibit B]

DaVita demonstrated its intent to continue to provide charity care to patients receiving treatment by submitting its current "Patient Financial Evaluation Policy" or charity care policy used for all dialysis centers owned, operated, or managed by DaVita. This is the same policy that is used at the Tacoma Dialysis Center. The policy outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. [source: 2nd Amendment Application, Exhibit 14] DaVita also include a 'charity care' line item as a deduction from revenue within the pro forma income statements for their current facility. [source: 2nd Amendment Application, Appendix 14]

Based on the source documents evaluated, the department concludes **this sub-criterion is met.**

DaVita-Fife

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current "Accepting End State Renal Disease Patients for Treatment" or admission policy, used for all dialysis patients admitted into a DaVita facility for services. This is the same policy that would be used at the Fife facility. The Admission Policy outlines the process/criteria that DaVita uses to admit patients for treatment, and ensures that patients will receive appropriate care at a dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, national origin, gender, sexual orientation, age, religion, provided that the patient is a candidate for dialysis services. [source: 1st Amendment Application, Appendix 14]

DaVita currently provides services to Medicare and Medicaid eligible patients at its operational dialysis centers throughout the nation. Details provided in the application demonstrate that DaVita intends to maintain this status and provide the same services at its Fife facility. A review of the anticipated revenue indicates that the facility expects to receive Medicare and Medicaid reimbursements. [source: 1st Amendment Application, Appendix 9 information, Exhibit B]

DaVita demonstrated its intent to provide charity care to patients receiving treatment by submitting its current "Patient Financial Evaluation Policy" or charity care policy used for all dialysis centers owned, operated, or managed by DaVita. This is the same policy that will be used at the Fife facility. The policy outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. [source: 1st Amendment Application, Exhibit 14] DaVita also include a 'charity care' line item as a deduction from revenue within the pro forma income statements for the Fife facility. [source: 1st Amendment Application, Appendix 9]

Based on the source documents evaluated, the department concludes **this sub-criterion is met.**

Franciscan Health System

FHS is currently a provider of health care services to the residents of Washington State through its healthcare facilities, including its five dialysis centers. To demonstrate compliance with this sub-criterion, FHS provided a copy of its current Admission Policy used at all FHS facilities. The policy outlines the process and guidelines that FHS uses to admit patients for treatments its healthcare centers, including the dialysis center. Attached to the Admission Policy is FHS's Non-Discrimination Policy. This policy ensures that FHS would not discrimination or deny benefits to patients based on race, color, national origin, religion, sexual orientation, physical, mental or other disability, economic status, citizenship, medical condition, or age. [source: Application, Exhibit 7]

FHS currently provides services to Medicare and Medicaid eligible patients at its healthcare facilities in Washington State. Details provided in the application demonstrate that FHS currently provides Medicare and Medicaid services within its five dialysis centers and intends to maintain this status with additional stations at the Tacoma center. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare and Medicaid reimbursements. [source: November 26, 2014, supplemental information, Attachment 3]

FHS currently provides charity care at its healthcare facilities in Washington State, including its dialysis centers. FHS demonstrated its intent to continue to provide charity care to patients receiving dialysis treatment by providing a copy of its submitting its current Uninsured/Underinsured Patient Discount Policy (Charity Care). This policy is used at all FHS

healthcare facilities, including the dialysis centers. The charity care policy outlines the process one would use to access services provided at FHS facilities. [source: Application, Exhibit 7] FHS also include a 'charity care' line item as a deduction from revenue within its pro forma income statement for St. Joseph Dialysis Center. [source: November 26, 2014, supplemental information, Attachment 3]

Based on the above information and standards, 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.
- DaVita HealthCare Partners, Inc.'s Tacoma project has met the financial feasibility criteria in WAC 246-310-220
- DaVita HealthCare Partners, Inc.'s Fife project has met the financial feasibility criteria in WAC 246-310-220
- Franciscan Health System'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.

Fresenius Medical Care

FMC anticipates the nine-station dialysis center in Fife would become operational in September 2016. Based on that timeline, year 2017 would be the Fife center's first full year of operation and 2019 would be year three. The table on the following page illustrates the projected utilization, revenue, expenses, and net income for years 2017 through 2019 for FMC's new Fife dialysis facility. [source: November 26, 2014, supplemental information, Revised Exhibit 14]

Table 4
FMC Fife Dialysis Center
Projected Revenue and Expenses Fiscal Year 2017-2019

	Year 1-2017	Year 2-2018	Year 3-2019
# of Stations	9	9	9
# of Treatments [1]	5,760	6,480	7,200
# of Patients [2]	40	45	50
Utilization Rate [2]	4.44	5.00	5.56
Net Revenue	$ 3,070,322	$ 3,374,633	$ 3,678,944
Total Expense [3]	$ 2,200,002	$ 2,391,092	$ 2,582,336
Net Profit or (Loss)	$ 870,320	$ 983,541	$ 1,096,608

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

The 'Net Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for FMC's Fife center. As shown in Table 4, at the projected volumes identified in the application, FMC anticipates that the nine-station facility would be operating at a profit in each of the first three full years of operation. [source: November 26, 2014, supplemental information, Revised Exhibit 14]

There are three separate entities involved in the Intent to Lease document. They are listed below.

- NWC Neil Walter Company – real estate company
- Renal Care Group – tenant (FMC)
- Harsch Investment Properties, LLC – landlord.

The executed Letter of Intent to Lease and Draft 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 Harsch Investment Properties, LLC, [landlord] and Renal Care Group Northwest, Inc. [tenant]. The Letter of Intent to Lease was executed on November 24, 2014, and is signed by representatives of the tenant and the real estate entity, NWC Neil Walter Company.

The lease agreement attached to the Letter of Intent to Lease is an unsigned draft. The draft identifies the tenant, but not the landlord. The lease is for 141 months [11.75 years] with two five year extensions. The annual lease costs are substantiated in the pro forma financial documents presented. [source: November 26, 2014, supplemental information, Revised Exhibit 11]

FMC also provided a copy of the executed Medical Director Agreement between FMC and Seth Thaler, MD. The medical director service costs are substantiated in the pro forma revenue and expense statements provided in the application. [source: November 26, 2014, supplemental information, Revised Exhibits 5 & 14]

Public Comments

DaVita and FHS provided the following public comments related to this sub-criterion.

- FMC made an 'opening date' error in its application that was corrected during screening. While some information was changed to reflect the correction, other data was not. The

projected number of treatments was not corrected, which results in errors in the financial statements that rely on the projected number of treatments. [source: DaVita public comments]

- FMC did not 'ramp up' its patent counts gradually over the projection years. [source: DaVita public comments]
- FMC did not document site control for the Fife center. The Letter of Intent [to lease] is not signed by the landlord; the draft lease agreement is an inadequate demonstration of site control. [source: DaVita and FHS public comments]

Rebuttal Comments

- The patient counts in each of the projection years is the average annual patient count expected in a given year; there is no expectation or statement implying that patient counts 'jump' on a specific day.
- The application also clarifies that there is an adjustment for 'ramp' in each of the years.
- FMC's documents disclose every key assumption necessary to generate reasonable patient projections.
- FMC provided specific documentation to demonstrate site control. First, a signed/executed Intent to Lease. This document is signed by representatives of the landlord. Additionally, FMC provided a copy of the signature page for the Intent to Lease with the landlord's signature.

Department's Evaluation

FMC changed its projected opening date from January 2016 to September 2016. FMC did not provide revised treatments/patients in its Pro Forma Revenue and Expense Statements. In its rebuttal comments, FMC provided reasonable rationale of why the projections may not change with the change in start date. FMC also provided its key assumptions used to project patients/treatments/revenues/expenses. The key assumptions are reasonable.

As previously stated, there are three separate entities involved in the Intent to Lease document. They are listed below.

- NWC Neil Walter Company – real estate company
- Renal Care Group – tenant (FMC)
- Harsch Investment Properties, LLC – landlord.

The real estate company assisted in locating the property owned by the landlord to lease to the tenant. While the Intent to Lease was on the real estate's company's letterhead, to be valid it must be signed by the both the landlord and the tenant. Instead, the document was signed by the real estate company and the tenant. FMC argues that the real estate company signed as representatives of the landlord. However, the real estate company is not representing the landlord; they are representing the tenant.[16] FMC did not provide any documentation from the landlord giving the real estate company authority to sign a document on its behalf.

[16] This is further evidenced by information provided on the NWC Neil Walter Company website, which states: *Since 1995, Neil Walter Company has been providing a full range of services including commercial real estate leasing and sales, tenant representation, property management, investment analysis, project management and entitlement service of the following property types*:…" [emphasis added]

FMC further states that a clause within the Intent to Lease demonstrates it is binding on the landlord. The clause states:

> *"Landlord and tenant agree that is Letter constitutes a formal binding agreement and that the provisions herein are binding to both parties. The parties shall use good faith efforts to finalize a lease containing the terms of this letter within a reasonable period of time following the full execution of this letter."*

The department would agree with FMC that the clause represents that the Intent to Lease is binding on both the landlord and the tenant, if it was signed by both. Since it was not signed by the landlord, it cannot be considered binding on the landlord. The documentation provided by FMC in rebuttal to correct this defect cannot be considered in this review. In summary, FMC did not provide site control in its application.

Based on the source documents evaluated, the department concludes that FMC's projected revenues and expenses cannot be substantiated and FMC did not demonstrate site control. The department concludes **this sub criterion is not met**.

DaVita-Tacoma

DaVita anticipates the additional nine stations will be operational at its Tacoma facility by August 1, 2015. Based on this timeline, 2016 is the facility's first full calendar year of operation with 22 stations and 2018 is year three. [source: 2nd Amendment Application, p14 and November 26, 2014, supplemental information, p2]

The table below illustrates the projected utilization, revenue, expenses, and net income for full calendar years 2016 through 2018. [source: November 26, 2014, supplemental information, Exhibit B]

Table 5
DaVita Tacoma Dialysis Center
Projected Revenue and Expenses for Years 2016-2018

	Year 1 - 2016	**Year 2 – 2017**	**Year 1 - 2018**
# of Stations	22	22	22
# of Treatments [1]	11,486	12,893	14,820
# of Patients [2]	80	94	106
Utilization Rate [2]	3.64	4.27	4.82
Net Revenue	$ 5,794,028	$ 6,562,936	$ 7,660,024
Total Expense [3]	$ 3,730,503	$ 4,296,637	$ 4,851,248
Net Profit or (Loss)	$ 2,063,525	$ 2,266,299	$ 2,808,776

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

The 'Net Revenue' line item is gross revenue minus any deductions for charity care and bad debt DaVita provided clarification regarding the contractual allowances. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for DaVita's Tacoma Dialysis Center. As shown in Table 5, at the projected volumes identified in the application, DaVita anticipates that Tacoma Dialysis Center would be operating at a profit in each of the first three full years of operation with 22 stations. [source: November 26, 2014, supplemental information, Exhibit B]

DaVita provided a copy of the existing Medical Director Agreement currently used at the Tacoma Dialysis Center. The agreement was executed on September 30, 2011, and includes roles and responsibilities for Total Renal Care, Inc. (DaVita), Pacific Nephrology Associates, and Catherine Richardson, MD (medical director). All costs identified in the agreement are substantiated in the pro-forma income statement. [source: 2nd Amendment Application, Appendix 3 and November 26, 2014, supplemental information, Exhibit B]

The lease agreement provided in the application was executed on August 20, 2004, when the Tacoma Dialysis Center was established. The executed lease has been previously extended however, a review of the lease shows that extended term expires on July 31, 2015. Therefore, the department considers the lease provided in the application a draft. If this project is approved, the department would require that DaVita submit a finalized lease agreement through at least year 2018, the third full year of operation as a 22-station facility. [source: 2nd Amendment Application Appendix 15]

Public Comments

FMC provided the following public comments related to this sub-criterion.

- Key assumptions used to project the financial statements were not provided when requested in screening.
- No contractual allowances were provided for the projected Revenue and Expense Statement for the Tacoma project.

Rebuttal Comments

A summary of DaVita's responses to the public comments is below.

- DaVita identified its key assumptions used to project the financial statements and restated the assumptions in rebuttal.
- In response to the department's request to identify contractual allowances in each of the projected years of operation, DaVita stated that it does not track contractual allowances on a facility basis and does not use contractual allowance in its revenue projection process. DaVita then explained its 'blended rate' for the projection of revenue and that the adjustments made account for unanticipated factors in the service area, such as future payer mix volatility that can affect a blended rate. DaVita cited an example of payer mix volatility to be increases or decreases in commercial reimbursements vs Medicare/Medicaid reimbursements. DaVita asserts that the blended rate reflects any offsets for contractual allowances.

Department's Evaluation

DaVita provided its key assumptions used to project revenues, patient counts, and expenses for the Tacoma Dialysis Center with 22 stations. The assumptions are:

- Revenue-projected using a blended rate derived from current facility operations, conservatively adjusted to reflect volatility in payer mix and unanticipated factors in the service area.
- Patient Counts-projected using patient counts from current facility operations.
- Expenses-projected using operating cost from current facility operations.

Part of FMC's concern is that DaVita does not identify who the 'current facility' is that DaVita relied on for its assumptions. In its rebuttal statements related to the issue raised by FMC, DaVita still does not identify the 'current facility' it relied on that was referenced in its assumptions.

Rather, DaVita continues to focus on FMC's financial projections provided in its own application. This type of rebuttal is not helpful to the department in its review.

FMC does not point to a specific error in DaVita's financial projections. DaVita's responses are brief, but provide the assumptions used to determine the projections for revenue, patient counts, and expenses. Historically, the department has accepted DaVita's blended rate approach in its applications for both station additions and new facilities.

DaVita did not identify contractual allowances as requested in the department's screening of the Tacoma project. In the screening of these four dialysis projects, the department requested revenue and expense information in a particular format that is simple to prepare by the applicants, easy to read by all, and would provide equal transparency of all four projects. DaVita chose not to provide the requested information. Rather, DaVita responded with an explanation of its blended rate calculations and then clarified that the blended rate reflects any offsets for contractual allowances; but did not provide the contractual allowance amounts.

WAC 246-310-220(1) requires the department to determine whether the immediate and long-range capital and operating costs of the project can be met. This is accomplished, in part, by reviewing an applicant's assumptions and methodologies used to project the revenue, patient counts, and expenses. DaVita provided this information.

The revenue, patient counts, and expenses are used to determine the net profit or (loss) of a project for the first three years of operation, following completion. According to the information provided by DaVita in its Revenue and Expense Statements [Table 5 above] the Tacoma Dialysis Center is projected to operate at a profit in all three projected years of operation. DaVita also provided this information.

FMC's concern is that DaVita did not provide the information in the format that would allow equal transparency of all four projects. At this time, the issues raised by FMC are not grounds for denial of DaVita's Tacoma project.

Based on the source documents evaluated, the department concludes that DaVita's projected revenues and expenses are reasonable and can be substantiated. With DaVita's agreement to the condition related to the lease agreement, the department concludes **this sub criterion is met**.

DaVita-Fife

DaVita anticipates the new nine-station facility in Fife will be operational by February 2016. Based on this timeline, 2017 is the facility's first full calendar year of operation and 2019 is year three. [source: 1st Amendment Application, p14]

The table on the following page illustrates the projected utilization, revenue, expenses, and net income for full calendar years 2017 through 2019. [source: 1st Amendment Application, Appendix 9]

Table 6
DaVita Fife Dialysis Center
Projected Revenue and Expenses for Years 2017-2019

	Year 1 - 2017	Year 2 – 2018	Year 1 - 2019
# of Stations	9	9	9
# of Treatments [1]	1,186	3,409	5,483
# of Patients [2]	16	30	44
Utilization Rate [2]	1.78	3.33	4.89
Net Revenue	$ 497,952	$ 1,460,244	$ 2,396,071
Total Expense [3]	$ 858,144	$1,277,040	$ 1,676,964
Net Profit or (Loss)	($ 360,192)	$ 183,204	$ 719,107

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

The 'Net Revenue' line item is gross revenue minus any deductions for charity care and bad debt. DaVita provided clarification regarding the contractual allowances. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for DaVita's Fife facility. As shown in Table 6, at the projected volumes identified in the application, DaVita anticipates Fife facility would operate at a loss in year one and a profit in projected years two and three. [source: 1st Amendment Application, Appendix 9]

DaVita provided a copy of the executed Medical Director Agreement to be used at the Fife facility. The agreement was executed on August 26, 2014 and includes roles and responsibilities for Total Renal Care, Inc. (DaVita), Pacific Nephrology Associates, and Yajuan He, MD (medical director). All costs identified in the agreement are substantiated in the pro-forma income statement. [source: 1st Amendment Application, Appendices 3 and 9]

The lease agreement provided in the application between Total Renal Care, Inc. (DaVita), and CRH Investments, LLC was executed on August 27, 2014. All costs identified in the agreement are substantiated in the pro-forma income statement. [source: 1st Amendment Application, Appendices 9 and 15]

Public Comments

FMC and FHS provided the following public comments related to this sub-criterion.

- Key assumptions used to project the financial statements were not provided when requested in screening. [source: FMC and FHS public comment]
- No contractual allowances were provided in the projected Revenue and Expense Statement. [source: FMC public comments]

Rebuttal Comments

In its rebuttal responses for this project, DaVita stated that this issue was address in the rebuttal for the Tacoma Dialysis Center expansion project.

Department's Evaluation

DaVita provided its key assumptions used to project revenues, patient counts, and expenses for the new nine-station Fife facility. The assumptions are:

- Revenue-projected using a blended rate derived from current facility operations, conservatively adjusted to reflect volatility in payer mix and unanticipated factors in the service area.
- Patient Counts-projected using patient counts from current facility operations.
- Expenses-projected using operating cost from current facility operations.

Again DaVita does not identify the 'current facility' it relied on that was referenced in its assumptions. Rather, DaVita continues to focus FMC's approach to its own financial projections. For DaVita's Fife project, this type of rebuttal is not helpful in this review.

As with the Tacoma project, FMC does not point to a specific error in DaVita's financial projections. DaVita's responses are brief, but provide the assumptions used to determine the projections for revenue, patient counts, and expenses. Historically, the department has accepted DaVita's blended rate approach in its applications for both station additions and new facilities.

DaVita did not identify contractual allowances as requested in the department's screening of the Fife project. In the screening of these four dialysis projects, the department requested revenue and expense information in a particular format that is simple to prepare by the applicants, easy to read by all, and would provide equal transparency of all four projects. DaVita chose not to provide the requested information. Rather, DaVita responded with an explanation of its blended rate calculations and then clarified that the blended rate reflects any offsets for contractual allowances; but did not provide the contractual allowance amounts. DaVita also does not identify the 'current facility' it relied on that was used for this blended rate assumption.

WAC 246-310-220(1) requires the department to determine whether the immediate and long-range capital and operating costs of the project can be met. This is accomplished, in part, by reviewing an applicant's assumptions and methodologies used to project the revenue, patient counts, and expenses. The revenue, patient counts, and expenses are used to determine the net profit or (loss) of a project for the first three years of operation, following completion. DaVita provided the financial information needed to review this sub-criterion. According to the information provided by DaVita in its Revenue and Expense Statements [Table 6 above] the nine-station Fife facility is projected to operate at a loss in year one and a profit in years two and three. At this time, the issues raised by FMC are not grounds for denial of DaVita's Fife project.

Based on the source documents evaluated, the department concludes that DaVita's projected revenues and expenses are reasonable with the information provided. The department concludes **this sub criterion is met**.

Franciscan Health System

SJDC has been operating for many years and has been at the current site in in the North Pavilion since 1982. As previously stated, through the years, FHS received approvals to add stations to the facility ultimately reaching a total of 50 dialysis stations at the site. The dialysis center continued to operate 50 stations until year 2010, when FHS established a 12-station facility in east Tacoma by relocating 12 of the 50 stations, resulting in 38 stations at SJDC. In year 2012, FHS established a

22-station facility in at another site in Tacoma using 22 of the remaining 38 stations, leaving 16 stations at SJDC.

If this project is approved, FHS anticipates the additional nine stations would become operational at SJDC by the end of September 2015. Under this timeline, calendar year 2016 would be the facility's first calendar year of operation with 25 stations 2018 would be calendar year three. [source: November 26, 2014, supplemental information, p2]

Table 7 below illustrates the projected utilization, revenue, expenses, and net income for full calendar years 2016 through 2018. [source: November 26, 2014, supplemental information, pp7-8 and Attachment 3]

Table 7
St. Joseph Dialysis Center
Projected Revenue and Expenses for Years 2015-2018

	Year 1-2016	**Year 2-2017**	**Year 3-2018**
# of Stations	25	25	25
# of Treatments [1]	16,536	18,096	19,500
# of Patients [2]	106	116	125
Utilization Rate [2]	4.2	4.6	5.0
Net Revenue	$ 9,662,918	$ 10,529,528	$ 11,323,502
Total Expense [3]	$ 6,800,537	$ 7,235,066	$ 7,486,748
Net Profit or (Loss)	$ 2,862,381	$ 3,294,462	$ 3,836,754

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

The 'Net Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for at SJDC. [source: November 26, 2014, supplemental information, p9] Table 7 shows at SJDC would be operating at a profit in year 2016 through 2018 as a 25 station facility.

There is no established lease agreement at SJDC since it is located within the St. Joseph Medical Center hospital campus. The current medical director for the dialysis center is Daniel Hu, MD. FHS provided a copy of the medical director agreement between Dr. Hu and FHS. The agreement was executed on October 14, 2013, and is for a three year term and includes annual automatic extensions. The costs associated with the medical director are substantiated in the pro forma revenue and expense statement provided in the application. [source: Application, Exhibit 5 and November 26, 2014, supplemental information, Attachment 3]

Public Comments

DaVita provided the following public comments related to this sub-criterion.

- FHS omitted required information about its facility payer mix.

Rebuttal Comments

A summary of FHS's responses to the public comments is below.

- The proposed payer mix is based on actual experience at the St. Joseph Medical Center unit. DaVita suggests that because we provided payer mix information related to our gross

revenue, not our net revenue, that FHS's application materials lack the information needed to determine the review criteria under WAC 246-310-220(1).

Department's Evaluation

In its November 26, 2014, supplemental information, FHS provided its assumptions used to prepare the pro forma revenue and expense statements for the proposed 25 station dialysis facility at St. Joseph Medical Center. On page 8 of the responses, FHS states that it based its revenue and payer mix on the current experience of SJDC. The dialysis facility is operational with 16 stations. With this application, FHS proposes to add nine stations to the dialysis center for a facility total of 25. FHS provided information in the application suggesting that the dialysis center would continue to treat patients similar to those currently treated at the dialysis center. It is reasonable for FHS to base some of its projections on its actual experiences. This is generally the approach taken by applicants when they have existing facilities and propose to expand.

Based on the source documents evaluated, the department concludes that FHS's projected revenues and expenses are reasonable with the information provided. The department concludes **this sub criterion is met**.

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

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

Fresenius Medical Care

The capital expenditure associated with the establishment of a new nine-station center in Fife is $1,764,119. FMC's share of the costs is $1,623,324 and the landlord's portion is $140,795. A breakdown of the costs for both FMC and the landlord is shown in Table 8 below.

Table 8
FMC Fife Dialysis Center Estimated Capital Costs

Item	Cost	% of Total
Building Construction	$ 1,033,908	63.7%
Fixed Equipment	$ 304,920	18.8%
Architect and Engineering Fees	$ 96,532	6.0%
Permits and Fees	$ 62,115	3.8%
Sales Tax	$ 125,849	7.7%
FMC Total Costs	**$ 1,623,324**	**100.0%**
Plus Landlord's Costs	$ 140,795	
Total Estimated Capital Costs	**$ 1,764,119**	

FMC intends to finance its portion of the project with existing FMC reserves and provided a letter from FMC's vice president and treasurer demonstrating a commitment to the project. [source: Application, p28 and Exhibit 7] A review of the historical financial statements provided in the

application indicates that FMC has sufficient cash assets to fund the project. [source: Application, Exhibit 15]

To further support compliance with this criterion, FMC provided the following source of its revenue projections. [source: Application, p14]

Table 9
FMC Fife Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	43.0%
Medicaid	3.0%
Commercial	33.4%
Other [1]	20.6%
Total	**100.0%**

[1] Other sources include Medicare Advantage, Medicaid Risk, miscellaneous insurance, and self-pay patients

The department recognizes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility; however, new facilities generally have a higher commercial/other payer mix for the first couple of years of operation. This is attributed to new patients dialyzing at the facility that do not yet qualify for either Medicare or Medicaid. As shown in Table 9, the Medicare and Medicaid reimbursements are projected to equal 46.1% of the revenue at FMC's Fife facility. CMS has recently implemented an ESRD prospective payment system (PPS). Under the new PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility. Each facility within a given geographic area may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider.

The department concludes that since Medicare and Medicaid revenue is dependent upon cost based reimbursement, they are not expected to have unreasonable impact on charges for services. The remaining 54.0% will be derived through a variety of reimbursement sources such as private insurance. Once the center has been operational for some time, the department recognizes that the majority of the patients will become eligible for Medicare reimbursement for services. As a result, the higher percentage for commercial/other is not expected to impact the services or patients.

Based on the source documents evaluated, the department concludes that FMC's project would probably not result in an unreasonable impact on the costs and charges for health services. **This sub criterion is met**.

DaVita-Tacoma

The capital expenditure associated with the addition of nine stations to Tacoma Dialysis Center is $99,920. The capital cost breakdown is shown in Table 10 on the following page. [source: 2nd Amendment Application, Appendix 7 and November 26, 2014, supplemental information, p5]

Table 10
DaVita Tacoma Dialysis Center Estimated Capital Costs

Item	Cost	% of Total
Leasehold Improvements	$ 23,040	23.1%
Fixed/Moveable Equipment (tax included)	$ 74,630	74.7%
Architect, Engineering, and Permit Fees	$ 2,250	2.2%
Total Estimated Capital Costs	**$ 99,920**	**100.0%**

DaVita intends to finance the project from existing reserves. 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: 2nd Amendment Application, p12 and Appendices 6 and 10]

To further demonstrate compliance with this sub-criterion, DaVita provided the sources of patient revenue shown in the table below. DaVita stated it does not anticipate any changes in revenue sources with the additional nine stations. [source: 2nd Amendment Application, p12 and p24]

Table 11
DaVita Tacoma Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	37.0%
Medicaid	7.0%
Other [1]	56.0%
Total	**100.0%**

[1] Other sources includes HMO, miscellaneous insurance, and self-pay patients

As shown in Table 11, the Medicare and Medicaid reimbursements are projected to equal 44% of the revenue at the DaVita Tacoma Dialysis Center. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the DaVita Tacoma facility, approximately 44.0% of the patients will have either Medicare or Medicaid. While the mix is unusual for an established dialysis center, the payer mix is consistent with the payer mix identified in DaVita's most recent application to add dialysis station capacity to Tacoma Dialysis Center.[17] CMS has recently implemented an ESRD prospective payment system (PPS). Under the new PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility. Each facility within a given geographic area may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider.

[17] Certificate of Need Application #11-10

The department concludes that since Medicare and Medicaid revenue is dependent upon cost based reimbursement, they are not expected to have unreasonable impact on charges for services. The remaining 56.0% will be derived through a variety of reimbursement sources such as private insurance.

Public Comments

FHS provided the following public comments related to this sub-criterion.

- DaVita did not allocate any construction costs for its Tacoma project.

Rebuttal Comments

A summary of DaVita's responses to the public comments is below.

- FHS's assertion that DaVita must disclose '*an allocation of historical construction costs*' for the Tacoma expansion project, including the '*capital costs for the eight stations that are constructed at the facility, but not made operational*.' We identified more than $25,000 in construction costs for our proposed expansion project. The original facility was ten approved stations with treatment floor space for expansion. We later reported and obtained CN approval for all costs associated with the three-station expansion. We have no obligation to re-report the costs reported and approved in 2007 (10 station facility) and 2010 (3 station addition).

Department's Evaluation

On August 7, 2007, CN #1353 was issued to DaVita approving the establishment of a ten-station dialysis center in Pierce Planning Area #4. The approved capital expenditure for this project was $1,392,924. [source: CN historical files for application #07-24] On August 25, 2011, CN #1449 was issued to DaVita approving the addition of three stations to the 10-station facility. The approved capital expenditure associated with the station addition was $45,575. Information within the historical files shows that DaVita did not allocate any construction costs for the addition of three stations. [source: CN historical files for application #11-10]

The CN Program has informed dialysis applicants that construction costs must be included within an application proposing additional stations to an operational facility. DaVita is not obligated to include costs for establishment of the initial ten-station facility or retroactively provide the costs for the three-station addition. DaVita must allocate construction costs for this nine station addition.

For this project, DaVita identified $23,040 in construction costs for nine additional stations. DaVita states that it purchased 'refurbished' machines, along with the addition of one machine and chair for back-up as recommended by the bio-medical department. Use of refurbished machines would make all machines consistent at the facility. DaVita suggests that these actions kept the capital costs lower than the costs identified in the 1st amendment application. [source: November 26, 2014, supplemental information, p2]

FHS acknowledges that the construction costs are included, but suggests that they are too low or inaccurate. DaVita provided a breakdown of construction costs allocated to this project and explained why the costs decreased in the 2nd amendment application. The department acknowledges that the capital expenditure for nine stations is very low; however, without specific concerns related to the costs, the department must rely on the integrity of the applicant when they are required to provide specific information.

Based on the source documents evaluated, the department concludes that DaVita's project in Tacoma would probably not result in an unreasonable impact on the costs and charges for health services. **This sub criterion is met**.

DaVita-Fife

The capital expenditure associated with the establishment of a new nine-station center in Fife is $2,049,810. DaVita's share of the costs is $1,846,959 and the landlord's portion is $202,851. A breakdown of the costs for both DaVita and the landlord is shown in the table below.

Table 12
DaVita Fife Dialysis Center Estimated Capital Costs

Item	Cost	% of Total
Leasehold Improvements	$ 1,230,000	66.6%
Fixed/Moveable Equipment (tax included)	$ 494,459	26.8%
Architect, Engineering, and Permit Fees	$ 122,500	6.7%
DaVita Total Costs	**$ 1,846,959**	**100.0%**
Plus Landlord's Costs	$ 202,851	
Total Estimated Capital Costs	**$ 2,049,810**	

DaVita intends to finance its portion of the project with existing DaVita reserves and provided a letter on behalf of DaVita's Board of Directors demonstrating a commitment to the project. A review of the historical financial statements provided in the application indicates that DaVita has sufficient cash assets to fund the project. [source: 1st Amendment Application, p12 and Appendices 6 and 10]

To further support compliance with this criterion, DaVita provided the following projected sources of revenue at the new facility. [source: Application, p25]

Table 13
DaVita Fife Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	56.7%
Medicaid	4.5%
Other [1]	38.8%
Total	**100.0%**

[1] Other sources includes HMO, miscellaneous insurance, and self-pay patients

As shown in Table 13, the Medicare and Medicaid reimbursements are projected to equal 61.2% of the revenue at the new Fife facility.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the DaVita Fife facility, approximately 61% of the patients will have either Medicare or Medicaid. CMS has recently implemented an ESRD prospective payment system (PPS). Under the new PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility. Each facility within a given geographic area may receive the same base rate. However, there are a number of adjustments both

at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider.

The department concludes that since Medicare and Medicaid revenue is dependent upon cost based reimbursement, they are not expected to have unreasonable impact on charges for services. The remaining 38.8% will be derived through a variety of reimbursement sources such as private insurance.

Based on the source documents evaluated, the department concludes that DaVita's project in Fife would probably not result in an unreasonable impact on the costs and charges for health services. **This sub criterion is met**.

Franciscan Health System

The capital expenditure associated with the addition of nine stations at St. Joseph Medical Center's dialysis unit is $206,572.[18] These costs are solely for moveable equipment and associated sales tax. The capital cost breakdown is shown in the table below. [source: Application, p34 and November 26, 2014, supplemental information, pp2-3]

Table 14
FHS-St. Joseph Dialysis Center Estimated Capital Costs

Item	Cost	% of Total
Moveable Equipment	$ 201,936	97.8%
Taxes	$ 4,636	2.2%
Total Estimated Capital Costs	**$ 206,572**	**100.0%**

FHS provided a listing of the needed equipment for the project and stated that it intends to finance the costs with existing FHS reserves. [source: Application, Exhibit 5] 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: Application, Appendix 1]

To further support compliance with this criterion, FHS provided its current sources of revenue by payer for the dialysis center. FHS does not anticipate any changes in revenue sources with the additional nine stations. The revenue sources are listed on the following page. [source: Application, p36]

[18] Consistent with WAC 246-310-280(2) and the department's memo dated April 15, 2011, FHS allocated construction costs to this project of $901,520, for a total cost of $1,108,092. This is the cost that will be used for the tie-breaker review as defined in WAC 246-310-288.

Table 15
FHS St. Joseph Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	75.2%
Medicaid	10.7%
Commercial	11.2%
Other [1]	2.9%
Total	**100.0%**

[1] Other sources includes Medicare Advantage, Medicaid Risk, miscellaneous insurance, and self-pay patients

As an established dialysis center, the Medicare and Medicaid patients make up the largest percentage of patients served at 85.9%. CMS has recently implemented an ESRD prospective payment system (PPS). Under the new PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility. Each facility within a given geographic area may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider.

The department concludes that since Medicare and Medicaid revenue is dependent upon cost based reimbursement, they are not expected to have unreasonable impact on charges for services. The remaining 14.1% will be derived through a variety of reimbursement sources such as private insurance.

Based on the source documents evaluated, the department concludes that FHS's project would probably not result in an unreasonable impact on the costs and charges for health services. **This sub criterion is met**.

(3) The project can be appropriately financed.

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

Fresenius Medical Care

FMC's share of the costs to establishment of a new nine-station center in Fife is $1,623,324. As previously stated, FMC intends to finance its portion of the project with existing FMC reserves and provided a letter from FMC's vice president and treasurer demonstrating a commitment to the project. [source: Application, p28 and Exhibit 7]

A review of the historical financial statements provided in the application indicates that FMC has sufficient cash assets to fund the project. [source: Application, Exhibit 15] Based on the information provided, the department concludes **this sub-criterion is met.**

DaVita-Tacoma

The capital expenditure associated with the expansion of DaVita Tacoma Dialysis Center is $99,920 and DaVita intends to finance the project entirely from its reserves. 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: 2nd Amendment Application, p12
Based on the information provided, the department concludes **this sub-criterion is met.**

DaVita-Fife

DaVita's share of the capital expenditure associated with the establishment of a new facility in Fife is $1,846,959. [source: 1st Amendment Application, Appendix 7] DaVita intends to finance its portion of the project with existing DaVita reserves and provided a letter on behalf of the DaVita Board of Directors demonstrating a commitment to the project. [source: 1st Amendment Application, p12 and Appendix 6]

A review of the historical financial statements provided in the application indicates that DaVita has sufficient cash assets to fund the project. [source: 1st Amendment Application, Appendix 10] Based on the information provided, the department concludes **this sub-criterion is met.**

Franciscan Health System

As previously stated, FHS intends to finance the project costs of $206,572 with existing FHS reserves. A review of the historical financial statements provided in the application indicates that FHS has sufficient cash assets to fund the project. [source: Application, Appendix 1]

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
- DaVita HealthCare Partners, Inc.'s Tacoma project has met the structure and process of care criteria in WAC 246-310-230
- DaVita HealthCare Partners, Inc.'s Fife 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

(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.

Fresenius Medical Care

FMC projects that the new nine-station center in Fife would become operational in September 2016. Under that timeline, years 2017 through 2019 are the first three full years of operation. [source: November 26, 2014, supplemental information, p1]

FMC provided a breakdown of all proposed staff beginning in 2016 through full year three (2019). [source: Application, p30]

Table 16
FMC Fife Dialysis Center Projected FTEs

Staff/FTEs	2016 Partial Year	2017 Full Year 1	2018 Increase	2019 Increase	Total
Medical Director	Contracted Position				
Nurse Manager	1.20	1.25	0.00	0.00	1.25
Registered Nurse	2.00	2.25	0.25	0.00	2.50
Patient Care Techs	2.00	2.50	0.25	0.00	2.75
Equipment Tech	0.25	0.25	0.00	0.00	0.25
MSW	0.53	0.58	0.02	0.00	0.60
Dietician	0.53	0.58	0.02	0.00	0.60
Secretary	0.25	0.50	0.00	0.00	0.50
Total FTEs	**6.76**	**7.91**	**0.54**	**0.00**	**8.45**

FMC states that it does not anticipate any difficulty in recruiting staff for the new Fife center because its geographic location allows FMC to draw on staff from the larger pool of neighboring counties. Further, FMC states that they offer competitive wage and benefit packages. [source: Application, p31]

For its medical director, FMC established a contract with Seth Thaler, MD and provided a copy of the medical director's agreement. The agreement identifies a Washington Professional Services Corporation named 'RVC, PLLC.' This corporation employs five physicians, including Dr. Thaler. The other four employed physicians are Julia Anuras, MD, Chris Burtner, MD, Michael Mondress MD, and Vo Nyugen MD. [source: November 26, 2014, supplemental information, Revised Exhibit 5]

The executed agreement is initially for three years, with automatic annual renewals with no end date. The agreement identifies roles and responsibilities for FMC and RVC, PLLC. The agreement clarifies a specific physician—in this case Seth Thaler—will be the designated medical director of the Fife facility, but also clarifies that with agreement between FMC and RVC, PLLC, any one of the other physicians could act as medical director if necessary. [source: November 26, 2014, supplemental information, Revised Exhibit 5]

The agreement identifies all costs associated with the medical director services. The costs are substantiated in the Pro Forma Revenue and Expense Statements provided in the application. [source: November 26, 2014, supplemental information, Revised Exhibit 5 and Revised Exhibit 14]

Based on the information reviewed, the department concludes adequate staffing for the nine-station Fife facility is available or can be recruited. **This sub-criterion is met.**

DaVita-Tacoma

DaVita currently operates the Tacoma Dialysis Center with 13 stations and projects that the additional nine stations would become operational in August 2015. Under that timeline, years 2016 through 2018 are the first three full years of operation for Tacoma Dialysis Center's dialysis unit as a 22-station facility. [source: 2nd Amendment Application, p14 and November 26, 2014, supplemental information, p2]

DaVita provided a breakdown of current and proposed staff beginning in 2015 through full year three (2018). [source: 2nd Amendment Application, p25] The table below shows the additional staff and incremental increases.

Table 17
DaVita Tacoma Dialysis Center Current and Projected FTEs

Staff/FTEs	2015 Current	2016 Increase	2017 Increase	2018 Increase	Total
Medical Director	Contracted Position				
Administrator	1.00	0.00	0.00	0.00	1.00
Registered Nurse (RN)	4.50	0.00	0.70	0.60	5.80
Patient Care Techs	6.70	0.00	1.10	1.00	8.80
Bio Medical Techs	0.30	0.00	0.00	0.10	0.40
Administrative Assistant	1.00	0.00	0.20	0.10	1.30
MSW	0.80	0.00	0.20	0.20	1.20
Dietician	0.80	0.00	0.20	0.20	1.20
Reuse Tech	1.00	0.00	0.00	0.10	1.10
Total FTEs	**16.10**	**0.00**	**2.40**	**2.30**	**20.80**

As shown in Table 17, DaVita expects a minimal increase in staff over the three year period with nine additional stations. DaVita states it expects no difficulty recruiting staff for the following reasons.

- DaVita offers a competitive wage and benefit package to employees.
- DaVita posts openings nationally and both internally and externally to DaVita.
- DaVita has an extensive employee traveling program which guarantees all DaVita centers will be appropriately staffed.

[source: 2nd Amendment Application, p26]

The current medical director for the dialysis center is Catherine Richardson, MD who is part of Pacific Nephrology Associates. DaVita provided a copy of the medical director agreement between itself and Pacific Nephrology Associates and Dr. Richardson. The agreement was executed on September 30, 2011, and is for a ten-year term and includes annual automatic extensions. The agreement identifies all costs associated with the services and the costs are substantiated in the pro forma revenue and expense statement provided in the application. [source: 2nd Amendment Application, Exhibit 3]

Based on the source documents evaluated, the department concludes adequate staffing for the nine station increase at DaVita Tacoma Dialysis Center is available or can be recruited. **This sub-criterion is met.**

DaVita-Fife

DaVita projects that the new nine-station center in Fife would become operational in February 2016. Under that timeline, years 2017 through 2019 are the first three full years of operation. [source: 1st Amendment Application, p14 and p22]

DaVita provided a breakdown of all proposed staff beginning in 2017 through full year three (2019). [source: 1st Amendment Application, p26]

Table 18
DaVita Fife Dialysis Center Projected FTEs

Staff/FTEs	2017 Increase	2018 Increase	2019 Increase	Total
Medical Director	Contracted Position			
Administrator	1.00	0.00	0.00	1.00
Registered Nurse (RN)	0.60	0.40	0.50	1.50
Patient Care Techs	1.60	0.90	0.50	3.00
Bio Medical Techs	0.30	0.00	0.00	0.30
Administrative Assistant	0.50	0.00	0.00	0.50
MSW	0.30	0.10	0.00	0.40
Dietician	0.30	0.10	0.00	0.40
Reuse Tech	0.00	0.00	0.00	0.00
Total FTEs	**4.60**	**1.50**	**1.00**	**7.10**

DaVita states it expects no difficulty recruiting staff for the new Fife facility for the following reasons.

- DaVita can draw staff from the larger geographic area of King, Pierce and Thurston counties.
- Staff from geographically adjacent DaVita facilities may choose to move to the Fife facility.
- DaVita offers a competitive wage and benefit package to employees.
- DaVita posts openings nationally and both internally and externally to DaVita.
- DaVita has an extensive employee traveling program which guarantees all DaVita centers will be appropriately staffed.

[source: 1st Amendment Application, p27]

DaVita provided a copy of the executed Medical Director Agreement between itself and Pacific Nephrology Associates and Yajuan He, MD to be used at the Fife facility. The agreement was executed on August 26, 2014 and is for a ten-year term and includes annual automatic extensions. The agreement identifies all costs associated with the services and the costs are substantiated in the pro forma revenue and expense statement provided in the application. [source: 1st Amendment Application, Appendices 3 and 9]

Based on the information reviewed, the department concludes adequate staffing for the nine-station Fife facility is available or can be recruited. **This sub-criterion is met.**

Franciscan Health System

FHS projects that the additional nine stations would become operational in September 2015. Under that timeline, years 2016 through 2018 are the first three full years of operation for St. Joseph Medical Center's dialysis unit as a 25-station facility. [source: November 26, 2014, supplemental information, p2]

FHS provided a breakdown of current and proposed staff beginning in 2014 through full year three (2018). [source: November 26, 2014, supplemental information, p4] The table below shows the additional staff and incremental increases.

Table 19
FHS St. Joseph Medical Center's Dialysis Unit Current and Projected FTEs

Staff/FTEs	2014 Current	2015 Increase	2016 Increase	2017 Increase	2018 Increase	Total
Medical Director	Contracted Position					
HD Tech	11.50	2.40	2.00	2.40	1.00	19.30
Registered Nurse (RN)	5.80	0.00	0.00	1.20	0.00	7.00
Resource RNs	1.00	0.00	0.10	0.10	0.10	1.30
Clinical Nurse Manger	1.00	0.00	0.00	0.00	0.00	1.00
Unit Secretary	1.00	0.00	0.20	0.00	0.00	1.20
MSW	1.00	0.00	0.00	0.20	0.10	1.30
Dietician	1.00	0.00	0.00	0.20	0.10	1.30
Total FTEs	**22.30**	**2.40**	**2.30**	**4.10**	**1.30**	**32.40**

FHS states that it does not anticipate any difficulty in recruiting staff necessary to accommodate the additional patients for a variety of reasons. Below is a summary information provided by FHS. [source: Application, pp38-39]

- FHS offers competitive wage and benefit packages to staff.
- FHS posts all open positions on its own website and contracts with several job boards for posting positions.
- FHS also advertises in The Seattle Times and the Tacoma News Tribune, two of the largest newspapers in the South Sound area.
- FHS contracts with more than 40 technical colleges, community colleges, and four-year universities throughout the United States to offer either training or job opportunities.

The current medical director for the dialysis center is Daniel Hu, MD. FHS provided a copy of the medical director agreement between Dr. Hu and FHS. The agreement was executed on October 14, 2013, and is for a three year term and includes annual automatic extensions. The agreement identifies all costs associated with the services and the costs are substantiated in the pro forma revenue and expense statement provided in the application. [source: Application, Exhibit 5 and November 26, 2014, supplemental information, Attachment 3]

Based on the information reviewed, the department concludes adequate staffing for the nine additional stations at SJDC 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.

Fresenius Medical Care

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 Fife center, social and dietary services would be provided on site. Ancillary and support services, such as pharmacy, laboratory, and radiology will be established in advance of opening. FMC states it has successfully established ancillary and support relationships in the past and does not anticipate any difficulties in meeting the clinical service demands of patients that will be cared for in the proposed facility. [source: Application, pp31-32]

Based on this information, the department concludes FMC has internal access to some ancillary and support services to support the new facility and has the ability to establish other ancillary and support services for the proposed facility. One typical agreement is a patient transfer agreement with a local hospital. FMC did not provide an executed transfer agreement because they are generally established within a few months of opening a new dialysis center. If this project is approved, the department would include a condition requiring FMC to provide a copy of the executed transfer agreement with a local hospital. **With the transfer agreement condition, this sub-criterion is met.**

DaVita-Tacoma

As a provider of dialysis services in Washington State and the Pierce County planning area #4, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For the Tacoma 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 provided on-site. Additional services are coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: 2nd Amendment Application, p26]

DaVita provided a copy of the existing patient transfer agreement used at Tacoma Dialysis Center. The transfer agreement is between Renal Life Link, Inc., a subsidiary of DaVita, and MultiCare Tacoma General/Allenmore Hospital. The patient transfer agreement will continue to be used at the Tacoma Dialysis Center with additional stations. [source: 2nd Amendment Application, Appendix 12]

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.**

DaVita-Fife

As a provider of dialysis services in Washington State and the Pierce County planning area #4, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers. For the new facility in Fife, 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 will be provided on-site. Additional services are coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: 1st Amendment Application, p27]

DaVita provided a copy of an example patient transfer agreement that would be used at the new Fife facility. If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed transfer agreement with a local hospital. **With the transfer agreement condition, this sub-criterion is met.**

Franciscan Health System

As a long-time dialysis provider of dialysis services in Pierce County, FHS currently maintains the appropriate relationships with ancillary and support services for its five existing dialysis centers. Specific to SJDC, all ancillary and support relationships have already been established and are continued for the 16 station facility. FHS does not anticipate any changes to the existing relationships if an additional nine stations are added to the facility. [source: Application, pp39-40]

Since the dialysis unit is located on the St. Joseph Medical Center hospital campus, hospital services are readily available if a patient were to need the services. A patient transfer agreement is unnecessary because of the location of the dialysis center with the hospital.

Based on this information, the department concludes FHS currently has access to necessary ancillary and support services to support the existing dialysis unit. **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.

Fresenius Medical Care

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

As previously stated, FMC is currently a provider of dialysis services within Washington State, and operates 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.[19] Historically, the department has requested quality of care compliance history from the licensing and/or surveying entities in each state where Fresenius Medical Care or any of its subsidiaries have healthcare facilities. The most recent quality of care survey for FMC was completed in February 2010. For this application, the department reviewed information on the Center for Medicare & Medicaid Services website.

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

"Today, the Centers for Medicare & Medicaid Services (CMS) added star ratings to the Dialysis Facility Compare (DFC) website. These ratings summarize performance data, making it easier for consumers to use the information on the website. These ratings also spotlight excellence in health care quality. In addition to posting the star ratings, CMS updated data on individual DFC quality measures to reflect the most recent data for the existing measures.

"Star ratings are simple to understand and are an excellent resource for patients, their families, and caregivers to use when talking to doctors about health care choices," said CMS Administrator Marilyn Tavenner. "CMS has taken another step in its continuous commitment to improve quality measures and transparency."

DFC joined Nursing Home Compare and Physician Compare in expanding the use of star ratings on CMS websites. The DFC rating gives a one to five-star rating based on information about the quality of care and services that a dialysis facility provides. Currently, nine DFC quality measures are being used collectively to comprise the DFC star ratings. In the future, CMS will add more measures.

In related news, CMS plans to add the Standardized Readmission Ratio (SRR) for dialysis facilities to the publicly reported quality outcome measures available on the Compare website. SRR is a measure of care coordination. SRR is not included in DFC's star rating at this time.

DFC quality measure data is either updated quarterly or annually. CMS plans to update the DFC's star rating on an annual basis beginning in October 2015."

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

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

Based on the star rating in each of the two categories, CMS then compiles an 'overall rating' for the facility. As with the separate categories: the more stars, the better the rating. The star rating is based on data collected from January 1, 2010 through December 31, 2013.[20]

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

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

NCH SAFs –Medicare claims data are made available quarterly in the DESY system for CMS and its contractors. The Standard Analytical Files (SAFs) contain information collected by Medicare to pay for

For Washington State, FMS owns, operates, or manages 19 facilities. Two of the 19 facilities did not have a CMS star rating because they were not open for the entire reporting period.[21] Below is the overview of the CMS star rating for the remaining 17 FMS facilities.

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

As shown above, typically FMC's dialysis centers received 3 stars. Information provided in the application shows that FMC operates in 44 of the 50 states, plus the District of Columbia and Puerto Rico.[22] [source: FMC Application, Exhibit 2]

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health care services provided to a Medicare beneficiary. SAFs are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers) claim type. The record unit of SAFs is the claim (some episodes of care may have more than one claim).

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

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

[22] Forty-four states are: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts,

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

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

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

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

DaVita-Tacoma and Fife

DaVita operates or provide administrative services to approximately 2,098 outpatient dialysis centers located in the United States, serving approximately 165,000 patients. [source: Amendment Applications, Tacoma-pp6-7 & Fife-pp6-7] 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.[23] For this application, the department reviewed information on the Center for Medicare & Medicaid Services website.

For Washington State, DaVita owns, operates, or manages 38 facilities in 18 separate counties. Nine of the 38 are CN approved, but not yet operational. For the remaining 29 operational dialysis centers, two did not have a CMS star rating.[24] An overview of the CMS star rating for the remaining 27 DaVita facilities is shown on the following page.

Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

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

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

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

As shown above, typically DaVita's Washington State dialysis centers received 4 stars. Information provided in the application shows that DaVita operates in 47 of the 50 states, plus the District of Columbia.[25] [source: DaVita Applications, Appendix 2]

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

DaVita-Tacoma

The current medical director for the dialysis center is Catherine Richardson, MD who is part of Pacific Nephrology Associates. DaVita provided a copy of the medical director agreement between itself and Pacific Nephrology Associates and Dr. Richardson. The agreement was executed on September 30, 2011, and is for a ten-year term and includes annual automatic extensions. The agreement identifies all costs associated with the services and the costs are

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

substantiated in the pro forma revenue and expense statement provided in the application. [source: 2nd Amendment Application, Exhibit 3]

DaVita-Fife

For the Fife facility, the medical director agreement between DaVita and Pacific Nephrology Associates includes 'Joinder to the Medical Director Agreement.' The joinder implies that any one of the other physicians associated with Pacific Nephrology Associates could act as medical director if necessary. [source: 1st Amendment Application, Appendix 3]

For this reason, the department reviewed the compliance history for all physicians listed below that are part of Pacific Nephrology Associates. The review revealed no outstanding sanctions.[26] [source: Compliance history provided by Medical Quality Assurance Commission and corporation information provided by Washington State Secretary of State website]

Name	Credential Status	Pacific Nephrology Associates Corporation Status
Zheng Ge	Active	VP and Chairman
Neil Hannigan	Active	Treasurer
Yajuan He-OK	Active	Secretary
Howard M. Lee-OK	Active	None
Catherine Richardson	Active	President
Di Zhao-OK	Active	None

Public Comments

FHS provided the following public comments related to this sub-criterion.

- DaVita has entered into a Corporate Integrity Agreement with the United States Office of Inspector General (OIG) related to its operation and management of certain dialysis centers. DaVita did not provide information in either of its applications to demonstrate that it would meet state and federal laws related to the operation of the facility(ies).

Rebuttal Comments

A summary of DaVita's responses to the public comments is below.

- DaVita asserts that the Corporate Integrity Agreement with the OIG was raised to cast uncertainty about DaVita's ability to provide care in accordance with applicable state and federal laws, rules, and regulations. The agreement is the result of four years of government review covering ten years and thousands of transactions. After completion and signing of the agreement, DaVita posted information about the agreement at DaVita.com/settlement. In this document, DaVita clarifies that '*patient care or billing practices were never at issue*' with the DOJ. The document goes on to '*correct potentially misleading statements made in the public record*.' DaVita asserts that the document raises no uncertainty about whether DaVita is committed to legal compliance.

Department's Evaluation

A Corporate Integrity Agreement (CIA) is a document that outlines the obligations an entity agrees to as part of a civil settlement. An entity agrees to the CIA obligations in exchange for the OIG's agreement that it won't seek to exclude the entity from participation in Medicare, Medicaid, or other Federal health care programs. While CIAs have common elements, each one is tailored to

[26] Catherine Richardson, MD sanction M2010-285 resolved on December 7, 2011.

address the specific facts of a case. CIAs are often drafted to recognize the elements of a pre-existing compliance program. [source: Department of Health and Human Services website: FAQ "*What is a Corporate Integrity Agreement*?"]

Within its applications, DaVita should have disclosed that it was under investigation with the OIG. However, the department was aware of DaVita's CIA with the OIG and obtained a copy of the final agreement that was signed on October 22, 2014. The department is also aware that the agreement focused on DaVita's joint ventures with nephrologists to operate dialysis clinics and did not focus on patient care or billing practices.

The department acknowledges that DaVita submitted its two applications for Pierce #4 planning area in August 2014, and subsequent amendment applications in September and October 2014. The CIA was completed after the submission of the applications for this review, so DaVita did not provide a copy of the CIA within the application documents. The issue was raised by FHS in public comment, which allowed DaVita to provide its responses in rebuttal. Given the timing of the signing of the CIA, this process is appropriate for this review. The department would expect DaVita to include a copy of the CIA in future applications.

DaVita's CIA has 16 specific sections under 'Term and Scope' that requires DaVita to:

- establish and maintain a Compliance Program that includes a Chief Compliance Officer and Management Compliance Committee;
- establish written standards for covered persons (as defined in the CIA);
- establish training and education for covered persons;
- ensuring compliance with anti-kickback statute;
- provide notice to joint venture partners and medical directors of specific information related to patient referrals and ownership information;
- unwind specific joint venture clinics;
- retain an independent monitor selected by OIG;
- establish compliance audits;
- establishment of a risk assessment and mitigation process;
- establish a financial recoupment process;
- cooperate with all OIG investigations;
- maintain its disclosure program;
- removal of 'ineligible persons' as defined in the CIA;
- notify the OIG of government investigation or legal proceedings;
- repayment of overpayments; and
- report all reportable events as defined in the CIA.

Appendix B of the CIA identifies the eleven separate joint ventures that must be unwound, which includes a total of 26 dialysis clinics in five different states.[27] None of the joint ventures or dialysis clinics are located in Washington State.

DaVita asserts that the agreement should raise no concerns because it "*is the result of four years of government review covering ten years and thousands of transactions*." DaVita does have a jointly owned entity in Washington State known as Refuge Dialysis, LLC. The corporation was established in 2009 and is jointly owned by Total Renal Care, LLC (DaVita) and The Everett

[27] The five states are: California (9); Colorado (7); Florida (5); Kentucky (1); and Ohio (4).

Clinic. Refuge Dialysis, LLC is approved to operate two dialysis centers in Snohomish County.[28] The information provided in the CIA is relevant to this review criterion for DaVita's two projects in the Pierce #4 planning area.

For this specific CIA, DaVita would not be excluded from participation in Medicare, Medicaid or other Federal health care programs provided that DaVita complies with the obligations outlined in the CIA.

Given the compliance history of DaVita, which includes continued compliance with the CIA, the compliance history of the current and/or proposed medical directors, and all physicians associated with the nephrology group of Pacific Nephrology Associates, the department concludes that there is reasonable assurance that the Tacoma Dialysis Center would continue to operate in compliance with state and federal regulations with an additional nine stations. The department also concludes that there is reasonable assurance that the new nine-station Fife dialysis center would operate in compliance with state and federal regulations. **This sub-criterion is met for both DaVita-Tacoma and DaVita-Fife.**

Franciscan Health System

FHS is a provider of healthcare services within Washington State and provides dialysis services within Pierce County. 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.[29]

FHS owns, operates, or manages six dialysis centers in Washington State. One of the six did not have a CMS star rating.[30] Below is the overview of the CMS star rating for the remaining four FHS facilities.

FHS Facility	City/County	Star Rating
Franciscan Eastside Dialysis Center	Tacoma/Pierce	5
Greater Puyallup Dialysis Center	Puyallup/Pierce	5
St. Joseph Dialysis Center Gig Harbor	Gig Harbor/Pierce	3
St. Joseph Dialysis Center Tacoma	Tacoma/Pierce	3

As shown above, FHS's dialysis centers received 3 stars or better.

For medical director services, FHS provided a copy of the current Medical Director Agreement between itself and Daniel Hu, MD. A review of the compliance history for Dr. Hu revealed no recorded sanctions. [source: Compliance history provided by Medical Quality Assurance Commission]

The department also reviewed the compliance history of the healthcare facilities, including the five dialysis centers, owned or operated by FHS from January 2009 through December 2014.[31] The

[28] Everett Dialysis Center and Pilchuck Dialysis Center.
[29] WAC 246-310-230(5).
[30] Franciscan South Tacoma Dialysis Center did not have enough quality measure data to calculate a star rating.
[31] **St. Joseph Medical Center** surveys completed June 2009, March 2010, and August 2011 (Joint Commission). **St. Anthony Hospital** surveys completed March 2009 [initial hospital survey], November 2009 (Joint Commission), May 2011, and October 2012 (Joint Commission). **St. Clare Hospital** surveys April 2010, June 2011 (Joint Commission), and January 2013. **St. Elizabeth Hospital** survey February 2010 and August 2011. **St. Francis Hospital** surveys June 2009 and June 2010 (Joint Commission). **Harrison Medical Center** August 2010, November 2012, and August 2013. **Highline Medical Center** April 2009, November 2010 (Joint

review revealed no significant issues related to the quality of care or compliance history at the healthcare facilities. It is noted that the CMS website still lists St. Joseph Dialysis Center with 50 stations, rather than the 16 that are currently operational at the facility. Documents obtained from the Department of Health's Office of Investigation and Inspections demonstrates that FHS has submitted the required paperwork to reduce the number of stations to 16. [source: ILRS database, CMS dialysis facility compare, and DOH IIO facility files]

Given the compliance history of the FHS healthcare facilities and that of current medical director, the department concludes that there is reasonable assurance that St. Joseph Medical Center's dialysis unit would continue to operate in compliance with state and federal regulations with the additional nine dialysis stations. **This sub-criterion is met.**

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

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

Fresenius Medical Care

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 a nine-station dialysis center in Fife 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 nine dialysis stations in Pierce County planning area #4. FMC submitted this application to establish a nine-station center in Fife within the planning area.

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. 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**.

Commission), and December 2014. **Regional Hospital for Respiratory and Complex Care** surveys February 2010 (Joint Commission), January 2012, and December 2012 (Joint Commission). **Franciscan Hospice** survey March 2011.

DaVita-Tacoma

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 additional stations at the Tacoma Dialysis Center would change these relationships. DaVita also submitted documentation that this facility will continue to cooperate with existing healthcare 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 nine stations in Pierce County planning area #4. DaVita submitted this application to add nine stations to the 13 stations at DaVita Tacoma Dialysis Center, for a facility total of 22 stations to serve the planning area.

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

Based on the source documents evaluated, 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**.

DaVita-Fife

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 an additional facility in the Pierce County Planning Area #4 would change these relationships. DaVita also submitted documentation that this facility would cooperate with existing healthcare 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 nine stations in Pierce County planning area #4. DaVita submitted this application to establish a nine-station facility in the planning area.

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

Based on the source documents evaluated, 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**.

Franciscan Health System

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 nine dialysis stations in Pierce County planning area #4. FHS submitted this application to add nine stations to the 16 station dialysis center in Tacoma within the planning area.

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**.

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

Fresenius Medical Care

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

DaVita-Tacoma

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

DaVita-Fife

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

Franciscan Health System

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's project has not met the cost containment criteria in WAC 246-310-240.
- DaVita HealthCare Partners, Inc.'s Tacoma project has not met the cost containment criteria in WAC 246-310-240.
- DaVita HealthCare Partners, Inc.'s Fife project has not met the cost containment criteria in WAC 246-310-240.
- Franciscan Health System's project has met the cost containment criteria in WAC 246-310-240.

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

(1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.*
To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

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

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

Fresenius Medical Care

Step One

For this project, the department determined that FMC's project did not meet the review criteria under WAC 246-310-220 [financial feasibility], resulting in a failure for the review criteria under cost containment [WAC 246-310-240]. The department concludes that FMC's proposal to establish a nine-station dialysis facility in Pierce County planning area #4 is not the best available alternative. Therefore, review of steps two and three for FMC under this criterion is not necessary.

DaVita-Tacoma and DaVita Fife

Step One

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

Step Two

DaVita-Tacoma

Before submitting its application to add nine stations to Tacoma Dialysis Center located in Tacoma, DaVita stated that it considered two other alternatives. The two alternatives and DaVita's rationale for rejecting them is summarized below and on the following page.

- Build a new facility for nine stations
  DaVita compared this alternative to the project and concluded that the costs associated with the expanding an existing center and the short timeframe to bring the additional stations on line outweighed the advantage of establishing a new facility in the planning area.

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

DaVita rejected the other two alternatives and chose to submit an application to add nine stations to its Tacoma Dialysis Center. [source: Application, p28]

DaVita-Fife

Before submitting its application to establish a nine-station dialysis center in Fife, DaVita stated that it considered two other alternatives. The two alternatives and DaVita's rationale for rejecting them is summarized below.

- Add nine dialysis stations to Tacoma Dialysis Center in Tacoma
  DaVita compared this alternative to the project and concluded the additional nine stations would provide access to services in the planning area. Adding stations in Tacoma does not provide expanded geographical services in the planning area.
- Do nothing
  Based on the department's numeric methodology, there is a need for nine additional stations in the planning area in year 2017. This option also does not improve patient access to additional stations in the planning area.

DaVita rejected the other two alternatives and chose to submit an application to establish a nine-station dialysis center in Fife. [source: Application, p28]

Public Comments

Both FHS and FMC provided the following public comments related to this sub-criterion.

- DaVita submitted two applications for the same planning area and the same number of stations. When asked [by the department] to 'rank' or prioritize the two projects, DaVita does not. DaVita instead claims that they are equal to each other and both are superior to the projects submitted by the other two applicants. [source: FMC public comments]
- Within the cost containment criteria for each of DaVita's applications, the Tacoma project rejects its Fife project; its Fife project rejects its Tacoma project. When asked [by the department] to 'rank' the two projects, DaVita states it does not have decision criteria that would rank them for purposes of the CN process. DaVita then clarifies with the following statement: "*Our preferred outcome would be an award of all 9 stations regardless of which application or applications receive approval*." [source: FHS public comments]

Rebuttal Comments

- DaVita states that the concept of the two applications canceling each other out because they are directly contradictory is absurd.
- DaVita further states that both projects have relative advantages and disadvantages, just like any competing dialysis projects. The Tacoma expansion project would increase dialysis schedule access at low cost in a convenient location. The new Fife project would increase geographic access in an underserved part of the planning area; but at a greater cost.
- DaVita then performs its version of an evaluation of the tie-breaker criteria under WAC 246-310-288 and concludes that its two projects tie with each other at six points each.

Department's Evaluation

It is true that the cost containment sections in each of DaVita's applications identify the other project as an alternative and then rejects the alternative in favor of whichever application was submitted. Further, within each of its competing applications, DaVita provided the rationale for why the other application should not be approved. It is also true that because of this approach in cost containment, within its screening of the two applications, the department asked DaVita to 'rank' the two projects using DaVita's criteria. DaVita did not rank the two projects; rather, DaVita used the tie-breaker criteria under WAC 246-310-288 and compared its two projects to the projects submitted by FMC and FHS.

In response to the comments submitted by both FHS and FMC, DaVita provided the following explanation for its approach to the department's request to 'rank' its two projects.

> *"We responded fully, saying that we do not have decision criteria that would rank our applications for purposes of the CN process, other than the Department criteria set forth in WAC 246-310-240. We applied the department's three-step approach to evaluate superior alternatives under WAC 246-310-240 and determined both of our applications would reach step three—the tiebreaker analysis. We applied the tiebreaker analysis and determined both of our applications may be superior alternatives; that is, each of our applications might tie with the other, with each earning the largest number of tiebreaker points among the four competing applications. We are aware of no other standards that could be used to rank dialysis CN applications and FMC offers none."*

It is the responsibility of the applicant to demonstrate why their application meets the sub-criterion under WAC 246-310-240(1). It is unreasonable to expect the department to develop criteria to rank DaVita's projects that compete with each other. The department concludes that neither project is the best available alternative under this sub-criterion.

The department concludes that DaVita's proposal to add nine stations to its Tacoma Dialysis Center in Pierce County planning area #4 is not the best available alternative. **This sub-criterion is not met.**

The department also concludes that DaVita's proposal to establish a nine-station dialysis facility in Fife, within Pierce County planning area #4 is not the best available alternative. **This sub-criterion is not met.**

For both of DaVita's projects, review of step three under this criterion is not necessary.

Franciscan Health System

Step One

The department concludes that FHS has met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

Before submitting its application to add nine stations to St. Joseph Medical Center's dialysis facility in Tacoma, FHS stated that it considered three other alternatives. The three alternatives and FHS's rationale for rejecting them is summarized on the following page.

- Establish a new nine-station center in the planning area
  FHS states this option was ruled out because there are already four geographically dispersed facilities in the planning area. Further, FHS asserts that there are no areas with significant patient population in which to place a new facility.
- Expand the Franciscan South Tacoma facility
  This is option was closely evaluated by FHS. As a newly constructed, 22-station facility in Tacoma, the facility could accommodate an additional nine stations. This option was ruled out because FHS asserts the need for additional dialysis capacity within a hospital setting to care for high acuity dialysis patients outweighs this option.
- Do nothing
  Based on the department's numeric methodology, there is a need for nine additional stations in the planning area in year 2017. This option also does not improve patient access to additional stations in the planning area. Additionally all existing facilities are operating above the 4.8 standard which allows the addition of stations in a planning area.

FHS rejected the other three alternatives and chose to submit an application to add stations to St. Joseph Medical Center in Tacoma. Part of FHS's rationale for this project is to serve higher acuity dialysis patients within a hospital setting. As previously stated in the need section of this evaluation, the numeric methodology is a mathematical calculation of the projected need for dialysis stations in a planning area. The methodology deliberately does not take into account in- or out-migration in a planning area nor does it consider patient acuity. The methodology projects station need for residents of a planning area based on existing resident use regardless of acuity. For these projects in Pierce #4 planning area, the methodology projected a need for an additional nine stations in year 2017.

All four applicants, including FHS, proposed to add nine in-center dialysis stations to the planning area. The configuration of a dialysis center and the types of dialysis services offered are determined by each applicant. For this project, the assertions made by FHS regarding the high acuity of the patients or the need for additional bed stations cannot be considered as rationale to approve this project over a project submitted by a competitor. **This sub-criterion is met.**

Step Three

This step is used to determine the best available alternative between two or more approvable projects. For this concurrent review cycle in Pierce County planning area #4, four projects were submitted, but only one is approvable. Therefore, a review of step three for FHS's project 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;

Fresenius Medical Care

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 codes. 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 FMC did not demonstrate site control of the facility. The denial of the project because of lack of site control does not necessarily result in a denial of this sub-criterion. FMC was able to demonstrate that if the Fife facility was built, the costs, scope, and method of construction would meet this sub-criterion. Based on the information, the department concludes **this sub-criterion is met.**

DaVita-Tacoma

DaVita proposes to add stations to its 13-station Tacoma Dialysis Center. DaVita states it has many existing facilities across the nation and has experience ensuring that they are compliant with Medicare certification and the local authority construction and energy conservation codes.

The department concluded the overall project did not meet the cost containment criterion because DaVita did not provide a reasonable evaluation of alternatives considered. The denial of the project in the cost containment section does not necessarily result in a denial of this sub-criterion. DaVita was able to demonstrate that if the Tacoma facility were expanded, the costs, scope, and method of construction would meet this sub-criterion. Based on the information, the department concludes **this sub-criterion is met.**

DaVita-Fife

DaVita proposes to add stations to its 13-station Tacoma Dialysis Center. DaVita states it has many existing facilities across the nation and has experience ensuring that they are compliant with Medicare certification and the local authority construction and energy conservation codes.

The department concluded the overall project did not meet the cost containment criterion because DaVita did not provide a reasonable evaluation of alternatives considered. The denial of the project in the cost containment section does not necessarily result in a denial of this sub-criterion. DaVita was able to demonstrate that if the Fife facility was built, the costs, scope, and method of construction would meet this sub-criterion. Based on the information, the department concludes **this sub-criterion is met.**

Franciscan Health System

FHS proposes to add stations to its 16-station St. Joseph Medical Center dialysis facility located in Tacoma. FHS has also had many years of experience ensuring its existing facilities are compliant with Medicare certification and the local authority construction and energy conservation codes. 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.

Fresenius Medical Care

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**

DaVita-Tacoma

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**

DaVita-Fife

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**

Franciscan Health System

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**.