

STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington 98504

March 27, 2018

CERTIFIED MAIL # 7014 2120 0002 7631 2117

Evan Moore
DaVita HealthCare Partners
32275 – 32nd Avenue South
Federal Way, Washington 98001

RE: CN Application #17-45

Dear Mr. Moore:

We have completed review of the Certificate of Need application submitted by DaVita HealthCare Partners, Inc. for the station addition at Graham Dialysis Center located in Pierce County ESRD planning area #2. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners Inc. agrees to the following in its entirety.

Project Description:

This certificate approves the addition of 3 dialysis stations to the 8-station Graham Dialysis Center, for a facility total of 11 dialysis stations. At completion of the station addition, DaVita HealthCare Partners, Inc. is approved to certify and operate 11 stations at Graham Dialysis Center. Services provided at Graham Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Station	1
Permanent Bed Station	1
Other In-Center Stations	9
Total In-Center Stations	11

Conditions:

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

Evan Moore, DaVita HealthCare Partners CN Application #17-45 March 27, 2018 Page 2 of 2

- 2. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of a signed, executed First Amendment to Medical Director Agreement consistent with the draft agreement provided in the application.
- 3. DaVita HealthCare Partners, Inc. shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this 3-station addition is \$31,622. This amount represents the costs for fixed and moveable equipment; construction and leasehold improvements; and architect and engineering fees and costs associated with utility hook-ups. All costs will be paid by DaVita.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response to the Certificate of Need Program, at one of the following addresses.

Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Physical Address:
Department of Health
Certificate of Need Program
111 Israel Road SE
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,

Nancy Tyson, Executive Director Health Facilities and Certificate of Need

Office of Community Health Systems

Enclosure

EVALUATION DATED MARCH 27, 2018, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA HEALTHCARE PARTNERS PROPOSING TO ADD THREE DIALYSIS STATIONS IN PIERCE COUNTY PLANNING AREA #2

APPLICANT DESCRIPTION

DaVita, Inc. is a for-profit end stage renal care provider that was acquired by HealthCare Partners Holding, Inc. in late 2012. 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 2,293 dialysis facilities located in the United States. [source: Applications, p5] In Washington State, DaVita owns or operates 42¹ kidney dialysis facilities in 18 separate counties. Listed below are the names of the facilities owned or operated by DaVita in Washington State. [source: CN historical files and Application, pp5-6]

Benton

Chinook Dialysis Center Kennewick Dialysis Center

Clark

Vancouver Dialysis Center Battle Ground Dialysis Center

Chelan

Wenatchee Valley Dialysis Center

Douglas

East Wenatchee Dialysis Center

Franklin

Mid-Columbia Kidney Center

Island

Whidbey Island Dialysis Center

King

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

Redondo Heights Dialysis Center

Westwood Dialysis Center

Pacific

Seaview Dialysis Center

Pierce

Graham Dialysis Center Lakewood Community Dialysis Center

Parkland Dialysis Center

Puyallup Community Dialysis Center

Rainier View Dialysis Center

Redondo Heights

Tacoma Dialysis Center

Skagit

Cascade Dialysis Center

Snohomish

Everett Dialysis Center Lynnwood Dialysis Center Mill Creek Dialysis Center Pilchuck Dialysis Center

Spokane

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

Stevens

Echo Valley Dialysis Center

As of the writing of this evaluation, two of DaVita's CN approved dialysis facilities are not yet surveyed and operational. The two facilities are: Lynnwood Dialysis Center [CN #1588 issued on October 21, 2016] and Wapato Dialysis Center [CN #1611 issued on August 18, 2017].

Kittitas

Ellensburg Dialysis Center

Lewis

Centralia Dialysis Center

Mason

Belfair Dialysis Center

Thurston

Olympia Dialysis Center Tumwater Dialysis Center

Yakima

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

PROJECT DESCRIPTION

This project focuses on DaVita's Graham Dialysis Center located at $10305 - 196^{th}$ Street Court East in Graham [98338] within Pierce County planning area #2. Current Graham Dialysis Center is an 8-station facility. This application proposes to add three additional stations, resulting in an eleven station dialysis center. Graham Dialysis Center would remain at its current location in Graham and would continue to provide in-center hemodialysis, backup dialysis service, home hemodialysis and home peritoneal dialysis training, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: Application, p1]

The capital expenditure associated with the additional three stations is \$31,622. Of that amount, approximately 88% is for fixed and moveable equipment; 9% is for construction and leasehold improvements; and the remaining 3% is for architect and engineering fees and costs associated with utility hook-ups. All costs would be paid by DaVita. [source: Application, p9 and Appendix 7 and 1st screening response, p3]

Within this application, DaVita determined this evaluation would be released in November 2017. Using that timeline, DaVita estimated the three station addition would be operational by the end of December 2017. [source: Application, p13] As noted in the timeline section of this evaluation, DaVita requested an extension to respond to the department's first screening of the application and requested a second screening of the project. As a result, DaVita's timeline for adding the stations is not possible.

Using the concept provided by DaVita that the project would be complete within 60 days of approval, for this evaluation the department re-calculated DaVita's timeline for completion. With the re-calculation, the department determines that DaVita would begin providing dialysis services in the three additional stations by the end of April 2018. Under this timeline, 2019 would be the facility's first full calendar year of operation with eleven stations and 2021 would be year three.

APPLICABILITY OF CERTIFICATE OF NEED LAW

DaVita HealthCare Partners, Inc. application proposes to add dialysis stations to an existing dialysis center. This application is subject to review as an increase in the number of dialysis stations in a kidney disease center under provisions of RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determination. 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 services 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 service or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and
 - (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

- (b) 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 contain service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment). DaVita must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted these three applications under the Kidney Disease Treatment Centers-Concurrent Review Cycle #2 for calendar year 2017. No other applications were submitted for the Pierce County planning area #2 during the cycle. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review. Below is a chronologic summary of the review.

APPLICATION CHRONOLOGY

Action	DaVita Graham Dialysis Center
Letter of Intent Submitted	April 25, 2017
Application Submitted	May 31, 2017
Department's Pre-review Activities including	,
DOH 1 st Screening Letter	June 30, 2017
Applicant's 1st Screening Responses Received	August 22, 2017^2
DOH 2 nd Screening Letter	September 13, 2017
Applicant's 2 nd Screening Responses Received	October 30, 2017
Beginning of Review	November 6, 2017
End of Public Comment	
Public comments accepted through the end of public comment	December 11, 2017
No public hearing requested or conducted	
Rebuttal Comments Received ³	December 27, 2017
Department's Anticipated Decision Date	February 12, 2018
Department Declares Pivotal Unresolved Issue (PUI)	January 29, 2018
DaVita (PUI) Data Due	February 1, 2018
Last Day to Request PUI Documentation	February 1, 2018
Public Comment on PUI Documentation due ⁴	February 15, 2018
DaVita Rebuttal Comments due PUI Documentation	February 23, 2018
Department's Anticipated Decision Date w/ PUI Data	April 9, 2018
Department's Actual Decision Date	March 27, 2018

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."

As noted above, WAC 246-310-010(2) requires an affected person to first meet the definition of an 'interested person.' WAC 246-310(34) defines "interested person" as:

- (a) The applicant;
- (b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;
- (c) Third-party payers reimbursing health care facilities in the health service area;
- (d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;

² DaVita requested and was granted an 8-day extension to respond to the department's first screening of the application. The extension moved the screening response due date from August 14 to August 22, 2017.

³ The department did not receive any public comment. As a result, DaVita cannot provide rebuttal comments.

⁴ The department did not receive any public comment on the PUI documents. As a result, DaVita cannot provide rebuttal comments

- (e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;
- (f) Any person residing within the geographic area to be served by the applicant; and
- (g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

For this project, no entity requested interested or affected person status.

SOURCE INFORMATION REVIEWED

- DaVita HealthCare Partners, Inc. Certificate of Need application received May 31, 2017
- DaVita HealthCare Partners, Inc. 1st screening response received August 22, 2017
- DaVita HealthCare Partners, Inc. 2nd screening response received October 30, 2017
- DaVita's Pivotal Unresolved Issue (PUI) documents received January 30, 2018
- Years 2011 through 2016 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2016 Northwest Renal Network December 31, 2016 (fourth quarter) utilization data released February 15, 2017
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- DaVita HealthCare Partners, Inc. website at www.davitahealthpartners.com
- Northwest Renal Network website at www.nwrn.org
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSIONS

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to add three dialysis stations to Graham Dialysis Center located in Pierce County planning area #2 is consistent with applicable criteria of the Certificate of Need Program. The approval requires agreement to the project description, conditions, and approved capital expenditure identified below.

Project Description:

This certificate approves the addition of 3 dialysis stations to the 8-station Graham Dialysis Center, for a facility total of 11 dialysis stations. At completion of the station addition, DaVita HealthCare Partners, Inc. is approved to certify and operate 11 stations at Graham Dialysis Center. Services provided at Graham Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Station	1
Permanent Bed Station	1
Other In-Center Stations	9
Total In-Center Stations	11

Conditions:

- 1. Approval of the project description as stated above. DaVita HealthCare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of a signed, executed First Amendment to Medical Director Agreement consistent with the draft agreement provided in the application.
- 3. DaVita HealthCare Partners, Inc. shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this 3-station addition is \$31,622. This amount represents the costs for fixed and moveable equipment; construction and leasehold improvements; and architect and engineering fees and costs associated with utility hook-ups. All costs will be paid by DaVita.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the DaVita HealthCare Partners, Inc. project has met the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-280 through 289.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need. WAC 246-310-284 requires the department to evaluate kidney disease treatment center applications based on the 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).

WAC 246-310-284 Kidney Disease Treatment Center Numeric Methodology

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 (NRN).⁵

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident incenter patients for each of the previous six consecutive years, concluding with the base year.⁶

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

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

WAC 246-310-284(5) identifies that for all planning areas <u>except</u> 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

⁵ 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]

⁶ WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report." For this project, the base year is 2016.

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)]

The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is a discussion of DaVita's numeric methodology.

DaVita Healthcare Partners, Inc. Numeric Need Methodology

DaVita performed each of the steps of the methodology as described above and also concluded need for an addition three stations in Pierce County planning area #2 by the end of year 2020. [source: Application pp16-17]

Public Comment

None

Rebuttal Comment

None

Department Evaluation of the Numeric Methodology for Pierce County Planning Area #2

Based on the calculation of the annual growth rate in the planning area as described above, both DaVita and the department used the 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. The result of both DaVita's and the department's numeric methodology is shown in Table 1 below.

Table 1
Pierce County Planning Area #2 Numeric Methodology Summary

•	4.8 in-c	enter patients per	station		
	2020 Projected Minus Current 2020 Net No # of stations # of stations or (Surplu				
DaVita HealthCare Partners	11	8	3		
Department of Health	11	8	3		

As shown in Table 1, the department's methodology showed a need for 11 dialysis stations in the planning area by the end of year 2020. Once the 8 existing stations are subtracted, Pierce County planning area #2 shows a net need of 3 stations. The department's methodology is included in this evaluation as Appendix A.

The department concludes DaVita met this numeric methodology standard.

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis

station need.⁷ The department uses the standards in WAC 246-310-284(5) and WAC 246-310-284(6).

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at a certain utilization before new stations are added. For Pierce County planning area #2, the utilization is 4.8 in-center patients per station.

DaVita HealthCare Partners, Inc.

DaVita relied on the NRN quarterly modality report for December 31, 2016, released on February 15, 2017 to demonstrate compliance with this standard. DaVita provided a table showing that the utilization of its Graham Dialysis Center as of December 31, 2016 was 6.0 patients per station. [source: Application, p18]

Public Comment

None

Rebuttal Comment

None

Department Evaluation of WAC 246-310-284(5)

The department uses data 'from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period' to evaluate this standard. For this application submitted on May 31, 2017, the most recent quarterly data is December 31, 2016, available as of February 15, 2017.

DaVita's 8-station Graham Dialysis Center is the only facility operating in Pierce County planning area #2. Table 2 below shows the operational status and a summary of the dialysis center.

Table 2
Department's Facility Utilization Calculations

Facility Name	# of Approved Stations	# of Operational Stations	# of Pts	# Pts/Station
DaVita Graham Dialysis Center	8	8	48	6.0

DaVita calculated Graham Dialysis Center's utilization above the required 4.8 patients per station standard. Table 2 above substantiates that the existing facility satisfies this standard. Meeting this standard indicates that the existing facility is effectively and appropriately serving the population. Meeting this standard also indicates stations are not or will not be sufficiently available to meet future need. **DaVita meets this standard for the planning area.**

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 station by the end of the third full year of operation. For Pierce County planning area #2, the requirement is 4.80 in-center patients per approved station. [WAC 246-310-284(6)(a)]

⁷ WAC 246-310-210(1)(b).

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, p13]

"The table below outlines anticipated dates of commencement and completion of the project based on approval dates, assuming all variable operate according to historical trends. DaVita continues to refine and streamline the facility development process."

	7	eplicated) Table 8 Fraham Dialysis Center	
Antic Approval of Project	cipated Dates of Con Construction Complete	mmencement & Completion 1st Treatment	on of Project State Inspection & Certification
November 6, 2017	N/A	November 28, 2017	December 28, 2017

Based on the timeline above, DaVita's projected its third year of operation to be year 2020. DaVita provided the following projections for the 11-station dialysis center for year three. [source: Application, p11]

Table 3
DaVita's Graham Dialysis Center
Third Year Projected Facility Utilization

Year 3	# of Stations	# of In-Center Patients	Patients/Station
2021	11	65	5.9

Public Comment

None

Rebuttal Comment

None

Department Evaluation of WAC 246-310-284(6)

As shown in Table 5 above, DaVita projects to meet this standard by the end of year three. As stated in the project description portion of this evaluation, the department moved DaVita's timeline to coincide with the decision date of this evaluation. To determine whether DaVita would meet this standard in year three, the department reviewed DaVita's utilization calculations for the first three years with 11 stations. Table 4 below that shows the calculations. [source: Application, p11]

Table 4
DaVita's Graham Dialysis Center
Three-Year Projected Facility Utilization

	# of Stations	# of In-Center Patients	Patients/Station
Year 1	11	53	4.8
Year 2	11	59	5.3
Year 3	11	65	5.9

As shown above, even though DaVita's year three is recalculated to be 2021 rather than 2020, DaVita would still meet this requirement for year three. **DaVita meets this utilization standard under WAC 246-310-284(6).**

WAC 246-310-287

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

- (1) All other applicable review criteria and standards have been met; and
- (2) One or more of the following have been met:
 - (a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or
 - (b) Existing dialysis stations in the dialysis facility are operating at six patients per station. Data used to make this calculation must be from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period; or
 - (c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and
- (3) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing.

Department Evaluation

This sub-criterion is not applicable to this application.

(2) <u>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.</u>

To evaluate this sub-criterion, the department evaluates an applicant's admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services.

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 planning area would have access to the proposed 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 certification is a measure of an agency's willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals age 65 and over. It is also well recognized that women live longer than men and therefore more likely to be on Medicare longer. One of the exceptions is Medicare coverage for patients with permanent kidney failure. Patients of any age with permanent kidney failure are eligible for Medicare coverage.

Medicaid certification is a measure of an agency's willingness to serve low income persons and may include individuals with disabilities.

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and whose income is equal to or below 200% of the federal poverty standards, adjusted for family size or is otherwise not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required

by a third-party payer. With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

DaVita HealthCare Partners, Inc.

DaVita provided the following statement related to this sub-criterion:

"The Department of Health knows, based on DaVita's history of providing dialysis services at numerous locations throughout Washington State, that all ESRD patients have access to DaVita's facilities, including members of the under-served groups referenced in the regulation. Appendix 14 includes a copy of the admission, patient financial evaluation, and patient involuntary transfer policies which documents that access will not be denied at DaVita Graham Dialysis Center due to indigence, racial or ethnic identity, gender or handicapped status. The pro forma shows that funds have been budgeted to provide charity care." [source: Application, p18]

DaVita provided copies of the following policies used at all DaVita dialysis centers, including the existing Graham Dialysis Center. [source: Application, Appendix 14]

- Accepting End Stage Renal Disease Patient for Treatment [Admission Policy] Revised and Approved December 2016
- Patient Financial Evaluation Policy Reviewed and Approved April 2014
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer Policy Reviewed and Approved May 2017

Medicare and Medicaid Programs

DaVita's Graham Dialysis Center is currently Medicare and Medicaid certified and provided the current percentages of revenues by payer and patient for the facility. The percentages are shown in Table 5 below. [source: Application, p11]

Table 5
DaVita Graham Dialysis Center
Current and Projected Payer Mix

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer	
Medicare	71.68%	39.19%	
Medicaid	0.18%	0.10%	
Insurance/HMO	28.14%	60.71%	
Total	100.00%	100.00%	

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita has been providing dialysis services to the residents of Washington State for many years. The Accepting End Stage Renal Disease Patients for Treatment provides the assurance that DaVita

⁸ WAC 246-453-010(4).

would accept patients for treatment without regard to "race, color, national origin, gender, sexual orientation, age, religion, or disability..." provided that the patient is a candidate for dialysis services.

All DaVita dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that Graham Dialysis Center would continue both Medicare and Medicaid certifications. DaVita projected the Medicare revenues for Graham Dialysis Center to be 71.68% of total revenues. Pro forma financial data provided in the application shows Medicare revenues. DaVita's Medicaid revenues are projected to be 0.18% of total revenues. Pro forma financial data provided in the application shows Medicaid revenues.

DaVita did not provide a policy specifically entitled "Charity Care." However DaVita's Patient Financial Evaluation Policy provides the necessary information and process a patient would use to obtain charity care at a DaVita facility. DaVita further demonstrated its intent to provide charity care for patients by including a 'charity' line item as a deduction from revenue within the pro forma income statement.

Given that DaVita currently operates dialysis centers in Washington State and uses the same policies and procedures at each center, the policies provided in the application are executed policies used by DaVita in its Washington State facilities. As a result, no draft policies were provided by DaVita. The department concludes DaVita's project **meets this sub-criterion**.

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

Department Evaluation

This sub-criterion is not applicable to this application.

(b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.

Department Evaluation

This sub-criterion is not applicable to this application.

(c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.

Department Evaluation

This sub-criterion is not applicable to this application.

- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:
 - (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.

Department Evaluation

This sub-criterion is not applicable to this application.

(b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.

Department Evaluation

This sub-criterion is not applicable to this application.

(5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

Department Evaluation

This sub-criterion is not applicable to this application.

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the DaVita HealthCare Partners, Inc. 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.

DaVita HealthCare Partners, Inc.

As previously stated, DaVita proposes the additional three stations would be operational in December 2017 based on a determination that this evaluation would be released in November 2017. Using that timeline, DaVita estimated the three station addition would be operational by the end of December 2017. [source: Application, p13] As noted in the timeline section of this evaluation, DaVita requested an extension to respond to the department's first screening of the application and requested a second screening of the project. As a result, DaVita's timeline for adding the stations is not possible.

Using the concept provided by DaVita that the project would be complete within 60 days of approval, for this evaluation the department re-calculated DaVita's timeline for completion. With the re-calculation, the department determines that DaVita would begin providing dialysis services in the three additional stations by the end of April 2018. Under this timeline, 2019 would be the facility's first full calendar year of operation with eleven stations and 2021 would be year three.

DaVita provided the assumptions used to project in-center and home treatments and patients for calendar years 2017 with eight stations and years 2018 through 2022 with eleven stations. Below is a summary of the assumptions. [source: Application, pp15-16 and 1st screening response, p2]

- Utilization projections were based on Network 16 patient data [department's numeric methodology], patients' geographic locations relative to the proposed location and existing facilities; the ESRD patient population growth rate; and DaVita's general experience and expertise.
- In-center treatments are based on an assumption of 3 treatments per week per patient for 52 weeks with a 5% allowance for missed treatments.
- The average projected number of treatments per patient for all years shows is 142.

Using the assumptions stated above, DaVita's projected number of in-center and home dialyses and patients for the 8-station facility in year 2017 and the 11 station facility for years 2018 through 2021 is shown in Table 6. [source: Application, p11 and Appendix 9]

Table 6
DaVita Graham Dialysis Center
Projected Patients and Dialyses for Years 2017 – 2021

	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021
# of Stations	8	11	11	11	11
Total Treatments	7,964	8,684	9,492	10,379	10,966
Total Patients	56	61	67	73	75

DaVita provided the following assumptions used to project revenue, expenses, and net income for its 8-station center. [source: 1st screening response, pp7-8]

- DaVita used its historical experience operating the Graham facility to estimate the future revenue and expenses. DaVita projects revenue by multiplying the average net revenue per treatment by the estimated number of treatments (per expected growth rate). This methodology is consistent with how the pro-forma has been prepared for other DaVita expansions that the Department has approved in the past.
- The "G & A Allocation" is \$18 per treatment. This is the standard G & A assumption and is consistent with what we have used for previous applications.
- The [lease] agreement grants a unilateral right to the tenant to extend the lease for two additional periods of five years each. Please see Article 4 Renewal in Appendix 15 Lease Agreement, which states "Lessee shall have the right and option to renew this lease for two (2) additional periods of five (5) years each ..." Therefore, although the initial term of the lease expires on August 1, 2018, DaVita has the unilateral right to extend the lease through August 1, 2028, which would meet the Program's requirement to have a lease agreement that is valid for at least three years following the project's completion.
- Other revenue represents revenue related to peritoneal dialysis clinic visits.
- As stated in Section 6.1 of Appendix 3 [of the medical director agreement] MDA, the annual compensation for ICHD, PD and HHD is \$75,000, \$10,000 and \$10,000, respectively. The \$95,000 total annual MD compensation identified in the pro forma is the correct sum of the compensation for each of these modalities. In the original application, we mistakenly excluded HHD as an additional service that would be provided. To clarify: Graham will provide training and support for patients for all forms of home dialysis.

• The current MDA expires on December 11, 2018. Find attached a draft amendment to the MDA (Appendix 3a) that extends the MDA term to December 31, 2021. If we are awarded the expansion, we will provide an executed MDA amendment prior to operationalizing the new stations.

Based on the assumptions above, DaVita projected the revenue, expenses, and net income for years 2017 through 2021. A summary of the projections are shown in Table 7. [source: 2nd screening response, Appendix 9A]

Table 7
DaVita Graham Dialysis Center
Projected Revenue and Expenses for Years 2017 - 2021

	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021
Net Revenue	\$4,431,881	\$4,233,806	\$4,697,845	\$5,215,305	\$5,593,748
Total Expenses	\$2,565,170	\$2,458,921	\$2,629,054	\$2,815,954	\$2,929,560
Net Profit / (Loss)	\$1,866,711	\$1,774,885	\$2,068,791	\$2,399,351	\$2,664,188

The 'Net Revenue' line item is gross in-center and training revenue, minus deductions for bad debt and charity care.

The 'Total Expenses' line item includes all expenses related to the projected operation of the existing 8-station facility in 2017 and 11-station facility in years 208 through 2021. The expenses also include allocated costs and medical director costs consistent with the executed Medical Director Agreement provided in the application. The line item also includes all lease expenses.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Within this application, DaVita determined this evaluation would be released in November 2017. As previously stated, DaVita's timeline for this project is not possible. However, using the concept provided by DaVita that the project would be complete within 60 days of approval, for this evaluation the department re-calculated DaVita's timeline for completion. With the re-calculation, the department determines that DaVita would begin providing dialysis services in the three additional stations by the end of April 2018. Under this timeline, 2019 would be the facility's first full calendar year of operation with eleven stations and 2021 would be year three.

DaVita has a history of providing dialysis services in Washington State, including Pierce County. Its Graham Dialysis Center has been operating at its current site since mid-year 2009. DaVita relied on its experience and expertise to determine a reasonable payer mix. DaVita also relied on the historical utilization and growth at Graham Dialysis Center to determine the utilization as an 11-station center. Based on DaVita's experience, the department concludes this approach by DaVita is reasonable.

Focusing on DaVita's revenue and expense statements provided, generally DaVita again relied on its historical experience at Graham Dialysis Center to project revenues and expenses as an 11-station center.

To determine lease costs, DaVita provided its current lease agreement for the site. The lease agreement was executed on September 25, 2008 and extends for ten years, or until September 25, 2018. Article 4 of the Lease Agreement address renewals for the lease. Article 4 provides the following renewal language.

"Lessee shall have the right and option to renew this lease for two (2) additional periods of five (5) years each, next immediately ensuing after the expiration of the initial Term of this lease and the subsequent renewal periods by notifying Lessor in writing not less than one hundred eighty (180) days before the expiration of the immediately preceding initial Tern or subsequent renewal Term of this Lease of the Lessee's intention to exercise its option to renew, but Lessee shall have no option to extend this Lease beyond two (2) renewal periods of five (5) years each after the initial Term. In the event that Lessee so elects to extend this Lease, then, for such extended period of the Term, all of the terms, covenants and conditions of this Lease shall continue to be and shall be in full force and effect during such extended period of the Term hereof, except for the Rent. The Rent for the first Lease Year of each extended period shall be as mutually agreed upon by Lessor and Lessee not less than sixty (60) days prior to the expiration of the then current Term hereof and shall be adjusted thereafter as set forth in Section 3 hereof. If Lessor and Lessee are unable to mutually agree on the new Rent for the first Lease Year of such extended period then, within fifty (50) days prior to the expiration of the then current Tern of this Lease each of Lessor and Lessee shall select a duly qualified real estate appraiser. The Rent shall be ninety five percent (95%) of the annual fair market rental value (the "FMRV") of the Premises, but no less than annual Rent in effect with respect to the commencement month of the initial term. or the first renewal term, as the case may be. FMRV will be as determined by the two (2) appraisers selected by Lessee and Lessor as of the date which is forty (40) days before the date of the expiration of the then existing Term of this Lease. The appraiser shall issue their reports within ten (10) days. If the higher of the two (2) appraisals is less than or equal to one hundred ten percent (110%) of the lower, FMRV shall be the average of the two: if not. the two (2) appraisers shall then mutually select the third (3rd) appraiser within ten (10) days. The third (3rd) appraiser so selected shall determine which of the two (2) appraisers' determination is closest to FMRV within ten (10) days and such determination shall be deemed to be the FMRV. Lessors shall pay the cost of the appraisal by the appraiser selected by Lessor. Lessee shall pay the cost of the appraisal by the appraiser selected by Lessee. Lessor and Lessee shall equally bear the cost of the third appraisal.

For purposes of making the CPI adjustment during any extended period, (1) the Rent for the first Lease Year of any extended period shall be determined as set forth herein, without adjustment, (2) subsequent years rent shall be adjusted according to CPI as set forth above."

Article 4 of the executed lease agreement ensures that DaVita can reasonably rely on the agreement for lease costs until year 2028. The lease amounts identified in DaVita's revenue and expense statements for Graham Dialysis Center can be substantiated.

DaVita also provided its executed Medical Director Agreement for Graham Dialysis Center. The Medical Director Agreement and the joinder are due to expire on December 11, 2018. These documents alone do not allow DaVita to rely on them for projecting expenses through year 2020. DaVita provided a draft "First Amendment to Medical Director Agreement." [source: January 30, 2018,

PUI documents] This draft document extends the medical director services through December 31, 2021. DaVita can reasonably rely on the draft First Amendment medical director costs through 2020. The medical director amounts identified in DaVita's revenue and expense statements for Graham Dialysis Center can be substantiated.

If DaVita's project is approved, the department would include a condition requiring DaVita to provide a copy of the executed First Amendment to Medical Director Agreement consistent with the draft agreement provided in the application. With the following condition, the department concludes DaVita's project **meets this sub-criterion**.

• Prior to commencing the project, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed First Amendment to Medical Director Agreement. The executed agreement must be consistent with the draft agreement provided in the application.

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

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

DaVita HealthCare Partners, Inc.

DaVita identified the costs for this project, which includes leasehold improvements to make the additional three stations operational. The capital cost breakdown is shown in Table 8 below. [source: Application, Appendix 7 and 1st screening response, p7]

Table 8
DaVita Graham Dialysis Center - Estimated Capital Costs

Item	Totals
Construction/Leasehold Improvements	\$2,750
Professional Service/Architect Fees	\$1,100
Fixed and Moveable Equipment	\$27,772
Architect/Engineering Fees	\$0
Real Estate Commission	\$0
Total Estimated Capital Costs	\$31,622

DaVita provided the following statements related to the estimated construction costs and equipment costs. [source: Application, pp19-20 and 1st screening response, p7]

"The \$31,622 cost includes costs for lease improvements, equipment, professional services and was determined based on DaVita's historical experience expanding and equipping facilities. DaVita notes that it has constructed many dialysis facilities locally and throughout the United States, and has an extensive history of effectively managing construction costs and capital expenditures. 'Professional service fees' includes any architecture and engineering costs as well as the costs associated with utilities hook-ups."

"No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project. The proposed facility will operate at utilization levels consistent with required utilization levels. Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The costs for adding 3 stations to the 8-station Graham Dialysis Center is \$31,622. The costs are comparable to those reviewed in past applications for similar size station addition. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the application shows that Graham Dialysis Center currently has Medicare and Medicaid reimbursements equal 71.86% of the revenue at the dialysis center. This amount is reasonable for a facility that has been in operation for almost ten years. Further, the amounts are consistent with percentages reviewed and approved in past DaVita projects.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD 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 does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by DaVita about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 28.14% of revenue is combined commercial and other revenues.

Based on the above information provided in the application, the department concludes that DaVita's projected costs associated with the addition of 3 stations to the 8-station dialysis center would probably not have an unreasonable impact on the costs and charges for healthcare services in Pierce County planning area #2. **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.

DaVita HealthCare Partners, Inc.

DaVita identified a capital expenditure of \$31,622 to add three stations to Graham Dialysis Center. DaVita intends to fund the project using corporate reserves. DaVita provided a letter from its corporate chief operating officer for kidney care to demonstrate an operational and financial commitment to the project. [source: Application, p20 and Appendix 6]

DaVita also provided a copy of its audited financial statements for years 2014, 2015, and 2016 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 10]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita intends to finance the project with reserves and demonstrated the funds are available. If this project is approved, the department would attach a condition requiring DaVita to finance the project consistent with the financing description provided in the application.

With a financing condition, the department concludes the DaVita project meets this sub-criterion.

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the DaVita HealthCare Partners, Inc. 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 determined whether the proposed staffing would allow for the required coverage.

DaVita HealthCare Partners, Inc.

If this project is approved, DaVita expects the additional three stations would be operational by the end of year 2018. Year 2019 would be the facility's first full calendar year of operational and 2021 would be year three. Table 9 provides a breakdown of projected FTEs for years 2017 through 2021. [source: 2nd screening response, p4]

Table 9 DaVita Graham Dialysis Center Projected FTEs for Years 2017 - 2021

FTE by Type	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	Total
FIE by Type	Current	Increase	Increase	Increase	Increase	FTEs
Administrator	0.51	0.49	0.00	0.00	0.00	1.00
Administrative Assistant	0.85	(0.29)	0.05	0.06	0.00	0.67
Medical Social Worker	0.48	0.03	0.05	0.05	0.00	0.61
Dietician	0.42	0.09	0.05	0.05	0.00	0.61
RN-InCenter/PD/HHD	6.80	0.18	0.00	0.67	0.17	7.82
Biomed Tech	0.25	0.03	0.00	0.00	0.00	0.28
Other	1.94	(1.18)	0.08	0.07	0.03	0.94
Total FTEs	11.25	(0.65)	0.23	0.90	0.20	11.93

DaVita also provided the following clarifications related to the staffing table above.

- the medical director is under contract at \$95,000 and not included in the table above.
- we assume a 1:12 nurse to patient ratio. All final staffing ratios are subject to the discretion of the facility's clinical team, as there may be occasions and instances of higher patient acuity that require additional staff. DaVita has historically and will continue to make any adjustments necessary to ensure the highest possible quality of care.
- Note that two categories decline in FTE from 2017-2018: "Admin Assistant" and "Other." Both are due to unique circumstances in 2017 that make historical FTE count unreflective of future operations. In 2017, the Administrative Assistant was an outlier due to the Administrative Assistant covering for multiple facilities and requiring a higher FTE. Similarly, "Other" is an outlier as it includes training, and 2017 included higher than usual training for Kidney Smart.

[source: 2nd screening response, p2]

DaVita provided a copy of the current Medical Director Agreement among Total Renal Care (DaVita), MultiCare Medical Associates a/k/a Good Samaritan Nephrology, and Mohammed Baccora, MD. The agreement was signed by all on September 29, 2011. DaVita also provided a copy of the Joinder to Medical Director Agreement. The joinder is among the same entities, focuses on confidentiality and non-compete, and was executed on December 10, 2015. The medical director agreement and the joinder expire on December 11, 2018. [source: Application, Appendix 3 and August 22, 2017, screening response, Appendix 3A]

During the review of this project, department declared a Pivotal Unresolved Issue (PUI). The purpose of the PUI was to obtain additional documentation related to the medical director agreement. In response to the PUI request, DaVita provided a revised draft amendment to the Medical Director Agreement. The draft amendment extends the Medical Director Agreement through December 2021. [source: January 30, 2018, PUI documents]

DaVita provided the following statements related to recruitment and retention of staff. [source: Application, p22]

"DaVita anticipates no difficulty in recruiting the necessary personnel to staff the DaVita Graham Dialysis Center. Based on our experience operating facilities in the planning area, DaVita anticipates that staff from existing Graham Dialysis Center and geographically adjacent facilities

will serve patients at the expended Graham Dialysis Center. Moreover, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer (davita.com/about/awards) and offers a competitive wage and benefit package to employees. DaVita posts openings nationally both internally and external to DaVita."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that DaVita is a well-established provider of dialysis services in Washington State and in Pierce County planning area #2. Its Graham Dialysis Center has been operational since mid-year 2009.

For this project, DaVita is proposing to add three stations to the existing center. The increase in stations will require addition of less than one FTE by the end of the third full year of operation—2021.

Based on the above information, the department concludes that DaVita has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. This sub-criterion is met.

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

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

DaVita HealthCare Partners, Inc.

DaVita provides dialysis services throughout Washington State, including its Graham Dialysis Center in Pierce County planning area #2. If this project is approved, Graham Dialysis Center's stations will increase from 8 to 11. DaVita states that the following ancillary and support services would be provided on site: social services, nutrition, financial counseling, pharmacy access, patient and staff education, human resources, material management, administration and biomedical technical services.

Additional services are coordinated through DaVita's corporate offices in Denver, Colorado and support offices in Federal Way and Tacoma, Washington; El Segundo, California; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: Application, p22]

DaVita also provided a listing of the entities it currently has working relationships with for its Graham Dialysis Center. [source: 1st screening response, p6]

Back Up Dialysis Services Agreement

Tumwater Dialysis, Parkland Dialysis, Rainier View Dialysis, Lakewood Community Dialysis Center, Puyallup Dialysis Center, Federal Way Community Dialysis Center, Kent Dialysis Center, Olympia Dialysis Center, Tacoma Dialysis Center, Olympia Dialysis Center, Federal Way Community Dialysis Center (Renal Life Link)

• Isolation Room Agreement

Parkland Dialysis Center, Lakewood Community Dialysis Center, Puyallup Dialysis Center

• Stat Laboratory

MultiCare Health System d/b/a Good Samaritan Hospital Laboratories, Pathology Associates Medical Laboratories, LLC, PacLab, LLC.

• Nursing Home Dialysis Transfer Agreement

Puyallup Nursing and Rehab Center

• Patient Transfer Agreement

MultiCare Health System d/b/a Good Samaritan Hospital

DaVita provided the following statement related to the existing working relationships for Graham Dialysis Center. [source: 1st screening response, p6]

"The working relationships Graham Dialysis Center has with the healthcare facilities named in the answer to Question #13 will not change as a result of this project."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Graham Dialysis Center has been operating in Pierce County planning area #2 since mid-year 2009. All ancillary and support services have been established for the 8-station center. DaVita states that no new agreement or revisions to existing agreement are necessary for this project.

During the review of this project, the department noted that the executed Medical Director Agreement would expire in December 2018. Since the addition of three stations would occur in 2018, and the third full year of operation is year 2021, the department requested DaVita to provide valid agreement that extends through at least year 2021.

As previously stated, during the screening of the DaVita project, the department noted that the executed Medical Director Agreement and associated joinder among Total Renal Care (DaVita), MultiCare Medical Associates a/k/a Good Samaritan Nephrology, and Mohammed Baccora, MD expire on December 11, 2018. Since the third full year of operation for this project is year 2021, the department requested DaVita to provide a document to extend through at least year 2021. In response, DaVita provided a "First Amendment to Medical Director Agreement" included with the first screening response. DaVita requested a second screening, which includes a screening of the

First Amendment to Medical Director Agreement. The department conducted a second screening, but failed to not a fatal flaw the First Amendment to Medical Director Agreement.

Specifically First Amendment to Medical Director Agreement included a header on each page with the following language.

DRAFT FOR DISCUSSION PURPOSES ONLY DO NOT EXECUTE CONFIDENTIAL-PROPRIETARY INFORMATION PROPERTY OF DAVITA INC. AND ITS AFFILIATES (COLLECTIVELY, "DAVITA"). DAVITA RESERVES THE RIGHT TO FURTHER MODIFY THIS DOCUMENT.

Based on the header above, the document provided by DaVita does not meet CN requirements as a draft. The department could not attach a condition to the draft requiring DaVita to provide an executed document because it was created for discussion purposes only; the draft includes a "Do Not Execute" statement; and DaVita reserves the right to modify the document. For these reasons, the draft is unreliable for Certificate of Need purposes.

Given that DaVita requested a second screening <u>and</u> the department overlooked the fatal language in the draft First Amendment to Medical Director Agreement, the department declared a Pivotal Unresolved Issue (PUI). During the PUI process, DaVita submitted a revised, draft First Amendment to Medical Director Agreement that did not include the header referenced above. The draft amendment extends the Medical Director Agreement through December 2021. [source: January 30, 2018, PUI documents]

The revised, draft First Amendment to Medical Director Agreement that DaVita provided under the PUI is the document that the department will rely on in this review. The department did not receive any public comments on this PUI document. As a result, DaVita did not provide rebuttal comments.

After reviewing the executed medical director agreement and joinder among Total Renal Care (DaVita), MultiCare Medical Associates a/k/a Good Samaritan Nephrology, and Mohammed Baccora, MD and the draft First Amendment to Medical Director Agreement, the department concludes that Davita provided the necessary documentation related to medical director services. The department also concludes that all other required ancillary and support agreements and relationships are already in place. If this project is approved, the department would attach a condition requiring DaVita to provide a copy of the executed First Amendment to Medical Director Agreement consistent with the draft agreement provided in the application. With the condition, the department concludes that DaVita's project meets this sub-criterion.

(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.

The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for these projects, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the 'star rating' assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS 'star ratings' for Washington State facilities. Finally, the department focused on its own state survey data performed by the Department of Health's Investigations and Inspections Office. Below is an overview of the CMS star rating review. The department's Washington State survey data is include in each applicant's separate review under this sub-criterion.

Centers for Medicare & Medicaid Services (CMS) Star Ratings

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 provided the following overview regarding its star rating for dialysis centers. [source: CMS website]

"The star ratings are part of Medicare's efforts to make data on dialysis centers easier to understand and use. The star ratings show whether your dialysis center provides quality dialysis care - that is, care known to get the best results for most dialysis patients. The rating ranges from 1 to 5 stars. A facility with a 5-star rating has quality of care that is considered 'much above average' compared to other dialysis facilities. A 1- or 2- star rating does not mean that you will receive poor care from a facility. It only indicates that measured outcomes were below average compared to those for other facilities. Star ratings on Dialysis Facility Compare are updated annually to align with the annual updates of the standardized measures."

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.

The Dialysis Facility Compare website currently reports on 9 measures of quality of care for facilities. These measures are used to develop the star rating. 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, 2012 through December 31, 2015.9

The measures used in the star rating are grouped into three domains by using a statistical method known as Factor Analysis. Each domain contains measures that are most correlated. This allows CMS to weight the domains rather than individual measures in the final score, limiting the possibility of overweighting quality measures that assess similar qualities of facility care. The three domains are as follows:

- "Standardized Outcomes (SHR, SMR, and STrR)" This first domain combines the three outcome measures for hospitalization, mortality and transfusions (SHR, SMR, and STrR).
- "Other Outcomes 1 (AV fistula, tunneled catheter)" The arteriovenous fistula and catheter measures forms the second domain.
- "Other Outcomes 2 (Kt/V, hypercalcemia)" The All Kt/V and hypercalcemia measures forms the third domain.

Facilities are rated as long as they have at least one measure in each of the three domains. Because the vascular access measures in the "Other Outcomes 1 (AV fistula, tunneled catheter)" domain do not apply to peritoneal dialysis patients, peritoneal dialysis-only facilities are rated based on the other two domains. They receive ratings as long as they have scores for at least one of the two domains not related to vascular access.

DaVita HealthCare Partners, Inc.

DaVita provided the following statement in response to this sub-criterion. [source: Application p22]

"The applicant has no adverse history of license revocation or decertification in Washington State."

⁹ The information or data on Dialysis Facility Compare comes from two key sources: 1) CMS Statistical Analytical Files (Medicare Claims); and 2) Consolidated Renal Operations in a Web-enabled Network (CROWN). Some ratios are calculated annually based on the information that facilities send Medicare each month; other ratios are calculated quarterly.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The department completed a review of DaVita's quality and compliance with state and federal requirements below.

CMS Star Rating for Out-of-State Centers

DaVita reports dialysis services to CMS for more than 2,488 facilities in 45 states and the District of Columbia. Of the 2,488 facilities reporting to CMS by DaVita, 295 had no star rating. For the remaining 2,193 facilities with a star rating, 85.9% had a rating of three or better.

CMS Star Rating for Washington State Centers

DaVita owns, operates, or manages 42 facilities in 18 separate counties. Of the 42 centers, 40 of them are currently operating. Of the 40 centers, 8 do not have the necessary amount of data to compile a star rating. ¹¹ The department reviewed the star rating for the remaining 32 centers. ¹²

Table 10
DaVita Washington State Dialysis Facilities

Facility Name	CMS Certification Number	CMS Star Rating	
OLYMPIC VIEW DIALYSIS CENTER	502525	3	
KENT COMMUNITY DIALYSIS CENTER	502526	4	
MID-COLUMBIA KIDNEY CENTER	502504	4	
NORTH SPOKANE RENAL CENTER	502538	3	
SPOKANE VALLEY RENAL CENTER	502537	5	
PARKLAND DIALYSIS CENTER	502566	3	
PUYALLUP COMMUNITY DIALYSIS CENTER	502534	3	
SEAVIEW DIALYSIS CENTER	502562	5	
ELLENSBURG DIALYSIS CENTER	502552	4	
FEDERAL WAY COMMUNITY DIALYSIS CENTER	502513	4	
EVERETT DIALYSIS CENTER	502560	5	
MT ADAMS KIDNEY CENTER	502514	5	
WENATCHEE VALLEY DIALYSIS	502568	5	
EAST WENATCHEE DIALYSIS	502569	5	
UNION GAP DIALYSIS CENTER	502543	5	
VANCOUVER DIALYSIS CENTER	502550	3	

¹⁰ The five states where DaVita does not operate are: Alaska, Delaware, Mississippi, Vermont, and Wyoming.

¹¹ The eight centers are: Battleground Dialysis Center, Belfair Dialysis Center, Cascade Dialysis Center, Echo Valley Dialysis Center, Rainier View Dialysis Center, Redondo Beach Dialysis Center, Renton Dialysis Center, and Tumwater Dialysis Center.

¹² CMS Star Rating Data updated as of January 24, 2018.

Table 10 (continued)
DaVita Washington State Dialysis Facilities

Du rau Washington State Di	CMS Certification	CMS Star
Facility Name	Number	Rating
WHIDBEY ISLAND DIALYSIS CENTER	502564	3
KENNEWICK DIALYSIS	502572	4
BELLEVUE DIALYSIS CENTER	502542	3
CHINOOK KIDNEY CENTER	502559	5
MILL CREEK DIALYSIS CENTER	502561	5
ZILLAH DIALYSIS	502571	4
DAVITA MT BAKER KIDNEY CENTER	502501	5
DOWNTOWN SPOKANE RENAL CENTER	502547	3
TACOMA DIALYSIS CENTER	502551	3
PILCHUCK DIALYSIS	502577	4
WESTWOOD DIALYSIS CENTER	502544	4
LAKEWOOD COMMUNITY DIALYSIS CENTER	502519	4
GRAHAM DIALYSIS CENTER	502554	5
OLYMPIA DIALYSIS CENTER	502555	5
YAKIMA DIALYSIS CENTER	502541	4

As shown above, all of DaVita's Washington State dialysis facilities show a three or better star rating.

Washington State Survey Data

For Washington State, DaVita owns, operates, or manages 42 facilities in 18 separate counties. Two of the 42 are CN approved, but not yet state surveyed and operational. The department reviewed the compliance history for the 40 operational DaVita dialysis centers listed above. For the Washington State facilities, on behalf of Centers for Medicare and Medicaid (CMS), the department has conducted and completed at least 40 surveys in the most recent three years. All surveys resulted in no significant non-compliance issues. [source: DOH IIO survey data]

In this application, DaVita provided its Medical Director Agreement and the draft First Amendment to the Medical Director Agreement. Physician information identified in both documents allows the department to review the compliance history for the medical director associated with Good Samaritan Nephrology—Mohammed Baccora, MD. Using data from the Medical Quality Assurance Commission, the department found that Dr. Baccora has no enforcement actions on his license.

DaVita is currently operating under a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the Department of Health and Human Services that was signed on October 22, 2014. DaVita provided a copy of the signed agreement. [source: Application, Appendix 4] The department notes that the agreement focuses on DaVita's joint ventures with nephrologists to operate dialysis clinics; rather than patient care or billing practices.

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.¹³ None of the joint ventures or dialysis clinics are located in Washington State.

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.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by DaVita. The department also considered the compliance history of the medical director associated with the facility. The department concludes that Graham Dialysis Center has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of stations to Graham Dialysis Center would not cause a negative effect on the facility's compliance history. The department concludes that DaVita's project meets this sub-criterion.

(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.

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, p22 & Appendices 12, 17, 18, & 20]

"Appendix 17 provides a summary of quality and continuity of care indicators used in DaVita's quality improvement program. The DaVita Continuous Quality Improvement (CQI) program

¹³ The five states are: California (9); Colorado (7); Florida (5); Kentucky (1); and Ohio (4).

incorporates all areas of the dialysis program. The program monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Dialysis-specific statistical tools (developed by DaVita) are used for measurement, analysis, communication, and feedback. Continuing employee and patient education are integral parts of this program. Appendix 17 includes an example of DaVita Quality Index (DQI) data. Appendix 18 includes an example of DaVita's Physician, Community and Patient Services offered through DaVita's Kidney Smart Education Program. Appendix 12 includes a copy of the affiliation letter between St. Clare Hospital and Lakewood Dialysis. DaVita has been honored as one of the World's Most Admired Companies® by FORTUNE® magazine since 2006, confirming its excellence in working effectively with the communities it serves. (davita.com/aboutawards)"

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita has been a provider of dialysis services in Washington State for many years. DaVita also has a history of establishing relationships with existing healthcare networks in Pierce County planning area #2 for its Graham Dialysis Center. Additionally, DaVita's project would promote continuity in the provision of healthcare services in the planning area #2 by adding needed stations to Graham Dialysis Center.

DaVita provided documentation in the application to demonstrate that the project would promote continuity in the provision of health care services in the community and not result in unwarranted fragmentation.

Based on the information above, the department concludes that DaVita's project meets this subcriterion.

(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.

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, pp22-23]

"The applicant has no adverse history of license revocation or decertification in Washington State.

The DaVita Graham Dialysis Center will provide comprehensive in-center dialysis services. As previously described, DaVita is committed to its highly-effective Continuous Quality Improvement program and seeks to assure the appropriate structure and process of care through uncompromising quality goals on an ongoing, continuous basis. DaVita has demonstrated industry leading performance in both of the CMS performance ranking system, the Quality Incentive Program (QIP) shown in Appendix 21, and Dialysis Facility Compare or Five-Star ranking program (davita.com, News Release January 11, 2016). Based on 2014 performance, DaVita had five times fewer facilities receive a revenue penalty for 2016 than its competitors as well as the highest number of centers to

receive four or five stars in the Five-Star metric. Further, the Department of Health surveys dialysis centers to ensure compliance with federal and state laws."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the DaVita HealthCare Partners, Inc. project has met the cost containment criteria in WAC 246-310-240.

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

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, in <u>step two</u>, the department assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in <u>Step three</u>. The superiority 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 type superiority criteria as directed by WAC 246-310-200(2) (a)(i), then the department would use WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

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

Step Two

For this sub-criterion, DaVita considered only the option of do nothing, or not submit this application. Below is DaVita's discussion related to the do nothing option. [source: Application, p24]

Do nothing

It has been established that Pierce 2 is growing in ESRD and serving patients who reside outside of Pierce 2, as well. Currently, DaVita Graham is the only facility in the service area and, without additional capacity, will be required to send patients outside of the geography for dialysis services which will come at great inconvenience to patients and their nephrologists who rely on proximity to be able to round on their patients consistently. This alternative was rejected.

Public Comment

None

Rebuttal Comment

None

Step Three

This step is applicable only when two or more projects can be approved. Since DaVita's application is the only application that met all previous applicable review criteria, this step does not apply.

Department Evaluation of Steps One and Two

DaVita provided a comprehensive discussion of the "do nothing" alternative before submitting this application. Specifically, DaVita operates the only dialysis center in Pierce County planning area #2 and rejected the 'do nothing' alternative because the numeric methodology shows need for stations in the planning area.

Given that the numeric methodology is based on the historical number of patients dialyzing in the planning area, the methodology also demonstrates patient growth in the planning area. DaVita appropriately rejected the 'do nothing' alternative.

Also, information provided in the application demonstrates that superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable for the patients in Pierce County planning area #2. An additional three stations at Graham Dialysis Center would result in patients having more flexibility scheduling for dialysis.

The capital expenditure associated with the additional three stations is \$31,622. Of that amount, approximately 88% is for fixed and moveable equipment; 9% is for construction and leasehold improvements; and the remaining 3% is for architect and engineering fees and costs associated with utility hook-ups. All costs would be paid by DaVita

Given that the only other option to this project is to do nothing and taking into account the projected need for additional stations in the planning area, the department concludes that the project submitted by DaVita is the best available alternative for the community. **This sub-criterion is met.**

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

(a) <u>The costs, scope, and methods of construction and energy conservation are reasonable;</u>
DaVita provided the following statement under this sub-criterion. [source: Application, p25]
"Experience with operating or managing over 2,293 Medicare-certified dialysis centers throughout the country including many in the Northwest, provides the background for designing facilities that satisfy all patient requirements and provide the greatest value for the investment dollar. DaVita Graham Dialysis Center will meet all current energy conservation standards. DaVita Graham

Dialysis Center is designed to meet current energy code requirements; therefore, additional energy costs associated with unused space does not substantially add to energy consumption.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita's project requires minor construction to Graham Dialysis Center. Through its experience and expertise, DaVita demonstrated determination of its costs for a project are reasonable. As stated in the financial feasibility section of this evaluation, the department concluded that the amount identified for the station addition is reasonable.

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

DaVita provided the following information for this sub-criterion. [source: Application, pp19-20] "No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project. The proposed facility will operate at utilization levels consistent with required utilization levels. Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita's project involves minor construction. This sub-criterion was evaluated under WAC 246-310-220(2), under which the department substantiated all costs identified for the station addition. With the need for additional stations in Pierce County planning area #2 and the assumptions related to the costs and charges discussed under the Financial Feasibility section of this evaluation, the department does not anticipate an unreasonable impact on the costs and charges to the public as a result of addition stations in the planning area. The department concludes that DaVita meets this sub-criterion.

(3) <u>The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.</u>

DaVita provided the following information for this sub-criterion. [source: Application, p24]

"DaVita uses staffing models to efficiently design and staff dialysis facilities and assure maximum utilization of resources. Dialysis facilities are required to have substantial clinical and support staff for ESRD patients (Managers, Administrative support, Registered Nurses, Technicians, Social Workers, and Dietitians). The key advantages to the DaVita Graham Dialysis Center proposal that promote staff and system efficiency include:

- Increased availability and flexibility of scheduling for all patients by introducing patient access and choice to the ESRD planning area.
- Commitment to Continuous Quality Improvement (CQI) all studies document that higher quality results in better clinical outcomes, lower hospitalization rates and accordingly lower costs to payers.
- Full use of the expanded facility designed to meet current energy utilization requirements."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita's project could have the potential to improve delivery of dialysis services to the residents of Pierce County planning area #2 with the addition of three dialysis stations in the planning area. This sub-criterion is met.

APPENDIX A



2017 Pierce County 2 ESRD Need Projection Methodology

	Planning Area 6 Year Utilization Data - Resident Incenter Patients						
	Pierce Two	2011	2012	2013 2014 2015			2040
	98304	0	0	0	0	0	2016
	98321	7	3	2	4	7	7
	98323	0	0	0	0	THE RESERVE OF THE PARTY OF THE	0
	98328	1	1	4	8	AND DESCRIPTION OF THE PARTY OF	4
	98330	0	0	0	0		0
	98338	12	15	16	14		19
	98360	11	9	7	7		9
	TOTALS	31	28	29	33	34	39
246-310-284(4)(2)	Data of Ohaman						
246-310-284(4)(a)	Rate of Change		-9.68%	3.57%	13.79%		14.719
	6% Growth or Greater? Regression Method:	Linear	FALSE	FALSE	TRUE	FALSE	TRU
040 040 004/41/							
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
Duningstond Denident				2017	2018	2019	2020
Projected Resident Incenter Patients	f 0.40 0.40 00.4/4\/II\					200000 200700	Notice and
Station Need for	from 246-310-284(4)(b)		_	40.70	43.40	46.10	48.8
Patients	Divide Resident Incenter	Patients by 4	.8	8.4792	9.0417	9.6042	10.166
	Rounded to next whole n	umber		9	10	3.03% FALSE Year 3 2019 46.10	1
246-310-284(4)(d)	Subtract (4)(s) form						
Existing CN Approved S	subtract (4)(c) from approv	ed stations					
Results of (4)(c) above	otations			8	8		
			-	9	10		11
Net Station Need				-1	-2	-2	:
Negative number indicates ne	eed for stations						
Planning Area Facil	ities						
Name of Center	# of Stations						
DaVita Graham	8						
Total	8						
	J						
Source: Northwest Renal							



2017 Pierce County 2 ESRD Need Projection Methodology

