



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

December 4, 2018

CERTIFIED MAIL # 7017 3380 0000 0863 8444

Evan Moore, Director Special Projects
DaVita, Inc. North Star Division
32275 – 32nd Avenue South
Federal Way, Washington 98001

RE: Certificate of Need Application #18-43-Spokane Valley Renal Center

Dear Mr. Moore:

We have completed review of the Certificate of Need application submitted by DaVita, Inc. The application proposes the addition of two dialysis stations to Spokane Valley Renal Center located in Spokane County planning area #1. The two stations are added under the special circumstance provisions of Washington Administrative Code 246-310-818. 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, Inc. agrees to the following in its entirety.

Project Descriptions:

This certificate approves the addition of two dialysis stations to the 10-station Spokane Valley Renal Center, for a facility total of 12 dialysis stations. Services provided at Spokane Valley Renal Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, and a shift beginning after 5:00 p.m.

Certificate of Need #1664 was issued to DaVita, Inc. approving the one-time addition of an isolation station to Spokane Valley Renal Center consistent with Washington Administrative Code 246-310-809(3). The certificate was effective on January 1, 2018.

The table below provides a breakdown of the total number of stations at Spokane Valley Renal Center, which includes two additional stations approved under the special circumstance criterion outlined in Washington Administrative Code 246-310-818.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	12	12
Permanent Bed Station	0	0
Private Isolation Station ¹	1	0
Total Stations	13	12

As required under Washington Administrative Code 246-310-818(10), the two additional stations must be operational within six months of approval, otherwise this Certificate of Need is revoked.

Conditions:

1. Approval of the project description as stated above. DaVita, 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. DaVita, Inc. shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this two-station addition is \$254,181. This amount represents the costs for construction, fixed and moveable equipment, associated fees and sales tax. 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

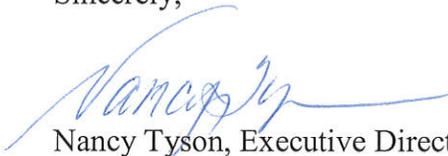
Physical Address:
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

¹ DaVita has not yet completed the administrative station adjustment as allowed under Washington Administrative Code 246-310-809.

Evan Moore, Director Special Projects
DaVita, Inc. North Star Division
CN Application #18-43 Spokane Valley Renal Center
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If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact the Certificate of Need Program at (360) 236-2955.

Sincerely,



Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure

**2018 CYCLE 1 SPECIAL CIRCUMSTANCE EVALUATION DATED DECEMBER 4, 2018,
FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA, INC.
PROPOSING TO ADD TWO DIALYSIS STATIONS TO SPOKANE VALLEY RENAL
CENTER LOCATED IN SPOKANE COUNTY PLANNING AREA #1**

APPLICANT DESCRIPTION

DaVita Inc., a Fortune 500® company, is the parent company of DaVita Kidney Care and DaVita Medical Group. DaVita Kidney Care is a leading provider of kidney care in the United States, delivering dialysis services to patients with chronic kidney failure and end stage renal disease. DaVita Medical Group is a division of DaVita Inc. that operates and manages medical groups and affiliated physician networks in California, Colorado, Florida, Nevada, New Mexico, Pennsylvania and Washington. In Washington State, DaVita Inc. is affiliated with both The Everett Clinic and Northwest Physicians Network. [source: DaVita, Inc. website and DaVita Medical Group website]

For this application, DaVita, Inc. is the applicant. Throughout this evaluation, the applicant will be referenced as ‘DaVita.’

Currently DaVita operates or provides administrative services in approximately 2,539 dialysis facilities located in the United States serving approximately 185,000 patients. [source: Applications, pp4-5] In Washington State, DaVita owns or operates 42¹ kidney dialysis facilities in 19 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

Pacific

Seaview Dialysis Center

Pierce

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

Skagit

Cascade Dialysis Center

Snohomish

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

¹ As of the writing of this evaluation, all of DaVita’s dialysis facilities are operational.

King

Bellevue Dialysis Center
 Federal Way Dialysis Center
 Kent Dialysis Center
 Olympic View Dialysis Center
 Renton Dialysis Center
 Redondo Heights Dialysis Center
 Westwood Dialysis Center

Kittitas

Ellensburg Dialysis Center

Lewis

Cooks Hill Dialysis Center

Mason

Belfair Dialysis Center

Spokane

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

Stevens

Echo Valley Dialysis Center

Thurston

Olympia Dialysis Center
 Tumwater Dialysis Center

Whatcom

Mount Baker Kidney 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 Spokane Valley Renal Center located at 12610 East Maribeu Parkway, #11, in Spokane Valley [99216] within Spokane County planning area #1. Currently, Spokane Valley Renal Center is a 10-station facility. This application proposes to add two additional stations, resulting in a 12-station dialysis center. Spokane Valley Renal Center would remain at its current location in Spokane Valley and would continue to provide in-center hemodialysis, backup dialysis service, home hemodialysis and home peritoneal dialysis training, and shifts beginning after 5 pm.² [source: Application, p10]

The capital expenditure associated with the additional two stations is \$264,181. Of that amount, approximately 61% is related to construction costs; 18% is for fixed and moveable equipment; and the remaining 21% is associated with fees, inspections, and state sales tax. All costs would be paid by DaVita. [source: Application, p21]

Within this application, DaVita determined this evaluation would be released in early November 2018. Using that timeline, DaVita estimated the two station addition would be operational by the end of April 2019. [source: Application, p10] Under this timeline, full year one is 2020 and full year three is 2022.

APPLICABILITY OF CERTIFICATE OF NEED LAW

DaVita’s 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).

² As of the writing of this evaluation, Spokane Valley Renal Center does not have an isolation or permanent bed station.

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.*

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 246-310-800 through 833. For ESRD applications submitted under WAC 246-310-818 ‘Special Circumstance One- or Two-Station Expansion,’ the following review criteria do not apply and will not be discussed in this evaluation.

WAC 246-310-809	One-time exempt isolation station reconciliation
WAC 246-310-812	Kidney disease treatment facilities—Methodology
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an existing facility
WAC 246-310-830	Kidney disease treatment facilities—Relocation of facilities
WAC 246-310-833	One-time state border kidney dialysis facility station relocation

WAC 246-310-803

WAC 246-310-803 requires an applicant submit specific data elements to the Certificate of Need Program. For the 2018 concurrent review cycle, the data must be received before February 16, 2018. DaVita submitted its data elements on February 15, 2018.

TYPE OF REVIEW

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Special Circumstances Concurrent Review Cycle #1 for calendar year 2018. Even though applications submitted under WAC 246-310-806 are reviewed under a concurrent review cycle, the applications are not reviewed competitively. Below is the chronologic summary of the application’s review.

APPLICATION CHRONOLOGY

Action	DaVita, Inc.
Letter of Intent Submitted	April 2, 2018
Application Submitted	May 1, 2018
Department’s Pre-review Activities including <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant’s 1st Screening Responses Received 	May 15 2018 June 15, 2018
Beginning of Review	June 25, 2018
End of Public Comment <ul style="list-style-type: none"> • Public comments accepted through the end of public comment • No public hearing requested or conducted 	July 25, 2018
Rebuttal Comments Received ³	August 1, 2018
Department's Anticipated Decision Date	August 16, 2018
Department’ Actual Decision Date	December 4, 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;*

³ The department did not receive any public comment. 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, Inc. Certificate of Need application received May 1, 2018
- DaVita, Inc. 1st screening response received June 15, 2018
- Years 2012 through 2017 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health’s ESRD Need Projection Methodology for Spokane County planning area #1 posted to its website March 2018
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Compliance history obtained from the Washington State Department of Health Office of Health Systems and Oversight
- DaVita, Inc. website at www.davita.com
- DaVita Medical Group website at www.davitamedicalgroup.com
- Northwest Renal Network website at www.nwrn.org
- Northwest Renal Network modality data
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSIONS

DaVita Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to add two dialysis stations to Spokane Valley Renal Center located in Spokane County planning area #1 is consistent with applicable criteria of the Certificate of Need Program, provided that the applicant agrees to the following in its entirety.

Project Description:

This certificate approves the addition of two dialysis stations to the 10-station Spokane Valley Renal Center, for a facility total of 12 dialysis stations. Services provided at Spokane Valley Renal Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, and a shift beginning after 5:00 p.m.

Certificate of Need #1664 was issued to DaVita, Inc. approving the one-time addition of an isolation station to Spokane Valley Renal Center consistent with Washington Administrative Code 246-310-809(3). The certificate was effective on January 1, 2018.

The table below provides a breakdown of the total number of stations at Spokane Valley Renal Center, which includes two additional stations approved under the special circumstance criterion outlined in Washington Administrative Code 246-310-818.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	12	12
Permanent Bed Station	0	0
Private Isolation Station ⁴	1	0
Total Stations	13	12

As required under Washington Administrative Code 246-310-818(10), the two additional stations must be operational within six months of approval, otherwise this Certificate of Need is revoked.

Conditions:

1. Approval of the project description as stated above. DaVita, 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. DaVita, Inc. shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this two-station addition is \$254,181. This amount represents the costs for construction, fixed and moveable equipment, associated fees and sales tax. All costs will be paid by DaVita.

⁴ DaVita has not yet completed the administrative station adjustment as allowed under Washington Administrative Code 246-310-809.

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, Inc. project has met the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-800 through 833.

- (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 246-310-818

WAC 246-310-818(1) - (13) outline the review requirements for dialysis projects submitted under the special circumstance review criteria. For this project, DaVita must demonstrate compliance with the following sub-sections of WAC 246-310-818.

WAC 246-310-818(1) The department will approve one or two additional special circumstance stations for an existing kidney dialysis facility (facility) if it meets the following criteria, regardless of whether the need methodology in WAC 246-310-812 projects a need for additional stations in the planning area:

- (a) *For 4.8 planning areas, the facility has operated at or above an average of 5.0 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; or*
- (c) *The facility can accommodate one or two additional stations within its existing building, which may include shelled space. If renovation is needed to accommodate the additional station(s), renovation must be within the existing building.*

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided the following documents:

- Six month utilization ‘raw’ utilization data from Northwest Renal Network.; and
- Single line drawing showing the stations and support areas of the dialysis center both before and after the two station addition.

[source: Application, Appendix 16 and June 15, 2018, screening response, Appendix 23]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

For this project, the six months preceding the letter of intent submission period for the Special Circumstance submission cycle #1 for Spokane County is October 2017 through March 2018. The data to be used by DaVita for this project is the same time frame – October 2017 through March 2018. The data provided in the application shows that DaVita’s Spokane Valley Renal Center was operating at an average of 5.73 patients per station.

The single line drawing shows the two new stations will be set up in existing space within the facility. Based on the information reviewed the department concludes the **sub-criterion is met**.

WAC 246-310-818(5) For 4.8 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 4.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided the following documents:

- Six month utilization ‘raw’ utilization data from Northwest Renal Network. This data focuses on DaVita’s Downtown Spokane Renal Center located in Spokane County planning area #1.

[source: June 15, 2018, screening response, Appendix 23]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The six months preceding the letter of intent submission period for the Special Circumstance submission cycle #1 for Spokane County is October 2017 through March 2018. The data to be used by DaVita for this project is the same time frame – October 2017 through March 2018. The data provided in the application shows that DaVita’s Downtown Spokane Renal Center was operating at an average of 5.39 patients per station. **This sub-criterion is met.**

WAC 246-310-818(7) For 4.8 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would fall below a calculated 4.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided the following documents:

- Six month utilization ‘raw’ utilization data from Northwest Renal Network.

[source: June 15, 2018, screening response, Appendix 23]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The six months preceding the letter of intent submission period for the Special Circumstance submission cycle #1 for Spokane County is October 2017 through March 2018. The data to be used by DaVita for this project is the same time frame – October 2017 through March 2018. If this project is approved, DaVita’s Spokane Valley Renal Center would be operating 12 in center dialysis stations. The data provided in the application shows that the 12-station center would be operating at an average of 4.78 patients per station. **This sub-criterion is met.**

WAC 246-310-818(10) Station(s) approved under this section must be operational within six months of approval, otherwise the approval is revoked.

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided the following table showing the projected timeline for operation of the two additional stations. [source: Application, p10]

<i>[DaVita's] Table 1 DaVita Spokane Valley Renal Center Anticipated Dates of Commencement & Completion of Project</i>	
<i>Event</i>	<i>Anticipated Date</i>
<i>Project Approval</i>	<i>November 1, 2018</i>
<i>Design Complete</i>	<i>November 2018</i>
<i>Construction Commenced</i>	<i>November 2018</i>
<i>Construction Completed</i>	<i>March 15, 2019</i>
<i>Facility Prepared for Survey</i>	<i>April 30, 2019</i>

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The timeline identified in DaVita's Table 1 above projects the two new stations would be operational at Spokane Valley Renal Center within six full months of approval. Given that WAC 246-310-818(10) requires stations to be operational within six months of approval, **this sub-criterion is met.**

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

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.⁵ 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 Inc.

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

“DaVita’s history of providing dialysis services at numerous locations throughout Washington State provides evidence that all ESRD patients have access to DaVita’s facilities, including members of the under-served groups referenced in WAC 246-310-210(2). Appendix 14 includes a copy of the admission, patient financial evaluation, and patient involuntary transfer policies which document that access will not be denied at DaVita Spokane Valley Renal 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, p19]

DaVita provided copies of the following policies used at all DaVita dialysis centers, including the existing FWCDC. [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 February 2018
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer Policy – Reviewed and Approved May 2017

Medicare and Medicaid Programs

Spokane Valley Renal Center is currently Medicare and Medicaid certified and DaVita provided the facility’s Medicare and Medicaid provider numbers. DaVita also included a table showing the current percentages of revenues by payer and revenues by patient for the facility. The information is summarized below. [source: Application, p12 and p23]

Medicare Provider Number:	502537
Medicaid Provider Number:	3990991

⁵ WAC 246-453-010(4).

Applicants Tables 15 and 16 Recreated

Current DaVita Spokane Valley Renal Center		
Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	53.98%	66.20%
Medicaid	0.96%	1.27%
Insurance/HMO	45.07%	32.53%
Total	100.00%	100.00%

Projected DaVita Spokane Valley Renal Center		
Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	49.17%	62.48%
Medicaid	0.70%	0.98%
Insurance/HMO	50.13%	36.55%
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 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 Spokane Valley Renal Center would continue both Medicare and Medicaid certifications. DaVita projected the Medicare revenues for Spokane Valley Renal Center to be 49.17% of total revenues. Pro forma financial data provided in the application shows Medicare revenues. DaVita’s Medicaid revenues are projected to be 0.70% 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, Inc. project has met the financial feasibility criteria in WAC 246-310-220 and WAC 246-310-815.

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

WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, DaVita must demonstrate compliance with the following sub-sections of WAC 246-310-815(1). 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.

WAC 246-310-815(1)

(1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.

- (a) The calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.*
- (b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payer mix and current expenses.*
- (c) New facilities.*
 - (i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.*
 - (ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.*
 - (iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.*
 - (iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.*
 - (v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities.*

Given that Spokane Valley Renal Center is currently operational, sub-sections (1)(a) and (b) above apply to this project.

DaVita Inc.

As previously stated, DaVita proposes the additional two stations would be operational in April 2019 and Spokane Valley Renal Center would be operating with 12 dialysis stations. Under this timeline, calendar year one of the project is 2020 and calendar year three is 2022. [source: Application, p10]

DaVita provided the assumptions used to project in-center and home treatments and patients for calendar years 2019, referenced as the 'expansion year' and full calendar years 2020 through 2022. The assumptions are restated below. [source: Application, Appendix 9 and June 15, 2018, screening responses, Appendix 9A]

- **First Full Year:** 2020, based on implementation by April 30, 2019 (on a November 1, 2018 approval date) and survey by the end of June 2019.
- **Total Stations:** CON Approved stations.
- **Total Chronic Capacity:** 6 shift capacity is assumed to be 100% utilization. Note this is conservative due to an active nocturnal program.
- **Patient Census Projections:** Census projections are based on a 5-year projection of planning area patients using a regression of 5 years historical data and DaVita's own experience and expertise.
- **Total Treatments:** Total Treatment Volume is assumed to be based on average yearly census, a 5% missed treatment rate consistent with DaVita's own experience and expertise, and three treatments weekly for 52 weeks per year.

Using the assumptions stated above, DaVita's projected number of in-center and home dialyses and patients for the 18-station facility in years 2019 through 2022 is shown in Table 1. [source: June 15, 2018, screening response, Appendix 9A]

Table 1
DaVita Spokane Valley Renal Center
Projected Patients and Dialyses for Years 2019 – 2022

	CY 2019	CY 2020	CY 2021	CY 2022
Number of Stations	12	12	12	12
Total In center Patients	65	68	70	73
Total In center Treatments	9,381	9,796	10,211	10,626
Total All Patients	76	79	82	86
Total All Treatments	10,969	11,458	11,951	12,448

DaVita provided the following assumptions used to project revenue, expenses, and net income for its 12-station center. [source: Application, Appendix 9]

- **Revenue per treatment:** No inflation is applied to revenue per treatment, which is based on the last full year of operation, 2017.
- **Charitable Care:** assumed to be equivalent to 2017 current rate of 1.31%.
- **Cost inflation:** DaVita's experience and expertise leads to an assumption that non-medical director or lease costs (which are previously contracted) are likely to inflate at ~2% per year, and each category is assumed as such.
- **Medical Director Expense:** based on contracted, known expenses in latest medical director agreement that runs through the extent of the three year projection window. This expense includes applicable contracted payment for active in-center hemodialysis, home hemodialysis, peritoneal dialysis, and nocturnal programs.
- **Lease Expense:** base rent is directly pulled from the lease contract that runs for at least five years from project completion. Tax and CAM are projected based on the 2017 rate of \$4.12 per square foot, with 2% per year inflation. As the Spokane Valley Renal Center lease includes a renewal clause with a readjustment of price based on 95% of Fair Market Value, the conservative approach here is to take 2% inflation of lease costs over the life of the proforma from current rates, which are \$14.31 per square foot annually.
- **Other purchased services include:** (1) pre-employment screening and time keeping services and (2) employment advertising.

- **Other direct expenses include:** (1) telephone, (2) travel, (3) freight & postage, (4) dues & subscriptions, and (5) insurance.

Specific to the base rent reference under the lease expense category, DaVita provided the following clarification. [source: June 15, 2018, screening response, p6]

“Please see the tables below outlining base rent expense and tax and CAM expense, tying out to that in Appendix 9A. Tax and CAM is based on actuals from 2017, increasing by 2% annually. Base Rent is based on 5,834 rentable square feet, established at a set \$14.31 through month 60 of the term, increasing by 2% annually thereafter in approximation of clause 4.”

DaVita’s Base Rent Table

Lease Years				Monthly Amounts	
From		To		Rent	Tax + CAM
Year	Month	Year	Month		
2018	4	2019	5	\$6,957	\$2,003
2019	6	2020	5	\$7,096	\$2,044
2020	6	2021	5	\$7,238	\$2,084
2021	6	2022	5	\$7,383	\$2,126
2022	6	2023	5	\$7,531	\$2,169

	FY19	FY20	FY21	FY22
Base Rent	\$84,459	\$86,148	\$87,871	\$89,628
Tax & CAM	\$24,322	\$24,808	\$25,305	\$25,811
Total	\$108,781	\$110,956	113,175	\$115,439

Based on the assumptions above, DaVita projected the revenue, expenses, and net income for years 2019 through 2022. A summary of the projections are shown in Table 2. [source: June 15, 2018, screening response, Appendix 9A]

Table 2
DaVita Spokane Valley Renal Center
Projected Revenue and Expenses for Years 2019 - 2022

	CY 2019	CY 2020	CY 2021	CY 2022
Net Revenue	\$3,659,098	\$3,822,371	\$3,986,809	\$4,152,466
Total Expenses	\$3,288,143	\$3,498,931	\$3,685,002	\$3,877,884
Net Profit / (Loss)	\$370,955	\$323,440	\$301,807	\$274,582

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 projected 12-station facility in years 2019 through 2022. The expenses also include allocated costs at approximately 12.0% of the total expenses per year. Medical director costs are \$115,000 annual and consistent with the executed Medical Director Agreement provided in the application.

During the screening of this application, the department noted that Spokane Valley Renal Center’s net profits is projected to decrease in each of the projections years and asked DaVita to provide

rationale for the decrease. DaVita provided the following information in response to the projected decrease in profits. [source: June 15, 2018, screening response, p5]

“The projection is by design conservative, because it holds revenue per treatment constant while allowing expenses per treatment to inflate, due to increases in rent, etc. But even with this assumption the facility is profitable in Year 3, which is what the Department historically has evaluated. Of course, if inflation were assumed for reimbursement rates, and revenue per treatment accordingly was modeled to increase over time at the same rate that expenses per treatment are projected to increase over time, EBIT would be projected to increase, not decrease, through the projection given increased treatment volume. But we thought the prudent approach would be to hold revenue per treatment constant and not assume our reimbursement rates will increase. As noted, even with this assumption, the facility shows “positive net income by the third full year of operation” as required by WAC 246-310-815(1).” [emphasis in original]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Spokane Valley Renal Center is currently operating with 10 dialysis stations. DaVita based its projected utilization of Spokane Valley Renal Center on its current utilization, plus two additional stations. This approach for an existing facility is reasonable.

As a special circumstance application, WAC 246-310-815(1)(b) requires an applicant to base its revenue projections on the current payer mix and base its expense projections on current expenses. DaVita provided both revenue and expense projections and based them on current operations. Focusing on the projected decrease in profits in each of the projection years, DaVita’s conservative approach is reasonable.

Since Spokane Valley Renal Center is currently operational, the facility has both an existing lease agreement and an existing medical director agreement. The lease agreement executed in May 2014 and is valid for five years, with two 5 year renewals. The agreement expires in May 2029. The costs identified in the lease agreement can be substantiated in the revenue and expense statement.

DaVita provided a copy of the current Medical Director Agreement among ISD Renal, Inc. (DaVita), Providence Health & Services-Washington-dba Providence Medical Group, and Vijayakumar Reddy, MD. The agreement was signed by all on February 8, 2016, and is effective for three years and includes automatic annual renewals with no end date. The costs identified in the medical director agreement can be substantiated in the revenue and expense statement.

Based on the above information provided in the application, the department concludes that DaVita’s projected revenue and expense statement is reasonable. **This sub-criterion is met.**

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

WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, DaVita must demonstrate compliance with the following sub-sections of WAC 246-310-

815(2). Using its experience and expertise the department compared the proposed project’s costs with those previously considered by the department.

WAC 246-310-815(2)

An applicant proposing to construct finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC 246-310-800(11) will be determined to have an unreasonable impact on costs and charges and the application will be denied. This does not preclude an applicant from constructing shelled space.

DaVita Inc.

For this sub-criterion, DaVita states that this project requires minimal construction to add two new stations to Spokane Valley Renal Center. DaVita provided its capital cost breakdown shown below. [source: Application, Appendix 7]

**Table 3
Estimated Capital Costs
DaVita Spokane Valley Renal Center**

Item	Total
Building Construction	\$160,985
Fixed Equipment	\$2,757
Moveable Equipment	\$44,605
Architect/Engineering Fees	\$19,500
Supervision & Site Inspection	\$18,000
Washington State Sales Tax	\$18,334
Total Estimated Capital Costs	\$264,181

Specific to costs and charges for health services, DaVita provided the following statements. [source: Application, p22]

“WAC 246-310-815(2) requires that applicants limit the costs of facility projects by creating a test of reasonableness in the construction of finished treatment floor area square footage. The treatment floor area must not exceed the maximum treatment floor area square footage defined in WAC 246-310-800(11). As outlined in response to Question Eleven under the Project Description, DaVita does not propose to construct treatment floor space in excess of the maximum treatment floor area square footage, and thus, under the WAC 246-310-815(2) test, this project does not have an unreasonable impact on costs and charges.

Additionally, as noted in response to question seven, 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.”

DaVita also provided the following information related to the construction necessary to add the two additional stations to Spokane Valley Renal Center. [source: June 15, 2018, screening response, p3]

“The construction will consist of moving one wall, relocating the scale and patient prep area, building three new nurses stations and medication prep station, and adding capacity for two general-use dialysis stations (the end focus of this project). Due to the fact that this clinic operates on a virtually 24/6 schedule, all work must be completed in 24-hour periods on Sundays.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The costs for adding two stations to the 10-station Spokane Valley Renal Center is \$264,181. 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 Spokane Valley Renal Center currently has Medicare and Medicaid reimbursements that equal 54.84% of the revenue at the dialysis center. This amount is reasonable for a facility that has been in operation for approximately 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 45.06% 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 two stations to the 10-station dialysis center would probably not have an unreasonable impact on the costs and charges for healthcare services in Spokane County planning area #1. **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 Inc.

DaVita identified a capital expenditure of \$264,181 to add two stations to Spokane Valley Renal 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, p21 and Appendix 6]

DaVita also provided a copy of its audited financial statements for years 2015, 2016, and 2017 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, 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 Inc.

If this project is approved, DaVita expects the additional two stations would be operational by April 30, 2019. Year 2020 would be the facility's first full calendar year of operation and 2022 would be year three. Table 4 provides a breakdown of projected FTEs for current year 2018, and projected years 2019 through 2022. [source: June 15, 2018, screening response, pdf#4]

**Table 4
DaVita Spokane Valley Renal Center
Current Year 2018 and Projected Years 2019 – 2022**

FTE by Type	CY 2018 Current	CY 2019 Increase	CY 2020 Increase	CY 2022 Increase	CY 2022 Increase	Total FTEs
Administrator	1.00	0.00	0.00	0.00	0.00	1.00
Administrative Assistant	0.63	0.04	0.03	0.03	0.03	0.76
Medical Social Worker	0.58	0.04	0.02	0.03	0.03	0.70
Dietician	0.45	0.03	0.02	0.02	0.03	0.55
RN-InCenter/PD/HHD	9.40	0.59	0.43	0.46	0.46	11.34
Biomed Tech	0.50	0.10	0.00	0.00	0.00	0.60
Other	0.72	0.04	0.03	0.04	0.03	0.86
Total FTEs	13.28	0.84	0.53	0.58	0.58	15.81

DaVita’s medical director is under contract at \$115,000 annual, but is not an employee and is not included in the table above. DaVita also provided the following clarifications related to the staffing table above. [source: June 15, 2018, screening response, pp2-3]

- *“other” includes among other miscellaneous categories, patient education and inventory management roles, as well as training hours-in historical settings it may include reuse technicians, although that role is no longer used at Spokane Valley Renal Center.*

DaVita provided a copy of the current Medical Director Agreement among ISD Renal, Inc. (DaVita), Providence Health & Services, Washington dba Providence Medical Group, and Vijayakumar Reddy, MD. The agreement was signed by all on February 8, 2016, and is effective for three years and includes automatic annual renewals with no end date. The agreement also identifies the following four physicians that have pre approval status for medical director services. [source: Application, Appendix 3]

Nelson Chow, MD Krishna Malireddi, MD Petru Groza, MD Henry Mroch, MD

DaVita provided the following statements related to recruitment and retention of staff. [source: Application, p26]

“DaVita anticipates no difficulty in recruiting the necessary personnel to continue to staff DaVita Spokane Valley Renal Center. Based on our experience operating facilities in the planning area, DaVita anticipates that staff from existing Spokane Valley Renal Center and geographically adjacent facilities will serve patients at the expanded DaVita Spokane Valley Renal 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 Spokane County planning area #1. Its Spokane Valley Renal Center has been operational since approximately 2002.

For this project, DaVita is proposing to add two stations to the existing center. The increase in stations will require addition of approximately 2.5 FTES by the end of the third full year of operation—2022.

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

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

DaVita provides dialysis services throughout Washington State, including its Spokane Valley Renal Center in Spokane County planning area #1. If this project is approved, Spokane Valley Renal Center's stations will increase from 10 to 12. 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, pp26-27]

DaVita also provided a listing of the entities it currently has working relationships with for its Spokane Valley Renal Center. [source: Application, Appendix 11]

DaVita provided the following statement related to the existing working relationships for Spokane Valley Renal Center. [source: Application, p27]

“DaVita Spokane Valley Renal Center has a number of strong working relationships that tie it to its community, including a Patient Transfer Agreement with Providence Sacred Heart Medical Center. Please find a listing of these relationships in Table 19 below.”

Table 19 referenced in DaVita's statement above provides a listing of the hospitals and other healthcare facilities that DaVita has established relationships.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Spokane Valley Renal Center has been operating in Spokane County planning area #1 since approximately 2002. All ancillary and support services have been established for the dialysis center since that time. DaVita states that no new agreements or revisions to existing agreements are necessary for this project.

The department also concludes that all other required ancillary and support agreements and relationships are already in place. **This sub-criterion is met.**

- (3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

DaVita Inc.

DaVita provided the following statement in response to this sub-criterion. [source: Application p29]

“The applicant has no adverse history of license revocation or decertification in Washington State. DaVita has no criminal convictions related to DaVita’s competency to exercise responsibility for the ownership or operation of its facilities. As previously reported, a DaVita facility in Tennessee was decertified and closed ten years ago (2007) and DaVita voluntarily temporarily shut down a facility in Texas nine years ago (2008). DaVita has also supplied, in Appendix 13, a list of all state regulatory agencies with which it interacts.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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.

Centers for Medicare & Medicaid Services (CMS) Star Ratings

CMS provides the following overview regarding its star rating for dialysis centers.

“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."

[source: CMS website]

CMS Star Rating for Out-of-State Centers

DaVita reports dialysis services to CMS for approximately 2,696 facilities in 46 states and the District of Columbia.⁶ Of the 2,696 facilities reporting to CMS by DaVita, 339 had no star rating. For the remaining 2,357 facilities with a star rating, 90.3% had a rating of three or better.

CMS Star Rating for Washington State Centers

DaVita owns, operates, or manages 42 facilities in 19 separate counties. All of the 42 centers are operational, however, five do not have the necessary amount of data to compile a star rating.⁷ The department reviewed the star rating for the remaining 37 centers. All of DaVita's Washington State dialysis facilities show a three or better star rating.

Finally, the department focused on its own state survey data performed by the Department of Health's Office of Health Systems and Oversight.

Washington State Survey Data

While all 42 facilities are operational, two have not yet been surveyed.⁸ The department reviewed the compliance history for the remaining 40 dialysis centers. The department has conducted and completed more than 40 surveys in the most recent three years. All surveys resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, DaVita provided its Medical Director Agreement with Providence Health & Services, Washington, and Vijayakumar Reddy, MD. The agreement also identifies the following four physicians that have pre approval status for medical director services.

Nelson Chow, MD Krishna Malireddi, MD Petru Groza, MD Henry Mroch, MD

Using data from the Medical Quality Assurance Commission, the department found that all four physicians are compliant with state licensure and have no enforcement actions on their license.

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 directors associated with the facility. The department concludes that Spokane Valley Renal 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 Spokane Valley Renal Center would not cause a negative effect on the

⁶ The four states where DaVita does not operate are: Alaska, Delaware, Vermont, and Wyoming.

⁷ The five centers are: Belfair Dialysis Center in Mason County, Cooks Hill Dialysis Center in Lewis County, Lynnwood Dialysis Center in Snohomish County, Renton Dialysis Center in King County, and Wapato Dialysis Center in Yakima County.

⁸ The two centers are Lynnwood Dialysis Center in Snohomish County and Wapato Dialysis Center in Yakima County.

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 Inc.

DaVita provided statements and supporting documentation to demonstrate compliance with this sub-criterion. The documentation focuses on DaVita's Continuous Quality Improvement (CQI) program and the April 2018 press release for Top Clinical Outcomes. [source: Application, Appendix 17 & 21]

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 Spokane County planning area #1 for its Spokane Valley Renal Center. Additionally, DaVita's project would promote continuity in the provision of healthcare services in the planning area by adding needed stations to Spokane Valley Renal 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 sub-criterion.**

- (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 Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, p29]

"The applicant has no adverse history of license revocation or decertification in Washington State. DaVita has no criminal convictions related to DaVita's competency to exercise responsibility for the ownership or operation of its facilities. As previously reported, a DaVita facility in Tennessee was decertified and closed ten years ago (2007) and DaVita voluntarily temporarily shut down a facility

in Texas nine years ago (2008). DaVita has also supplied, in Appendix 13, a list of all state regulatory agencies with which it interacts.”

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, Inc. project has met the cost containment criteria in WAC 246-310-240.

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

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, in step two, 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 Step three. Under WAC 246-310-818(11) this step does not to apply Special Circumstance applications.

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, p29]

- Do nothing
“It has been established that Spokane 1 is growing in ESRD population. Currently, DaVita Spokane Valley Renal Center is a very busy facility, with utilization of 5.7 patients per station in the latest monthly data available from the NWRN, and thus little additional capacity to provide access to Spokane 1 patients. DaVita Downtown Spokane is also quite full, with 5.58 patients per station in the latest monthly data available from the NWRN. With strong demand for access to

DaVita's services, without expansion patients will be forced to dialyze at less convenient times, locations, or even out of the planning area entirely. This alternative was rejected.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita provided a comprehensive discussion of the “do nothing” alternative before submitting this application. Specifically, DaVita operates two dialysis stations in the Spokane #1 planning area and both are operating above 5.0 patients per stations. DaVita appropriately rejected the ‘do nothing’ alternative.

Special circumstance applications are designed to quickly bring stations online in highly utilized facilities. The department is satisfied that the applicant appropriately chose to submit a special circumstance application for Spokane Valley Renal Center in order to promote immediate access to services.

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) The costs, scope, and methods of construction and energy conservation are 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 Inc.

DaVita provided the following information related to the construction necessary to add the two additional stations to Spokane Valley Renal Center. [source: Application, p22]

“As required per WAC 246-310-815(1)(b), that proforma is based on the facility's current payor mix and current expenses. All major pro forma assumptions are also outlined in Appendix 9.

No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project, as Spokane Valley Renal Center is already operating at or near capacity by virtue of its utilization eligibility for a special circumstances application. 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.”

Department Evaluation

DaVita’s project requires minor construction to Spokane Valley Renal Center. Through its experience and expertise, DaVita demonstrated its costs for this 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.

This sub-criterion was also 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 Spokane County planning area #1 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) *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.*

DaVita Inc.

DaVita provided the following information for this sub-criterion. [source: Application, p30]

“DaVita Spokane Valley Renal Center will meet all current energy conservation standards. In addition, expansion will allow 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 Spokane County planning area #1 with the addition of two dialysis stations in the planning area. Consistent with the special circumstance rules, DaVita would be operating the two new stations within six months of approval. **This sub-criterion is met.**