



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

May 14, 2019

CERTIFIED MAIL # 7018 2290 0001 8591 8414

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

RE: Certificate of Need Application #19-24-Bellevue Dialysis Center

Dear Mr. Moore:

We have completed review of the Certificate of Need application submitted by DaVita, Inc. The application proposes the addition of one dialysis station to Bellevue Dialysis Center located in Bellevue, within King County planning area #7. The one station is 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 Description:

This certificate approves the addition of one dialysis station to the ten-station Bellevue Dialysis Center, for a facility total of eleven dialysis stations. Services provided at Bellevue Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, and shifts beginning after 5:00 pm.

Certificate of Need #1633 was issued to DaVita, Inc. approving the one-time addition of an isolation station to Bellevue Dialysis 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 Bellevue Dialysis Center, which includes one additional station 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	11	11
Permanent Bed Station	0	0
Private Isolation Station ¹	1	0
Total Stations	12	11

As required under Washington Administrative Code 246-310-818(10), the additional station 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 \$20,571. This amount represents the costs for moveable equipment. 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:

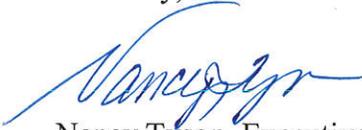
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

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 #19-24 Bellevue Dialysis 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 2 SPECIAL CIRCUMSTANCE EVALUATION DATED MAY 14, 2019, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA, INC. PROPOSING TO ADD ONE DIALYSIS STATION TO BELLEVUE DIALYSIS CENTER LOCATED IN KING COUNTY PLANNING AREA #7

APPLICANT DESCRIPTION

DaVita, Inc.

DaVita submitted this application under its subsidiary of Total Renal Care, Inc. For Certificate of Need purposes, DaVita, Inc. is the applicant. DaVita is a national provider of dialysis services operating in 45 states and the District of Columbia.¹ In Washington State, DaVita is approved to own and operate a total of 42 dialysis centers in 19 separate counties.² Listed below are the names of the facilities owned or operated by DaVita in Washington State. [source: CN historical files and Application, pp5-8]

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
Renton Dialysis Center
Redondo Heights Dialysis Center
Westwood 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

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

¹ DaVita operates in 45 states and the District of Columbia. The five states where DaVita is not located are: Alaska, Delaware, Mississippi, Vermont, and Wyoming.

² The department acknowledges that DaVita has submitted applications to establish additional dialysis centers in the counties of Cowlitz (#19-37), King (#18-59 & #19-39), Kitsap (#19-38), Pierce (#18-62) Snohomish (#18-63), Spokane (#18-62), and Thurston (#18-60). As of the writing of this evaluation, final decisions on these projects have not been released.

Kittitas

Ellensburg Dialysis Center

Lewis

Cooks Hill Dialysis Center

Mason

Belfair Dialysis Center

Pacific

Seaview 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 Bellevue Dialysis Center located at 533 Factoria Boulevard Southeast, #150 in Bellevue [98006] in King County planning area #7. Currently, Bellevue Dialysis Center is a 10-station facility as shown in Table 1 below.³

**Department's Table 1
Bellevue Dialysis Center**

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	10	10
Permanent Bed Station	0	0
Isolation Station	1	0
Total Stations	11	10

This application proposes to add one additional station at Bellevue Dialysis Center, resulting in 11 in-center stations and one isolation station. Bellevue Dialysis Center would remain at its current location in Bellevue and would continue to provide the following services.

- Hemodialysis patients who dialyze in the chronic setting,
- Hemodialysis patients requiring isolation,
- Hemodialysis patients requiring treatment shifts that begin after 5:00 PM.
- Continuous Ambulatory Peritoneal Dialysis (CAPD) patients, and
- Continuous Cycle Peritoneal Dialysis (CCPD) patients

Additional services provided will include:

- Treatment for visiting hemodialysis patients from other areas outside King 7, and
- Community education for patients recently diagnosed with Chronic Kidney Disease (CKD).

[source: Application, p10]

The capital expenditure associated with the addition of one station is \$20,571 and all costs are associated with the equipment. Sales tax is not assessed on dialysis machines. All costs would be paid by DaVita. [source: Application, p20]

³ Effective January 1, 2018, Bellevue Dialysis Center was issued CN #1633 allowing the addition of one isolation station consistent with WAC 246-310-809(3).

Within this application, DaVita determined this evaluation would be released in in mid-February 2019. Using that timeline, DaVita estimated the additional station would be operational in July 2019. [source: Application, p9] Under this timeline, full year one is 2020 and full year three is 2022.

Department Information on Timelines for Completion of the Projects

DaVita identified a timeline for completion of this project based on a February 2019 evaluation release date. Due to delays in releasing this evaluation, DaVita's timeline may not be achievable or accurate. If this project is approved, the department will adjust the operational timeline to account for the additional days of delay of the release of this evaluation.

APPLICABILITY OF CERTIFICATE OF NEED LAW

DaVita's application proposes to add one dialysis station 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.*

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 to 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 #2 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	October 1, 2018
Application Submitted	November 1, 2018
Department’s Pre-review Activities including <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant’s 1st Screening Responses Received 	November 15, 2018 December 17, 2018
Beginning of Review	December 24, 2018
End of Public Comment ⁴ <ul style="list-style-type: none"> • Public comments accepted through the end of public comment • No public hearing requested or conducted 	January 23, 2019
Rebuttal Comments Received	January 30, 2019
Department’s Anticipated Decision Date	February 14, 2019
Department’s Anticipated Decision Date with a 90-day extension ⁵	May 15, 2019
Department’ Actual Decision Date	May 14, 2019

⁴ Public comments were accepted through January 23, 2019, however no public comments were submitted for this project. As a result, DaVita did not provide rebuttal comments.

⁵ Thirty-day extension letters were sent to DaVita on February 14, 2019, March 19, 2019, and April 12, 2019.

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;*
- (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 November 1, 2018
- DaVita, Inc. 1st screening response received December 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 King 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 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

CONCLUSION

DaVita Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to add one dialysis station to Bellevue Dialysis Center located in King County planning area #7 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 one dialysis station to the ten-station Bellevue Dialysis Center, for a facility total of eleven dialysis stations. Services provided at Bellevue Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, and shifts beginning after 5:00 pm.

Certificate of Need #1633 was issued to DaVita, Inc. approving the one-time addition of an isolation station to Bellevue Dialysis 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 Bellevue Dialysis Center, which includes one additional station 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	11	11
Permanent Bed Station	0	0
Private Isolation Station ⁶	1	0
Total Stations	12	11

As required under Washington Administrative Code 246-310-818(10), the additional station 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 \$20,571. This amount represents the costs for moveable equipment. All costs will be paid by DaVita.

⁶ 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 station addition.

[source: Application, Appendix 16 and December 17, 2018, screening response, Appendix 21]

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 #2 for King County planning area #7 is April 2018 through September 2018. The data to be used by DaVita for this project is the same time frame. The data provided in the application shows that DaVita's Bellevue Dialysis Center was operating at an average of 5.20 patients per station.

The single line drawing shows the one additional station 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 Bellevue Dialysis Center located in King County.

[December 17, 2018, screening response, Appendix 21]

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 #2 for King County planning area #7 is April 2018 through September 2018. The data to be used by DaVita for this project is the same time frame. King County planning area #7 has two operational dialysis centers. One facility—Bellevue Dialysis Center—is operated by DaVita. The data provided in the application shows that DaVita’s Bellevue Dialysis Center was operating at an average of 6.42 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. This data focuses on DaVita’s Bellevue Dialysis Center located in King County.

[December 17, 2018, screening response, Appendix 21]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The six months preceding the letter of intent submission period for the Special Circumstance submission cycle #2 for King County planning area #7 is April 2018 through September 2018. The

data to be used by DaVita for this project is the same time frame. If this project is approved, DaVita’s Bellevue Dialysis Center would be operating 11 in center dialysis stations. The data provided in the application shows that the 11-station center would be operating at an average of 4.82 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 additional station. [source: Application, p9]

Applicant’s Table

Table 1 DaVita Bellevue Dialysis Center Anticipated Dates of Commencement & Completion of Project	
Event	Anticipated Date
<i>Project Approval</i>	<i>February 13, 2019</i>
Design Complete	February 2019
Construction Commenced	N/A
Construction Completed	N/A
Facility Prepared for Survey	July 1, 2019

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The timeline identified in DaVita’s Table 1 above projects the new dialysis station would be operational at Bellevue Dialysis Center within five months of approval. DaVita identified a timeline for completion of this project based on a February 2019 evaluation release date. Due to delays in releasing this evaluation, DaVita’s timeline could not be achievable, so the department recalculated an operational date for this project. Using the actual May 2019 decision date, plus five months is October 2019. Given that WAC 246-310-818(10) requires additional 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.⁷ 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). [source: Application, p18]

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

- Accepting End Stage Renal Disease Patient for Treatment [Admission Policy]
- Patient Financial Evaluation Policy
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer Policy

Medicare and Medicaid Programs

Bellevue Dialysis 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 pp21-22]

Medicare Provider Number: 502513
Medicaid Provider Number: 30990876

⁷ WAC 246-453-010(4).

Applicants Tables 14 and 15 Recreated

Current DaVita Bellevue Dialysis Center		
Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	19.99%	44.58%
Medicaid	2.21%	5.48%
Insurance/HMO	77.80%	49.94%
Total	100.00%	100.00%

Projected DaVita Bellevue Dialysis Center		
Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	20.81%	41.57%
Medicaid	1.79%	4.06%
Insurance/HMO	77.40%	54.37%
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 Bellevue Dialysis Center would continue both Medicare and Medicaid certifications. DaVita projected the Medicare revenues for Bellevue Dialysis Center to be 20.81% of total revenues. Pro forma financial data provided in the application shows Medicare revenues. DaVita’s Medicaid revenues are projected to be 1.79% 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.
 - (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.
 - (c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.
- (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.
 - (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.
- (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

WAC 246-310-210(3), (4), and (5) do not apply to this dialysis project under review.

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 Bellevue Dialysis Center is currently operational, sub-sections (1)(a) and (b) above apply to this project.

DaVita Inc.

As previously stated, DaVita proposes the one additional station would be operational July 2019 based on a February 2019 evaluation release date. [source: Application, p9] Under this timeline, calendar year one of this project is 2019 and full year one is 2020; calendar year three is 2022.

Once the additional station is added, Bellevue Dialysis Center would be operating with 11 in center dialysis stations and one isolation station. DaVita provided the assumptions used to project in-center 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]

- ***First Full Year:*** 2020, based on a first patient date in July 2019 for the expansion.
- ***Total Stations:*** CON Approved stations. One CON-exempt isolation station is also included in driving relevant category calculations (bio-med FTE, overall existing facility depreciation).
- ***Total Chronic Capacity:*** 6 shift capacity of CON-approved stations is assumed to be 100% utilization.
- ***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. This is the same trend line (based on the Department’s methodology as applied through 2022), but extended out through 2024 to project planning area census through the projection period. DaVita uses projected planning area census, existing planning area capacity, and additional market and experiential knowledge to project new facility census. Peritoneal dialysis patients are projected as a constant ratio to in-center patients
- ***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 dialyses and patients for the 5-station facility in years 2019 through 2022 is shown in Table 1. [source: Application, Appendix 9]

**Department's Table 1
Bellevue Dialysis Center
Projected Patients and Dialyses for Years 2019 – 2022**

	CY 2019	CY 2020	CY 2021	CY 2022
Number of Stations	11	11	11	11
Total In center Patients	52	53	53	53
Total In center Treatments	7,731	7,782	7,832	7,883

DaVita provided the following assumptions used for its projected financial statements. [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 for the facility, 2017, and its payor mix.
- **Charity Care:** estimated at 1.3% of gross revenue, consistent with DaVita's historical experience.
- **General expenses:** Based on cost per treatment for the last full calendar year (2017) by category. This excludes lease expenses (noted below), depreciation expense (based on projected capital expenditures and existing depreciation), medical director expense (noted below), and labor costs (noted below).
- **Cost inflation:** DaVita does not assume inflation in any expense category – no current contract cost increases are known, and thus none are included, except for the lease, noted below.
- **Medical Director Expense:** based on contracted, known expenses in latest medical director agreements that run through the extent of the three-year projection window.
- **Lease Expense:** base rent is directly pulled from the lease contract for each calendar year and the lease term and rent tables. Tax, CAM and sign rent are calculated based on actual 2017 tax, CAM and sign rent per square foot for the facility.
- **Labor Assumptions:** Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits, taxes, and non-base pay are assumed at a rate of 52% of base salaries and wages based on 2017 facility data.

Specific to various line items in the revenue and expense statement, DaVita provided the following clarification. [source: December 17, 2018, screening response, pdf4]

- *Other Purchased Services includes (1) pre-employment screening and time keeping services and (2) employment advertising. It is projected based on a cost-per-treatment basis from DaVita Bellevue data in 2017.*
- *Other Direct Expenses includes (1) telephone, (2) travel, (3) freight & postage, (4) dues & subscriptions, and (5) insurance. It is projected based on a cost-per-treatment basis from DaVita Bellevue data in 2017.*
- *G&A allocation is assigned at the corporate level and accounts for the cost of overhead functions related to the day-to-day operation of the business (for items including, among other areas, corporate management and billing costs). It is projected on a cost-per treatment basis from DaVita Bellevue data in 2017. Thus the actual G&A allocation from 2017 is divided by the total number of treatments, yielding an actual G&A allocation for DaVita Bellevue of \$46.10 in 2017, which is then multiplied by the projected number of treatments in the projection year.*

- *DaVita Bellevue Dialysis Center actually has two medical director agreements in effect: one for in-center dialysis and one for peritoneal dialysis. Both agreements are contained in Appendix 3 of the Application. In addition to the \$80,000 compensation identified by the program for in-center compensation and payable to Dr. Kandala that is enumerated in the “Bellevue Dialysis Facility Medical Director Agreement,” the “Bellevue Dialysis Associate Medical Director Agreement” with Dr. King identifies compensation for the peritoneal dialysis modality only (which is excluded from the “Facility Medical Director Agreement” per the 2nd “Whereas...” recital). This compensation is set, per Clause 6, at \$15,000 per year, leaving total Medical Director Compensation of \$95,000 annually for both modalities.*

Specific to the lease expense category, DaVita provided the following clarification. [source: December 17, 2018, screening response, pdf5]

“Please see the table below. The “Total” row matches Appendix 9 to the dollar, and the 2019-2020 base rent change is consistent with C(2)(a) of the First Amendment. Tax and CAM is based on 2017 actual Tax and CAM charges per square foot.”

DaVita’s Base Rent Table

	FY19	FY20	FY21	FY22
Base Rent	\$316,784	\$354,759	\$354,759	\$354,759
Tax & CAM	\$27,299	\$27,299	\$27,299	\$27,299
Total	\$344,083	\$382,057	\$382,057	\$382,057

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: Application, Appendix 9]

**Department’s Table 2
Bellevue Dialysis Center
Projected Revenue and Expenses for Years 2019 - 2022**

	CY 2019	CY 2020	CY 2021	CY 2022
Net Revenue	\$5,036,005	\$5,068,707	\$5,101,621	\$5,134,750
Total Expenses	\$3,371,296	\$3,427,833	\$3,446,218	\$3,464,889
Net Profit / (Loss)	\$1,664,709	\$1,640,874	\$1,655,403	\$1,669,861

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 11-station facility in years 2019 through 2022. The expenses also include allocated costs as described above. Medical director costs are \$95,000 annual and consistent with the executed Medical Director Agreements provided in the application.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Bellevue Dialysis Center is currently operating with ten dialysis stations. DaVita based its projected utilization of Bellevue Dialysis Center on its current utilization, plus one additional station. 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.

Since Bellevue Dialysis Center is currently operational, the facility has both an existing lease agreement and an existing medical director agreement. The lease agreement was executed May 2003 and is valid for ten years, through December 2013. DaVita also provided a copy of the First Amendment to the Lease Agreement that was executed in February 2010. The lease is effective from December 1, 2013 through December 31, 2024. The Amendment to the Lease Agreement includes two 5-year renewals. The costs identified in the lease agreement can be substantiated in the revenue and expense statement.

DaVita provided a copy of the Medical Director Agreement among Renal Treatment Centers, West Inc. (DaVita), Washington Nephrology and Hypertension, PLLC, and individual physician Madhuri Kandala, MD. The agreement was executed in May 2016. The agreement is currently effective and includes automatic annual renewals.

DaVita also provided a copy of the Associate Medical Director Agreement among Renal Treatment Centers, West Inc. (DaVita), Bellevue Kidney Specialists, PLLC, and individual physician Philip King, MD. The Associate Medical Director Agreement was signed in April 2016. The agreement is currently effective and includes automatic annual renewals.

The costs identified in both the Medical Director Agreement and the Associate 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 equipment, but no construction, to add a station to Bellevue Dialysis Center. DaVita provided its capital cost breakdown shown below. [source: Application, p20]

**Department’s Table 3
Estimated Capital Costs
DaVita Bellevue Dialysis Center**

Item	Total
Moveable Equipment (dialysis machines)	\$20,571
Total Estimated Capital Costs	\$20,571

Specific to costs and charges for health services, DaVita provided the following statements. [source: Application, p21]

“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.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The costs for adding one station to the 10-station Bellevue Dialysis Center is \$20,571. 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 Bellevue Dialysis Center currently has Medicare and Medicaid reimbursements that equal 22.60% of the revenue at the dialysis center. This amount is reasonable and 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 77.40% 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 one station to Bellevue Dialysis Center would probably not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #7. **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 \$20,571 to add one station to Bellevue 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 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 station would be operational by the end of July 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: Application, p23]

**Department’s Table 4
DaVita Bellevue Dialysis 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	0.68	0.02	0.00	0.01	0.03	0.74
Administrative Assistant	0.90	0.10	0.00	0.00	0.00	1.00
Medical Social Worker	0.55	(0.01)	0.01	0.00	0.00	0.55
Dietician	0.62	0.02	0.00	0.01	0.00	0.65
RN-InCenter/PD/HHD	8.34	0.20	0.06	0.04	0.07	8.71
Biomed Technician	0.30	0.00	0.00	0.00	0.00	0.30
Other	1.35	0.04	0.00	0.01	0.01	1.41
Total FTEs	12.74	0.37	0.07	0.07	0.11	13.36

DaVita’s two medical directors are under contract at a combined total of \$95,000 annual, but are not an employees and not included in the table above. DaVita also provided the following clarifications related to the staffing table above. [source: Application, p24 and December 17, 2018, screening response, pdf3]

- *DaVita projects FTEs based on staffing ratios for patients per shift, FTE, or station count (including any exempt isolation station, in the case of biomed), combined with clinical expertise and historical experience with the facility. “*
- *“other” includes among other miscellaneous categories, patient education and inventory management roles, as well as training hours.*

DaVita provided a copy of the Medical Director Agreement among Renal Treatment Centers, West Inc. (DaVita), Washington Nephrology and Hypertension, PLLC, and individual physician Madhuri Kandala, MD. The agreement was executed in May 2016. The agreement is currently effective and includes automatic annual renewals.

DaVita also provided a copy of the Associate Medical Director Agreement among Renal Treatment Centers, West Inc. (DaVita), Bellevue Kidney Specialists, PLLC, and individual physician Philip King, MD. The Associate Medical Director Agreement was signed in April 2016. The agreement is currently effective and includes automatic annual renewals. [source: Application, Appendix 3]

DaVita provided the following statements related to recruitment and retention of staff. [source: Application, p24]

“DaVita anticipates no difficulty in recruiting the necessary personnel to continue to staff DaVita Bellevue Dialysis Center. Based on our experience operating facilities in the planning area, DaVita anticipates that staff from the existing Bellevue Dialysis Center and geographically adjacent facilities will serve patients at the expanded Bellevue 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 King County. Its Bellevue Dialysis Center has been operational since May 2003.

For this project, DaVita is proposing to one station to the existing center. The one station increase will require addition of less than one FTE 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 Bellevue Dialysis Center in King County. If this project is approved, Bellevue Dialysis Center’s in-center stations will increase from 10 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, p25]

DaVita also provided a listing of the entities it currently has working relationships with for its Bellevue Dialysis Center. [source: Application, pp25-26 and Appendix 11]

DaVita provided the following statement related to the existing working relationships for Bellevue Dialysis Center. [source: Application, p25 and p27]

“DaVita Bellevue Dialysis Center has a number of strong working relationships that tie it to its community, including a Patient Transfer Agreement with Overlake Medical Center in [Bellevue], WA. Please find a listing of these relationships in Table 18 below.”

Table 18 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

Bellevue Dialysis Center has been operating in King County since mid-year 2003. 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.

The evaluation of WAC 246-310-230(5) is also evaluated under this sub-criterion, as it relates to facility compliance history. Compliance history is factored into the department’s determination that an applicant’s project would be operated in compliance with WAC 246-310-230(3).

DaVita Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application p26 and p28]

“DaVita and the United States Department of Health and Human Services, Office of Inspector General entered into a Corporate Integrity Agreement (“CIA”) to promote compliance with the

statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs and, in particular, included the appointment of an Independent Monitor to prospectively review DaVita's arrangements with nephrologists and other health care providers for compliance with the Anti-Kickback Statute (collectively, "Federal Health Care Programs and Laws"). That Independent Monitor completed the prospective review process in the fall of 2017. Each arrangement is now reviewed by the Risk Rating team to ensure that it is compliant with these Federal Health Care Programs and Laws. A full copy of the Corporate Integrity Agreement is included with this application in Appendix 19.

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 this project, 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.

CMS Star Rating for Out-of-State Centers

DaVita reports dialysis services to CMS for approximately 2,728 facilities in 45 states and the District of Columbia. Of the 2,728 facilities reporting to CMS by DaVita, 371 do not have the necessary amount of data to compile a star rating. For the remaining 2,357 facilities with a star rating, the national average rating is 3.71.

CMS Star Rating for Washington State Centers

For Washington State, DaVita owns, operates, or manages 42 facilities in 19 separate counties. All of the 42 centers are operational, however, three do not have the necessary amount of data to compile a star rating.⁸ For the remaining 39 centers with a star rating, the Washington State average rating is 4.08

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

⁸ The three centers are: Belfair Dialysis Center in Mason County, Cooks Hill Dialysis Center in Lewis County, and Renton Dialysis Center in King County.

Washington State Survey Data

While all 42 of DaVita facilities are operational, in the most recent three years, 24 facilities have been surveyed. All surveys resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, DaVita provided its initial Medical Director Agreement with physician Madhuri Kandala, MD associated with Washington Nephrology and Hypertension, PLLC. Included in the agreement is an Associate Medical Director Agreement with physician Philip King, MD associated with Bellevue Kidney Specialists, PLLC. Using data from the Medical Quality Assurance Commission, the department found that both physicians are compliant with state licensure and have no enforcement actions on the license.

The department also reviewed the compliance history of all known staff working at Bellevue Dialysis Center, which includes six registered nurses, four dialysis technicians, two dietitians, and a medical social worker. All known staff are compliant with state licensure and have no enforcement actions on the 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 two physicians that would be associated with the facility. The department concludes that DaVita 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 one new station to Bellevue Dialysis Center would not cause a negative effect on DaVita'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 & 20]

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 King County for its

Bellevue Dialysis Center. Additionally, DaVita's project would promote continuity in the provision of healthcare services in King County planning area #7 by increasing the number of stations at Bellevue 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 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.

Department Evaluation for DaVita, Inc.

This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered 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 and discussed two options before submitting this application. Below is DaVita's discussion related to both options. [source: Application, p28 and December 17, 2018, screening response, pdf 3-4]

Do nothing

“Currently, DaVita Bellevue Dialysis is a very busy facility, with utilization of 5.10 patients per station in the latest monthly data available from the NWRN, and thus has little additional capacity to provide access to King 7 patients. With strong and consistent demand for access to DaVita’s services and 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.”

Add two stations to Bellevue Dialysis Center, rather than one station

“While DaVita would have loved to have been able to pursue the option of adding two stations, rather than one, this option was not legally feasible per WAC 246-310-828(7), which requires that “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.”

In this case, the addition of two (2) stations would mean that Bellevue would have had 4.33 patients per station over the previous six (6) month period, per the patient census data provided by the NWRN in Table 10. Operationally, DaVita Bellevue Dialysis Center would have little difficulty accommodating an additional two stations, rather than one, and patients would be well-served by the access provided, but given the WAC 246-310-828(7) threshold was not cleared, DaVita rejected that option.”

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 only one center in King County planning area #7 and asserts it is a highly utilized facility. DaVita appropriately rejected the ‘do nothing’ alternative.

DaVita’s rationale for rejecting the option of adding two stations to Bellevue Dialysis Center is reasonable because it is consistent with the standard outlined in WAC 246-310-828(7).

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 Bellevue Dialysis 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.

Department Evaluation

Since DaVita’s capital expenditure is solely related to dialysis equipment, this sub-criterion does not apply to this project.

- (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, p29]

“DaVita Bellevue Dialysis 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 King County planning area #7 with the addition of another station in the planning area. Consistent with the special circumstance rules, DaVita would be operating the additional station within six months of approval. **This sub-criterion is met.**