

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

May 15, 2019

CERTIFIED MAIL # 7018 2290 0001 8591 8445

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

RE: CN Application #18-56 – DaVita Westwood Dialysis Center

Dear Mr. Moore:

We have completed review of the Certificate of Need application submitted by Renal Treatment Centers – West, Inc. a subsidiary of DaVita. Inc., for King County planning area #3. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the application submitted by Renal Treatment Centers – West, Inc. a subsidiary of DaVita. Inc., proposing to add seven new stations to DaVita Westwood Dialysis Center in Seattle within King County planning area #3 is consistent with 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 seven stations to DaVita Westwood Dialysis Center in Seattle within King County planning area #3. At project completion, the dialysis center is approved to certify and operate 15 dialysis stations. The table below provides a breakdown of the total number of stations at DaVita Westwood Dialysis Center.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	13	13
Permanent Bed Station	1	1
Private Isolation Station ¹	1	0
Total Stations	15	14

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 Office Certificate of Need Application #18-56 May 15, 2019 Page 2 of 2

Services to be provided at DaVita Westwood Center includes in-center hemodialysis, home peritoneal and home hemodialysis training, backup support for home peritoneal and home hemodialysis dialysis, a permanent bed station, and dedicated isolation/private room and treatment shifts beginning after 5:00 p.m.

Conditions:

- 1. DaVita, Inc. agrees with 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 consistent with the financing described in the application.

Approved Costs:

The total capital expenditure for this project is \$1,999,150, which includes costs for building and construction costs, purchasing equipment, and for associated fees and taxes.

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

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

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

Mailing Address:
Department of Health
Certificate of Need Program

Mail Stop 47852

Olympia, WA 98504-7852

Physical Address:

Department of Health

Certificate of Need Program

111 Israel Road SE

Tumwater, WA 98501

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

Sincerely,

Nancy Tyson, Executive Director

Health Facilities and Certificate of Need

Enclosure

2018 CYCLE 1 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED MAY 15, 2019, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY RENAL TREATMENT CENTERS—WEST, INC. A SUBSIDARY OF DAVITA, INC PROPOSING TO EXPAND DAVITA WESTWOOD DIALYSIS CENTER BY SEVEN STATIONS IN KING COUNTY PLANNING AREA #3.

APPLICANT DESCRIPTION

Renal Treatment Centers – West, Inc. is a subsidiary of DaVita Inc., a publicly held for-profit Delaware corporation. Renal Treatment Centers – West, Inc.'s UBI number is 602-250-340. [Source: Application pages 4] DaVita Inc., is a Fortune 500® company and it 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. and it 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]

DaVita, Inc. is a national provider of dialysis services operating in 45 states and the District of Columbia.¹ [Source: Applications, page 3] 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, pages 5-8]

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

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 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), 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.

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

Note – this application refers to a seven station need in King County planning area #3. Per WAC 246-310-800(9), exempt isolation stations are not counted in the methodology. Shortly following the department's first screening of the applications, the department sent out supplemental screening letters asking all applicants to clarify whether their isolation stations would meet the definition under WAC 246-310-800(9). Though this evaluation will consistently refer to a seven station need, the approved project would reflect one additional exempt isolation station, if identified by the applicant in response to screening.

Renal Treatment Centers—West, Inc.

Renal Treatment Centers – West, Inc., is proposing to expand the seven station DaVita Westwood Dialysis Center located in King County planning area #3, by adding 7 new stations to the facility for a total of 14 stations plus an exempt isolation station. DaVita Westwood Dialysis Center³ is located at 2615 SW Trenton Street in Seattle [99218]. [Source: DaVita Application, page 3]

Below is the breakdown of all existing stations operational at DaVita Westwood Dialysis Center.

Before After **Stations Counted CMS CMS Stations Counted Station Type** Certified for Station Use Certified for Station Use **Stations** and Methodology **Stations** and Methodology General Use In-Center Stations 7 7 7 7 Permanent Bed Station 0 0 0 0 **Isolation Station** 0 0 0 1 **Total Stations** 7 7 8 7

³ On January 1, 2018, DaVita Westwood Dialysis Center was issued CN#1670 allowing the addition of one isolation station consistent with WAC 246-310-809(3).

Services provided at DaVita Westwood Dialysis Center include:

- 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.
- Emergency backup dialysis,
- Training and support for patients for peritoneal dialysis,
- Treatment for visiting hemodialysis patients from other areas outside King 3, and
- Community education for patients recently diagnosed with Chronic Kidney Disease (CKD).

When the new stations are added to existing capacity, DaVita Westwood Dialysis Center will

 Have a permanent bed station available for Hemodialysis patients. [Source: DaVita Application, page 10]

The total capital expenditure associated with the 14-station kidney dialysis center is \$1,999,150. Of that amount 63% or \$1,265,284, is related to building construction improvement; 26% or \$511,177 is for fixed and moveable equipment, 11% or \$222,689; is for taxes and consulting fees. [Source: Application Page 19]

If this project is approved, DaVita Westwood Dialysis Center would be operational with 14-stations by November 2020. Under this timeline, year 2021 would be DaVita Westwood Dialysis Center first full calendar year of operation and year 2023 the third year of operation. [Source: Application, page 10]

For ease of reference in this evaluation Renal Treatment Centers – West, Inc., will be referred to as ("DaVita") and the 14-station DaVita Westwood Dialysis Center will be referred to as ("DaVita Westwood").

APPLICABILITY OF CERTIFICATE OF NEED LAW

DaVita's application proposes to add dialysis stations to an existing dialysis center. Therefore, 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's application must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. For ESRD applications submitted under WAC 246-310-806 'Nonspecial Circumstance Cycle 1,' 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 246-310-818	Special circumstances one- or two-station expansion—Eligibility criteria and
	application process
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an
	existing facility
WAC 246-310-824	Kidney disease treatment centers—Exceptions
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 <u>before</u> February 16, 2018. Each applicant submitted the data elements on February 15, 2018. This data is used to calculate superiority in the event that more than one application meets the applicable review criteria. Consistent with WAC 246-310-827, these data elements are the only means by which two or more applications may be compared to one another.

WAC 246-310-803 and 246-310-827 allow for public review and correction to data submissions prior to any concurrent review cycle. Therefore, if the department receives public comments related to WAC 246-310-803 or 246-310-827 during a review, the comments will not be considered and discussed.

TYPE OF REVIEW

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle #1 for calendar year 2018. Below is the chronological summary for this application review timeline.

APPLICATION CHRONOLOGY

Action	DaVita
Letter of Intent Submitted	May 1, 2018
Application Submitted	June 1, 2018
Department's pre-review activities	
DOH Screening Letter	June 29, 2018
 Applicant's Responses Received 	July 31, 2018
Beginning of Review	August 6, 2018
Public Hearing Conducted	None Requested or Conducted
 Public comments accepted through the end 	September 5, 2018
of public comment	
 No public hearing requested or conducted⁴ 	
Rebuttal Comments Submitted ⁵	
Department's Anticipated Decision Date	December 19, 2018
Department's Anticipated Decision Date with 150-day extension ⁶	May 20, 2019
Department's Actual Decision Date	May 15, 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

⁴ No Public hearing was requested or conducted

⁵ The department did not receive any public comment therefore, the applicant did not submit rebuttal comments.

⁶ Thirty day extension letters sent to the applicant on December 20, 2018, January 18, 2019, February 20, 2019; March 20, 2019; and April 26, 2019.

(g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

For this project the followings persons or entity sought interested person status to this project.

Health Facilities Planning & Development

Health Facilities Planning & Development (HFPD) located in King County, is a consultation firm hired by applicants to prepare and submit Certificate of Need applications on their behalf. Health Facilities Planning & Development requested interested person status to the two applications, and to be informed of the department's decision. Health Facilities Planning & Development does meet the definition of an "interested person" under WAC 246-310-010(34). HFPD did not provide independent written or oral comment on this application. Therefore, it does not meet the definition of an "affected person" under WAC 246-310-010(2).

Northwest Kidney Centers

Northwest Kidney Centers is an end stage kidney dialysis provider that owns and operates dialysis facilities in King County. Northwest Kidney Centers sought and received interested person status under WAC 246-310-010(34) to the application submitted by DaVita. However, Northwest Kidney Centers did not submit written comments to the department so it cannot qualify as an "affected person" under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- DaVita, Inc., Certificate of Need application received June 1, 2018
- DaVita, Inc., screening response received September 13, 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 #3 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
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSIONS

For the reasons stated in this evaluation, the application submitted by Renal Treatment Centers – West, Inc. a subsidiary of DaVita. Inc., proposing to add seven new stations to DaVita Westwood Dialysis Center in Seattle within King County planning area #3 is consistent with 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 seven stations to DaVita Westwood Dialysis Center in Seattle within King County planning area #3. At project completion, the dialysis center is approved to certify and operate 15 dialysis stations. The table below provides a breakdown of the total number of stations at DaVita Westwood Dialysis Center.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	13	13
Permanent Bed Station	1	1
Private Isolation Station ⁷	1	0
Total Stations	15	14

Services to be provided at DaVita Westwood Center includes in-center hemodialysis, home peritoneal and home hemodialysis training, backup support for home peritoneal and home hemodialysis dialysis, a permanent bed station, and dedicated isolation/private room and treatment shifts beginning after 5:00 p.m.

Conditions:

- 1. DaVita, Inc. agrees with 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 consistent with the financing described in the application.

Approved Costs:

The total capital expenditure for this project is \$1,999,150, which includes costs for building and construction costs, purchasing equipment, and for associated fees and taxes.

⁷ 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 DaVita, Inc. has met the need criteria in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-812(5) and (6).

(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 246-310-812 requires the department to evaluate kidney disease treatment centers applications based on the population's need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology is applied and detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria and also identified in WAC 246-310-812(5) and (6).

WAC 246-310-812 Kidney Disease Treatment Center Numeric Methodology

WAC 246-310-812 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network (NWRN).⁸

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-812(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident incenter patients for each of the previous six consecutive years, concluding with the base year.⁹

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

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NWRN data, again concluding with the base year. [WAC 246-310-812(4)(b) and (c)]

[WAC 246-310-812(5)] identifies that for all planning areas <u>except</u> Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to

⁸ NWRN was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [Source: Northwest Renal Network website]

⁹ WAC 246-310-280 defines base year as the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report." For this project, the base year is 2017.

determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved incenter stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-812(4)(d)] The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is the discussion of the two applicant's numeric methodology.

DaVita

DaVita proposes to expand the existing seven station DaVita Westwood Dialysis Center located in King County planning area #3, by adding seven new stations resulting in 14 stations plus an exempt isolation station for a total of 15 stations. DaVita submitted the numeric methodology posted to the department's website for King County ESRD planning area #3. The methodology projected need for seven new stations in year 2018.

Public Comment

None

Rebuttal Comment

None

<u>Department Evaluation of the Numeric Methodology for Snohomish County planning area #2</u> The department calculates the numeric methodology for each of the 57 ESRD planning areas in Washington and posts each of the results to its website. The department's year 2018 numeric methodology was posted in March 2018 and it will be used for evaluating this project.

Based on the calculation of the annual growth rate in the planning area, the department used the linear regression to determine numeric need. The number of projected patients was divided by 4.5 to determine the number of stations needed in King County planning area #3. A summary of the department's numeric methodology is shown in Table 1 below.

Department's Table 1
King County Planning area #3 Numeric Methodology Summary

	4.5 in-center patients per station		
	2022 Projected Minus Current 2022 Net March 4 of stations # of stations or (Surpl		2022 Net Need or (Surplus)
	# Of Stations	# 01 stations	or (Surprus)
DOH Methodology Post to Website	34	27	7

As shown in the table above, once the 27 existing stations are subtracted from the projected need, the result is a net need of seven stations. The department's methodology is included in this evaluation as Appendix A. The department concludes that DaVita meet the numeric methodology standard.

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

station need.¹⁰ For this review, the department uses the standards in WAC 246-310-812(5) and WAC 246-310-812(6).

WAC 246-310-812(5)

Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 incenter patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 incenter patients per station standard met for those facilities when:

- (a) All stations for a facility have been in operation for at least three years; or
- (b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.

...Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.

For King County planning area #3, WAC 246-310-812(5) requires all CN approved stations in the planning area be operating at 4.5 in-center patients per station. Below is the discussion of the information DaVita submitted for this standard.

DaVita

Currently there are two kidney dialysis facilities operating in King County ESRD planning area #3 including DaVita Westwood Dialysis Center. DaVita provided a table showing that DaVita Westwood Dialysis Center, is operating above the 4.5 standard. However, NKC West Seattle the other facility in the planning area, is operating below the standard. DaVita provided the statement below.

"...WAC 246-310-812(5)(a) provides that the department will consider the 4.5 in-center patients per station standard met for facilities whose census is not at least 4.5 patients per station if "all stations for a facility have been in operation for at least three years." NKC West Seattle dates to an initial CMS survey in 1998, and all stations have been in operation for more than three years. According to WAC 246-310-812(5), NKC West Seattle is therefore seen to meet the 4.5 patients per standard, regardless of its census. As DaVita Westwood Dialysis Center is in excess of 4.5 patients per station, the 4.5 patients per station standard appears met for King 3". [Source: Application Page 14]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

WAC 246-310-812(5) states that the "data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date". The date of the letter of intent is May 1, 2018. The data available as of May 1, 2018, is December 31, 2017, end of year data that was available on February 15, 2018. The

¹⁰ WAC 246-310-210(1)(b).

utilization of the two existing dialysis facilities located in King County planning area #3 is shown below.

Department's Table 2

December 31, 2017, Utilization Data King County ESRD planning area #	rea #3
--	--------

Facility	# of Stations	# of Patient	Patients/Station
DaVita Westwood Dialysis Center	7	39	5.57
NKC West Seattle Dialysis Center	20	87	4.35

The information in the table above shows that DaVita Westwood Dialysis Center meet this standard, but NKC West Seattle Dialysis Center is operating at 4.35 and did not meet this standard.

WAC 246-310-812(5)(a) provides that the department will consider the 4.5 in-center patients per station standard met for facilities if all stations in a facility have been in operation for at least three years. NKC West Seattle Kidney Center initial Medicare certification was in 1998. This mean NKC West Seattle Kidney Center has been operational for more than three years. Therefore, all approved stations in the planning area meet the standard. The department concludes that **DaVita meet this sub-criterion.**

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

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

The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the planning area would have access to the proposed services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

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

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

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

¹¹ WAC 246-453-010(4).

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

In response to this sub-criterion, DaVita provided the following statement:

"Copies of these policies are provided in Appendix 14. Additionally, DaVita's history of providing dialysis services at numerous locations throughout Washington State, including at DaVita Westwood Dialysis Center, shows that all persons, including the underserved groups identified in WAC 246-310-210(2), have adequate access to DaVita's facilities". [Source: Application page 17]

DaVita provided copies of the following policies used at all DaVita dialysis centers in Washington, including the existing DaVita Westwood. [Source: Application page 17, Appendix 14]

- Admission policy/ Accepting End Stage Renal Disease Patients for Treatment
- Indigent Care Policy
- Involuntary Discharge or Involuntary Transfer
- Patient Rights Policy

Public Comments

None

Rebuttal comments

None

Department Evaluation

DaVita provided copies of the necessary policies used DaVita Westwood and at all DaVita dialysis centers.

Medicare and Medicaid Programs

DaVita Westwood is currently Medicare and Medicaid certified and DaVita provided the facility's Medicare and Medicaid provider numbers listed below.

Medicare Provider Number:

502544

Medicaid Provider Number:

3990900

DaVita also included two tables showing the current and projected percentages of revenues by payer source and revenues by patient for the facility. The information is summarized below. [Source: Application page 20-21]

DaVita Tables 12 Payor Mix

Projected DaVita Westwood Dialysis Center					
Source	Percentage by Revenue	Percentage by Patients			
Medicare	26.14%	45.10%			
Medicaid	1.21%	2.42%			
Commercial, HMO, Other, Government, and Other	72.65%	52.8%			
Total	100.00%	100.00%			

DaVita Table 13 Payor Mix

Current DaVita Westwood Dialysis Center					
Source	Percentage by Revenue	Percentage of Patients			
Medicare	31.72%	51.28%			
Medicaid	1.68%	3.16%			
Commercial, HMO, Other, Government, and Other	66.6%	45.57%			
Total	100.0%	100.0%			

Within its application, DaVita did not provide a policy specifically entitled "Charity Care." However, the policy provided by DaVita titled Indigent Care Policy provides the necessary information and process a patient would use to obtain charity care at a DaVita facility. Furthermore, DaVita demonstrated its intent to continue to provide charity care for patients treating at DaVita Westwood by including a 'charity' line item as a deduction from revenue within its pro forma financial statement.

Given that DaVita currently operates dialysis centers in Washington State and uses the same policies and procedures provided in the application at the dialysis centers, including DaVita Westwood no draft policies were provided by in this application. Based on the information, 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) <u>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.</u>
 - (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 DaVita's 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 DaVita, Inc. has meet 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 the two projects, 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.

DaVita

Given that DaVita Westwood is currently operational, sub-sections (1)(a) and (b) above apply to this project. As previously stated, DaVita proposes to expand the existing seven-station DaVita Westwood by adding seven new stations for a total of fourteen stations. The fourteen station kidney dialysis facility would be operational in November 2020. Under this timeline, full calendar year one of the project is 2021 and year three is 2023. [Source: Application, page 10]

DaVita provided the assumptions used to project in-center patients treatments for partial calendar years 2021, and full calendar years 2022 through 2023. The assumptions are restated below. [Source: Screening response received August 13, 2018, page 10, Appendix 9A Revised]

First Full Year: 2021, based on a first patient date in November, 2020. 2020 is a partial year, with existing station count for 10 months of the year.

Total Stations: CON Approved stations. Excludes CON-exempt isolation station.

Total Chronic Capacity: 6 shift capacity 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.

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. In 2020, average patient census is based upon slightly more than 39 projected patients from Jan-Oct, increasing to the average of -39 and 43 patients (the year-end figure) for Nov-Dec. This average patient census is then adjusted by a 5% missed treatment rate and 3 treatment per week frequency.

"Table 12 provides the projected payor mix for the DaVita Westwood Dialysis Center, projected using DaVita's market knowledge, experience, and expertise". [Source: Application page 21]

DaVita's Tables 12—Projected Payor Mix

Table 12 DaVita Everett Dialysis Center Projected Payor Mix	Percentage of Revenue by Payer	Percentage of Patients by Payer	
Medicare	26.14%	45.10%	
Medicaid	1.21%	2.42%	
Commercial, HMO, Other Government and Other	72.65%	52.48%	
Total	100.00%	100.00%	

Using the assumptions stated above, DaVita's projected the end-of-year number of in-center and dialyses and patients for the 14-station DaVita Westwood in years 2021 through 2023 are shown in Table 3. [Source: Application, page 16]

Department's Table 3
DaVita Westwood Dialysis Center
Historical Year 2018, Current year 2019, Projected Years and Patients
Dialyses Years 2021 – 2024

	Historical Year 2018	Current Year 2019	Partial Year 2020	Projection Year- 1 2021	Projection Year -2 2022	Projection Year -3 2023
Total In-center stations (excluding exempt)	7	7	14	14	14	14
Total In center Patients	39	39	43	51	63	74
Total In center Treatments	5,700	5,826	6,138	7,013	8,452	10,173
Total Home Patients	4	5	6	7	8	10
Total Home Treatments	541	606	742	909	1,113	1,363

DaVita also provided the assumptions used to project revenue, expenses, and net income for the 14-station DaVita Westwood. [Source: Screening response received August 13, 2018, Appendix 9A]

Revenue per treatment: No inflation is applied to revenue per treatment, which is based on the last full year of operation, 2017 and the payor mix resulting in its blended revenue per treatment.

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 agreements that run through the extent of the three year projection window.

Lease Expense: base rent is directly pulled from the lease contract and inflated at 2% per year for the period of the signed 2nd amendment renewal, consistent with historical precedent (as the lease agreement provides for determination based on market value). Tax and CAM are calculated based on 2017 total of \$9.82 per square foot annually, inflating at 2% annually.

Labor Assumptions: Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits are assumed at a rate of 38.32% of wages based on historical precedent. Salaries and wages are projected to inflate at 2% annually.

Specific to the base rent reference under the lease expense category, DaVita provided the following clarification.

"Please see the lease assumption worksheet outline below- the total row at the bottom will match Appendix 9A. Note that the signed lease renewal is scheduled to take effect in February, 2020, and assumes 2% increase in base rent annually (the lease year) through the life of the renewal. Tax and CAM is also projected to increase at 2% annually for each lease year from a 2017 per-square foot basis". [Source: Screening response received August 13, 2018, page 7]

DaVita's Lease Expenses and Base Rent Table

Lease Years				Monthly	y Amounts
I	From		To		Tax + CAM
Year	Month	Year	Month		
2020	2	2021	1	\$26,500	\$6,944
2021	2	2022	1	\$27,030	\$7,083
2022	2	2023	1	\$27,570	\$7,225
2023	2	2024	1	\$28,122	\$7,369
2024	2	2025	1	\$28,684	\$7,517
2025	2	2026	1	\$29,258	\$7,667
2026	2	2027	1	\$29,843	\$7,820
2027	2	2028	1	\$30,440	\$7,977
2028	2	2029	1	\$31,049	\$8,136
2029	2	2030	1	\$31,669	\$8,299
2030	2	2031	1	\$32,303	\$8,465

Base Rent Outlined in Existing 1st Amendment p.1			(Existing le Feb += re		Based on signed Renewal Tern			ewal Terms	
	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23
Base Rent	\$252,480	\$294,100	\$300,100	\$306,113	\$311,760	\$317,476	\$323,825	\$330,302	\$336,908
Tax &CAM	\$67,022	\$70,342	\$78,526	\$80,096	\$81,698	\$83,196	\$84,860	\$86,557	\$88,288
Total	\$319,589	\$378,626	\$378,626	\$386,210	\$393,458	\$400,672	\$408,685	\$416,859	\$425,196

Based on the assumptions above, DaVita provided its historical year 2018 and current 2019 revenue and expense statement. Also DaVita provided its projected revenue, expenses, and net income for years 2020 through 2023. A summary of the projections are shown in Table 4. [Source: Screening response received July 31, 2018, Appendix 9A]

Department's Table 4
DaVita Westwood Dialysis Center Current Year 2019, and Projected Revenue and
Expenses for Years 2020 - 2023

	Current Year 2019	Partial Year 2020	Full Year 1- 2021	Full Year 2- 2022	Full Year 3- 2023
Net Revenue	\$2,952,837	\$3,044,065	\$3,683,884	\$4,390,055	\$5,294,455
Total Expenses	\$2,515,137	\$2,646,870	\$3,132,504	\$3,551,062	\$4,057,495
Net Profit / (Loss)	\$437,700	\$397,195	\$503,490	\$838,993	\$1,236,960

The 'Net Revenue' line item is gross in-center treatments and home treatments minus deductions for bad debt and charity care. The 'Total Expenses' line item includes all expenses related to the projected operation of the projected 14-station facility in years 2019 through 2023. The expenses also include allocated costs per treatment which is multiplied by the projected number of treatments. Medical director costs are \$101,500 annually and is consistent with the executed medical director agreement provided in the application.

Public Comments

None

Rebuttal comments

None.

Department Evaluation

DaVita proposes to expand the existing 7-station DaVita Westwood by adding 7 new stations to the facility. At project completion, DaVita Westwood will be certify to operate 14 stations. DaVita based its projected utilization of DaVita Westwood consistent with WAC 246-310-815(1)(b). Based on a review of the assumptions used for projecting utilization of the 14 station dialysis center, the department concludes they are reasonable.

Since DaVita Westwood is currently operational the facility has both an existing lease agreement and existing medical director agreement. The initial lease agreement between Westwood Town Center, Inc., (landlord) and Renal Treatment Center—West, Inc., was executed in July 2004 and was valid until November 30, 2014. The lease has been renewed for another 15 years and the costs identified in the amended lease agreement can be substantiated in the revenue and expense statement.

DaVita provided a copy of the current Medical Director Agreement between Renal Treatment Centers—West, Inc. and Dr. Edwin Chin, MD from South Seattle Nephrology Associates, PLLC. The Medical Director Agreement was executed on May 24, 2018 and is valid through December 31, 2023. 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) <u>The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.</u>

WAC 246-310-815 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 a finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC <u>246-310-800(11)</u> 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

DaVita also provided the following statements.

"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." [Source: Application, page 20]

DaVita provided a copy of its line drawing for the relocation project. [Source: Application, pages 11-12]

Consistent with WAC 246-310-800(11), DaVita Westwood's maximum treatment floor are square footage for 13 stations and one isolation station is 4,637.5. DaVita will use 2,827 square feet. [Source: Application, page 12]

Specific to the costs and charges for health services, DaVita provided the statements below.

"Construction cost is estimated based on the non-binding contractor estimate presented in response to Question 6. Construction cost number includes sales tax. Sales tax is assumed at the Seattle, King County rate of 10.1%". [Source: Application, page 19]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The estimated costs for this project is \$1,999,150, which includes \$1,256,284 for building and construction. The project costs are comparable to those reviewed in past applications for similar type projects and similar sized facilities. The department does not consider the capital expenditure to be excessive for this project.

DaVita Westwood's current Medicare and Medicaid reimbursements revenue is 27.35% and for commercial insurance/HMO it is 72.60%. The projected revenue for Medicare and Medicaid reimbursements is 47.52% and for commercial insurance/HMO it is 52.48%. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, DaVita Westwood expectation that 52.48% of its revenue would come from commercial/HMO is reasonable.

Regardless of the number of patients projected, under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment and that 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 payors 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 the department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by DaVita about its revenue indicate that this project would not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement.

To be compliant with WAC 246-310-800(11), DaVita Westwood maximum floor space for a 14 station facility is 4,637.5. DaVita calculated that its actual floor space will be 2,827. However, the department notes above that DaVita did not take into consideration the one isolation station that is not counted at the center.¹² Rather DaVita calculated its floor plans using 14 in-center stations instead of 15. When recalculated, DaVita's floor space does not exceed the maximum treatment floor area square footage.

Based on the above information provided in the application, the department concludes that DaVita's projected costs associated with the existing seven-station dialysis center and expansion by seven new stations would probably not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #3. **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 DaVita's projected source of financing to those previously considered by the department.

¹² Consistent with WAC 246-310-809, if a new dialysis center will be established and it will provide isolation services, the isolation is not counted in the numeric need methodology, but is counted in the floor plan space for calculations.

DaVita

DaVita provided the following information about financing the \$1,999,150, costs for this project.

"DaVita Inc., via its subsidiary Renal Treatment Centers - West, Inc., is solely responsible for the capital costs identified above". [Source: Application, page 19]

"Construction cost is estimated based on the non-binding contractor estimate presented in response to Question 6. Construction cost number includes sales tax. Sales tax is assumed at the Seattle, King County rate of 10.1%" [Source: Application, page 19]

Department's Table 5
DaVita Westwood Dialysis Center Estimated Capital Costs

Item	Total
Building Construction	\$1,265,284
Fixed & moveable equipment	\$511,177
Washington State sales taxes and fees	\$222,689
Total Estimated Capital Costs	\$1,999,150

Public Comment None

Rebuttal Comment None

Department Evaluation

DaVita intends to finance the project with reserves and demonstrated that 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) <u>A sufficient supply of qualified staff for the project, including both health personnel and</u> 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

DaVita provided the table below showing current and projected FTE's. DaVita also provided the statements in its application.

"Table 15 below presents the staffing for the DaVita Westwood Dialysis Center. The salary and wage and benefit costs for the facility are detailed below. Note that historic staffing levels on a category basis are estimated based on ratios and DaVita management expertise for historic years off of a total number of known FTEs of all categories." [Source: Application, page 23]

Department's Table 6
DaVita Westwood Dialysis Center Historic Year 2018, Current Year 2019, and Projected Years 2020 – 2023

FTE by Type	Historic 2018	2019 Current	2020	2021	2022	2023
Administrator	1.00	1.00	1.00	1.00	1.00	1.00
Administrative Assistant	1.00	1.00	1.00	1.00	1.00	1.00
Social Worker	0.35	0.36	0.39	0.39	0.54	0.65
Dietician	0.35	0.36	0.39	0.45	0.54	0.65
RN-In-Center	2.50	2.50	2.50	2.50	2.50	2.50
PCT	3.00	3.00	3.87	4.45	5.38	6.49
RN- PD	0.19	0.23	0.28	0.34	0.42	0.51
Biomed Tech	0.50	0.50	0.50	0.50	0.50	0.50
Other	0.53	0.54	0.58	0.67	0.81	0.97
Total FTEs	9.42	9.49	10.51	11.30	12.69	14.27

"DaVita projects FTEs based on staffing ratios for patients per shift, combined with clinical expertise. Standard ratios are noted in Table 15. Overall census estimates are based on the assumptions describing the pro forma in Appendix 9". [Source: Application, page 23]

DaVita also provided the following clarification regarding the staffing table above.

"DaVita does not expect any significant barriers to recruiting staff for an expanded Westwood Dialysis Center. First, existing Westwood Dialysis Center staff would be expected to continue as teammates in an expanded Westwood Dialysis Center, significantly lessening recruitment needs in sync with the gradual growth projected in the projected operating statement. Additionally, as outlined in its application, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer and offers a competitive wage and benefit package to employees, and posts openings nationally. However, in the unlikely event Westwood Dialysis Center faces any barriers to recruiting staff, DaVita would take a multi-faceted approach, utilizing those methods necessary to ensure timely patient care. These methods may include, but are not limited to, selective use of signing bonuses and incentives for select staff recruitments, cross-staffing with nearby DaVita facilities where possible, and if absolutely essential, limited use of agency temporary staff, with a continued focus on recruitment and retention of permanent teammates as soon as possible. As mentioned, however, DaVita does not expect any significant barriers to recruiting staff, especially given its existing expertise with operating Westwood Dialysis Center". [Source: screening response August 13, 2018, page 2]

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. DaVita Westwood is currently an existing dialysis facility in King County planning area #3. As an existing provider with existing facilities located in King County, the department does not expect that DaVita will have difficulty recruiting FTE's based on its experience operating facilities in the planning area. Currently DaVita Westwood has 9.42 FTEs this number is projected to increase to 14.27 FTEs.

A review of DaVita's historic, current and projected FTE increase shows that most of the increase is expected to occur by year 2023. By that year, DaVita anticipate it will add 4.85 new FTEs. DaVita expects the PCT category to increase by 3.49 and the in-center RN would remain the same, and for the other category consisting of FTEs who provide patient education, inventory management roles, and training hours this category would increase by 0.44 FTE.

DaVita's medical director is under contract at \$101,500 annual, and is not DaVita's employee so the medical director's information is not included in the table above. DaVita provided a copy of the current First Amendment to Associate Medical Director Agreement ("Agreement"), between Renal Treatment Centers—West, Inc. ("Company") and South Seattle Nephrology Associates, PLLC ("Contractor") DaVita Westwood current medical director is Dr. Edwin Chin, MD ("Physician") an employee of South Seattle Nephrology Associates, PLLC and the facility peritoneal dialysis medical director is Dr. Andrew Somlyo. The First Amendment to Associate Medical Director Agreement was executed on May 28, 2018, and is valid until December 31, 2023. [Source: Application, page 24 and Appendix 3]

The department notes that DaVita has a history of recruiting staff for its dialysis facilities in Washington therefore, it does did not expect the addition of 4.85 FTE's to DaVita Westwood to be any different from previous applications submitted by DaVita. Based on the information reviewed, the department concludes **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

To comply with this sub-criterion the applicant states, "DaVita Westwood Dialysis Center has a number of strong working relationships that tie it to its community, including a Patient Transfer Agreement with Highline Medical Center, found in Appendix 12. Please find a listing of these relationships in Table 16 below." [Source: Application, page 25]

DaVita also provided the following statements.

"The proposed expansion of DaVita Westwood Dialysis Center will have an appropriate relationship to the service area's existing health care system. DaVita Westwood Dialysis Center is a key component of the existing health care system in the service area, and the project will enable enhanced patient access in an already highly utilized facility with a census of more than 5.0 patients per station. Furthermore, DaVita Westwood Dialysis Center has a long track record of working with area providers to provide the highest possible quality of care to patients, as evidenced by its CQI process outlined in Appendix 17". [Source: Application page 27]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

As an establish provider of dialysis services in Washington, including the existing DaVita Westwood; DaVita has an appropriate relationship with the service area existing health care system. If this project is approved DaVita proposes to add seven new stations to the facility. Upon project completion, DaVita Westwood will be operating 14 kidney dialysis stations.

For ancillary and support services at DaVita Westwood, DaVita states that it will provide social services, nutrition, financial counseling, pharmacy access, patient and staff education, human resources, material management, administration and biomedical technical services on site. 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, page 26]

Based on the information reviewed, the department concludes that all 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

DaVita provided the following statement in response to this sub-criterion.

"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 20.

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." [Source: Application pages 26 and 27]

In this application, DaVita provided its medical Director Agreement with South Seattle Nephrology Associates, PLLC. The agreement identifies Dr. Edwin Chin, MD as the medical director and Dr. Andrew Somlyo, MD, as the facility peritoneal dialysis medical director. DaVita provided a copy of the current First Amendment to Associate Medical Director Agreement ("Agreement"), between Renal Treatment Centers—West, Inc. ("Company") and South Seattle Nephrology Associates, PLLC ("Contractor") DaVita Westwood current medical director is Dr. Edwin Chin, MD ("Physician") an employee of South Seattle Nephrology Associates, PLLC and the facility peritoneal dialysis medical director is Dr. Andrew Somlyo. The First Amendment to Associate Medical Director Agreement was executed on May 28, 2018, and is valid until December 31, 2023

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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 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.

CMS Star Rating for Out-of-State Centers

In the application, DaVita states that it provides outpatient dialysis centers and services approximately 185,000 patients in 45 states and the District of Columbia. DaVita reports dialysis services to CMS for approximately 2,728 facilities in 46 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.¹³ 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.

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 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 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 dialysis stations to DaVita Westwood 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

To comply with this sub-criterion DaVita provided supporting documentation to demonstrate compliance with this sub-criterion. The documents focuses on DaVita's Continuous Quality Improvement (CQI) program and the April 2018 press release for Top Clinical Outcomes.

Specifically DaVita states, "Appendix 17 provides a summary of quality and continuity of care indicators used in DaVita's quality improvement program. The DaVita Continuous Quality Improvement (CQI) program incorporates all areas of the dialysis program. The program monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Dialysis-specific statistical tools (developed by DaVita) are used for measurement, analysis, communication, and feedback. Continuing employee and patient education are integral parts of this program. Appendix 17 includes an example of DaVita Quality Index (DQI) data.

Appendix 18 includes an example of DaVita's Physician, Community and Patient Services offered through DaVita's Kidney Smart Education Program. Appendix 12 includes a copy of the transfer agreement between DaVita Everett Dialysis Center and Providence Everett Medical Center. DaVita has been honored as one of the World's Most Admired Companies® by FORTUNE® magazine since

¹³ The three centers are: Belfair Dialysis Center in Mason County, Cooks Hill Dialysis Center in Lewis County, and Renton Dialysis Center in King County.

2006, confirming its excellence in working effectively with the communities it serves (davita.com/about/awards).

"The proposed expansion of DaVita Westwood Dialysis Center will have an appropriate relationship to the service area's existing health care system. DaVita Westwood Dialysis Center is a key component of the existing health care system in the service area, and the project will enable enhanced patient access in an already highly utilized facility with a census of more than 5.0 patients per station. Furthermore, DaVita Westwood Dialysis Center has a long track record of working with area providers to provide the highest possible quality of care to patients, as evidenced by its CQI process outlined in Appendix 17". [Source: Application pages 26 and 27]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita has been a provider of dialysis services in Washington State for many years. DaVita has a history of establishing relationships with existing healthcare networks in King County planning area #3. In the application, DaVita provided documentation of its current ancillary and support agreements between local vendors and DaVita Westwood. DaVita also provided a copy of the dialysis facility existing patient transfer agreement between Renal Treatment Centers—West, Inc. and Highline Medical Center.

The documents provided by DaVita provided in the application demonstrated that after the stations are added to capacity, DaVita Westwood would continue to 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

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

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

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in <u>Step three</u>. The department completes step three under WAC 246-310-827.

Step One

DaVita

For this project, DaVita met the applicable review criteria under WAC 246-310-210, 220, and 230.

Step Two

DaVita

For this sub-criterion, DaVita considered one option before submitting this application. Below is the option DaVita considered.

Alternative 1: Do nothing that is do not apply for seven additional special circumstances stations in King 3 to expand DaVita Westwood Dialysis Center. It has been established that King 3 is growing in ESRD population. Currently, DaVita Westwood Dialysis Center is a very busy facility, with utilization of 5.57 patients per station as of December 31, 2017, and thus little additional capacity to provide access to King 3 patients. The Department's methodology shows substantial patient demand for dialysis services in King 3, beyond that which could be provided for by Westwood's current configuration. With NKC West Seattle's status as officially meeting 4.5 patient per station threshold and the clear need for additional DaVita Westwood Dialysis Center capacity, 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. [Source: Application, pages 27 and 28]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita provided a comprehensive discussion of the alternative considered before submitting this application. Although, one other facility in the planning area is currently operating below 4.5 patients per stations, the department record shows that all approved stations in the planning area have been operational for more than three years. Therefore, the department concludes that DaVita appropriately rejected the alternative before accepting the expansion alternative.

Step Three

WAC 246-310-827 states: For purposes of determining which of the competing applications should be approved, the criteria in this section will be used as the only means for comparing two or more applications to each other. No other criteria or measures will be used in comparing two or more applications to each other under any of the applicable sub-criteria within WAC <u>246-310-210</u>, <u>246-310-220</u>, 246-310-230 or 246-310-240.

Department Evaluation

DaVita is the only applicant to submit an application for King County planning area #3. Based on the information, the department concludes that the project submitted by DaVita is the best available alternative for the community. **This sub-criterion is not 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 for DaVita

This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and is considered met.

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

DaVita

In compliance with this sub-criterion the applicant states, "DaVita Westwood Dialysis Center meets all current energy conservation standard requirements. In addition, expansion will allow full use of the expanded facility designed to meet current energy utilization requirements". [Source: Application page 28]

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 #3 with the addition of seven station kidney dialysis stations in the planning area. **This sub-criterion is met**



2018 King County 3 ESRD Need Projection Methodology

		•					
	Planning Area	6 Year Utili	-ation Data	Danislant	lu a a u ta u Da	4! 4 -	
	King 3	2012	2013	2014	2015	2016	2017
	98070	2	1				
	98106	36	33	6 29	5 26	5 26	<u>6</u> 32
	98116	14	9	10	9	9	9
	98126	24	27	15	20	24	23
	98136	4	2	4	4	5	6
	98146	37	40	34	32	34	37
	98168	45	53	55	47	56	51
	TOTALS	Annual Control of the	165	153	143	159	164
	*						
246-310-812(4)(a)	Rate of Change		1.85%	-7.27%	-6.54%	11.19%	3.14%
	6% Growth or Greater?		FALSE	FALSE	FALSE	TRUE	FALSE
· ·	Regression Method:	Linear			771202	INGL	TALO
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	Year 5
240 010 012(4)(0)			2018	2019	2020	2021	2022
Projected Resident			2010	2019	2020	2021	2022
Incenter Patients	from 246-310-812(4)(b)		158.00	158.40	158.80	159.20	159.60
Station Need for	110111 2 10 0 10 0 12(1)(5)		100.00	100.40	100.00	100.20	133.00
Patients	Divide Resident Incenter	by 4.8	32.92	33.00	33.08	33.17	33.2
	Rounded to next whole n	umber	33	33	34	34	34
9					•		
246-310-812(4)(d)	subtract (4)(c) from approv	ed stations					
Existing CN Approved Stations		Total	27	27	27	27	27
Results of (4)(c) above			33	33	34	34	34
Net Station Need			-6	-6	-7	-7	-7
Negative number indicates n	eed for stations						
Planning Area Faci	lities						
Name of Center							
NKC - West Seattle	20						
DaVita Westwood	7						
Total	27						
	Network data 2012-2017						
Most recent year-end da	ta: 2017 posted 02/07/2018						



2018 King County 3 ESRD Need Projection Methodology

