

February 17, 2016

CERTIFIED MAIL # 7009 0960 0000 5565 0178

Kathryn Cullen, Director Special Projects
DaVita HealthCare Partners, Inc. – North Star Division Office
32275 – 32<sup>nd</sup> Avenue South
Federal Way, Washington 98001

CN: 16-07

Dear Ms. Cullen:

We have completed review of the Certificate of Need (CN) application submitted by DaVita Healthcare Partners, Inc. proposing to add four stations to the existing eight station Union Gap dialysis facility located in the Yakima County. For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided DaVita Healthcare Partners, Inc. agrees to the following in its entirety.

## **Project Description:**

This certificate approves the addition of four kidney dialysis stations to the Certificate of Need approved eight station DaVita Union Gap Dialysis Center. This facility is approved to certify and operate 12 station. Services provided at DaVita Union Gap Dialysis Center include in center hemodialysis, peritoneal dialysis, peritoneal and hemodialysis training and support for patients. The 12 dialysis stations that would be operational at the existing facility would include a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	10
Total	12

Kathryn Cullen, Director Special Projects DaVita HealthCare Partners, Inc. February 17, 2016 Page 2 of 2

# Conditions:

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

# **Approved Costs:**

The approved capital expenditure associated with this project is \$123,208.

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 entirety, your application will be approved and a Certificate of Need sent to you.

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

Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

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

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

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

Sincerely,

Steven M. Saxe, FACHE

Director, Office of Community Health Systems

Enclosure

EVALUATION DATED FEBRUARY 17, 2016, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA HEALTHCARE PARTNERS, INC., PROPOSING TO ADD FOUR KIDNEY DIALYSIS STATIONS IN YAKIMA COUNTY END STAGE RENAL DISEASE PLANNING AREA

# **APPLICANT DESCRIPTION**

DaVita Healthcare Partners, Inc. is a for-profit corporation and it provides dialysis services in over 2,197 outpatient centers located in 43 states and the District of Columbia. DaVita Healthcare Partners, Inc. also provides acute inpatient dialysis services in approximately 720 hospitals throughout the country. In Washington State, DaVita owns or operates 38 kidney dialysis facilities in 17 separate counties. Below is a listing of DaVita Healthcare Partners, Inc. facilities in Washington. [Source: DaVita Application, page 7]

#### **Benton**

Chinook Dialysis Center Kennewick Dialysis Center

#### Chelan

Wenatchee Valley Dialysis Center DaVita Dialysis Center

#### Clark

Vancouver Dialysis Center Battleground Dialysis Center

## **Douglas**

East Wenatchee Dialysis Center

#### Franklin

Mid-Columbia Kidney Center

#### Island

Whidbey Island Dialysis Center

# King

Bellevue Dialysis Center
Des Moines Dialysis Center
Federal Way Community Dialysis Center
Kent Dialysis Center
Olympic View Dialysis Center (management only)
Westwood Dialysis Center

# **Pacific**

Seaview Dialysis Center

#### Pierce

Graham Dialysis Center

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

#### Snohomish

Everett Dialysis Center<sup>1</sup> Mill Creek Dialysis Center Everett Dialysis Center<sup>2</sup>

## Spokane

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

#### Thurston

Olympia Dialysis Center Tumwater Dialysis Center

## Yakima

Mt. Adams Dialysis Center Union Gap Dialysis Center

<sup>&</sup>lt;sup>1</sup> Refuge Dialysis, LLC ownership is 80% by DaVita and 20% by The Everett Clinic.

<sup>&</sup>lt;sup>2</sup> Refuge Dialysis, LLC, is owned 80% by DaVita, Inc. and 20% by The Everett Clinic and managed by DaVita.

Redondo Heights Dialysis Center<sup>3</sup> North Federal Way Dialysis Center

Yakima Dialysis Center Zillah Dialysis Center

Kittitas

Ellensburg Dialysis Center

Mason

Belfair Dialysis Center

**Stevens** 

Echo Valley Dialysis Center

Skagit

Cascade Dialysis Center

# PROJECT DESCRIPTION

DaVita Healthcare Partners, Inc. proposes to expand its existing 8 station DaVita Union Gap Dialysis Center located at 1236 Ahtanum Ridge Drive within the city of Union Gap in Yakima County planning area by an additional 4 stations. [Source: Application, page 1]

Services provided at DaVita Union Gap Dialysis Center include in center hemodialysis, peritoneal dialysis, peritoneal and hemodialysis training and support for patients. The 12 dialysis stations that would be operational at the facility will include a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. [Source: Application, Page 11]

If this project is approved, DaVita Healthcare Partners, Inc. anticipates the additional four stations would become operational in August 2016. Under this timeline, 2017 would be the facility's first full calendar year of operation with 12 station. [Source: Application, page 13]

The capital expenditure associated with the four station addition is \$123,208 and all of the costs are associated with fixed and moveable equipment's. [Source: Application Appendix 7] For ease of reference, DaVita Healthcare Partners, Inc. is the applicant and would be referred to as ("DaVita") and the dialysis facility as ("DaVita Union Gap")

# APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need (CN) review because it increases the number of dialysis stations at an existing kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

## **EVALUATION CRITERIA**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the Department must make for the application. WAC 246-310-200(2) provides additional direction in how the Department is to make its determinations. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the Department in making the required determinations.

- (a) In the use of criteria for making the required determinations, the department shall consider:
  - (i) The consistency of the proposed project with service or facility standards contained in this chapter;
  - (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the

<sup>&</sup>lt;sup>3</sup> Not yet operational

- department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and
- (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."

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

"The department may consider any of the following in its use of criteria for making the required determinations:

- (i) Nationally recognized standards from professional organizations;
- (ii) Standards developed by professional organizations in Washington State;
- (iii) Federal Medicare and Medicaid certification requirements;
- (iv) State licensing requirements;
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application."

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment). Additionally, the applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 288.<sup>4</sup>

<sup>&</sup>lt;sup>4</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to either project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(2), (3), and WAC 246-310-286, 287, 288, and 289.

#### TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this project under the year 2015 Kidney Disease Treatment Centers-Concurrent Review Cycle #3. Below is a chronologic summary of the project.

APPLICATION CHRONOLOGY

Action	Dates
Letter of Intent Submitted	July 31, 2015
Application Submitted	August 31, 2015
Department's Pre-review Activities including	
DOH 1st Screening Letter	September 30, 2015
<ul> <li>Applicant's 1st Screening Responses Received</li> </ul>	November 16, 2015
<ul> <li>DOH 2nd Screening Letter</li> </ul>	N/A
<ul> <li>Applicant's 2nd Screening Responses Received</li> </ul>	N/A
Beginning of Review	November 23, 2015
End of Public Comment	
<ul> <li>Public comments accepted through</li> </ul>	December 28, 2015
• Public hearing conducted <sup>5</sup>	N/A
• Rebuttal Comments Received <sup>6</sup>	January 12, 2016
Department's Anticipated Decision Date	February 26, 2016
Department's Actual Decision Date	February 17, 2016

# **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."

For this project, no entities sought or received an affected person status.

## SOURCE INFORMATION REVIEWED

- DaVita Healthcare Center Certificate of Need application submitted August 31, 2015
- DaVita Healthcare Center Inc., Supplemental Information received November 16, 2015
- Years 2010 through 2014 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2014 Northwest Renal Network 4<sup>rd</sup> Quarter Data
- Survey data provided by the Department of Health's Investigations and Inspections Office
- Certificate of Need historical files
- Medicare.gov—Dialysis Facility Compare

<sup>&</sup>lt;sup>5</sup> The department did not conduct a public hearing.

<sup>&</sup>lt;sup>6</sup> There were no public comments received for this project. Therefore, the applicant did not provide rebuttal comments.

# **CONCLUSION**

For the reasons stated in this evaluation, the application submitted by DaVita Healthcare Partners, Inc., proposing to add four stations to its existing 8 station DaVita Union Gap Dialysis Center in Yakima County planning area is consistent with applicable criteria of the Certificate of Need Program, provided DaVita Healthcare Partners, Inc., agrees to the following in its entirety.

# **Project Description:**

This certificate approves the addition of four kidney dialysis stations to the Certificate of Need approved eight station DaVita Union Gap Dialysis Center. This facility is approved to certify and operate 12 station. Services provided at DaVita Union Gap Dialysis Center include in center hemodialysis, peritoneal dialysis, peritoneal and hemodialysis training and support for patients. The 12 dialysis stations that would be operational at the existing facility would include a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Total	12
Other In-Center Stations	10
Permanent Bed Station	1
Private Isolation Room	1

# **Conditions:**

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

#### **Approved Costs:**

The approved capital expenditure associated with this project is \$123,208.

# **CRITERIA DETERMINATIONS**

# A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the condition stated in the 'conclusion' section of this evaluation, the department determines that DaVita HealthCare Partners, Inc.'s project has met the applicable need criteria in WAC 246-310-210 and the kidney disease treatment standards in WAC 246-310-284.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need. WAC 246-310-284 requires the department to evaluate kidney disease treatment center applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

# Numeric need methodology

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network (NRN).<sup>7</sup>

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

WAC 246-310-284(5) identifies that for all planning areas <u>except</u> Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area.

<sup>&</sup>lt;sup>7</sup> Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

<sup>&</sup>lt;sup>8</sup> WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report." For these projects, the base year is 2014.

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 in-center stations are then subtracted from the total need and the result is the net need for the planning area. [WAC 246-310-284(4)(d)]

# DaVita Application of the Numeric Methodology

DaVita proposes to add four stations to its existing 8 station DaVita Union Gap Dialysis Center. Based on the calculation of the annual growth rate in the planning area as described above, DaVita used the same linear regression to determine planning are need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [Source: Application, Pages 17-18]

# Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project need for Yakima County. The department also divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5). The table below shows the summary of the projected net need provided by the applicants and the department for Yakima County.

Table 1
Summary of Department's Numeric Methodology for Yakima County

	Year	Year	Year	Year
	2015	2016	2017	2018
In-center Patients	243.10	246.60	254.10	259.60
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	50.6	51.8	52.9	54.1
Total Station Need Rounded Up	51	52	53	55
Minus # CN Approved Stations	51	51	51	51
Net Station Need / (Surplus)	0	1	2	4

As shown in the table above the department application of the numeric methodology show need for four stations in the planning area. The department's complete numeric methodology for Yakima County ESRD planning area is attached to this evaluation as Appendix A.

## WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the NRN as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period for this project is August 1, 2015. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 2014. For Yakima County planning area, there are fifty-one stations available. The table below shows the utilization of the existing fifty-one dialysis stations in the planning area.

Table 2 NWRN Facility Utilization Data

Facility Name	# of Stations	# of Pts.	Pts./Station
DaVita Mt. Adams	14	68	4.8
DaVita Union Gap	8	49	6.1
DaVita Yakima	21	104	4.9
DaVita Zillah	8	40	5.0

Table 2 demonstrates that the four existing facilities in Yakima County satisfy this utilization requirement. **This sub-criterion is met.** 

# WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For Yakima County planning area, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, the applicants must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

DaVita anticipate the four additional stations would become operational by the end of August 2016. Under this timeline, year 2017 would be the existing facility's first full calendar year of operation with 12 stations and 2019 would be year three. A summary of the projected utilization for the third year of operation is shown in the table below. [Source: Application, page 13 and supplemental information received September 21, 2015, Appendix 9]

Table 3
DaVita Union Gap Third Year Projected Utilization

Facility Name	Year 3	# of Stations	# of Pts.	Pts./Station
DaVita Union Gap	2019	12	60	5.0

As shown above, DaVita Union Gap is expected to exceed this standard. Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. **This sub-criterion is met**.

(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>

As previously stated, currently provides health care services to residents of Washington State. To determine whether all residents of the Yakima County planning area would continue have access to healthcare services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission polity that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current policy for Accepting Patients for Treatment that is currently used in its facilities. The policy outlines the process/criteria that DaVita facilities use to admit patients for treatment, and ensures that patients will continue to receive appropriate care at DaVita Union Gap. The policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at DaVita facilities without regard to race, color, nation origin, sex, age, religion, or disability. [Source: Application, Appendix 14]

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

DaVita currently provides services to Medicaid eligible patients in Yakima County planning area. It expects to continue to provide services to patients at DaVita Federal Way. A review of the anticipated revenue indicates that DaVita Union Gap expects it will continue to receive Medicaid reimbursements. [Source: Application page 12 and Appendix 9]

DaVita currently provides services to Medicare eligible patients in Yakima County. It expects to continue to provide services to those patients. A review of the anticipated revenues indicates that DaVita Union Gap expects to continue receiving Medicare reimbursements. [Source: Application page 12 and Appendix 9]

DaVita demonstrated its intent to continue to provide charity care to Yakima County planning area residents by submitting the 'Indigent Care Policy' currently used within its facilities. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. DaVita also included a 'charity care' line item as a deduction from revenue within the pro forma income statements<sup>9</sup>. [Source: Application, Appendix 14] The department concludes that all residents of the service area have and would continue to have access to health services at DaVita Union Gap. **This sub-criterion is met.** 

## 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 DaVita, Healthcare, Inc. has met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met. WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the Department evaluates if the applicant's pro forma income statements reasonably

<sup>&</sup>lt;sup>9</sup> The department acknowledges that the Affordable Care Act will likely have a long-term impact on the amount of charity care provided by facilities. The regional average used to measure an applicant's compliance with the charity care standard is a self-correcting three year rolling average. The department expects the applicant to make documented reasonable efforts to meet that level of charity care

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.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates that the four new stations would become operational by the end of August 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation with 12 stations. Year 2019 would be the third full year of operation. [Source: Application, Page 13] DaVita provided the revenue and expense statement for the expansion of DaVita Union Gap. Table 4 below, summarizes that information. [Source: Application, Appendix 9]

Table 4
DaVita Union Gap Dialysis Center
Projected Revenue and Expenses Years 2016 - 2019<sup>10</sup>

	Partial Year 2016	Year 1- 2017	Year 2 – 2018	Year 3 – 2019
# of Stations	12	12	12	12
# of Treatments [1]	8,003	8,225	8,670	9,188
# of Patients [2]	54	57	60	64
Utilization Rate [2]	4.50	4.75	5.0	5.0
Net Revenue [1]	\$7,579,514	\$7,945,858	\$8,542,871	\$9,205,272
Total Expense [1,3]	\$4,254,269	\$4,434,214	\$4,783,300	\$5,161,840
Net Profit or (Loss) [1]	\$3,325,245	\$3,511,644	\$3,759,571	\$4,043,432

<sup>[1]</sup> Includes in-center patients only; [2] in-center patients only; [3] includes bad debt, charity care and allocated costs

As shown in the table above, DaVita Union Gap would be operating at a profit beginning in partial year of operation or by year 2016 though the third full year or by year 2019 with 12 stations. As an existing facility, DaVita provided a copy of the executed First Amendment to the Lease Agreement between Fletcher Venture, LLC ("Lessor") as the successor-in-interest to Genesis Development Worldwide, LLC and Renal Treatment Centers — West, Inc. ("Lessee"). [Source: Application, Appendix 15 and Supplemental information received November 16, 2015, Exhibit D]

DaVita also provided a copy of DaVita Union Gap medical director agreement. The agreement identified the annual compensation for the medical director position. Additionally, DaVita's proforma financial income statement also identified the annual compensation for the medical director. [Source: Application, Appendix 3 and 9]

Based on the source documents evaluated, the department concludes DaVita's projected revenues and expenses are reasonable and can be substantiated. This sub-criterion is met.

<sup>&</sup>lt;sup>10</sup> Whole numbers may not add due to rounding.

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

WAC 246-310 does not contain specific 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.

The capital expenditure associated with the addition of four stations to the existing DaVita Union Gap facility is \$123,208, and the cost is dedicated to fixed and moveable equipment. The capital expenditure cost breakdown is shown in Table 5 below. [Source: Application Appendix 7]

Table 5
DaVita Union Gap Estimated Capitals Costs

Item	Cost	% of Total
Fixed & Moveable Equipment	\$98,208	79.7%
Professional Service Fees	\$25,000	20.3%
<b>Total Estimated Capital Costs</b>	\$123,208	100%

The department recognizes that the majority of the numbers of patients for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 10. [Source: Application, Page 12]

Table 6
DaVita Union Gap

Sources of Revenue Type of Payor		Sources of Revenue Percentage of Patients per Payor
Source	Percent	Percent
Medicare	33.6%	79.4%
Medicaid/State	3.0%	6.0%
Insurance/HMO	63.4%	14.6%
Total	100%	100%

As shown above, DaVita provided two breakdowns of its revenue sources. In its breakdown by payor type DaVita expects that 14.6% of its patients would be commercial insurance and the remainder 85.4% is Medicare and Medicaid enrollees. In its breakdown by percentage of revenue per payor, Medicare and Medicaid patients make up 36.6% of the revenue. [Source: Application, page 12]

Medicare and Medicaid patients typically make up the largest percentage of patients by a dialysis facility. Under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment, 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 at both the facility and patient-specific level that impacts 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 payor the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payor from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. However, the cost of the three station project is \$123,208, and it is expected to have a minimal, if any, impact on the cost, and charges for health services.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. **This subcriterion 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.

The capital expenditure associated with the addition of four station to DaVita Union Gap is \$123,208. DaVita stated that the project would be funded from its parent entity's available board reserves. DaVita states the project will be funded from its own reserves. A letter from the applicant's Chief Operating Officer (COO) was provided confirming the corporate funding. [Source: Application, Appendix 6] A review of DaVita's financial statements shows the funds necessary to finance the project are available. [Source: Application, Appendix 6]

A review of DaVita's statements of financial position show the funds necessary to finance the project are available. [Source: Application, Appendix 9]

Based on the information provided, the department concludes that the project can be financed and approval of this project would not adversely affect the financial stability of DaVita as a whole. **This sub-criterion is met**.

# 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 DaVita 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 management personnel, are available or can be recruited.</u>

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 FTEs that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

As an existing facility, DaVita Union Gap has 11.4 FTEs with the additional four stations; DaVita Union Gap expects to increase FTE's 0.8 by the end of year 2021. DaVita Union Gap existing and proposed FTEs are shown in Table 7 below. [Source: Application page 22]

Table 7
DaVita Union Gap Current and Projected FTEs

Staff/FTEs	Current FTE	Year 1 - 2017	Year 2 - 2018	Year 3 - 2019	Year 4 - 2020	Year 5 - 2021	Total
Medical Director			Profession	nal Services			
Administrator	1.0	0.0	0.0	0.0	0.0	0.0	1.0
RNs	4.0	0.0	0.0	0.1	0.0	0.1	4.2
Patient Care Tech	4.0	0	0.1	0.1	0.1	0.1	4.4
Biomedical Tech	0.3	0.0	0.0	0.0	0.0	0.0	0.3
Admin Asst	0.7	0.0	0.0	0.0	0.0	0.0	0.7
Social Worker	0.7	0.0	0.0	0.0	0.0	0.1	0.8
Dietician	0.7	0.0	0.0	0.0	0.0	0.1	0.8
LVN	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total FTE's	11.4	0.0	0.1	0.2	0.1	0.4	12.2

As shown above, DaVita does not expect to increase FTE's in year 2018. DaVita states it does not anticipate any difficulty recruiting staff if there is need because it offers competitive wages and benefits package to employees. Additionally, DaVita states that job openings are posted nationally and internally and it has extensive employee travelling program that guarantee it will maintain staffing at its facilities. [Source: Application, pages 23 and 25]

DaVita identified J. Hamilton Licht, MD as the current medical director for the existing DaVita Union Gap and provided an executed medical director's agreement between Nephrology Associates of Yakima ("Group"), and Renal Treatment Center-West, Inc. ("Company"). According to the medical director agreement recitals, Dr. J. Hamilton Licht is the sole physician employee of the Group. [Source: Application, Appendix 3]

The medical director agreement outlines the roles and responsibilities of the Group and Company. Additionally, the agreement also identifies the annual compensation for the medical director. [Source: Application Page 8 and Appendix 3] A review of the medical director's agreement between Company and Group shows that the agreement outlines the roles and responsibilities of both parties involved. Based on the information reviewed, the department concludes **this sub-criterion** is met.

(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>

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 Union Gap Dialysis Center is an existing facility information provided by DaVita stated ancillary and support services such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site. DaVita stated that services would be coordinated through DaVita's corporate office in El Segundo California and support offices in Washington. [Source: Application, Pages 23 and 24]

Based on the evaluation of supporting documents provided, the department concludes that there is reasonable assurance that DaVita Union Gap Dialysis Center will continue to have appropriate ancillary and support services with a healthcare provider in Yakima County. **This sub-criterion is met.** 

(2) 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 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.

For this application, the department reviewed information available at the Center for Medicare & Medicaid Services (CMS) website related to dialysis facilities star ratings. CMS assigns a one to five 'star rating' in two separate categories: best treatment practices, hospitalizations, and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

# Best Treatment Practices

This is a measure of the facility's treatment practices in the areas of anemia management; dialysis adequacy, vascular access, and mineral & bone disorder. This category reviews both adult and child dialysis patients.

# • Hospitalization and Deaths

This measure takes a facility's expected total number of hospital admissions and compares it to the actual total number of hospital admissions among its Medicare dialysis patients. It also takes a facility's expected patient death ratio and compares it to the actual patient death ratio taking into consideration the patient's age, race, sex, diabetes, years on dialysis, and any comorbidity.

Based on the star rating in each of the two categories, CMS then compiles an 'overall rating' for the facility. As with the separate categories: the more stars, the better the rating. The star rating is based on data collected from January 1, 2010 through December 31, 2013. DaVita is a forprofit corporation that provides dialysis services in over 2,197 outpatient centers located in 43 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in approximately 720 hospitals throughout the country.

In Washington State, DaVita owns or operates 38 kidney dialysis facilities in 17 separate counties. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public. Historically, the department has requested quality of care compliance history from the licensing and/or surveying entities in each state where DaVita or any of its subsidiaries have healthcare facilities.

In April 2013, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for conducting surveys where DaVita or any of its subsidiaries have healthcare facilities. Of the 45 states<sup>12</sup> and the non-state entities surveyed, the department received 30<sup>13</sup> responses or 65.2% of those surveyed. One of the states<sup>14</sup> responding to the survey indicated significant compliance and the rest reported non-compliance deficiencies were cited at DaVita facilities in the past three years. DaVita submitted and implemented acceptable plans of correction. Given the results of the out-of-state compliance history of the facilities owned or operated by DaVita, the department concludes that considering that it owns or operates more than 2,197 facilities the number of out-of-state non-compliance surveys is acceptable. [Source: Application, Page 6 and Licensing and/or survey data provided by out of state health care survey programs]

As stated earlier DaVita owns, operates, or manages 38 facilities in Washington the department reviewed CMS star ratings for these facilities. The department review shows that nine of the 38 facilities did not have a CMS star rating because they were not open for the entire reporting period. Below is the overview of the CMS star rating for the remaining 29 DaVita facilities.

Table 8
DaVita Dialysis Centers Medicare and Medicaid Star Rating

Facility	City	Star Rating
Battle Ground Dialysis Center	Battle Ground	_
Belfair Dialysis Center	Belfair	_
Bellevue Dialysis Center	Bellevue	4
Burlington Dialysis Center	Burlington	_
Chinook Kidney Center	Richland	4
Downtown Spokane Renal Center	Spokane	3
East Wenatchee Dialysis Center	East Wenatchee	5
Echo Valley Dialysis Center	Colville	=
Ellensburg Dialysis Center	Ellensburg	3
Everett Dialysis Center	Everett	4
Federal Way Community Dialysis Center	Federal Way	4
Olympic View Dialysis Center	Seattle	2
Parkland Dialysis Center	Tacoma	3
Pilchuck Dialysis Center	Marysville	-
Puyallup Community Dialysis Center	Puyallup	3

<sup>&</sup>lt;sup>11</sup> WAC 246-310-230(5)

<sup>&</sup>lt;sup>12</sup> This figure excludes Washington. The department did not send a survey to itself for compliance.

<sup>13</sup> The department did not receive responses from California, Georgia, Illinois, Louisiana, Massachusetts, Maryland, Maine, Michigan, Mississippi, North Carolina, Nebraska, Rhode Island, Utah, Virginia and Wyoming.

<sup>&</sup>lt;sup>14</sup> Indiana reported significant citation

<sup>&</sup>lt;sup>15</sup> Burlington, Belfair, Battleground, Tumwater, Pilchuck, Echo Valley, Rainier View, Redondo and Renton,

Facility	City	Star Rating
Rainer View Dialysis Center	Tacoma	-
Redondo Dialysis Center	Federal Way	-
Renton Dialysis Center	Renton	-
Seaview Dialysis Center	Seaview	4
Spokane Valley Renal Center	Spokane	3
Tacoma Dialysis Center	Tacoma	4
Tumwater Dialysis Center	Tumwater	-
Graham Dialysis Center	Graham	5
Kennewick Dialysis Center	Kennewick	3
Kent Dialysis Center	Kent	4
Lakewood Community Dialysis Center	Lakewood	4
Mid-Columbia Kidney Center	Pasco	4
Mill Creek Dialysis Center	Bothell	4
Mt. Adams Kidney Center	Sunnyside	5
North Spokane Renal Center	Spokane	3
Olympia Dialysis Center	Olympia	5
Union Gap Dialysis Center <sup>16</sup>	Union Gap	5
Vancouver Dialysis Center	Vancouver	3
Wenatchee Valley Dialysis Center	Wenatchee	4
Westwood Dialysis Center	Seattle	3
Whidbey Island Dialysis Center	Oak Harbor	4
Yakima Dialysis Center	Yakima	5
Zillah Dialysis Center	Zillah	5

On October 22, 2014, DaVita entered into a final settlement agreement with the United Sates Department of Justice (DOJ) on behalf of United States Department of Health and Human Services and other governmental agencies to resolve the US Attorney Physician Relationships Investigations. Under the settlement agreement, DaVita agreed to pay the sum of \$350 million plus accrued interest and a civil forfeiture of \$39 million. In addition, DaVita also agreed to pay certain state Medicaid claim in the amount of \$11.5 million plus interest.

Under the DOJ settlement agreement, DaVita is released from any civil or administration monetary liability arising from allegations that it caused the submission of certain claims to the government healthcare programs that were ineligible for reimbursement due to violations of the Anti-Kickback Statute in connection with the operations of some of its dialysis centers joint venture arrangements. Information provided by DaVita within the application stated the DOJ settlement agreement reflects its disagreement with the government regarding the allegations. According to information in the documents provided, DaVita is not prohibited from billing or participating in Federal healthcare programs. [Source Application Appendix 4]

As shown in Table 8 above, with the exception of one facility, all DaVita dialysis centers received three stars or better. [Source: Application, Page 2] DaVita identified J. Hamilton Licht, MD as the current medical director for the existing DaVita Union Gap and provided an executed medical director's agreement between Nephrology Associates of Yakima ("Group"), and Renal Treatment

<sup>&</sup>lt;sup>16</sup> DaVita Union Gap Dialysis Center was last surveyed on December 11, 2013 by DOH

Center-West, Inc. ("Company"). According to the medical director agreement recitals, Dr. J. Hamilton Licht is the sole physician employee of the Group. [Source: Application, Appendix 3] A review of the compliance history for the following seven physicians associated with Group revealed no recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission and corporation information provided by Washington State Secretary of State website]

Given the compliance history of DaVita, and the medical director, the department concludes that there is reasonable assurance that DaVita Union Gap Dialysis Center would continue to operate in compliance with state and federal regulations. **This sub-criterion is met.** 

(3) 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.

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, DaVita also provided examples of its quality index data and its physician, community, and patient services program known as 'Kidney Smart Program'. In addition, DaVita also provided a copy of its executed patients transfer agreement between Yakima HMA, LLC d/b/a Yakima Regional Medical and Cardiac Center and Renal Treatment Center-West, Inc. [Source: Application, Appendices 12, 17 & 18]

Based on this information, the department concludes the applicant has demonstrated it has, and will continue to have appropriate relationships with the planning area health care delivery systems. This sub-criterion is met.

(4) 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.

For this project, this sub-criterion is addressed in sub-section (3) above and is considered met.

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

Based on the source information reviewed, the department determines that DaVita's application 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. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

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

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

# Step One

DaVita proposed to add four stations to existing eight Yakima Union Gap kidney dialysis facility in Yakima County. The department concludes that the project met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

#### Step Two

Before submitting this application, DaVita considered the options below. [Source: Application, Page 25]

#### Do nothing

DaVita stated it considered doing nothing, but recognized this option would not improve patient access within the planning area. Therefore, it rejected this option.

# Add stations at different facility

DaVita stated it considered continue using the existing and adding stations at a different facility. This option was rejected because DaVita Union Gap is the only facility that shows immediate need while the facilities considered, did not show immediate need.

#### Add four stations

DaVita Union Gap shows the greatest number of patients demand therefore, the option was chosen DaVita stated that depending on CN approval timeline, it could quickly restore access in the planning area.

# **Department Evaluation**

To determine if the applicant proposal present a superior alternative under WAC 246-310-240(1) in reviewing the materials submitted by the applicant, the department determined that DaVita's application to add four stations to the existing eight station DaVita Union Gap in Yakima County is the best available alternative. Within the application, DaVita stated that the addition of four stations would promote systems efficiency because it would increase availability and flexibility of scheduling for all patients. Additionally, it will provide efficient use of RNs, management and administrative assets and it will result in the commitment of better continue quality improvement initiatives (CQI) studies. In addition, DaVita stated the project will translates to better clinical outcomes, lower patient's hospitalization rates and lower healthcare costs. [Source: Application Page 26] Based on the information considered it appears that DaVita's application present a superior alternative in Yakima County. The department concludes that DaVita's application proposing to expand the existing eight station DaVita Union Gap Dialysis Center by additional four station is the best available alternative. **This sub-criterion is met** 

# Step Three

This step is used to determine the best available alternative between two or more approvable projects. DaVita is the only applicant that submitted an application to add stations in Yakima County during the ESRD review cycle #3 in 2015. DaVita's project met all Certificate of Need criterion under WAC 246-310-210, 220, 230, and 240. Therefore, step three is not necessary.

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

a. The costs, scope, and methods of construction and energy conservation are reasonable;

DaVita's proposes to add four stations to an existing facility. DaVita's lease costs were evaluated in the financial feasibility section of this analysis. The department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes **this sub-criterion is met.** 

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

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concluded **this sub-criterion is met.** 

# Appendix A



# 2015 Yakima County ESRD Need Projection Methodology

	Planning Area	6 Year Utiliza	zation Data - Resident Incenter Patients				
	Yakima Yakima Yakima County	2009 2010		2011	2012	2013	2014
*		201	214	235	213	224	247
	TOTALS	201	214	235	213	224	247
246-310-284(4)(a)	Rate of Change		6.47%	9.81%	-9.36%	5.16%	10.27%
	6% Growth or Greater?		TRUE	TRUE	FALSE	FALSE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
				2015	2016	2017	2018
Projected Resident							
Incenter Patients	from 246-310-284(4)(b)			243.10	248.60	254.10	259.60
Station Need for Patients	Divide Resident Incenter Patients by 4.8		50.6458	51.7917	52.9375	54.0833	
	Rounded to next whole r	umber		. 51	52	53	55
			20				
246-310-284(4)(d)	subtract (4)(c) from approved stations						
<b>Existing CN Approved</b>	Stations			51	51	51	51
Results of (4)(c) above	)		-	51	52	53	55
Net Station Need				0	-1	-2	-4
Negative number indicates	need for stations						
Planning Area Fac	ilities						
Name of Center	# of Stations						
DaVita Mt. Adams	14						
DaVita Union Gap	8				- 1		
DaVita Yakima	21						
DaVita Zillah	8						



# 2015 Yakima County ESRD Need Projection Methodology

