

State of Washington Department of Health

August 7, 2017

Certified Mail 7014 2120 0002 7631 1724

Austin Ross, Vice President of Planning Administration Northwest Kidney Centers 700 Broadway Seattle, WA 98122

CN17-16

Dear Mr. Ross:

We have completed the review of the Certificate of Need application submitted by Northwest Kidney Centers proposing to establish a six station dialysis facility in Yakima within Yakima County ESRD planning area. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Tie Breaker

WAC 246-310-288

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any interested or affected person may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

Austin Ross, Vice President of Planning Administration Northwest Kidney Centers August 7, 2017 Page 2

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

<u>Physical Address</u> Janis Sigman, Manager Certificate of Need Program Department of Health 111 Israel Road SE Tumwater, WA 98501

Appeal Option 2:

You or any affected person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address: Adjudicative Service Unit Mail Stop 47879 Olympia, WA 98504-7879 <u>Physical Address</u> Adjudicative Clerk Office 111 Israel Road SE Tumwater, WA 98501

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

Sincerely,

Nancy Tyson, Executive Director Community Health Systems

Enclosure

EXECUTIVE SUMMARY

EVALUATION DATED AUGUST 7, 2017, FOR THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY IN YAKIMA COUNTY ESRD PLANNING AREA

- DAVITA HEALTHCARE PARTNERS, INC. IS PROPOSING TO ESTBLISH A SIX STATION KIDNEY DIALYSIS CENTER IN THE CITY OF WAPATO WITHIN YAKIMA COUNTY
- NORTHWEST KIDNEY CENTERS IS PROPOSING TO ESTABLISH A SIX STATION DIALYSIS FACILITY IN THE CITY YAKIMA WITHIN YAKIMA COUNTY

BRIEF PROJECTS DESCRIPTIONS

DaVita Healthcare Partners, Inc.

DaVita Healthcare Partners, Inc. is a private for-profit corporation. DaVita Healthcare Partners, Inc. provides dialysis services through its 41dialysis centers located throughout Washington. DaVita Healthcare Partners, Inc. proposes to establish a six-station kidney dialysis facility in the City of Wapato in Yakima County. [Source: DaVita Application, pages 1 & 5]

The capital expenditure associated with the six-station facility is \$1,929,681. If this project is approvable, DaVita Healthcare Partners, Inc. anticipates the six-station facility would be operational by July 2018. Under this timeline, year 2019 would be the facility's first full calendar year of operation and year 2021 the third year of operation. [Source: DaVita Application, page 14]

Northwest Kidney Centers

Northwest Kidney Center is a private, not-for-profit corporation, incorporated in the state of Washington. Northwest Kidney Center provides dialysis services through its facilities located in King and Clallam counties. Established in 1962, Northwest Kidney Center operates as community based dialysis program working to meet the needs of dialysis patients and their physicians. A volunteer board of trustees governs Northwest Kidney Center. The board is comprised of medical, civic and business leaders from the community. An appointed Executive Committee of the Board oversees Northwest Kidney Center's operating policies and performance and approves capital expenditures for all of its facilities. [Source: CN historical file and Application, page 5 Exhibits 2, and 3]

The total capital expenditure associated with the establishment of the six-station kidney dialysis center is \$2,522,601. If this project is approvable, Northwest Kidney Center anticipates the six-station facility would be operational by the end of February 2019¹. Under this timeline, fiscal year (FYE)² year 2020 would be the facility's first full year of operation and FYE 2022 would be year three. [Source: Application, Page 9]

¹ Footnote on page 9 of Northwest Kidney Center application

² Northwest Kidney Center operates using the fiscal year calendar

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need review as the construction, development, or other establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

CONCLUSIONS

DaVita Healthcare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita Healthcare Partners, Inc. proposing to establish a six station kidney dialysis center in the city of Wapato within Yakima County ESRD 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 construction of a new six station dialysis center in the city of Wapato within Yakima County ESRD planning area. At project completion, the dialysis center is approved to certify and operate six dialysis stations. Services to be provided at DaVita Wapato Dialysis Center include in-center hemodialysis, training and support for peritoneal dialysis, emergency backup for other dialysis, hemodialysis treatment shifts beginning after 5:00 p.m., a permanent bed station, and a dedicated isolation/private room. A breakdown of the approved three stations is shown below:

1 3	
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	4
Total	6

DaVita Wapato Dialysis Center

Conditions:

- 1. DaVita Healthcare Partners, Inc. agrees with the project description as stated above. DaVita Healthcare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Prior to providing services, DaVita Healthcare Partners, Inc. will provide an executed copy of the medical director agreement for the department's review and approval. The executed medical director agreement must be consistent with the draft provided in the application.
- 3. Prior to commencement DaVita Healthcare Partners, Inc. will provide an executed copy the lease agreement for the department's review and approval. The executed lease agreement must be consistent with the draft provided in the application.
- 4. Prior to providing services at DaVita Wapato Dialysis Center, DaVita Healthcare Partners, Inc. will provide an executed copy of the patient transfer agreement for the department's review and approval. The executed patient transfer agreement must be consistent with the draft provided in the application.

Approved Costs:

The total cost of this project is \$1,929,681. Of this amount, \$1,819,681 is DaVita Healthcare Partners, Inc. approved cost. The remaining \$110,000 is the amount the landlord will incur.

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers proposing to establish a six station dialysis facility in city of Yakima within Yakima County ESRD planning area is not consistent with applicable criteria and a Certificate of Need is denied.

EVALUATION DATED AUGUST 7, 2017, FOR THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD KIDENY DIALYSIS CAPACITY IN YAKIMA COUNTY

- DAVITA HEALTHCARE PARTNERS, INC. IS PROPOSING TO ESTBLISH A SIX STATION KIDNEY DIALYSIS FACILITY IN THE CITY OF WAPATO WITHIN YAKIMA COUNTY
- NORTHWEST KIDNEY CENTERS IS PROPOSING TO ESTABLISH A SIX STATION DIALYSIS FACILITY IN THE CITY OF YAKIMA WITHIN YAKIMA COUNTY

APPLICANT DESCRIPTIONS

DaVita Healthcare Partners, Inc.

DaVita Healthcare Partners, Inc. is a for-profit corporation that provides dialysis services in about 2,293 outpatient centers located in the United States serving about 185,000 patients. DaVita Healthcare Partners, Inc. also provides acute inpatient dialysis services in hospitals throughout the country. In Washington State, DaVita Healthcare Partners, Inc. owns or operates 41 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

Chelan Wenatchee Valley Dialysis Center

Clark Vancouver Dialysis Center Battleground Dialysis Center

Douglas East Wenatchee Dialysis Center

Franklin Mid-Columbia Kidney Center

Island Whidbey Island Dialysis Center Pacific Seaview Dialysis Center

Pierce Elk Plain Dialysis Center Graham Dialysis Center Lakewood Dialysis Center Parkland Dialysis Center Puyallup Dialysis Center Tacoma Dialysis Center Rainier View Dialysis Center

Snohomish Everett Dialysis Center³

Mill Creek Dialysis Center

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

³ Refuge Dialysis, LLC is 80% owned by DaVita and 20% by The Everett Clinic.

King

Bellevue Dialysis Center Des Moines Dialysis Center Federal Way Dialysis Center Kent Dialysis Center Olympic View Dialysis Center (management only) Westwood Dialysis Center Redondo Heights Dialysis Center North Federal Way Dialysis Center

Kittitas

Ellensburg Dialysis Center

Lewis County Centralia Dialysis Center

Stevens County Echo Valley Dialysis Center

Northwest Kidney Center

Thurston

Olympia Dialysis Center Tumwater Dialysis Center

Yakima

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

Mason Belfair Dialysis Center

Skagit Cascade Dialysis Center

Northwest Kidney Center is a private, not-for-profit corporation, incorporated in the state of Washington. Northwest Kidney Center provides dialysis services through its facilities located in King and Clallam counties. Established in 1962, Northwest Kidney Center operates as community based dialysis program working to meet the needs of dialysis patients and their physicians. A volunteer board of trustees governs Northwest Kidney Center. The board is comprised of medical, civic and business leaders from the community. An appointed Executive Committee of the Board oversees operating policies, performance and approves capital expenditures for all of its facilities. [Source: CN historical file and Application, pages 4 - 5 and Exhibits 2 and 3]

Northwest Kidney Center does not own or operate any healthcare facilities outside of Washington State. In Washington State, Northwest Kidney Center owns and operates 16 kidney dialysis facilities. Of the 16 facilities, 15 are located within King County. Below is a listing of Northwest Kidney Center facilities in Washington. [Source: Application 6, Exhibit 4]

King County

Auburn Kidney Center Broadway Kidney Center Elliot Bay Kidney Center Enumclaw Kidney Center Kent Kidney Center Kirkland Kidney Center Lake City Kidney Center Federal Way Kidney Center

Clallam County

Port Angeles Kidney Center

Lake Washington Kidney Center Renton Kidney Center Scribner Kidney Center Seattle Kidney Center SeaTac Kidney Center Snoqualmie Ridge Kidney Center West Seattle Kidney Center

PROJECT DESCRIPTIONS

DaVita Healthcare, Partners Inc.

DaVita Healthcare Partners, Inc. proposes to establish a six-station kidney dialysis center in Yakima County. The six-station kidney dialysis facility would be known as Wapato Dialysis Center and it would be located at 502 West 1st Street within the city of Wapato within Yakima County. [Source: DaVita Application, page 10]

Services to be provided at the Wapato Dialysis Center include in-center hemodialysis and peritoneal dialysis, peritoneal training and support, emergency backup, treatment shifts beginning after 5:00 p.m., a permanent bed station, and a dedicated isolation/private room. [Source: DaVita Application, pages 11 and 12] If this project is approvable, DaVita Healthcare Partners, Inc. anticipates the six-station facility would be operational by July 2018. Under this timeline, year 2019 would be Wapato Dialysis Center first full calendar year of operation and year 2021 the third year of operation. [Source: DaVita Application, page 14]

The total capital expenditure associated with the establishment of the six-station kidney dialysis center is \$1,929,681. Of that amount 61% or \$1,167,500, is related to building construction improvement; 25% or \$489,681 is for fixed and moveable equipment, 8% or \$162,500; is for consulting fees and the remaining 6% or \$110,000 is related to indirect project cost. [Source: Application Page 10 and Appendix 7] If this project is approvable, DaVita Healthcare Partners, Inc. anticipates the six-station facility would be operational by July 2018. Under this timeline, year 2019 would be the facility's first full calendar year of operation and year 2021 the third year of operation. [Source: DaVita Application, page 14]

For ease of reference, DaVita Healthcare Partners Inc. would be referred to as ("DaVita") and the proposed 6 station dialysis facility as ("DaVita Wapato").

Northwest Kidney Centers

Northwest Kidney Centers proposes to establish a six-station kidney dialysis facility in Yakima County. The new six-station dialysis center to be known as NKC Yakima Kidney Center would be located at 1010 South 64th in the city of Yakima within Yakima County. The Yakima County assessor parcel identification number for the property is 181329-1441. Services to be provided NKC Yakima Kidney Center includes in-center hemodialysis, peritoneal and hemodialysis training and backup, home peritoneal dialysis training and backup, a permanent bed station, and dedicated isolation/private room and treatment shifts beginning after 5:00 p.m. [Source: Application, pages 4 and 8, and Exhibit 9]

The total capital expenditure associated with the establishment of the six-station kidney dialysis center is \$2,522,601. The property owner is responsible for \$933,701 of this amount. Northwest Kidney Center's portion of the cost is \$1,588,900. Of that amount 63% or \$1,001,297 is related to building construction and engineering fees; 24% or \$374,299 is for fixed and moveable equipment; and the remaining 13% or \$213,304 is related to architecture fees and sales tax. [Source: Application Page 28]

If this project is approvable, Northwest Kidney Center anticipates the six-station facility would be operational by the end of February 2019. Under this timeline, fiscal year (FYE) year 2020 would be the facility's first full year of operation and FYE 2022 would be year three. [Source: Application, Page

9] For ease of reference, Northwest Kidney Center would be referred to as ("NKC") and the proposed six station dialysis facility as ("NKC Yakima").

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need review as the construction, development, or other establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

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 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 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 288 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). For this project, both applicants must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 (definitions); WAC 246-310-282 (concurrent review cycle); and WAC 246-310-284 (methodology) and WAC 246-310-288 (tie breaker).

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this project under the year 2016 Kidney Disease Treatment Centers-Concurrent Review Cycle #4. Below is a chronologic summary of the project.

APPLICATION CHRONOLOGY

Action	DaVita	NKC	
Letter of Intent Submitted	October 31, 2016	October 31,2016	
Application Submitted	November 30, 2016	November 30, 2016	
Department's pre-review Activities			
Department 1st Screening Letter	December 30, 2016	December 30, 2016	
• Applicant Response to 1st Screening Letter	January 31, 2017	January 31, 2017	
Beginning of Review	February 16,2017		
End of Public Comment			
No public hearing conducted			
• Public comments accepted through end of	April 1	7, 2017	
public comment			
Rebuttal Comment Received	May 1	7, 2017	
Department's Anticipated Decision Date	July 3	, 2017	
Department's Actual Decision Date	August	7, 2017	

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."

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

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

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

Under concurrent review, each applicant is an affected person for the other application.

No other entities requested interested or affected person status for either application.

SOURCE INFORMATION REVIEWED

- DaVita Healthcare Partners, Inc. application received November 30, 2016
- Northwest Kidney Centers application received November 30, 2016
- DaVita Healthcare Partners, Inc. Screening responses received January 31, 2017
- Northwest Kidney Centers screening responses received January 31, 2017
- DaVita Healthcare Partners, Inc. public comments received April 17, 2017
- Northwest Kidney Centers public comments received April 17, 2017
- DaVita Healthcare Partners, Inc. rebuttal comments received May 16, 2017
- Northwest Kidney Centers rebuttal comments received May 17, 2017
- Years 2010 through 2015 historical kidney dialysis data obtained from the Northwest Renal Network
- Year end 2015 Northwest Renal Network December 2015 (4th Quarter) Utilization Data released February 5, 2016
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- DaVita website <u>www.davita.com</u>
- Northwest Kidney Centers website <u>www.nwkidney.org</u>
- Northwest Renal Network website <u>www.nwrn.org</u>
- Centers for Medicare and Medicaid website <u>www.medicare.gov/dialysisfacilitycompare</u>
- Certificate of Need historical files

CONCLUSIONS

DaVita Healthcare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita Healthcare Partners, Inc. proposing to establish a six station kidney dialysis center in the city of Wapato within Yakima County ESRD 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 construction of a new six station dialysis center in the city of Wapato within Yakima County ESRD planning area. At project completion, the dialysis center is approved to certify and operate six dialysis stations. Services to be provided at DaVita Wapato Dialysis Center include in-center hemodialysis, training and support for peritoneal dialysis, emergency backup for other dialysis, hemodialysis treatment shifts beginning after 5:00 p.m., a permanent bed station, and a dedicated isolation/private room. A breakdown of the approved three stations is shown below:

Davita wapato Diarysis v	
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	4
Total	6

DaVita Wapato Dialysis Center

Conditions:

- 1. DaVita Healthcare Partners, Inc. agrees with the project description as stated above. DaVita Healthcare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Prior to providing services, DaVita Healthcare Partners, Inc. will provide an executed copy of the medical director agreement for the department's review and approval. The executed medical director agreement must be consistent with the draft provided in the application.
- 3. Prior to commencement DaVita Healthcare Partners, Inc. will provide an executed copy the lease agreement for the department's review and approval. The executed lease agreement must be consistent with the draft provided in the application.
- 4. Prior to providing services at DaVita Wapato Dialysis Center, DaVita Healthcare Partners, Inc. will provide an executed copy of the patient transfer agreement for the department's review and approval. The executed patient transfer agreement must be consistent with the draft provided in the application.

Approved Costs:

The total cost of this project is \$1,929,681. Of this amount, \$1,819,681 is DaVita Healthcare Partners, Inc. approved cost. The remaining \$110,000 is the amount the landlord will incur.

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers proposing to establish a six station dialysis facility in city of Yakima within Yakima County ESRD planning area is not consistent with applicable criteria and a Certificate of Need is denied.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

DaVita Healthcare Partners, Inc.

Based on the source information reviewed and agreement to the conditions identified in this "conclusion" section of this evaluation, the department concludes that DaVita Healthcare Partners, Inc. has met the need criteria in WAC 246-310-210 and the applicable kidney disease treatment facility criteria in WAC 246-310-280; WAC 246-310-282; and WAC 246-310-284.

Northwest Kidney Centers

Based on the source information reviewed the department concludes that Northwest Kidney Centers has met the need criteria in WAC 246-310-210 and the applicable kidney disease treatment facility criteria in WAC 246-310-280; WAC 246-310-282; and WAC 246-310-284.

(1) <u>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.</u> WAC 246-310-284 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 applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

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

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network (NWRN).⁴

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.⁵

In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five years), 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.

⁴ 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]

⁵ 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 2015.

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 246-310-284(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. 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, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

WAC 246-310-280(9) identifies the 57 separate ESRD planning areas for the state. Yakima County is a single planning area. DaVita and NKC propose to add six new dialysis stations to the existing in capacity Yakima County. The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. The year 2016 numeric methodology was posted March 2016 and will be used for evaluating this project.

DaVita Healthcare Partners, Inc. – Numeric Methodology

- The project proposes to establish a new (6) station dialysis center in the Yakima County ESRD Planning Area in order to improve patient access where it is most needed in the geography. DaVita Yakima Dialysis and Union Gap Dialysis have historically been the most heavily utilized facilities, serving over half of the dialysis patients that currently treat in the planning area. Union Gap was operating at 4.17 utilization as of the March 31 Network 16 data, but has since reached 4.92 with continued expected growth. WAC criteria require that all facilities be above 80% utilization prior to a provider becoming eligible to apply for that need. DaVita therefore withdrew its application to relocate stations from Mt. Adams in order to apply to establish a new six station facility that could meet the priority need in the northern end of the planning area without compromising Mt. Adam's ability to treat additional patients in Sunnyside.
- The target population includes current and future residents throughout the Yakima County ESRD Planning Area who require chronic dialysis services. Appendix 8 provides the five year population forecast produced by the Nielson Company for Yakima County ESRD Planning Area as well as the State of Washington. Table 9 shows population for the Yakima County ESRD Planning Area. As Table 9 shows, the Yakima County ESRD Planning Area population base is forecast to grow at a lower rate than the overall state population from 2016 through 2021 at an annual rate of 0.75%

Table 9 (Reproduced)Table 9Population Estimate and Forecasts							
Area	2010	2016	Annual Growth	2021 Projection	Projected Annual Growth		
Washington Sate	6,724,540	7,155,334	1.04%	7,577,197	1.15%		
Yakima County243,919251,5360.51%261,148Washington State data from OFM; Yakima Co. data from The Nielson OFM; Yakima Co. data from OFM; Yakima Co. data from Co. data							

• As Table 10 illustrates, the ESRD prevalence rate is higher in Yakima County ESRD Planning than the State as a whole. DaVita projects that both general population and ESRD population will continue to grow in Yakima county such that there will be sufficient ESRD population to support the 5-year in-center projection showing full utilization of the new Wapato Dialysis Center in years three through five, as indicated on the pro forma. [Source: Application: Page 16]

Table 10 (Reproduced)Table 10DaVita Wapato Dialysis CenterIn-Center Hemodialysis Prevalence Rates (NWRN)								
Area	June 30, 2016 H.D. Patients	2016 Population	Rate per 100,000					
Washington Sate	5,998	7,155,334	83.83					
Yakima County	287	251,536	114.10					
State Population Data Nielson Company ES		~ 1	0					

- Table 10 presents Wapato Dialysis utilization based on the projected number of patients in Yakima County ESRD Planning Area. 2021 is the third complete year of operation after project commencement and the utilization rate exceeds 80% of the 3-shift utilization standard of 4.8 patients per station. Year1 projection assumes a conservative figure of 25 patients which approximately captures the number of expected new ESRD patients to Yakima in 2019. We then apply the 3 Year growth rate of 7.15% to forecast through 2023. In-center treatments are based on an assumption of 3 treatments per week per patient for 52 weeks with a 5% allowance for missed treatments.
- Table 12 presents the required 5-year historical volume for Yakima County.

Table 12 (Reproduced)							
Table 12							
ing Area	In-Cente	e <mark>r Hemod</mark> i	ialysis Pati	ients By Y	'ear		
2010	2011	2012	2013	2014	2015		
•	•		•				
214	235	213	224	247	262		
214	235	213	224	247	262		
	2010	ing Area In-Cente 2010 2011 214 235	Table 12 ing Area In-Center Hemody 2010 2011 2012 214 235 213	Table 12 ing Area In-Center Hemodialysis Pate 2010 2011 2012 2013 214 235 213 224	Table 12 ing Area In-Center Hemodialysis Patients By Y 2010 2011 2012 2013 2014 214 235 213 224 247		

- Table 14 projects dialysis utilization for four years after the last calendar year when yearend in-center patient data by planning area is available prior to the beginning of the filling period. [Source: Application: Page 16]
- This fourth future year is deemed to be projection year for identifying the maximum number of stations that can be approved within a planning area under the state methodology. This methodology is based on the following:
- Performing a 4-year future regression of 5-year historical data, described in WAC 246-310-284 using either the linear or non-linear regression methodology determined in the prior table to determine total patient volume. In this case, the linear method is selected two of the past five-years experienced less than 6% growth.
- Applying the patient to station conversion factor –either 4.8 patients per station for urban areas or 3.2 patients per station for designated rural counties –to determine total station need in the area. In this case, the 4.8 patients per station utilization is applied.
- Subtracting existing stations for dialysis facilities in the planning area from total station need and rounding up to the next whole number of stations to determine net station need.

Table 14 (Reproduced) Table 14 Projected Station Need for the Planning Area by Year						
	Year 1	Year 2	Year 3	Year 4		
Yakima	2018	2017	2018	2019		
Hemodialysis Patients	262.60	271.40	280.20	289		
Patients Station Conversion Factor	4.8	4.8	4.8	4.8		
Total Station Need	54.71	56.54	58.38	60.21		
Rounded to the next whole number	55	57	59	61		
Existing Stations	55	55	55	55		
				-		
Net Station Need	0	-2	-4	-6		

T 11 14 (D

7

• The addition of 6 stations will address the needs of a rapidly growing area. The 2021 through 2023 utilization, as indicated in the pro forma, based on continuation of historical growth patterns from 2011 to 2015. [Source: Application: Pages 17 - 18]

Public Comments None

Rebuttal Comments
None

Department Evaluation

DaVita submitted a methodology for Yakima County ESRD planning area as part of its application and it shows need. Based on the calculation of the annual growth rate of the planning area, the department used linear regression to project the need for Yakima County ESRD planning area. The department 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 department's methodology showed a need for six new stations in the planning area by the end of year 2019. The department's methodology is included in this evaluation as Attachment A.

The department concludes DaVita meet this numeric methodology standard.

Northwest Kidney Centers – Numeric Methodology

• The methodology in WAC identified a need for 6 additional stations in Yakima County and growth in the number of patients at the existing facilities such that the four station approved earlier in the year (DaVita Union Gap) are already operating above 4.8 patients per station utilization target. NKC attributed part of the need to the high prevalence rates of

hemodialysis in Yakima County. As Table 1B demonstrates, the Yakima County prevalence rate is 40% higher than the statewide rate. And, in the first 9 months of 2016, the number of dialysis patients in Yakima County has grown by nearly 10% (+25 patients).

• Using available population and prevalence data (the number of hemodialysis patients) Table 7 demonstrates the prevalence rate in Yakima County.

Yaki	Yakima County and WA State Hemodialysis Prevalence Rates, 2015					
	12/31/2015 HD Patient	HD Prevalence Rate				
Yakima WA State	287 5,766	250,185 7,061,410	114.71 81.66			

Table 1B (Reproduced)	
Yakima County and WA State Hemodialysis Prevalence Rates, 201	5

[Source: OFM November 2015 Population Estimates (1 year age increments) for WA State and Nielson Claritas for Yakima County. Northwest Renal Network Modality Reports, 12/31/2015 for Hemodialysis patient census]

- "As noted in response to earlier questions, NKC Yakima Kidney Center would be a new entrant in the Yakima County planning area. NKC Kidney Center will improve access and choice for residents of Yakima County by providing a new location and provider for dialysis service. [Source: Application Page 15]
- The new facility will improve access to patients in the City of Yakima as well as those within easy access to the surrounding communities. Today all patients needing treatments only have one choice (DaVita). This proposed center will reduce time for patients, provide options in this market and make treatments more convenient.
- A failure to add stations in the planning area will result in a continuing lack of access to treatments and limited schedule options as a result of the current DaVita centers being full. The model shows that the 6 stations are needed in this community. [Source: Application Page 16]
- Table 3 details the year end number of in-center hemodialysis patients in Yakima. Table 3 demonstrates, growth did not exceed six percent in four previous annual change calculations. As a result, a linear regression is to be used to project station need.

Table 3 (Reproduced)Yakima Year-End Residents In-Center Hemodialysis Patients and Annual Rateof Change from Prior Year 2010-2015

Year	2010	2011	2012	2013	2014	2015
Number of Patients	214	235	213	224	247	262
Rate of Change from Prior Year		9.81%	-9.36%	5.16	10.27%	6.07%

[Source: Application Page 18]

• Table 4 details the number of projected in-center in Yakima in the Year 2016 -2019.

Table 4 (Reproduced)

Projected Year-End Resident In-Center Hemodialysis Patients Linear Projection

Year	2016	2017	2018	2019
Number of Patients	262.6	271.4	280.2	289.0

- Per WAC, the projection year is 2019. For Yakima, the appropriate resident in-center patient per station number is 4.8. Assuming 289 patients, 61 stations are calculated as needed in 2019.
- Table 5 demonstrates that there are currently 55CN approved and/or operational stations in Yakima which, when total projected need is subtracted, leaves a net need for six stations in 2019. [Source: Application Page 19]

Analysis of Current Supply vs. Net Station Need				
	Stations			
DaVita Mt. Adams	14			
DaVita Union Gap	12			
DaVita Yakima	21			
DaVita Zillah	8			
Total Supply	55			
2019 Projected Need	61			
Net Station Need	6			

Table 5 (Reproduced)			
Analysis of Current Supply vs. Net Station Need			
	Stations		

In addition to the above steps, WAC 246-310-284 requires that certain utilization levels be attained by existing providers prior to expanding and that the applicant demonstrate its ability to achieve optimal occupancy within 3 years. The specific standards applicable to our Yakima County proposal are delineated below.

Further, to comply with this subcriterion, NKC provided the public comments summarized below.

Public Comments

Northwest Kidney Centers provided the following public comment. [Source: Received April 17, 2017 pages 1, 2, 5 and 6]

- "On October 31, 2016 both DV and Northwest Kidney Centers (NKC) filed letters of intent to establish new six station dialysis facilities in Yakima County. On November 14, 2016, the 45th day after the September screening letter, DV withdrew its Q3 Wapato application, thus allowing both NKC and DV to file new applications (consistent with the October 2016 letters of intent) on November 30, 2016".
- "The publication of the December 31, 2016 number (available on February 15, 2017) demonstrates that station need has grown exponentially and is now projected to 21 or 3.5 times the current need. Data shows that Yakima County hemodialysis patients grew by 11% between 2015 and 2016 (+29 patients)."
- "Adding only six more stations to the planning area will not be sufficient to meet the needs of the Yakima County dialysis planning area population. NKC is concerned of the inability to address the need issue until at least three to four years from now."
- "NKC is also very concerned about access for dialysis patients and in particular Yakima where health inequalities and social determinants make access more challenging. In the

highly unlikely event that the Program finds both applicants meet all criteria in 246-310-210 through 240, we believe the Program should consider the latitude it is afforded in WAC 246-310-287."

• "Given that both applicants are proposing new facilities, and station need has grown significantly, the exception language contained in WAC 246-310-287 allows the Program to approve additional stations beyond the current need."

Rebuttal Comment

DaVita provided the following rebuttal comments. [Source: Received May 17, 217, page 1]

- "NKC points out that DaVita filed an application to relocate stations in the planning area, but it then drew the application. It is not clear why NKC raises the point. DaVita assumes it is to suggest that DaVita was somehow holding up need in Yakima. DaVita withdrew its application so that it can apply to add more stations in the planning area. NKC in contrast recently help up 12-station need in King 11 for at least three years until its relocated stations to Federal Way are operational and at utilization."
- In other words, NKC is accusing DaVita of doing what it has done in King #11 planning area. NKC gamed the system for protective gain and the planning area will be underserved for the foreseeable future.

Department Evaluation

NKC's stated need data that became available after November 2017 ESRD application submission period show that more stations are needed in Yakima County ESRD planning area. NKC wants the department to use the latitude granted it under WAC 246-310-287 and approve more stations than the six stations projected when both DaVita and NKC submitted their applications.

WAC 246-310-287 states the following:

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

- (1) All other applicable review criteria and standards have been met; and
- (2) One or more of the following have been met:

(a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or

(b) Existing dialysis stations in the dialysis facility are operating at six patients per station. Data used to make this calculation must be from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period; or

(c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and

(3) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing."

NKC did not provide specific documentation to support any of the criteria above. Absent any documentation, the department cannot take any action.

NKC submitted the department's posted methodology for Yakima County ESRD planning area as part of the application. No other methodology was produced. Based on the calculation of the annual growth rate of the planning area, the department used linear regression to project the need for the ESRD King #11 planning area. The department 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 department's methodology showed a need for six new stations in the planning area by the end of year 2019. The department's methodology is included in this evaluation as Attachment A. The department concludes NKC **meet this numeric methodology standard.**

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis station need.⁶ The department uses the standards in WAC 246-310-284(5) and WAC 246-310-284(6) for this determination.

WAC 246-310-284(5)

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

DaVita Healthcare Partners, Inc.

• The four existing providers of services for dialysis patients in the Yakima County ESRD Planning area are DaVita Yakima Dialysis, Union Gap Dialysis, Zillah Dialysis, and Mt. Adams Dialysis. Table 15 demonstrates that they are all operating at above the 4.8 utilization requirement, based on NWRN June 30 data. [Source: Application Page 19]

Table 15 (Reproduced)Analysis of Current Supply vs. Net Station Need					
T Existing Latest Quarterly	able 15	f Existing Station	la l		
Reporting Period		<u> </u>	06/30/16		
Existing Dialysis Facilities	Approved	Patients	Patients per station		
DVA MT ADAMS Sunnyside 502514	14	73	5.21		
DVA UNION GAP 502543	12	59	4.92		
DVA YAKIMA 502541	21	111	5.29		
DVA ZILLAH 502571	8	45	5.63		

Public Comment

None

⁶ WAC 246-310-210(1)(b)

Rebuttal Comment None

Department Evaluation

WAC 246-310-284(5) requires the department to use the most recent quarterly modality report from the NWRN to calculate the number of patients per station at each of the planning area's dialysis facilities. This application was submitted during the 2016 ESRD concurrent review Cycle 4. The first day of the application submittal period was November 1, 2016. The most recent quarterly modality report as of June 30, 2016 was December 31, 2015 (4th Quarter) posted by the NWRN on February 5, 2016. As shown in DaVita's reproduced table 15 above, DaVita is the only kidney dialysis provider located in Yakima County ESRD planning area. The department's methodology shows that all four DaVita facilities located in the planning area are operating above the 4.8 patients per station. The department concludes this criterion is met.

Northwest Kidney Centers

Per WAC, the required in-center patients per station in Yakima County is 4.8. Northwest Renal Network data for the quarter ending June 30, 2016 (summarized in Table 6) demonstrates that the existing facility are currently operating at or above 4.8 patients per station. [Source: Application Page 20]

Tuble 0 (Reproduced)					
Operating Ratio/Standard of Use as Applied to Peirce 1 Facilities					
Ор	Operating Ratio/Standard to Use: 4.8 Patients per Stations				
Facility	Number of Patients Per Most	Number of	Current		
	Patients/Station				
DaVita Mt. Adams	74	14	5.29		

60

111

42

Table 6 (Reproduced)

12

21

8

5.00

5.29

5.63

Public Comment None

DaVita Yakima

DaVita Zillah

DaVita Union Gap

Rebuttal Comment None

Department Evaluation

WAC 246-310-284(5) requires the department use the most recent quarterly modality report from the NWRN to calculate the number of patients per station at each of the planning area's dialysis facilities. This application was submitted during the 2016 ESRD concurrent review Cycle 4. The first day of the application submittal period was November 1, 2016. The most recent quarterly modality report as of November 1, 2016 was December 31, 2015 (4th Quarter) posted by the NWRN on February 5, 2016. DaVita is the only kidney dialysis provider in Yakima County ESRD planning area and all four DaVita facilities are operating above 4.8 patient per station. The department concludes this criterion is met.

WAC 246-310-284(6)

By the third full year of operation, new in-center kidney dialysis stations must reasonably project to be operating at:

(a) 4.8 in-center patients per station for those facilities required to operate at 4.8 in-center patients as identified in subsection (5) of this section; or

(b) 3.2 in-center patients per station for those facilities required to operate at 3.2 in-center patients as identified in subsection (5) of this section.

DaVita Healthcare Partners, Inc.

- "The Wapato Dialysis Center will achieve projected patients volumes without an adverse impact on other dialysis facilities that serve the ESRD planning area." [Source: Application Page 12]
- "Table 11 presents Wapato Dialysis utilization based on the projected number of patients in Yakima County ESRD Planning Area. 2021 is the third complete year of operation after project commencement and the utilization rate exceeds 80% of the 3-shift utilization standard of 4.8 patients per station". [Source: Application Page 17]
- DOH staff reproduction of DaVita projected year 2021 patient volume from DaVita projected operating statement (pro forma) [Source: Application Appendix 9]

	Table 1 DaVita Wapato Utilization year 2021					
	FY 1 FY 2- FY 3- FY 4 2019 2020 2021 202					
# of Stations	6	6	6	6		
# of Treatments ⁷	2,001	4,133	4,483	4,851		
# of Patients ⁸	27	29	32	34		
Utilization Rate	4.50	4.83	5.33	5.66		

Public Comments None

Rebuttal Comments
None

Department Evaluation

The patients per station standard for Yakima County planning area is 4.8 in-center patients per approved station. DaVita Wapato third full year of operation is 2021. DaVita projected the facility would have 5.33 patients per station by that time. The department concludes the standard **is met.**

⁷ Includes in-center and home dialysis patients

⁸ Includes in-center and home dialysis patients

Northwest Kidney Centers

• As Table 7 demonstrates, with a total of 6 stations, and our estimated patient volume, NKC Yakima Kidney Center will operate in excess of 4.8 in-center patients per station by the 3rd full year of operation (FYE 2022)

	Trojecied NKC Takima Occupancy, FTE 2019-2022				
		6 Stations			
Year	Full or partial Year	Projected Patients	Patients/station		
FYE 6/30/2019	Partial	10	1.67		
FYE 6/30/2020	Full	18	3.00		
FYE 6/30/2021	Full	24	4.00		
FYE 6/30/2022	Full	30	5.00		

Table 7 (Reproduced)Projected NKC Yakima Occupancy, FYE 2019-2022

[Source: Application Page 21]

The department received public comments from DaVita related NKC Yakima third year patients volume. The summary of the comments are provided below.

Public Comments

DaVita provided the following comments. [Source: Received on April 17, 2017, Pages 6 and 7]

- NKC stated that its facility would open in 2019 and the facility third full year of operation will be 2022. The department requires that by the third full year of operation, new facilities should be operating at 4.8 patients per station in Yakima County.⁹ NKC's application does not satisfy the requirement. NKCs projected it would have 30 patients and 6 stations or 5.0 patients per station¹⁰ however, its pro forma shows it has miscalculated its third year utilization.
- The 30 patients in the fiscal year ending 6/30/22 is NKC's yearend patient count as the last date of NKC's fiscal year¹¹. The average patient count during that year would be 27 the midpoint between NKC's projected 24 patients as of 06/30/21 and NKC's projected 30 patients as of 06/30/22. This means that NKC's actual projected utilization during year 3 is only 4.5 patient per station (27/6) and NKC's application fails WAC 246-310-284(6)¹²

Rebuttal Comments

Northwest Kidney Centers provided rebuttal comments, below. [Source: Received May 17, 2017, page 4]

• NKC's utilization and proforma financials shows that it would meet the 4.8 utilization standard by the 3rd full year of operation. NKC's application noted that the facility will open in February 2019 with 10 patients. NKC's third year of operation is FYE2022 at which time

⁹ WAC 246-310-284(6)(a)

¹⁰ NKC's application page 10

¹¹ NKC's application p. 132; NKC's Screening Responses (providing revise pro forma)

¹² NKC also miscalculated utilization at two of DaVita's existing facilities. On page 20 of its application NKC stated that the utilization at Union Gap is 5.0 and utilization at Mt. Adams is 5.29. The correct figures are 4.92 and 5.21 respectively. It is also unclear whether these miscalculations affect other figures or assumptions in NKC's application.

it would have at least 30 patients. NKC provided 3.5 years of financial information as is typically required by the CN program.

Department Evaluation

The department noted that NKC operates using a fiscal year. For example, a typical NKC's fiscal year ending would be the end of June and a new fiscal year would begin July 1. The proforma submitted by NKC projected 30 patients at the end of fiscal year 6/30/22 and using this information, NKC would serve 5.00 patients per station based on the information provided in its proforma. The department disagrees with DaVita's characterization that the number of patients in NKC's beginning fiscal year and the end varies because of midpoint data. DaVita did not say why the midpoint data is not the same as it was at the beginning of that fiscal year. The patients per station standard for Yakima County ESRD planning area is 4.8 in-center patients per approved station. The third full year for the NKC Yakima Kidney Center is FYE 2022 and it projected the facility would have 5.00 patients per station by that time. The department concludes **the standard is met.**

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

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

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

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

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 do not have private insurance, do not qualify for Medicare, do not qualify for Medicaid or are under insured. With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear.

DaVita Healthcare Partners, Inc.

• Appendix 14 includes a copy of the admission patient financial evaluation, and patient involuntary transfer policies which documents that access is not denied due to indigence,

racial or ethnic identify, gender or handicapped status. Further, DaVita is for-profit organization and contributes tax revenues to support a broad array of social services statewide. [Source: Application Page 19]

• "Source of patient's revenue by type of payor are included in Table 4. Source of patient revenue outlined by percentage of patients per payor are included in Table 5". [Source: Application Page 12]

Tables 4 and 5 (Reproduced)					
Table	4		Table 5		
DaVita Compo	DaVita Company-Wide		DaVita Company-Wide		
Sources of Revenue			Sources of Revenue		
Type of Payor			Percentage of Patients per Paye		
Revenue	% of		Revenue % of		
Source	Revenue		Source Patients		
Medicare	56.7%		78.9%		
Medicaid/State	4.5%		7.7%		
Insurance/HMO	38.8%		13.4%		
Total	100%		1	00%	

Tables 4 and 5 (Reproduced)

The department received public comments from NKC related to DaVita's source of revenue and payor source. Those comments would be addressed in the financial feasibility section of this evaluation.

Public Comments

NKC public comment are addressed in the financial feasibility section.

Rebuttal Comments

DaVita's rebuttal comments are addressed under the financial feasibility section of this evaluation.

Department Evaluation

The department does not have an adopted standard on what constitutes an unreasonable impact on charges for healthcare services. Medicare and Medicaid patients typically make up the largest percentage of patients served 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 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 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. Based on the source information reviewed, the department concludes that all residents of the service area would have access to the healthcare services provided at DaVita Wapato. This sub-criterion is met.

Northwest Kidney Centers

- "NKC has a long established history of developing and providing services that meet the healthcare needs of the communities it serves. NKC Yakima Kidney Center, as with all other NKC facilities, will provide services to all regardless of race, color, ethnic origin, religious belief, sex, age or lack of ability to pay".
- "Copies of the admission policies and procedures and the charity care policy for the proposed NKC Yakima Kidney Center are included in Exhibit 13." [Source: Application Page 22]
- The proposed sources of revenue, by payer, for NKC Yakima Kidney Center were based on the three closet NKC facilities (Enumclaw, Auburn and Snoqualmie Ridge)

Payer	% Patients	% Net Revenue
Medicare	71.9%	45.4%
Medicaid	14.4%	8.5%
Other	13.7%	46.1%
Total	100.0%	100.0%"
		[Source: Application Page 11]

Public Comments None

Rebuttal Comments
None

Department Evaluation

The Admission Policy provided by NKC outlines the current process/criteria used to admit patients for treatment and ensures that patients will receive appropriate care at any of its dialysis centers. NKC's Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color religion, sex, national origin, or age. This same Admission Policy would be used at the NKC Federal Way facility.

NKC currently provides dialysis services to Medicare and Medicaid eligible patients at its dialysis centers. NKC intends to maintain this status for patients receiving treatment at the NKC Yakima Kidney Center. NKC projects that 86.3% of the facility's patients will be on Medicare or Medicaid. A review of the anticipated revenue shows the facility expects to receive 53.9% of its revenue from Medicare and Medicaid reimbursements. [Source: Application Page 11 and Screening responses received 31, 2017, Attachment 3]

NKC submitted its "Financial Services-Patient Funding Sources Policy" or charity care policy used by all of the dialysis centers owned, operated, or managed by NKC. This same policy would be used at the NKC Yakima Kidney Center. The policy outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. In addition, the pro forma operating statement for the NKC Yakima Kidney Center includes a 'charity care' line item. Based on the source information reviewed, the department concludes that all residents of the service area would have access to the healthcare services provided at NKC Yakima Kidney Center. **This sub-criterion is met.**

(3) <u>The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.</u>

 (a) <u>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.</u>

Department Evaluation

This criterion is not applicable to this application.

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

Department Evaluation

This criterion is not applicable to this application.

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

Department Evaluation

This criterion is not applicable to this application.

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

Department Evaluation

This criterion is not applicable to this application.

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

Department Evaluation

This criterion is not applicable to this application.

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

Department Evaluation

This criterion is not applicable to this application.

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

DaVita Healthcare Partners, Inc.

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "conclusion" section of this evaluation, the department concludes that the DaVita Healthcare Partners, Inc. project has met the financial feasibility criteria in WAC 246-310-220.

Northwest Kidney Centers

Based on the source information reviewed the department concludes that the Northwest Kidney Centers project has met the financial feasibility criteria in WAC 246-310-220.

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

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

DaVita Healthcare Partners

- The Wapato Dialysis Center Detailed Operating Statement (Pro Forma) is included in Appendix 9. No existing facility is expected to lose volume or market share below Certificate of Need standards as a results of this project. The proposed facility will operate at utilization levels consistent with required utilization levels. Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increase charges for services within the ESRD planning area.
- DOH summary of detailed projected operating statement (Pro Forma) Appendix 9

*					
	Partial Year 2018	Full Year 1 - 2020	Full Year 2 - 2021	Full Year 3 - 2022	
# of Stations	6	6	6	6	
# of Total Treatments [1]	2,001	4,134	4,482	4,850	
# of Patients [2]	27	29	32	34	
Total Net Revenue [1, 2]	\$1,115,144	\$2.304.115	\$356,001	\$384,229	
Total Salaries, Wages & Benefits	\$296,548	\$320,346	\$356,001	\$384,229	
Total other Operating Expenses [1, 2; 3]	\$652,808	\$975,117	\$1,039,878	\$1,109,516	
Total Direct Expenses	\$949,356	\$1,295,463	\$1,395,880	\$1,493,745	
Pre-G&A EBIT	\$165,788	\$1,008,652	\$1,102,469	\$1,209,772	
EBIT	\$129,776	\$934,243	\$1,021,787	\$1,216,662	

Table 2Summary of DaVita Wapato projectedRevenue and Expense Statement

1] Includes both in-center and home dialysis patients; [2] charity care; [3] includes bad debt and allocated costs.

"Table 16 provides the expected sources of revenue for the Wapato Dialysis Center by Payor *Category*". [Source: Application Page 21]

10000 10	(Itopi ounceu)	
DaVita Wapato Dialysis	Center Revenue Source	ce
Table	e 16	
DaVita Com	pany-Wide	
Sources of Rev	enue by Payor	
Revenue	0/ of Dougram	
Source	% of Revenue	
Medicare	56.7%	
Medicaid/State	4.5%	
Insurance/HMO	38.8%	
Total	100%	

Table 16 (Reproduced) by Payer

- "The Wapato Dialysis Center executed lease documentation is included in Appendix 15". [Source: Application Page 15 and Appendix 15]
- "Appendix 3 provides a copy of the DRAFT Medical Director agreement". [Source: Application Page 8 and Appendix 3]

The department received comments from NKC related to DaVita's payor mix assumptions. The summary of those comments are below.

Public Comments

NKC provided the following comments. [Source: Received April 17, 2017, Pages 3 and 4]

• In order to determine whether each project will have an unreasonable impact on cost or charges (WAC 246-310-220 (2)), the Program must determine that assumptions used by the applicant are reasonable. NKC reviewed the 2016 evaluation of DV's CN application to expand its Union Gap facility by four stations. Table 2 calculates and compares the net revenue per treatment for both the Wapato new facility and the Union Gap expansion. We used the Union Gap application because it was a recent application for the same planning area. For comparison, Table 2 also includes the payer mix that NKC used

Source	Sources of Revenue by Payor Union Gap Application ¹³	Sources of Revenue by Payor Wapato Application ¹⁴	Percent Difference (Union Gap vs. Wapato)	NKC Yakima Projected revenue by payor
Medicare	33.6%	56.7%	+68.75%	42.55
Medicaid/State	3.0%	4.5%	+50.0%	10.6%
Insurance/HMO	63.4%	38.8%	-38.8%	46.0%
Total	100.0%	100.0%		100.0%

 Table 2 (Reproduced)

 DaVita Payer Mix: Wapato New Facility vs. Union Gap Facility Expansion

• This difference in payer mix directly impacts the costs and charges for dialysis services. Table 3 compares the average net revenue per treatment between the DV Wapato application, the DV Union Gap Expansion and the current NKC Yakima application. As Table 3 indicates, the average net revenue per treatment is significantly different between the two DV applications for the same planning area and 1.4 to 2.3 times higher than NKC's proposed Yakima County facility. This difference is likely due, almost exclusively, to DV's payer mix assumption-for which they provide absolutely no data to substantiate its reasonableness.

Table 3 (Reproduced)Net Revenue Per Treatment: NKC Yakima, DV Wapato and
DV Union Gap, 3rd Full Year of Operation

	J - I					
Source	NKC -Yakima	DV Wapato	DV Union Gap			
Net Revenue (3 rd Full year)	2,107,174	2,703,517	9,205,272			
Treatment (Total)	4,884	4,851	9,188			
Net Revenue/Treatment	431.44	613,60	1,001.88			

Source: NKC Updated Pro forma (Screening responses), DaVita Wapato (Appendix 9) and DaVita Union Gap CN Evaluation, Table 4, p. 10

- As Table 3 details, DV's proposed payer mix directly impacts revenue. Net revenue per treatment for the proposed Wapato facility is 61 % lower than the DV Union Gap net revenue per treatment for the same planning area while NKC's anywhere from 43% to 67% lower than either of those of DY.
- Given the inconsistency in the DV Wapato application with its own previous Union Gap application, the Program lacks sufficient information to determine the financial feasibility of the DV Wapato project: either DV's charges are excessive and will result in impacts that are unreasonable (especially in comparison to its competitor), or DV has simply misstated them, and the Program cannot determine the feasibility of the DV Wapato CN application.

¹³ DaVita Certificate of Need Application for new 6 station Wapato Facility, November 2016, Table 4 and 5 p. 12.

¹⁴ Certificate of Need Program Evaluation of DaVita Union Gap 4 station expansion, February 2016, p. 11

Rebuttal Comments

DaVita provided the following rebuttal. [Source: Received May 16, 2016, page 2]

- As the Program knows well from previous DaVita applications, DaVita projects revenue for a new facility by multiplying the average net revenue per treatment for the existing DaVita facilities in the appropriate region by the projected number of treatments at the new facility. Here, we used the average net revenue per treatment for DaVita's existing facilities in Eastern Washington.
- DaVita provides its company-wide payor mix in new-facility applications, because there is no historical data for the proposed facility, but this is not used in the pro forma. The pro forma is based on the actual net revenue per treatment in the region, not the payor mix for the company as a whole.
- The Department has repeatedly determined that this is an acceptable approach. There is no difference between how the pro forma was prepared for this application and how pro formas have been prepared for other new DaVita facilities that the Department has approved.

Department Evaluation

DaVita currently provides dialysis services to Medicare and Medicaid eligible patients at its dialysis centers. DaVita intends to maintain this status for patients receiving treatment at the DaVita Wapato. DaVita projected that 86.6% of the facility's patients will be on Medicare or Medicaid. A review of the anticipated revenue shows the facility expects to receive 61.2 % of its revenue from Medicare and Medicaid reimbursements. [Source: Application Pages 12, 21, and Appendix 9]

DaVita submitted its "Patient Financial Evaluation Policy " or charity care policy used by all of the dialysis centers owned, operated, or managed by DaVita. This same policy would be used at the DaVita Wapato. The policy outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. In addition, the pro forma operating statement for the DaVita Wapato includes a 'charity care' line item.

Related to the public comments provided by NKC regarding DaVita's payor sources and its sources of revenue, the department noted that both applicant's percentages of expected patients and the revenue percentages are comparable. Both applicants expect that majority of their patients and the sources of revenue would be Medicare. Summarized in Table 3 below is the department comparison of both applicants expected patients and sources of revenue.

	DaVita		NF	КС
Revenue Source	% of Patients per Payor	% of Revenue	% of Patients	% Net Revenue
Medicare	78.9%	56.7%	71.9%	45.4%
Medicaid	7.7%	4.5%	14.4%	8.5%
Insurance/Other	13.4%	38.8%	13.7%	46.1%
Total	100%	100%	100%	100%

 Table 3

 Department Comparison of DaVita and NKC Payor Sources and Percentages of Patients by Source of Revenue

As noted in Table 3 above, the explanation provided by DaVita about its payor mix and what data was used for its DaVita Wapato project is reasonable. Moreover, when the two applicant's payor mix are compared side by side, it shows a slight difference which is not significant. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for healthcare services. Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. As shown in the table above, DaVita's percentage of patients under Medicare is 78.9% and the revenue is 56.7%. For NKC the percentage of patients under Medicare is 71.9% and the revenue is 45.4%.

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 number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate, each facility will receive.

Regarding the applicant's percentages of patients and the revenue expected from commercial insurance and other, DaVita percentage of patients under Insurance/other is 13.4% and the revenue is 38.8%. For NKC the percentage of patients under Insurance/other is 13.7% and the revenue is 46.1%. While the two applicant's expectations about the percentages of patients are similar, the department does not know if the revenue would be the same because 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 for each individual provider.

The department noted that NKC did not provide documentation related to its assertions about DaVita's payer mix assumptions and neither did it provide any data to substantiate the reasonableness of its own payor mix.

DaVita anticipates the proposed six station DaVita Wapato would be operational by July 2018. Under this timeline, year 2019 would be Wapato Dialysis Center first full calendar year of operation and year 2021 the third year of operation. [Source: DaVita Application, page 14] Table 4, reproduced from above, illustrates the projected revenue, expenses, and net income for years 2018 through 2021 for DaVita Wapato.

	Partial Year 2018	Full Year 1- 2019	<u>: Years 2019 - 20</u> Full Year 2- 2020	Full Year 3- 2021
# of Stations	6	6	6	6
# of Treatments ^[1]	2,001	4,133	4,483	4,851
# of Patients ^[1]	27	29	32	34
Utilization Rate ^[1]	4.17	4.50	4.83	5.17
Net Patient Revenue ^[3]	\$1,115,144	\$2,304,115	\$2,498,349	\$2,703,517
Total Expense ^[2]	\$949,356	\$1,295,463	\$1,395,879	\$1,493,745
Net Profit or (Loss) ¹⁵	\$129,775	\$934,243	\$1,021,788	\$1,122,464

Table 4DaVita Wapato Kidney Dialysis CenterProjected Revenue and Expenses Calendar Years 2019 - 2022

[1] Includes in-center patients only; [2] includes bad debt, charity care, and overhead [3] in-center revenue

The 'Net Patient Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes such items as salaries and wages, pharmacy, repair & maintenance, depreciation, and overhead. At DaVita's projected volumes, the six station facility would make a profit in each of the facility's first three full years of operation.

Revenue sources identified by DaVita are comparable with previous dialysis applications the department has reviewed and approved¹⁶. Lease costs for the proposed DaVita Wapato Dialysis Center to be located at 502 W. 1st Street in Wapato, within Yakima County were identified in the executed lease agreement and verified in the pro-forma operating statement.

The draft medical director agreement identified the initial term of the agreement as two years with annual automatic renewals. Compensation for medical director services was identified in the draft medical director agreement. These costs were verified in the pro-forma operating statement.

The department review of DaVita's executed lease agreement and site control documentation shows that rent costs¹⁷ identified in the lease are consistent with the financial information used to prepare DaVita's pro-forma financial income statement projections summarized in Table 4. Based on the information above, the department concludes that the immediate and long-range operating costs of the project can be met. **This sub-criterion is met.**

Northwest Kidney Centers

• DoH summary of NKC's operating revenues and expenses based on Attachment 3 revised Exhibit 15 pro forma financial statement screening responses.

¹⁵ Amounts may not add due to rounding

¹⁶ CN historical files for projects from Franciscan Health System, NKC, and Fresenius Medical Care

¹⁷ DaVita's lease agreement identified costs associated with the property common areas and taxes.

STATISTICS	Implementation Partial Year 6/30/2019	Project Year 1 Ending 6/30/2020	Project Year 2 Ending 6/30/2021	Project Year 3 Ending 6/30/2022
Total Gross Revenues	\$1,55,181	\$5,038,318	\$6,801,729	\$8,313,224
Total Deductions	(\$862,374)	(\$3,761,242)	(\$5,077,677)	(\$6,206,051)
Net Revenues	\$292,807	\$1,277,076	\$1,724,052	\$2,107,173
Total Direct Expenses	\$483,046	\$1,076,919	\$1,335,675	\$1,558,219
Excess of Direct Revenue over				
Direct Expenses	(\$190,239)	\$200,158	\$388,377	\$548,956
Overhead	\$56,777	\$247,634	\$334,305	\$408,595
Net Profit or Loss	(\$247,016)	(\$47,476)	\$54,072	\$140,361

 Table 5

 Summary of NKC Yakima Projected Revenue and Expense Statement

- "Charity Care and Bad Debt are calculated based on the actual experience of the three closet facilities on a per treatment basis". [Source: Screening responses received on January 31, 2017, Page 3, Attachment 3]
- The proposed sources of revenue, by payer, for NKC Yakima Kidney Center were based on the three closet NKC facilities (Enumclaw, Auburn and Snoqualmie Ridge.

Payer	% Patients	% Net Revenue
Medicare	71.9%	45.4%
Medicaid	14.4%	8.5%
Other	13.7%	46.1%
Total	100.0%	100.0%"

[Source: Application, page 30]

- A draft lease agreement between West Valley MOB, LLC ("Landlord") and Northwest Kidney Centers ("Tenant") was provided. [Source: Application, Exhibit 11]
- NKC identified Dr. Bonnie Collins as the medical director for NKC Yakima Kidney Center and provided a draft copy of the medical director agreement. [Source: Application, Exhibit 6]

The department received public comments from DaVita related to NKC proposed project. Those comments are summarized below.

Public Comments

DaVita provided the following comments. [Source: Received on April 17, 2017, Pages 6-7]

- To demonstrate site control for a proposed dialysis facility, the Department requires "clear legal title to the proposed site"; a "lease for at least one year with options to renew for not less than a total of five years"; or a "legally enforceable agreement to give such title or such lease in the event that a Certificate of Need is issued for the proposed project."
- NKC has failed to meet this standard: NKC has provided only a draft lease. The draft includes a number of notes for discussion by the parties and has not been executed. NKC's draft lease is not legally binding or enforceable.

• Additionally, while NKC claims in its application that the facility will be operational by February 1, 2019, there is nothing in its draft lease to show that the as-yet-unconstructed facility will be delivered by that date. While the landlord has an obligation to commence construction on the effective date of the lease and complete it in accordance with a construction schedule attached as an exhibit to the lease, the construction schedule has not been determined in the draft NKC has provided. Additionally, while the landlord is required to deliver the constructed premises within five months after NKC's receipt of a CN, the lease expressly disclaims any liability on the part of the lease and recoup its out-of pocket costs from the landlord."

Rebuttal Comments

NKC provided the following rebuttal. [Source: Received May 17, 2017]

- Consistent with CN requirements NKC provided a draft lease agreement for our selected site that outlined all of the terms and conditions. A draft lease, as long as it includes all terms and conditions, meets the Program's requirement for site control. In fact, NKC provided a draft lease in its recent application proposing to establish a new facility in the King 11 dialysis planning area. This application, with only a draft lease, was approved in February 2017. In the evaluation, the Program concluded:
- 'When draft leases are submitted, if a project is approved, the department attaches a condition requiring the applicant to provide a copy of the final, executed agreement consistent with the draft lease agreement.'
- In addition to refute DV's arguments about the timing of the building construction, included in Attachment 1 is a letter from the landlord stating his commitment to move forward to construct the building immediately upon NKC's award of a CN.
- *Clearly, DV's criticisms of site control are unfounded and must be disregarded.*

Department Evaluation

The department agrees with NKC that when an applicant provides a draft document that outlines all terms, conditions and costs associated with a draft agreement, it has accepted such documents on a conditional bases. The draft agreement provided by NKC in its application, is an example of a draft document that the department accepts based on the understanding that if NKC's application were approved, it would have an attached condition related site control.

NKC anticipates the six station Yakima Kidney Center would be operational by the end of June 2019. NKC operates on a fiscal year (July 1 through June 30) rather than on a calendar year. Table 6, reproduced from above, illustrates the projected revenue, expenses, and net income for partial year 2019 through FY's 2022 for NKC Yakima Kidney Center.

Projected Revenue and Expenses Partial Year 2019 and Fiscal Years 2020 - 2022					
	Partial FY	FY 1-	FY 2-	FY 3-	
	2019	2020	2021	2022	
# of Stations	6	6	6	6	
# of Treatments ^[1]	617	2,664	3,552	4,440	
# of Patients ^[1]	10	18	24	30	
Utilization Rate ^[1]	1.67	3.00	4.00	5.00	
Net Patient Revenue ^[3]	\$292,807	\$1,277,076	\$1,724,052	\$2,107,173	
Total Expense ^[2]	\$483,046	\$1,076,919	\$1,335,675	\$1,558,219	
Net Profit or (Loss) ¹⁸	(\$247,016)	(\$47,476)	\$54,072	\$140,361	

Table 6NKC Yakima Kidney CenterProjected Revenue and Expenses Partial Year 2019 and Fiscal Years 2020 - 2022

[1] Includes in-center patients only; [2] includes bad debt, charity care, and overhead [3] in-center revenue

The 'Net Patient Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes such items as salaries and wages, pharmacy, repair & maintenance, depreciation, and overhead. At NKC's projected volumes, the six station facility would operating at a loss starting in partial year 2019 and FY year 2020 and then it would turn profit in the facility's second and third full years of operation.

Revenue sources identified by NKC are comparable with previous dialysis applications the department has reviewed and approved¹⁹. Lease costs for the proposed NKC Yakima Kidney Center to be located at 1010 South 64th Avenue in Yakima within Yakima County, were identified in the draft lease agreement and verified in the pro-forma operating statement.

The draft medical director agreement identified the initial term of the agreement as one year with annual automatic renewals. Compensation for medical director services was identified in the draft medical director agreement. These costs were verified in the pro-forma operating statement.

Based on the information above, the department concludes that the immediate and long-range operating costs of the project can be met. **This sub-criterion is met.**

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

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

¹⁸ Amounts may not add due to rounding

¹⁹ CN historical files for projects from Franciscan Health System, DaVita Healthcare Partners, and Fresenius Medical Care

DaVita Healthcare Partners, Inc.

- Appendix 7 list the Capital Expenditure required for the project. This will be a new facility in an existing leased structure. As such, there are no acquisition or historical costs associated with the construction of the facility to report to the Department
- As noted earlier, DaVita has constructed, expended, or manages over 2,293 Medicarecertified dialysis community centers throughout the nation, including many operating in the Northwest. DaVita has an extensive history of both constructions costs and capital expenditure trends. Further, DaVita works with an architecture firm to assure that local conditions are taken into account in cost estimating. [Source: Application page 20]
- "Table 1 provides the Projected Cost estimates for the facility".

Table 1		
Wapato Dialysis Center Project Cost Summary		
Expenditure Category	Allocated Project Cost	
Leasehold Improvements	\$1,167,500	
Professional Service Fees	\$162,500	
Fixed & Moveable Equipment's	\$489,681	
Total Direct Project Costs	\$1,819,681	
Landlord Direct Costs		
Hard Costs (Incl. Contractor Fees, Sales and		
B&O Tax)	\$55,000	
Real Estate Commission	\$52,500	
Permitting, A/E, Legal	\$2,500	
Total indirect Project Costs	\$110,000	
Total Capital Expenditure	\$1,929,681	

Table 1 (Reproduced)Estimated Capital Expenditures

Public Comments
None

Rebuttal Comments
None

Department Evaluation

DaVita has a history of developing kidney dialysis facilities within Washington. For this project, DaVita stated that it used average net revenue per treatment of its facilities in eastern Washington to develop the cost estimates. The estimated construction costs are comparable to other kidney dialysis facilities reviewed by the department.

DaVita identified the location of the new dialysis facility as 502 W. 1ST Street, Wapato, Washington 98951. A copy of an executed lease between Wapato Convention, LLC (landlord) and Total Renal Care, Inc. (tenant). The lease identifies the specific facility site, lease costs,

terms, and certain requirements for use of the facility by the tenant. The lease outlines roles and responsibilities of both tenant and landlord.

The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the proposed DaVita Wapato Dialysis Center 86.6 % of the patients are projected to be Medicare and Medicaid. Revenue from these two sources are projected to equal 61.2%. The remaining 38.8% of revenue will come from a variety of sources including private insurance.

CMS has implemented an ESRD Prospective Payment System (PPS). Under this ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider.

Based on the department's understanding of how kidney dialysis facilities are reimbursed for their services, the department concludes this project is not expected to have an unreasonable impact on the costs and charges of health services. **This sub-criterion is met.**

Northwest Kidney Centers

- "Northwest Kidney Centers has extensive experience in the design, construction and equipping of dialysis facilities. Northwest Kidney Centers has based the construction costs on its recent projects when creating smaller centers like Enumclaw Kidney Center as well larger ones like Kirkland Center".
- "Northwest Kidney Centers proposes to design this six station unit to maximize cost effective options for resources utilization. We will not build a water treatment room. Instead our plan is to use a portable Reserve Osmosis (RO) unit that uses heat sterilization".
- "The equipment we will use: Our standard Evolution Braun machine with Marcor heat disinfection RO's. The advantage of heat disinfection RO's is that no chemicals are required for disinfection which improves patient safety. Also it is more efficient as the nightly disinfection can be done on an automated basis without requiring staff presence. For a small unit, this is a cost effective way to provide safer dialysis than purchasing a full centralized water system". [Source: Application, page 29]
- "The capital costs for the project are detailed in Table 11".

Estimatea Capital Experiation es				
NKC Federal	Landlord Costs	Total Project		
Way		Costs		
\$1,001,297	\$727,576	\$1,728,873		
\$41,980		\$41,980		
\$267,389		\$267,389		
\$105,600	\$50,937	\$156,537		
\$107,704	\$70,188	\$177,892		
\$64,930		\$64,930		
	\$85,000	\$85,000		
\$1,588,900	\$933,701	\$2,522,601		
	NKC Federal Way \$1,001,297 \$41,980 \$267,389 \$105,600 \$107,704 \$64,930	NKC Federal Way Landlord Costs \$1,001,297 \$727,576 \$41,980 \$267,389 \$105,600 \$50,937 \$107,704 \$70,188 \$64,930 \$85,000		

Table 11 (Reproduced) Estimated Canital Expenditures

[Source: Application, Page 28]

- "There are no restrictions (as described above) with regards to the elected site."
- "The site is zoned GC (General Commercial). Included in Exhibit 10 is the Yakima County zoning description as well as an email from the City of Yakima documenting the zoning for the selected site. The zoning GC allows for outpatient medical services including dialysis as a permissible use."
- "A draft lease agreement for the selected site is included in Exhibit 11. The initial term is for 120 months and includes two successive five year renewal options." [Source: Application, page 13]
- "The majority of reimbursements for dialysis services flow from Medicare and Medicaid, which are not subject to, or affected by, capital improvements and expenditures by providers. As NKC has noted in other CN applications, its charge structure is not based on the capital costs of its projects but is separately set and is based on its contracts with payers." [Source: Application page 29]

Public Comments

DaVita provided the following comments.

- "NKC disclosed in its application that to save expenses of "purchasing a full centralized water system", it would use portable RO units in Yakima. NKC described these units as "state-of –the-art," but this is a stretch portable units have been available for years".²⁰ [Source: Received on April 17, 2017, Page 5]
- "If NKC uses portable RO units at any of its existing facilities, it did not say so. Presumably, all of NKC's King County facilities have industry standard water rooms. So, why is NKC unwilling to build a water room at the proposed facility in Yakima". [Source: Received on April 17, 2017, Page 5]
- "As the Department knows, NKC has attempted to omit capital costs in previous applications. One of those applications led to a superior court decision providing clear guidance as to what must be included consistent with Department's current rules:

²⁰ NKC's Application, p.34.

"Where a kidney dialysis facility applicant proposes to lease space in an existing building, it must disclose in its CON application all capital costs incurred by the applicant and the landlord to allow the leased space to be used as kidney dialysis facility. The applicant is not required to ascertain and report the original costs incurred by a third party to construct a retail center in which space is being leased.²¹." [Source: Received on April 17, 2017, Page 7]

"NKC is not leasing space in an existing building. A new building is being constructed for NKC as the tenant occupying eighty five percent of the building. The building is being constructed for NKC as kidney dialysis facility consistent with NKC's design". [Source: Received on April 17, 2017, Page 7]

• "NKC claimed that this building would have been constructed regardless whether it proceeds with the project²², but it did not provide evidence. While the landlord could be expected to construct a building on this site whether NKC is a tenant or not, DaVita does not believe that the landlord would build a kidney dialysis facility unless NKC was going to lease it." [Source: Received on April 17, 2017, Page 7]

Rebuttal Comments

NKC provided rebuttal, below. [Source: Received May 17, 2017, page 4]

- NKC's proposal to not construct a standard water room will not impact patient care. The individual RO units proposed to be used by NKC are the state of the art single patient ROs. They became available in 2015 and are identical to the ones that NKC uses in the acute care setting for its hospital services program. NKC's biomed department and Water Purification Engineer has significant experience with these RO's and can provide the necessary equipment maintenance and service to the Yakima facility.
- NKC evaluated the cost/benefit of a standard water room and concluded that given the size of the facility and the interest in value based health care, an individual RO system was a cost-effective alternative. There is no CMS prohibition to this form of water treatment.

Department Evaluation

Given the size of the facility and distance from other existing NKC's facilities, using individualized RO systems at the proposed Yakima facility is advantageous. NKC provided a letter from the proposed facility landlord West Valley MOB, LLC. The letter signed by a managing member of West Valley MOB, LLC stated,

"West Valley MOB purchased the lot free and clear and we have submitted the site plan and building plans to the City of Yakima planning department for review and approval... We are totally committed to building this building immediately, should Northwest Kidney Centers be awarded this Certificate of Need". [Source: NKC's rebuttal comment received May 17, 2017 Attachment 1]

²¹ Northwest Kidney Center V. Department of Health of the State of Washington, King County Superior Court, No. 14-2-29824-2 SEA, Judicial Review Order, June 16, 2015, p. 6.

²² NKC's Application, page 8.

NKC has a history of developing kidney dialysis facilities within Washington. For this project, NKC stated that it used its recent history of developing projects in King County to develop the cost estimates. The estimated construction costs are comparable to other kidney dialysis facilities reviewed by the department.

NKC identified the proposed site as Yakima County assessor parcel number 181329-14412 and the physical address as 1010 South 64th Avenue, Yakima, Washington. A copy of the draft lease between West Valley MOB, LLC (landlord) and Northwest Kidney Centers (tenant) was provided. The draft lease identifies the specific facility site, lease costs, terms, and certain terms associated with the draft lease. The lease outlines the roles and responsibilities of both tenant and landlord. When draft leases are submitted, if a project is approved, the department attaches a condition requiring the applicant to provide a copy of the final, executed agreement consistent with the draft lease agreement. If the NKC project is approved, the department would attach a similar condition.

The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the proposed dialysis facility 86.3 % of the patients are projected to be Medicare and Medicaid. Revenue from these two sources are projected to equal 53.9%. The remaining 46.1% of revenue will come from a variety of sources including private insurance.

CMS has implemented an ESRD Prospective Payment System (PPS). Under this ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider.

Based on the department's understanding of how kidney dialysis facilities are reimbursed for their services, the department concludes this project is not expected to have an unreasonable impact on the costs and charges of health services.

Based on the information reviewed and with NKC's agreement to the condition identified above, the department concludes **this sub-criterion is met.**

(3) <u>The project can be appropriately financed.</u>

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2) (a) (i). There are also no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

DaVita Healthcare Partners, Inc.

• *"The project will be funded from DaVita capital expenditure budget. DaVita operations in the Pacific Northwest have experienced continued growth".* [Source: Application, page 20]

- "A letter of Operational and Financial commitment is included as Appendix 6." [Source: Application, page 20]
- *"Appendix 7 lists the Capital Expenditures required for the project."* [Source: Application, page 20]

Public Comments None

<u>Rebuttal Comments</u> None

Department Evaluation

The total cost of the project is \$1,929,681. Of this amount, \$1,819,681 is DaVita's financial responsibility. The remaining \$110,000 is the responsibility of the landlord. The letter from DaVita chief operating officer kidney care demonstrates the board's financial commitment to this project. DaVita also provided it SEC 10k -2013, 2014, 2015 statement. [Source: Application Appendix 10] DaVita is publicly traded company and demonstrated more than enough unrestricted assets to finance the proposed project.

The department concludes the DaVita Wapato Dialysis Center can be appropriately financed. **This sub criterion is met**

Northwest Kidney Centers

- "This project will be funded through existing capital reserves of NKC. No financing is necessary". [Source: Application, page 29]
- "A copy of the board commitment letter is included in Exhibit 14." [Source: Application, page 29]
- "This is the least costly alternative." [Source: Application, page 30]

Public Comments

DaVita provided the following comment. [Source: Received on April 17, 2017, Page 8]

• NKC submitted five letters of intent with varying cost estimates of \$1,327,592, \$1,635, 725; \$2,015,375; \$2,834,354; and \$3,653,334. NKC did not attach to its application the letter of intent it is relying upon, DaVita will assume that it is relying upon the letter of intent estimating costs at \$2,834,354 as this the closet estimate to the \$2,522,601 capital costs identified in NKC's application.

Rebuttal Comments

NKC provided rebuttal, below. [Source: Received on May 17, 2017, Page 5]

• "As DaVita notes in its public comments, NKC's capital cost was 11% different than its LOI. As the Program indicates in the letter it sends to potential applicants upon receipt of LOIs, an LOI is not consistent with the application when the capital costs increased or decreased by **more than 12%.** Clearly, this was not the case for NKC in Yakima County".

Department Evaluation

The total cost of the project is \$2,522,601. Of this amount, \$1,588,900 is NKC's responsibility. The remaining \$933,701 is the responsibility of the landlord. The letter from NKC chairman, board of trustees demonstrates the board's financial commitment to this project. The department also reviewed NKC's audited fiscal years 2014 and 2015 financial statements and its shows that NKC has enough unrestricted assets to finance the proposed project. [Source: Application page 28, Exhibit 14, and Appendix 1]

NKC's rebuttal correctly identifies that the estimated capital expenditure in the application is within 12% of the value identified in the letter of intent.

The department concludes the NKC Yakima Kidney Center can be appropriately financed. **This sub criterion is met.**

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

DaVita Healthcare Partners, Inc.

Based on the source information reviewed and the applicant's agreement to the conditions identified in the "conclusion" section of this evaluation, the department concludes DaVita HealthCare Partners, Inc. has met the structure and process of care criteria in WAC 246-310-230.

Northwest Kidney Centers

Based on the source information reviewed the department concludes Northwest Kidney Centers has met the structure and process of care criteria in WAC 246-310-230; and

(1) <u>A sufficient supply of qualified staff for the project, including both health personnel and</u> <u>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.

DaVita Healthcare Partners, Inc.

- DaVita anticipates no difficulty in recruiting the necessary personnel to start the Wapato Center.
- Based on our experience establishing a new facility within a planning area, DaVita anticipates that staff from the DaVita Yakima, DaVita Union Gap and geographically adjacent facilities will serve patients at the Wapato Dialysis Center.
- DoH summary DaVita's FTE's based on screening responses received January 31, 2017.

	r					1
	Staffing	Full Year	Year	Year	Year	Year
	Ratio	2019	2020	2021	2022	2023
	(Pts per shift)					
Administrator	80	0.34	0.36	0.40	0.42	0.46
Admin Assistant	110	0.25	0.26	0.29	0.31	0.34
Social Worker	120	0.23	0.24	0.26	0.28	0.31
Dietician	120	0.23	0.24	0.26	0.28	0.31
				•	•	
RN- in-Center	12	0.69	0.74	0.80	0.85	0.92
LPN		0.00	0.00	0.00	0.00	0.00
PCT	4	2.08	2.23	2.39	2.56	2.75
RN - PD	18	0.11	0.11	0.17	0.17	0.22
RN - HHD	14	0.00	0.00	0.00	0.00	0.00
Biomed	40	0.15	0.15	0.15	0.15	0.15
Reuse		0.00	0.00	0.00	0.00	0.00
Other	80	0.34	0.36	0.40	0.42	0.46

Table 7Summary of DaVita Wapato Projected FTE's

Public Comments None

Rebuttal Comments
None

Department Evaluation

When the new facility opens in 2019, DaVita is expected to have 4.42 FTEs. Within the Yakima County ESRD planning area, DaVita operate four kidney dialysis facilities and FTEs from the existing facilities are expected to also provide serve at the new Wapato facility. DaVita has a history of recruiting and retaining sufficient supply of qualified staff for its dialysis facilities. The department does not expect it to be any different with this facility.

The medical director for the proposed dialysis center is Rodrigo Alfaro, MD. DaVita provided a draft medical director agreement between itself and Rodrigo Alfaro of Sunnyside Community Hospital. The initial term of the draft agreement is two-years with annual automatic renewals. [Source: Application, page 8, and Appendix 3] If this application is approved, the department would attach a condition that prior to providing services DaVita must submit to the department for review and approval the executed medical director agreement that is consistent with the draft provided in the application.

The department concludes **this sub-criterion is met.**

Northwest Kidney Centers

• "Table 12 details the proposed staffing for this project". [Source: Application, page 31]

	Table 12 (Reproduced)			
	NKC Yakima Kidney Center			
	1	Proposed To	otal Staffin	g
	FYE	FYE	FYE	FYE
	2019	2020	2021	2022
HD Tech	1.16	2.50	2.33	4.16
RN	0.62	1.34	1.79	2.24
RN-Home Training (PD & HH)	0.50	0.50	0.50	0.50
Clinical Nurse Manager	1.00	1.00	1.00	1.00
Facility System Specialist	0.50	0.50	0.50	0.50
MSW	0.09	0.16	0.22	0.27
Dietician	0.08	0.15	0.20	0.25
Receptionist	1.00	1.00	1.00	1.00
Total	4.95	7.15	8.54	9.92

• "A complete listing of NKC Medical Staff is included in Exhibit 5 and includes 51 active staff and 43 courtesy staff. The proposed Medical Director for NKC Yakima Kidney Center is Bonnie Collins, MD. Dr. Collin's professional license number is MD00025706. The draft Medical Director Agreement with Dr. Collins is included in Exhibit 6." [Source: Application, page 6]

NKC also provided the following statement:

"NKC offers a competitive wage and benefit package and has been very successful in recruiting and retaining staff in its existing centers. NKC's mission, "To promote the optimal health, quality of life, and independence of people with kidney disease through patient care, education, and research" has made NKC a desirable place to work for staff committed to caring for dialysis patients. NKC has not experienced difficulty in recruiting and retaining staff." [Source: Application page 32]

The department received public comments from DaVita related to NKC's project regarding this sub criterion summarized below are the comments.

Public Comments

DaVita provided comments, below. [Source: Received on April 17, 2017, Pages 3 and 4]

• "NKC's application identified Dr. Bonnie Collins, MD, as the medical director of the proposed facility. Dr. Collins is an associate chief medical officer at NKC and it appears that she is located at offices in Seattle²³. NKC has identified a medical director located approximately 150 miles from its proposed facility. NKC should have selected a medical

²³ https//www.nwkidney.org/about-us/who-we-are/administration/ (last visited April 14, 2017) (identifying Dr. Collins as one of the eleven members of NKC's executive team)

director based in Yakima or at least one located in within eastern Washington, to serve the Yakima facility."

- It is DaVita's understanding that Dr. Collins is no longer a practicing nephrologist, as she closed her practice and is no longer seeing patients. Rather, one of her current duties is to "fill in" for vacant medical directorships at NKC facilities until a permanent medical director can be found. NKC should address in its rebuttal comments whether this understanding is accurate. But NKC represented in its application that Dr. Collins would be the medical director for its Yakima facility. If this representation is accurate, that means that NKC has appointed a medical director based 150 miles from the facility, which is not a good model. If it is not accurate, and NKC is just using Dr. Collins's name as a placeholder, then NKC has misled the Department in its application as to how it will ensure quality care at this proposed facility.
- NKC's staffing model is based on partial FTEs. While this would be appropriate for one of NKC's facilities in King County, where a staff member may be shared between multiple facilities, it does not make sense for NKC's proposed Yakima facility for the simple reason that NKC does not have any other facilities in the area between which staff may be shared. Specifically, in year three (2022), NKC projects that it will employ 4.16 hemodialysis technicians; 2.24 registered nurses; 0.5 registered nurses for home training; 0.5 facility system specialists; 0.27 social workers, and 0.25 dieticians. How is this possible? For example, how does NKC propose to hire a 0.27-FTE social worker?
- Yakima is a difficult area to recruit staff because NKC does not have any operations in the region, it should demonstrate how it would recruit qualified staff in Yakima. NKC is not going to be able to recruit part time staff in Yakima unless it is willing to hire full time staffs.
- "NKC proposes to build its first facility in Eastern Washington but has failed to present a viable plan to do so: (1) it proposes to use a medical director based in Seattle, (2) it will not employ a local facility administrator; (3) it assumes it can staff the facility with part time employees, but not explain how it will do so; (4) it plans to use portable RO units rather than spend the money to build an industry standard water room; and (5) it has to date failed to secure the site where it will build the facility. In addition, NKC facility is not projected to achieve 4.8 utilization in its full year operation". [Source: Public comments submitted by DaVita received on April 17, 2017, Page 8]

Rebuttal Comments

NKC provided rebuttal, below. [Source: Received on May 17, 2017, Pages 1-3]

- NKC's medical director arrangement is appropriate. In communities in which DaVita has previously proposed to establish its first facility, it has also named a medical director that resided in another community and miles away. Specifically, in its 2007 application to establish a facility in Colville, Stevens County, DaVita proposed its Tri-Cities medical director.
- In addition, DV argues that our proposed medical director no longer maintains a clinic and is no longer seeing patients outside of a dialysis center. That is correct. However, Dr. Collins, our proposed medical director, is employed by NKC (not at Pac Med) and is our Associate Chief Medical Officer (CMO). NKC purposefully selected Dr. Collins to serve as

medical director in Yakima, as NKC wanted an experienced medical director in Yakima to be involved from the 'get go' in the establishment of this new facility. Dr. Collins has been a medical director at two NKC facilities over the past five years and served as interim CMO for two years. Clearly, Dr. Collins is an experienced NKC leader who knows and understands the responsibilities of a medical director. NKC intentionally selected Dr. Collins for this role.

• Finally, as noted earlier, NKC operates a remote unit in Port Angeles. This unit operates successfully with a Seattle based medical director. As DV is well aware, it is not a CMS requirement to have a locally based nephrologist. Our Port Angeles medical director routinely travels to Port Angeles for Quality Assessment/Performance Improvement, staff education, and water oversight duties as well as other medical director responsibilities, including patient care. Again, DV's comments are without merit.

Department Evaluation

There is no CMS requirement that a medical director must live within the vicinity of a facility the physician plan to serve. The general overview of how NKC recruits and retain FTEs discussed in the application, is what NKC has done in King County where there are many opportunities to recruit staffs. Given there is no requirement that a dialysis provider must follow when proposing to establish a facility in places where that provider does not currently operates, the department thinks that NKCs rebuttal comments are reasonable.

The majority of the FTEs are expected to be in the categories of nursing and HD Techs that are direct patient care positions. When NKC Yakima opens in FY2019, it is expected to have 4.95 FTEs. Between FY 2019 and FY 2022 NKC expects to add 4.97 FTEs. Although, NKC has a history of recruiting and retaining sufficient supply of qualified staff for its dialysis facilities, but if this project is approved, it would be NKC's first kidney dialysis in eastern Washington. NKC did not specifically discussed how it would recruit FTE's in Yakima, but the department does not expect that the approval of NKC Yakima would be any different.

The medical director for the proposed dialysis center is Bonnie Collins, MD. NKC provided an executed medical director agreement between itself and Dr. Collins. The initial term of the agreement is one-year with annual automatic renewals. [Source: Application, page 6, and Exhibit 6] The department concludes **this sub-criterion is met.**

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

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

DaVita Healthcare Partners

• "Ancillary services such as social services, nutrition services, financial counseling, pharmacy access, patient education, staff education, information services human resources, material management administration and biomedical technical services are provided on site.

Additional services are coordinated through 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 23]

Public Comments
None

Rebuttal Comments
None

Department Evaluation

DaVita currently operate four kidney dialysis facilities in Yakima County and ancillary and support services are currently available at one of DaVita's several support offices in the planning area. DaVita provided a draft patient transfer agreement. If this application is approved, the department would attach a condition requiring that prior to providing services, DaVita must submit to the department for review and approval the executed patient transfer agreement that is consistent with the draft provided in the application. The department concludes there is reasonable assurance DaVita Wapato Dialysis Center would have the necessary ancillary and support services. **This sub-criterion is met.**

Northwest Kidney Centers

• Ancillary and support services include the following:

Social Services	Business Office
Nutrition Services	Administration
Patient Financial Counseling	Information Systems
Pharmacy	Human Resources
Patient Education	Plant Operations
Technical Services	Material Management
Visitor Dialysis	Community Relations
Informatics Nurses	Public Relations
Water Purification Specialists	Dialysis Academy (training)

[Source: Application, page 32]

Each of these departments/functions is based at one of our support offices in Seattle, Lake Forest Park, SeaTac or Bellevue, and already provides services daily or on demand at all NKC treatment centers". [Source: Application, page 32]

• "A copy of the existing transfer agreement between NKC and Yakima Valley Memorial Hospital (dba Virginia Mason Memorial) is included in Exhibit 16." [Source: Application, page 32]

Public Comments None

Rebuttal Comments
None

Department Evaluation

NKC provided a listing of its ancillary and support services necessary for a kidney dialysis facility. These services are currently available at one of several NKC support offices and will be used by NKC Yakima Kidney Center. NKC provided a draft transfer agreement between NKC and Yakima Valley Memorial Hospital. The draft agreement would be used at NKC Yakima Kidney Center. If this application is approved, the department would attach a condition requiring that prior to providing services, NKC must submit to the department for review and approval the executed patient transfer agreement that is consistent with the draft provided in the application. The department concludes there is reasonable assurance the NKC Yakima Kidney Center would have the necessary ancillary and support services. **This sub-criterion is met.**

(3) <u>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.</u> 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. As part of its review, the department must conclude that the proposed service would be operated in a manner that ensures safe and adequate care to the public. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

The department reviewed information from 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.

- <u>Best Treatment Practices</u> 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.
- <u>Hospitalization and Deaths</u>

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 co-morbidities

DaVita Healthcare Partners

• "The Wapato Dialysis Center will provide comprehensive in-center dialysis services. As previously described DaVita is committed to its highly effective Continuous Quality Improvement program and seeks to assure the appropriate structure and process of care through uncompromising quality goals on an ongoing, continuous basis. Moreover, for the third year in a row, DaVita has been recognized as a clinical leader in the CMS Five-Star ranking program (davita.com, News Release October 24, 2016). DaVita also maintains a strong history of compliance in Department of Health surveys that ensure our centers meet the highest standards for clinical excellence". [Source: Application Page 14]

Public Comments None

Rebuttal Comments
None

Department Evaluation

DaVita 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 also provides acute inpatient dialysis services in approximately 720 hospitals throughout the country.

The Department of Health's Investigations and Inspections Office (IIO), acting as the contractor for the centers for Medicare and Medicaid Services, completed four compliance surveys for the facilities²⁴ own or managed by DaVita in Yakima County ESRD planning area. These surveys revealed minor non-compliance issues typical of a dialysis facility. DaVita submitted and implemented acceptable plans of correction. [Source: Facility survey data provided by the Investigations and Inspections Office]

In Washington State, DaVita owns or operates 42 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.²⁵ The department reviewed the CMS star ratings for these facilities and the review shows that ten of the 42 facilities did not have a CMS star rating because they were not open for the entire reporting period. [Source: Facility survey data provided by the Investigations and Inspections Office]

Table 8 below shows the dialysis facilities owned, managed or operated by DaVita Healthcare Partners, Inc. CMS star ratings. [Source: May 25, 2017, CMS Compare Data]

DaVita Dialysis Centers Medicare and Medicaid Star Rating			
Facility Name	City	Star Rating	
Battle Ground Dialysis Center	Battle Ground	n/a	
Belfair Dialysis Center	Belfair	n/a	
Bellevue Dialysis Center	Bellevue	3	
Cascade Dialysis	Burlington	n/a	
Chinook Kidney Center	Richland	5	
Centralia Dialysis Center	Centralia	n/a	
Downtown Spokane Renal Center	Spokane	3	
East Wenatchee Dialysis Center	East Wenatchee	5	
Echo Valley Dialysis Center	Colville	n/a	

 Table 8

 DaVita Dialysis Centers Medicare and Medicaid Star Rating

²⁴ Yakima Dialysis Center was surveyed on 2/5/15, Union Gap Dialysis Center was on 4/7/2016; Mt. Adams was surveyed on 9/17/15, and Ellensburg Dialysis Center was surveyed on 5/21/14.

²⁵ WAC 246-310-230(5)

Facility Name	City	Star Rating
Ellensburg Dialysis Center	Ellensburg	4
Elk Plain Dialysis Center	Spanaway	n/a
Everett Dialysis Center	Everett	5
Federal Way Community Dialysis Center	Federal Way	4
Graham Dialysis Center	Graham	5
Kennewick Dialysis Center	Kennewick	5
Kent Dialysis Center	Kent	3
Lakewood Community Dialysis Center	Lakewood	4
Mid-Columbia Kidney Center	Pasco	4
Olympia Dialysis Center	Olympia	5
Olympic View Dialysis Center	Seattle	3
Parkland Dialysis Center	Parkland	3
Pilchuck Dialysis Center	Marysville	4
Puyallup Dialysis Center	Puyallup	3
Rainier View Dialysis Center	Tacoma	n/a
Redondo Heights Dialysis Center	Federal Way	n/a
Renton Dialysis Center	Renton	n/a
Seaview Dialysis Center	Seaview	5
Spokane Valley Dialysis Center	Spokane	5
Tacoma Dialysis Center	Tacoma	3
Tumwater Dialysis Center	Tumwater	n/a
Union Gap Dialysis Center	Union Gap	5
Vancouver Dialysis Center	Vancouver	3
Wenatchee Valley Dialysis Center	Wenatchee	5
Westwood Dialysis Center	Seattle	4
Whidbey Island Dialysis Center	Oak Harbor	3
Yakima Dialysis Center	Yakima	4
Mill Creek Dialysis Center	Bothell	5
Mt. Adams Kidney Center	Sunnyside	5
Mount Baker Renal Center	Bellingham	5
North Spokane Renal Center	Spokane	3

Facility Name	City	Star Rating
Zillah Dialysis Center	Zillah	4

As shown in Table 8 thirty two DaVita dialysis centers received at least three stars or better star ratings. DaVita identified Rodrigo Alfaro, MD as the medical director for the proposed DaVita Wapato and provided a draft medical director agreement between Sunny side Community Hospital Association ("Hospital"), and Total Renal Care, Inc. ("Company"). According to the draft medical director agreement recitals, Dr. Alfaro is a physician employee of Hospital. [Source: Application page 8, and Appendix 3]

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

Under the DOJ settlement agreement, DaVita would be 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 Statue in connection with the operations of some its dialysis center joint venture arrangements. Information provided by DaVita stated the DOJ settlement agreement reflected its disagreement with the government regarding the allegations. According to information in the documents provided, DaVita has not been prohibited from billing or participating in federal healthcare programs. [Source: Application Appendix 4]

The department concludes there is reasonable assurance the DaVita Wapato would be operated in conformance with applicable state and federal licensing and certification requirements. **This sub criterion is met.**

Northwest Kidney Centers

- "NKC has no history with respect to the actions noted in CN regulation WAC 248-19-390(5)(a), now codified at WAC 246-310-230(5)(a)".
- *"NKC operates all existing programs in conformance with applicable federal and state laws, rules and regulations"*. [Source: Application, page 33]

Public Comments None

Rebuttal Comments
None

Department Evaluation

NKC does not own or operate any out-of-state healthcare facilities. NKC provides dialysis services in Clallam and King Counties within Washington State. All of the dialysis facilities owned, operated, or managed by NKC are Medicare certified. Those facilities quality of care enforcement were reviewed by the department. The Department of Health's Investigations and Inspections Office (IIO), acting as the contractor for the centers for Medicare and Medicaid Services, completed eight compliance surveys for some of the facilities own or managed by NKC in King County.²⁶ These surveys revealed minor non-compliance issues typical of a dialysis facility. NKC submitted and implemented acceptable plans of correction. [Source: Facility survey data provided by the Investigations and Inspections Office]

Table 9 below shows the fifteen NKC dialysis centers and the CMS star ratings. [Source: May 25, 2017, CMS compare data]

Northwest Kidney Centers Dialysis Facilities CMS Star Rating				
Facilities Name	City	Star Rating		
NKC Auburn Center	Auburn	4		
NKC Broadway Kidney Center	Seattle	5		
NKC Elliot Bay Kidney Center	Seattle	4		
NKC Enumclaw Kidney Center	Enumclaw	5		
NKC Kent Kidney Center	Kent	4		
NKC Kirkland Kidney Center	Kirkland	4		
NKC Lake City Kidney Center	Lake Forest Park	4		
NKC Lake Washington	Seattle	4		
NKC Port Angeles Kidney Center	Port Angeles	5		
NKC Renton Kidney Center	Renton	4		
NKC Scribner Kidney Center	Seattle	5		
NKC SeaTac	SeaTac	5		
NKC Seattle Kidney Center	Seattle	4		
NKC Snoqualmie Kidney Center	Snoqualmie	4		
NKC West Seattle Center	Seattle	3		

 Table 9

 Northwest Kidney Centers Dialysis Facilities CMS Star Rating

As shown in Table 9 above, the facilities operated or owned by NKC have an average rating of 4 stars.

NKC identified Dr. Bonnie Collins, MD as the proposed medical director for NKC Yakima Kidney Center. A review of Dr. Collin's compliance history with the Department of Health's Medical Quality Assurance Commission did not revealed any recorded sanctions. [Source: Compliance history provided by Medical Quality Assurance Commission]

The department concludes there is reasonable assurance the NKC Yakima Kidney Center would be operated in conformance with applicable state and federal licensing and certification requirements. **This sub criterion is met.**

²⁶ Most recent quality of care surveys conducted for NKC Kirkland Kidney Center 2014; year 2015 for Kent Kidney Center, year 2017 for NKC Seattle, year 2016 for NKC Renton; year 2017 for NKC Auburn, year 2017 for NKC Broadway, and year 2016 for Renton Kidney Center and West Seattle Kidney Center.

(4) <u>The proposed project will promote continuity in the provision of health care, not result in an</u> <u>unwarranted fragmentation of services, and have an appropriate relationship to the service</u> <u>area's existing health care system.</u>

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 no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

DaVita Healthcare Partners, Inc.

• "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 and 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". [Source: Application Page 23]

Public Comments None

Rebuttal Comments
None

Department Evaluation

DaVita operates four kidney dialysis in Yakima since has maintained appropriate relationships with the service area's existing healthcare providers. If the project is approved, this would be DaVita's fifth facility in the planning area. Nothing in the materials reviewed by the department suggests that approval of the proposed DaVita Wapato Dialysis Center will change the relationships DaVita has with the existing service area providers. The department concludes **this sub-criterion is met**.

Northwest Kidney Centers

- "Although NKC Yakima Kidney Center will be a new facility in Yakima County, Northwest kidney Centers has operated throughout King County from the early 1960's and supported patients in community like Port Angeles (Clallam County) and Enumclaw (King 12). Providing lifesaving support within Yakima County is directly aligned with our mission and we welcome the opportunity if granted".
- "While our relationship with Yakima Memorial Valley Hospital is new, our relationship with Virginia Mason Medical Center has been strong for many years. With the linking between these two organization forming Virginia Mason Memorial we see a strong collaborative environment with NKC entering the market to support patients". [Source: Application Page 33]

Public Comments None Rebuttal Comments
None

Department Evaluation

NKC does not currently operate a kidney dialysis facility in Yakima County, but it has been providing services in Washington for many years it and has maintained appropriate relationships with the service area's existing healthcare providers. Nothing in the materials reviewed by the department suggests that approval of the NKC Yakima Kidney Center will change the relationships NKC has with existing service providers in Washington, nor would it have a negative impact on the existing providers in Yakima County. The department concludes **this sub-criterion is met**

(5) <u>There is reasonable assurance that the services to be provided through the proposed project will</u> <u>be provided in a manner that ensures safe and adequate care to the public to be served and in</u> <u>accord with applicable federal and state laws, rules, and regulations.</u>

This sub-criterion is evaluated in sub-section (3) above. The department concludes that DaVita and NKC both **met this sub-criterion**.

D. COST CONTAINMENT (WAC 246-310-240)

DaVita Healthcare Partners

Based on the source information reviewed and provided the applicant agree to the conditions identified in the "conclusion" section of this evaluation, the department concludes DaVita Healthcare Partners, Inc. has met the cost containment criteria in WAC 246-310-240.

Northwest Kidney Centers

Based on the source information reviewed, the department concludes Northwest Kidney Centers has not 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 including any project type specific criteria. 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 including any project type specific criteria, the department then assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in <u>Step three</u>. The superiority criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects, which is the best

alternative. If WAC 246-310 does not contain any service or facility type superiority criteria as directed by WAC 246-310-200(2) (a)(i), then the department would use WAC 246-310-240(2)(a)(ii) and (b) as the 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.

<u>Step One</u>

The department determined DaVita and NKC met the applicable review criteria under WAC 246-310-210, 220, and 230 including WAC 246-310-284(5) and (6). Therefore, the department moves to step two.

Step Two

DaVita Healthcare Partners, Inc.

- *"Two alternatives were considered:*
 - 1) Maintain the application to relocate four (4) stations from Mt. Adams to the leased space in Wapato.
 - 2) Forego the relocation application and apply to add six (6) new capacity stations to the leased space in Wapato". [Source: Application Page 25]

Alternative 1: Maintain the Application to relocate four (4) stations from Mt Adams to the lease space in Wapato.

• DaVita considered relocating stations from Mt. Adams in order to accommodate the priority capacity issues in the Yakima and Union Gap area. This option was rejected because DaVita Union Gap that was previously operating below capacity started operating at capacity the next quarter, which prompted DaVita to withdraw its previous application proposing to relocate stations from the existing Mt. Adams facility.

Alternative 2: Forego the relocation application and apply to add six (6) new capacity stations to the lease space in Wapato.

- "The Yakima ESRD growth rate is quickly outstripping capacity. At 300 patients, every existing center will have reached 100% utilization and DaVita projects that there will be approximately 345 total patients in the planning area by 2019. Moreover, the zip code comprising the northern portion of the planning area represent more than half of the total ESRD population, a trend which we expect will advance in coming years".
- "The establishment of a new six station facility in Wapato provides patients with greater access, enhanced treatment options, ongoing continuity of care with their provider, and all at the least possible capital expense. This alternative was selected". [Source: Application page 25]

Department Evaluation

The department noted that DaVita considered several options before selecting the option to establish a six-station kidney center in Wapato. As noted by DaVita, its goal is to improve access for patients in the planning area. The department did not identify any other alternative that was

a superior alternative, in terms of cost, efficiency, or effectiveness, which is available or practicable.

<u>Step Two</u>

Northwest Kidney Centers

- 1) "Create a new center with 6 stations based on a traditional water room and standard operation;
- 2) Create a new center with 6 stations based on a new state-of-the-art heat disinfection water treatment system that eliminates that need for a more costly water room. This application is written for this option;
- *3) Choose to not apply for the need in this planning area;*
- 4) Apply for need other than the 6 stations specified; [Source: Application Page 34]
- "Option 1, was very carefully evaluated but was not selected due to cost."
- "Option 2, was selected: The creation of a state-of-the –art 6 station unit with an new heat treated water system scaled for use in a smaller center. We believe that this will deliver quality care at a lower cost. Given the CN Program's dialysis projection methodology, these stations will be fully needed within the next 3 years, so it was determined that it would be in the best interest of our patients to build them."
- "Option 3: NKC has monitored need and utilization in Yakima Center very closely. Given the growth in patient census just this year alone, NKC concluded that doing nothing was not an option with the existing facilities operating above 4.8 patients per station."
- *"Option 4 was rejected as not appropriate based on the CN rules and process."* [Source: Application Page 34]

Public Comment None

Rebuttal None

Department Evaluation

The department noted that NKC considered several options before selecting the option to establish a six-station kidney center in Yakima. As noted by NKC, its goal is to improve access for our patients in the planning area. The department did not identify any other alternative that was a superior alternative, in terms of cost, efficiency, or effectiveness, which is available or practicable.

Department Evaluation Step Three

Each applicant met the applicable review criteria in WAC 246-310-210 through 230, as well as the facility specific kidney dialysis criteria under WAC 246-310-280, 282, and 284. The applications are tied.

WAC 246-310-288 identifies specific tie-breaker criteria that must be applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. Under tie-breaker criteria, the department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.

Below is an evaluation of the tie-breaker criteria under WAC 246-310-288(1) and (2).

WAC 246-310-288(1) - A total of five points is possible.

(1) The department will award one point per tie-breaker to any applicant that meets a tie-breaker criteria in this subsection.

(a) Training services (1 point):

(i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or

(ii) The applicant is an existing provider in the planning area that offers training services in any of its existing facilities within thirty-five miles of the proposed new facility and either intends to offer training services at the new facility or through those existing facilities; or

(iii)The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and

(*iv*)Northwest Renal Network's most recent year-end facility survey must document the provision of these training services by the applicant.

(b) Private room(s) for isolating patients needing dialysis (1 point).

(c) Permanent bed stations at the facility (1 point). Page 64 of 70

(d) Evening shift (1 point): The applicant currently offers, or as part of its application proposes to offer at the facility a dialysis shift that begins after 5:00 p.m.

(e) Meeting the projected need (1 point): Each application that proposes the number of stations that most closely approximates the projected need.

DaVita Healthcare Partners, Inc.

Table 10 below shows the distribution of tie-breaker points under this sub-criterion for DaVita.

Table 10
WAC 246-310-288(1)
DaVita Tie-Breaker Review

WAC 246-310-288(1)	Point	Source
Training Services	1	Screening response received January 31, 2017, page 4
Private Isolation Room	1	Application, page 9 and Appendix 11
Permanent Bed Station	1	Application, Pages 10 and 11
Evening Shift	1	Application, Page 11 and Appendix 11
Meeting the projected need	1	Application Page 1
Total Points	5	

Northwest Kidney Centers

Table 11 below shows the distribution of tie-breaker points under this sub-criterion for NKC. **Table 11**

WAC 246-310-288(1)

NKC Tie-Breaker Review						
WAC 246-310-288(1)	Point	Source				
Training Services	1	Application, page 9 and Table 7				
Private Isolation Room	1	Application, page 9 and Table 7				
Permanent Bed Station	1	Application, page 9 and Exhibit 9				
Evening Shift	1	Application, page 9 and Table 7				
Meeting the projected need	1	Application Page 1				
Total Points	5					

Under WAC 246-310-288(1), each applicant could receive a maximum of five points. Both applicants received five points.

WAC 246-310-288(2) - only once applicant may be awarded a point for each criterion

(2) Only one applicant may be awarded a point for each of the following four tie-breaker criteria:

(a) Economies of scale (1 point): Compared to the other applications, an applicant demonstrates its proposal has the lowest capital expenditure per new station.
(b) Historical provider (1 point)

(b) Historical provider (1 point)

(i) The applicant was the first to establish a facility within a planning area; and

(ii) The application to expand the existing facility is being submitted within five years of the opening of its facility; or

(iii)The application is to build an additional new facility within five years of the opening of its first facility.

(c) Patient geographical access (1 point): The application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of Page 65 of 70 them. The department will award the point for the facility located farthest away from existing facilities within the planning area provided:

(i) The facility is at least three miles away from the next closest existing facility in planning areas that qualify for 4.8 patients per station; or

(ii) The facility is at least eight miles from the next closest existing facility in planning areas that qualify for 3.2 patients per station.

(d) Provider choice (1 point):

(i) The applicant does not currently have a facility located within the planning area;(ii) The department will consider a planning area as having one provider when a single provider has multiple facilities in the same planning area;

(iii)If there are already two unrelated providers located in the same planning area, no point will be awarded.

Only one applicant may receive a point for each of the four tie-breaker criteria under this section. Table 22 below shows the distribution of tie-breaker points under this sub-criterion for each applicant.

DaVita Tie-Breaker Review						
WAC 246-310-288(1)	Point	Source				
Economies of Scale	1	Application, page 1				
Historical Provider	0					
Patient Geographical Access	1	Application Appendix 15				
Provider Choice	0					
Total Points	2					

Table 12 WAC 246-310-288(2) aVita Tie-Breaker Review

Table 12 WAC 246-310-288(2) NKC Tie-Breaker Review

TAKE TRE-DICARCI REVIEW						
WAC 246-310-288(1)	Point	Source				
Economies of Scale	0					
Historical Provider	0					
Patient Geographical Access	0					
Provider Choice	1	Application page 26				
Total Points	1					

The historical provider point was not awarded, as DaVita – the existing provider in the planning area – has been in operation in excess of the five years identified in rule.

The economies of scale point under WAC 246-310-288(2)(a) is awarded to the applicant that demonstrates its project has the lower capital expenditure per new station. To ensure that competing projects are reviewed fairly, the department requires applicants adding stations to an existing facility to allocate construction costs already expended to the new stations. A description of the formula used by an applicant to determine the amount of costs to allocate is provided in the application.

NKC proposes to establish a new six station dialysis facility within Yakima and projected capital expenditure for the project is \$2,522,601. The department calculated that of the \$2,522,601 projected by NKC one station would cost the sum of <u>\$420,433.50</u>. When NKC's cost per station

is compared to DaVita's cost per station, NKC's per station cost is more than DaVita's. No point is awarded.

DaVita proposes to establish a new 6-station dialysis facility in Wapato within Yakima County and the projected capital expenditure for the project is \$1,929,681. The department calculated that of the \$1,929,681 projected by DaVita, the cost per a dialysis station would be <u>\$321,613.50</u>. When DaVita's per station is compared to NKC's per station cost below, NKC's cost is more than DaVita's cost. A point is awarded.

To receive the geographical access point under WAC 246-310-288(2)(c), the new facility be must be at least three miles away from the next closest existing facility in planning area.

The proposed DaVita Wapato Dialysis Center would be located more than three miles away from the any of the four DaVita facilities located within Yakima. DaVita Wapato would be located 7.7 miles away from the closest existing dialysis facility. Therefore; DaVita's project qualifies for geographical access tie-breaker criteria.

The proposed NKC Yakima would be located more than three miles away from the any of the four DaVita facilities located within Yakima. The facility would be located 3.7 miles away from the closest existing dialysis facility. Therefore; NKC's project qualifies for geographical access tie-breaker criteria.

Though both facilities are proposed to be located more than three miles away from the closest existing facility, DaVita proposes to serve Wapato which according to NWRN data, has 23 dialysis patients that are currently traveling out of their community to receive dialysis. The rule states that a point will be awarded to the application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of them. DaVita's Wapato facility meets this criterion because it is located the furthest away from the existing facilities, and receives the tie-breaker point.

To receive the provider choice point under WAC 246-310-288(2)(d), the applicant must not currently have a facility located within the planning area. The point would not be awarded if the planning area already has two unrelated providers. In this case, DaVita is the only existing provider, and NKC is a new provider. NKC receives the point.

Table 13, below, shows the total accumulation of tie-breaker points for both DaVita and NKC.

WAC 246-310-288 – Tie Breaker Summary Table					
	DaVita	NKC			
Training Services	1	1			
Private Room	1	1			
Permanent Bed Station	1	1			
Evening Shift	1	1			
Meets full Need	1	1			
Economies of Scale	1	0			
Historical Provider	0	0			
Geographical Access	1	0			
Provider Choice	0	1			
Cumulative Total	7	6			

Table 13

As shown above, DaVita received 7 points under tiebreakers to NKC's 6. The tie is broken, and DaVita is awarded the 6 stations.

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

(a) The costs, scope, and methods of construction and energy conservation are reasonable; WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable.

DaVita Healthcare Partners

- "Experience with operating or managing over 2,293 Medicare-certified dialysis throughout the country including many in the Northwest, provides the background for designing facilities that satisfy all patient requirements and provide the greatest value for the *investment dollar*" [Source: Application Page 26]
- "The Wapato Dialysis Center will meet all current energy conservation standards". [Source: Application Page 26]

Public Comments None

Rebuttal Comments None

Department Evaluation

The information reviewed by the department is consistent with similar dialysis projects. The department concludes this sub-criterion is met.

Northwest Kidney Centers

• "The new facility will be designed and built to meet or exceed all applicable state and local codes and CMS conditions of coverage".

- "This location has been carefully reviewed by our architectural firm, contractors and our clinical staff, Chief Medical Officer and Director of Facilities to create a center that will meet our patient and staff needs.
- *"The new facility will comply with the State Energy Code, latest edition."* [Source: Application Page 35]

Public Comments
None

Rebuttal Comments
None

Department Evaluation

The information reviewed by the department is consistent with similar dialysis projects. 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.*

DaVita Healthcare Partners

"Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area." [Source: Application page 22]

Public Comments None

Rebuttal Comments
None

Department Evaluation

The information reviewed by the department is consistent with similar dialysis projects. Because there is a demonstrated need for additional dialysis stations, the department does not anticipate an unreasonable impact on the costs and charges to the public for providing these type services. The department concludes **this sub-criterion is met**

Northwest Kidney Centers

"The majority of reimbursements for dialysis services flow from Medicare and Medicaid, which are not subject to contract negotiations based on capital improvements and expenditures by providers." [Source: Application page 29]

Public Comments None

Rebuttal Comments
None

Department Evaluation

The information reviewed by the department is consistent with similar dialysis projects. Because there is a demonstrated need for additional dialysis stations, the department does not anticipate an unreasonable impact on the costs and charges to the public for providing these type services. The department concludes **this sub-criterion is met**.

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

DaVita Healthcare Partners, Inc.

DaVita uses national standardized staffing models to efficiently design and staff dialysis facilities and assure maximum utilization of resources. Dialysis facilities are required to have substantial clinical and support staff DaVita Yakima Dialysis Center for ESRD patients (Managers, Administrative support, Registered Nurses, Technicians, Social Workers, and Dietitians).

The key advantages to the Wapato Dialysis Center proposal that promote staff and system efficiency include:

- Increased availability and flexibility of scheduling for all patients by introducing patient access and choice to the ESRD planning area.
- Commitment to Continuous Quality Improvement (CQI) all studies document that higher quality results in better clinical outcomes, lower hospitalization rates and accordingly lower costs to payers
- *Full use of a new facility designed to meet current energy utilization requirements.* [source: Application pages 25 and 26]

Public Comments None

Rebuttal Comments
None

Department Evaluation

This project will improve the delivery of health services by locating those services closer to a portion of Yakima County ESRD dialysis patients. Additionally, with the projected need for additional dialysis stations within Yakima County ESRD planning area, the construction costs for this will appropriately improve the delivery of health services. The department concludes **this sub-criterion is met**.

Northwest Kidney Centers

"This project is directed at meeting the future needs of Yakima County dialysis patients for high quality, accessible care. NKC will utilize its existing infrastructure to ensure that unnecessary duplication will be minimized and/or avoided. Economies of scale will also be realized with the sharing of administrative and support staff. Having a new center will allow staff the chance for

advancement and create a new opportunity for new staff to join the NKC team (who live in Yakima)." [Source: Application page 35]

Public Comments
None

Rebuttal Comments
None

Department Evaluation

This project will improve the delivery of health services by locating those services closer to a portion of Yakima County ESRD dialysis patients. Additionally, with the projected need for additional dialysis stations within Yakima County ESRD planning area, the construction costs for this project will appropriately improve the delivery of healthcare services. The department concludes **this sub-criterion is met**.

APPENDIX A



2016 Yakima County ESRD Need Projection Methodology

	Planning Area	6 Year Utiliza	tion Data - R	esident Incen	ter Patients		
	Yakima	2010	2011	2012	2013	2014	2015
	Yakima County	214	235	213	224	247	262
	TOTALS	214	235	213	224	247	262
246-310-284(4)(a)	Rate of Change		9.81%	-9.36%	5.16%	10.27%	6.07%
	6% Growth or Greater?		TRUE	FALSE	FALSE	TRUE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
240-310-204(4)(0)				2016	2017	2018	2019
Projected Resident Incenter Patients	from 246-310-284(4)(b)			262.60	271.40	280.20	289.00
Station Need for Patients	Divide Resident Incenter	Patients by	4.8	54.7083	56.5417	58.3750	60.208
	Rounded to next whole n	umber		55	57	59	6′
246-310-284(4)(d)	subtract (4)(c) from approv	red stations					
Existing CN Approved S Results of (4)(c) above	Stations			55 55	55 57	55 59	5; 61
			-				
Net Station Need				0	-2	-4	-6
Negative number indicates n	eed for stations						
Planning Area Faci	lities						
Name of Center	# of Stations						
DaVita Mt. Adams DaVita Union Gap	14						
Davita Union Gap	21						
DaVita Zillah	8						
Total	55						
Source: Northwest Renal	Network data 2010-2015						
	a: 2015 posted 02/05/2016						

٦



Washington State Department of
Health2016
Yakima County
ESRD Need Projection Methodology

x	У	Linear						
2011	235	219						
2012	213	213						
2012	213	236						
2013	247	230						
2014	262	254						
2013	202	262.600						
2017		271.400						
2018		280.200						
2010		289.000						
2013		205.000						
			350 T					
			300 -				-	
SUMMARY OUTPU	г					+		
	1	# of Patients	250 -	+			-	
Regression S	tatistics	tien	200 -				-	
Multiple R	0.725614348	Pa	150 +				-	
R Square	0.526516182	fo					-	
Adjusted R Square	0.368688242	~	100 -				-	
Standard Error	15.23592246		50 +				-	
Observations	13.23392240							
Observations	5		0				-	
ANOVA								
	df	SS	MS	F	Significance F			
Regression	1	774.4	774.4	-	0.165249393			
Residual	3	696.4	232.1333333	3.330013765	0.105249595			
Total	4	1470.8	232.1333333					
TOLAI	4	1470.0						
	On officients	Otomological Free	4 0 (- (Durcher			1	Linner 05 001
latere et	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept X Variable 1	-17478.2	9698.680124			-48343.72873	13387.32873		
X Variable 1	8.8	4.818021724	1.826475783	0.165249393	-6.533095434	24.13309543	-6.533095434	24.13309543
	r							
RESIDUAL OUTPUT								
Observation	Due elis (1) (Deelstrict						
Observation	Predicted Y	Residuals						
1	208.4	-7.4						
2	212.9	1.1						
3	217.4	17.6						
4	221.9	-8.9						
5	226.4	-2.4						