STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

November 6, 2017

CERTIFIED MAIL # 7014 2120 0002 7627 2070

Austin Ross, Vice President of Planning
Northwest Kidney Centers
700 Broadway
Seattle, Washington 98122-4302

RE: CN 17-31

Dear Mr. Ross:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers proposing to construct a new 10-station kidney dialysis facility, within ESRD Pierce County planning area #4. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Northwest Kidney Centers agrees to the following in its entirety.

Project Description:
This certificate approves the construction of a new ten-station dialysis center in Fife within Pierce County planning area #4. At project completion, the dialysis center is approved to certify and operate ten dialysis stations. Services to be provided at NKC Fife Kidney Center include in-center hemodialysis, home hemodialysis training and backup, home peritoneal dialysis training and backup, treatment shifts beginning after 5:00 p.m., a permanent bed station, and a dedicated isolation/private room. A breakdown of the approved ten stations is shown below:

NKC Fife Kidney Center

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	8
Total	10

Conditions:

1. Northwest Kidney Centers agrees with the project description as stated above. Northwest Kidney Centers 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, Northwest Kidney Centers 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 Northwest Kidney Centers will provide an executed copy of the lease agreement for the department's review and approval. The executed lease agreement must be consistent with the draft provided in the application.

Approved Costs:
The approved capital expenditure for this project is $1,707,381. This amount represents to the total project cost of total cost of $2,179,918, minus the landlord's cost of $472,537.

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

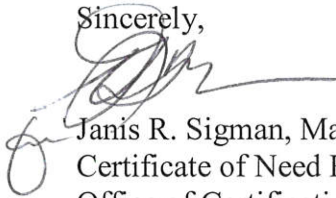
If you reject any of the above provision, your application will be denied. The department will send you a letter denying your application and provide you information regarding your appeal rights. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

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

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

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

Sincerely,



Janis R. Sigman, Manager
Certificate of Need Program
Office of Certification and Technical Support

Enclosure

EVALUATION DATED NOVEMBER 6, 2017, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING TO ESTABLISH A 10 STATION KIDNEY DIALYSIS FACILITY IN PIERCE COUNTY END STAGE RENAL DISEASE PLANNING AREA #4

APPLICANT DESCRIPTION

Northwest Kidney Center's (NKC) is a private, not-for-profit corporation, incorporated in the state of Washington. NKC provides dialysis services through its facilities located in King and Clallam counties. Established in 1962, NKC operates as community based dialysis program working to meet the needs of dialysis patients and their physicians. A volunteer board of trustees governs NKC. 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: Application, pages 2-3, Exhibit 2, and Exhibit 3]

NKC does not own or operate any healthcare facilities outside of Washington State. In Washington State, NKC owns and operates 17 kidney dialysis facilities. Of the 17 facilities, 16 are located within King County. Below is a listing of NKC facilities in Washington. [Source: Application, Exhibit 4]

King County

Auburn Kidney Center
Broadway Kidney Center
Elliot Bay Kidney Center
Enumclaw Kidney Center
Federal Way-East Kidney Center[1]
Federal Way-West Kidney Center[2]
Kent Kidney Center
Kirkland Kidney Center
Lake City 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

Clallam County

Port Angeles Kidney Center

PROJECT DESCRIPTION

NKC proposes to construct a 10-station kidney dialysis facility at 6021 - 12th Street East, Suite 100 in Fife [98424] within Pierce County ESRD planning area #4. The new 10-station facility would be known as NKC Fife Kidney Center. Services to be provided include in-center hemodialysis, home hemodialysis training and backup, peritoneal dialysis training and backup, treatment shifts beginning after 5:00 p.m., a permanent bed station, and a dedicated isolation/private room. [Source: Application, page 6]

The total capital expenditure associated with this project is $2,179,918. The property owner is responsible for $472,537 and NKC is responsible for $1,707,381. Of NKC's amount, 55% is related to

[1] CN#1593 issued March 10, 2017
[2] CN#1600 issued May 10, 2017

building construction; 23% for fixed and moveable equipment; and the remaining 22% is related to taxes and fees. [Source: Application page 26]

If this project is approved, NKC anticipates the 10 new stations would be available by the end of June 2018. Under this timeline, FYE year 2019 would be the facility's first full year of operation and FYE 2021 would be year three. [Source: Application, page 8]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is 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 284 contain 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, NKC 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).

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1. On February 28, 2017, DaVita Healthcare Partners, Inc. (DaVita) also submitted an application to establish either a 13 or 10 station facility within the same planning area. DaVita's application was returned because the department determined the application as submitted was significantly different than the project identified in the letter of intent[3]. Because DaVita's application was returned, NKC's application became the only application submitted for the planning area. As allowed under WAC 246-310-282(5), NKC's application was converted to regular review.

[3] Under WAC 246-310-080(5) (a), DaVita was required "to submit a letter of intent according to the applicable schedule [in WAC 246-310-282]. The "significant change" meant that under WAC 246-310-080(3) the application became the letter of intent. Accordingly, the letter of intent failed to meet the requirement in WAC 246-310-282 that letters of intent be submitted through the last working day of January in order to qualify for consideration during the year's first concurrent review cycle.

APPLICATION CHRONOLOGY

Action	Northwest Kidney Centers
Letter of Intent Submitted	January 31, 2017
Application Submitted	February 28, 2017
Department's Pre-review Activities including	
• DOH 1st Screening Letter	March 31, 2017
• Applicant's Responses Received	May 15, 2017
• DOH 2nd Screening Letter[4]	N/A
• Applicant's Responses Received	N/A
Beginning of Review	May 22, 2017
Public Comment	
• Public comments accepted through	June 28, 2017
• Public hearing conducted[5]	N/A
• Rebuttal Comments Received	July 12, 2017
Department Declares Pivotal Unresolved Issue (PUI)[6]	August 28, 2017
End Public Comments on PUI Documents	September 19, 2017
Rebuttal Comments Submitted for PUI Document	October 5, 2017
Department's Anticipated Decision Date	November 6, 2017
Department's Actual Decision Date	November 6, 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;]

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[4] The applicant asked the department to begin review of the application

[5] The department did not conduct a public hearing.

[6] On August 28, 2017, the department declared Pivotal Unresolved Issue (PUI) regarding this application. The department declared PUI because it did not provide to DaVita Healthcare Partners, Inc., a copy of the amended pro forma income financial statement that NKC submitted on May 18, 2017 within the allowable ten days following this project formal beginning of review.

(f) Any person residing within the geographic area to be served by the applicant; and
(g) Any person regularly using health care facilities within the geographic area to be served by the applicant

For this application DaVita Healthcare Partners, Inc. and Fresenius Kidney Care sought "interested person" or "affected person" status.

DaVita HealthCare Partners, Inc.
DaVita Healthcare Partners, Inc. (DaVita) requested interested person status and to be informed of the department's decision. DaVita provides kidney dialysis services in Pierce County ESRD planning area #4 and meets the definition of an "interested person" under WAC 246-310-010(34)(b). DaVita provided comments on the NKC application and submitted rebuttal comments. DaVita Healthcare Partners, Inc. therefore qualifies as an "affected person".

Fresenius Kidney Care
Fresenius Kidney Care an affiliate of Fresenius Medical Care requested interested person status and asked to be informed of the department's decision. Fresenius Kidney Care provides kidney dialysis services in Pierce County ESRD planning area #4 and meets the definition of an "interested person" under WAC 246-310-010(34)(b), However, Fresenius did not provide public comment therefore Fresenius does not qualify as an "affected person" as it relates to this application.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers application received February 28, 2017
- Northwest Kidney Centers screening responses received May 15, 2017
- Northwest Kidney Centers supplemental screening responses received May 18, 2017
- Years 2010 through 2015 historical kidney dialysis data obtained from the Northwest Renal Network
- 2015 Northwest Renal Network 3rd Quarter Utilization Data released November 15, 2016[7]
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Northwest Kidney Centers website at www.nwkidney.org
- Northwest Renal Network website at www.nwrn.org
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files
- DaVita Healthcare Partners, Inc. PUI public comment received September 19, 2017
- Northwest Kidney Centers PUI rebuttal comment received October 5, 2017

[7] WAC 246-310-242 states: *"....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."* The first day of the application submission period was February 1, 2017.

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers proposing to establish a new ten-station kidney dialysis center in Fife within Pierce County planning area #4 is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Centers agrees to the following in its entirety.

Project Description:

This certificate approves the construction of a new ten-station dialysis center in Fife within Pierce County planning area #4. At project completion, the dialysis center is approved to certify and operate ten dialysis stations. Services to be provided at NKC Fife Kidney Center include in-center hemodialysis, home hemodialysis training and backup, home peritoneal dialysis training and backup, treatment shifts beginning after 5:00 p.m., a permanent bed station, and a dedicated isolation/private room. A breakdown of the approved ten stations is shown below:

NKC Fife Kidney Center

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	8
Total	10

Conditions:

1. Northwest Kidney Centers agrees with the project description as stated above. Northwest Kidney Centers 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, Northwest Kidney Centers 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 Northwest Kidney Centers will provide an executed copy of the lease agreement for the department's review and approval. The executed lease agreement must be consistent with the draft provided in the application.

Approved Costs:

The approved capital expenditure for this project is $1,707,381. This amount represents to the total project cost of total cost of $2,179,918, minus the landlord's cost of $472,537.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Northwest Kidney Centers project 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) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

WAC 246-310-284 requires the department to evaluate kidney disease treatment 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).[8]

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.[9]

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

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NWRN data, again concluding with the base year. [WAC 246-310-284(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

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

[9] WAC 246-310-280 defines base year as the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report." For this project, the base year is 2015.

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. Pierce County is broken into 5 sub-planning areas. NKC proposes to add dialysis stations capacity to Pierce County planning area # 4. The following zip codes are included in this planning area.

Zip	City
98402	Tacoma
98403	Tacoma
98404	Tacoma
98405	Tacoma
98406	Tacoma
98407	Tacoma
98408	Tacoma
98409	Lakewood
98416	Tacoma
98418	Tacoma
98421	Tacoma
98422	Brown Point/Dash Point
98424	Fife
98443	Tacoma
98465	Tacoma
98466	Fircrest/University Place

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.

NKC's Application of the Numeric Methodology

"In-center dialysis station[10] need for the planning area was determined by applying the five step methodology set forth in WAC 246-310-284. The specific methodology as applied to Pierce 4 is detailed below. A copy of the CN Program's methodology is included in Exhibit 12." [Source: Application, page 15]

"Table 4 details the year end number of in-center hemodialysis patients in Pierce 4. As Table 4 demonstrates, growth did not exceed six percent in each of the previous five annual change calculations. As such, a linear regression is to be used to project station need." [Source: Application, page 15]

"Table 5 details the number of projected in-center patients in Pierce 4 in the years 2016-2019

[10] Defined as in-center hemodialysis and home training patients.

Table 5 (Reproduced)
Projected Year-End Resident In-Center Hemodialysis Patients
Linear Projection

Year	*2016*	*2017*	*2018*	*2019*
Number of Patients	*362*	*376*	*389*	*403"*

[Source: Application, page 16]

"Per WAC, the projection year is 2019. For Pierce 4, the appropriate resident in-center patient per station number is 4.8. Assuming 403 patients, 84 stations are calculated as needed in 2019." [Source: Application, page 16]

"Table 6 demonstrates that there are currently 74 CN approved and/or operational stations in Pierce 4 (provided by both DaVita and the CHI/Franciscans which, when total projected need is subtracted, leaves a net need for ten stations in 2019. [Source: Application, page 16]

Table 6 (Reproduced)
Analysis of Current Supply vs. Net Station Need

	Stations
Current Supply:	
CHI Franciscan Eastside	*14*
CHI Franciscan South	*22*
CHI Franciscan St. Joseph Medical Center	*20*
DaVita Tacoma	*18*
TOTAL SUPPLY	*74*
2019 Projected Need	*84*
Net Station Need	*10"*

[Source: Application, page 17]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
NKC submitted the department's posted methodology for Pierce County ESRD planning area #4 as part of the application. No other methodology was produced.

Based on the calculation of the annual growth rate of the planning area described above, the department used linear regression to project the need for the Pierce County ESRD #4 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 ten 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 **met 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.[11] 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)

Before the department approves new in-center kidney dialysis stations, all certificate of need approved stations in the planning area must be operating at 4.8 in-center patients per station for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties. For these exception planning areas all certificate of need approved stations in the planning area must be operating at 3.2 in-center patients per station. Both resident and nonresident patients using the dialysis facility are included in this calculation. 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.

Northwest Kidney Centers

"NKC Fife (once approved) will be one of five centers in Pierce 4 (of the other four, one is owned by DaVita and three by CHI/Franciscan (Fresenius)). Per review of the September 30, 2016 data published by the Northwest Renal Network, Table 7 demonstrates that each of the existing centers is operating above 4.8 patients per station:"

Table 7 (Reproduced)
Pierce 4 Dialysis Census and Utilization

Treatment Center	*Stations*	*# of Treatments*	*Patients/ Station*
DaVita Tacoma Dialysis Center	*18*	*89[12]*	*4.94*
Franciscan Dialysis Center - Eastside	*14*	*80*	*5.71*
Franciscan Dialysis center –South Tacoma	*22*	*132*	*6.00*
Franciscan Dialysis Center- St. Joseph	*20*	*115*	*5.75*

[Source: Application, page 17]

Public Comments
None

Rebuttal Comments
None

Department Evaluation

The department uses data '*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*' to evaluate this standard. For this project submitted on February 28, 2017, the most recent quarterly data is September 30, 2016, available as of November 15, 2016.

There are four dialysis facilities located in Pierce County planning area #4. Summarized in the table below are the facilities utilization.

[11] WAC 246-310-210(1)(b)

[12] Footnote included in NKC's application: "*Includes one IPD patient. Even if this patient is excluded, DaVita Tacoma is still above the 4.8 utilization standard.*"

Table 1
Pierce County ESRD #4 Dialysis Facilities and Utilization

Facility Name	# of Station	# of Patients	Patient per Station
DaVita Tacoma Dialysis Center	18	89	4.94
Franciscan Dialysis Center Eastside	14	80	5.71
Franciscan Dialysis Center S. Tacoma	22	132	6.00
Franciscan Dialysis Center St. Joseph	20	115	5.75

As shown in the table above, the all of the stations operational at the four facilities located in the planning area are operating above the required standard. Meeting this standard indicates that the existing facilities are effectively and appropriately serving the population. Meeting this standard also indicates stations are not or will not be sufficiently available to meet future need. **This standard is met**.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For Pierce County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)]

Northwest Kidney Centers

"As table 8 demonstrates, with a total of 10 stations, and our estimated volume, NKC Fife will operate in excess of 4.8 in-center patients per station by the 3rd full year of operation (FYE2021)".

Table 8 (Reproduced)
Projected NKC Fife Kidney Center Occupancy, FYE2018-2021

Year	*Full or Partial Year*	*10 Stations*	
		Projected Patients	*Patients/ Station*
FYE 6/30/2018	*Partial*	*10*	*1*
FYE 6/30/2019	*Full*	*24*	*2.40*
FYE 6/30/2020	*Full*	*38*	*3.80*
FYE 6/30/2021	*Full*	*50*	*5.00*

[Source: Application page 18]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

NKC projects to be operating above the 4.8 standard in fiscal year 2021, its third year of operation. The department concludes the standard **is met.**

(2) *All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.*
To evaluate this sub-criterion, the department evaluates an applicant's admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services.

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

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

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

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and have an inability to pay for services. With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

Northwest Kidney Centers
NKC provided copies of the following policies used at all NKC dialysis Centers. [Source: Application, Exhibit 13]

- New Patient Admission Policy for all NKC facilities
- Charity Care Policy for all NKC facilities
- Financial Services-Patient Accounts-Patient Compliancy Policy
- Financial Services-Patient Accounts-Charity Adjustments Policy
- Financial Services-Patient Accounts-Billing Patient Charges Policy
- Financial Services-Patient Accounts-Patient Funding Sources Policy
- Financial Services-Patient Accounts-Patient Financial Account Agreement

NKC also provided the following statements regarding admission for all NKC dialysis centers. [Source: Application, page 19]

"NKC has a long established history of developing and providing services that meet the healthcare needs of the communities it serves. NKC Fife, as with all other NKC facilities, will provide services to all patients regardless of race, color, ethnic origin, religious belief, sex, age, or lack of ability to pay."

NKC provided its projected percentages of revenue and patient by source for NKC Fife Kidney Center and its assumptions used to calculate the revenue sources. [Source: Application, page 8 and page 12]

"The proposed sources of revenue, by payer, for NKC Fife are based on the actual payer mix for our three closet facilities of NKC Kent, NKC Auburn and NKC SeaTac and are:

Payer	***% Patients***	***% Net Revenue***
Medicare	*70.0%*	*43.2%*
Medicaid	*17.0%*	*10.2%*
Other	*13.0%*	*46.6%*
Total	***100.0%***	***100.0%"***

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 Fife Kidney Center.

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 Fife Kidney Center. NKC projects 87% of the facility's patients will be on Medicare or Medicaid. A review of the anticipated revenue shows the facility expects to receive 53.4% of its revenue from Medicare and Medicaid reimbursements.

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 Fife 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 Fife 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 Fife Kidney Center. **This sub-criterion is met.**

(3) *The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.*
(a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

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

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

Department Evaluation
This criterion is not applicable to this application.

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

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 Northwest Kidney Center's 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.

Northwest Kidney Centers
NKC anticipates the new dialysis center will be operational by the end of June 2018. Since NKC operates on a July to June fiscal year, NKC calculated its projected utilization for partial fiscal year ending 2018 and full fiscal years 2019 through 2021.

NKC provided the assumptions used to project in-center and home treatments and patients for the fiscal years shown. [Source: Application, page 28 and May 15, 2017, screening responses, page 11 and Attachment 3]

- In-Center dialysis patient growth was based on the growth rate experience at NKC's Auburn Kidney Center, NKC Kent Kidney Center, and NKC SeaTac Kidney Center located in the adjacent planning area.
- Home dialysis patient census estimates are based on current home dialysis patients and growth at experienced by NKC.
- In-center dialysis treatments are based on NKC's experience and assumed at approximately 148 treatments per patient per year for patient census.

Using the assumptions stated above, NKC's projected number of in-center / home patients and dialyses for the ten-station facility shown in Table 2 below. [Source: May 18, 2017, supplemental screening responses, page 11]

Table 2
NKC Fife Kidney Center
Projected Patients and Dialyses for FYE 2018-2021

	Partial Year FYE 2018	**Fiscal Year 1 FYE 2019**	**Fiscal Year 2 FYE 2020**	**Fiscal Year 3 FYE 2021**
# of Stations	10	10	10	10
In-center Treatments	123	3,552	5,624	7,400
In-center Patients	10	24	38	50
Home Treatments	0	470	1,036	1,480
Home Patients	0	5	7	10
Total Treatments	123	4,292	6,660	8,880
Total Patients	10	29	45	60

The assumptions NKC used to project revenue, expenses, and net income for its Fife center for FYE 2018 through 2021 are summarized below. [Source: May 15, 2017, screening responses, page 3, and May 18, 2017, supplemental screening responses, page 11]

"The proposed sources of revenue, by payer, for NKC Fife are based on the actual payer mix for our three closet facilities of NKC Auburn Kidney Center, NKC Kent Kidney Center, and NKC SeaTac Kidney Center. These center will best represent the payer mix for this community.

Payer	***% Patients***	***% Net Revenue***
Medicare	*70.0%*	*43.2%*
Medicaid	*17.0%*	*10.2%*
Other	*13.0%*	*46.6%*
Total	***100.0%***	***100.0%"***

- *No payment increases or decreases have been reflected.*
- *Operating costs are based on the actual costs pert treatment of a similar sized unit. No assumptions for inflation or cost escalation have been reflected.*
- *Rent costs based on lease agreement.*
- *Medical director fees are based on medical director agreement for the new facility and assumed at $65,000 annual.*
- *Expenses include annual allocated costs under the line item of 'overhead.'*
- *Medicare and Medicaid have fixed non-negotiated bundled payments that are below our cost of providing care to patients. Commercial (Other) payers have negotiated contract rates that vary by contract and are higher than Medicare and Medicaid. Therefore, commercial patients account for 13% of our patients but 46% of our net revenue (net of contractual allowances and other deductions). This is similar to what other dialysis providers have reported in previously approved CN application.*
- *A draft lease agreement for the selected site is included in Exhibit 11. The initial term is for 120 months and includes three successive five year renewal options. Included in Exhibit 11 is documentation from the Pierce County Assessor's office that the landlord, 12th Street East Development is also the property owner."*

Using the assumptions above, NKC projected the revenue, expenses, and net income for NKC Fife Kidney Center with ten dialysis stations and its home dialysis treatment program. A summary of the projections is shown in Table 3 below. [Source: May 18, 2017, supplemental screening response, page 11]

Table 3
NKC Fife Kidney Center
Revenue and Expense Statement for Projected FYE 2018 through 2021

	Partial Year FYE 2018	Full Year 1 FYE 2019	Full Year 2 FYE 2020	Full Year 3 FYE 2021
Net Revenue	$51,028	$1,775,780	$2,755,521	$3,674,028
Total Expenses	$146,675	$1,615,345	$2,320,729	$2,950,680
Net Profit / (Loss)	($95,647)	$160,435	$434,793	$723,348

Public Comments
DaVita provided public comments related to this sub criterion. DaVita's comments by topics are restated below. [Source: DaVita public comments received June 28, 2017, pages 1-5]

Patient and Dialysis Projections
"In FY 2019, NKC projects that the facility will have 24 " in-center patients" (column 2) and 4,292 "in-center dialyses." Dividing the number of treatments by the number of patients shows a projected utilization of 178.83 treatments per patient. Similarly, in FY 2020, NKC projects that the facility will have 38 in-center patients and 6,660 in-center treatments. This results in a calculation of 175.26 treatments per patient. And, in FY 2021, NKC projects 50 in-center patients and 8,880 in-center treatments, or 177.6 treatments per patient.

This is impossible. The standard assumption would be about 148.2 treatments per patient, based on three treatments per week and a missed-treatment rate of 5%. Even if NKC assumes that none of its patients will ever miss a treatment that is only 156 treatments per patient. Since there is no logical reason why NKC would project 175-179 treatments per patient, this is an obvious mistake in NKC's utilization projection.

We believe we have identified the source of the error: it appears that NKC may have double-counted home treatments and included them in both the "home dialyses" column and the "in-center dialyses" column. But whatever the source of the error, the point is that NKC did not provide reliable information to the Department in response to Question 2(F)".

Revenue and Expense Statement Information and Calculations
"In FY 2019 NKC projects 4,292, total hemo equivalent dialyses (3,552 in-center and 740 home) and $7,341,127 in net revenue. Dividing the net revenue by total treatments results in a net revenue per treatment assumption of $1,710. Since NKC projects that 13% of its patients are non-Medicare/Medicaid (557.96 treatments in 2019) and 46.6% of its net revenue is commercial ($3,420,965 in FY 2019), this means that NKC is projecting commercial net revenue per treatment of $6,131. Obviously that is a mistake. And the mistake is repeated in the FY 2020 and FY2021 columns". [Source: DaVita public comment received June 28, 217, page 2]

At first glance, it might appear that NKC simply forgot to subtract its "contractual deductions" from gross revenue to calculate net revenue. That almost certainly explains most of the discrepancy. But it does not explain all of the discrepancy. Because even setting aside that error, NKC's number still do not add up.

In FY 2019, NKC's net revenue is projected to be $7,341,127. We are unable to determine how this figure was calculated based on the other figures in the pro forma. Deducting "bad debt" and "charity care" from the $7,344,046 gross revenue results in net revenue of $7,337,050. Deducting just the bad debt results in $7,342,587. Deducting just charity care results in $7,338,509. Therefore, even setting aside the obvious failure to subtract "contractual deductions," there is no way to make NKC's numbers add up to the net revenue line. The same problem exists in the FY 2020 and FY 2021 net revenue calculations.

Finally, NKC's bottom-line in the revised projection also cannot be reconciled with net revenue. In FY 2019, net revenue is $7,341,127. As explained above, NKC obviously forgot to subtract contractual deductions when calculating net revenue, so if we subtract from net revenue the contractual deductions ($5,561,270}, as well as direct expenses ($1,256,276) and overhead ($359,069), the FY 2019 bottom-line should be $164,512. But it's not. It's $160,435. This error is replicated in the following years as well. If the same calculation is performed for FY 2020, the bottom-line should be $441,117, but it is $434,790. In FY 2021, the bottom-line should be $731,783, but it is $723,347. If we ignore the net revenue figures altogether, and start with the gross revenue figures, the numbers appear to add up to the bottom-line -figures. But this simply underscores that NKC's net revenue projections clearly are wrong".

Site Control

"NKC proposes to lease property for its proposed facility from 12th Street East Development, LLC. (Exhibit 11 - Draft Lease.) But NKC did not provide documentation confirming that this landlord actually owns the property. It provides documentation showing that this company has paid taxes on the property, but the taxpayer is not necessarily the owner.

Additionally, Section 2(P) of the Department's application form requires an applicant to provide (1) clear legal title, (2) a lease, or (3) a legally enforceable agreement to give title or a lease. NKC did not do so. NKC provides only a draft lease, which is not legally enforceable. There is no information that the proposed lease terms have even been approved by the purported landlord.

Based on the information provided by NKC, the Department has no assurance that (a) the purported landlord has the legal ability to lease the property to NKC, since there is no documentation that the landlord is the owner, or (b) the landlord will enter into a lease with NKC, since it is not legally obligated to do so and if it finds a tenant between now and the Program's decision who will enter into a lease sooner, or sign a longer lease, or pay higher rent, or is preferred to NKC for some other reason, it likely will rent to that other tenant. Because NKC has failed to provide the documentation that is specifically required by the Department's application form, NKC's application should be denied based on lack of site control."

Medical Director

"NKC's application identifies Bonnie Collins, MD, an employee of NKC, as the medical director for its proposed facility. This is the same physician that NKC recently identified as the medical director for its proposed facility in Yakima-approximately 150 miles away from this proposed facility in Fife.

Moreover, it is DaVita's understanding that Dr. Collins is no longer a practicing nephrologist, and that she has closed her practice and is no longer seeing patients. But, one of Dr. Collins's current duties is to "fill in" for vacant medical directorships at NKC facilities until a permanent medical director can be found.

On page 4 of its application, NKC proposed Dr. Collins as the medical director for this facility. And it provided a draft medical director agreement designating Dr. Collins. If Dr. Collins will not actually be the medical director-and that appears to be the case given that she is being identified as the medical director for various proposed NKC facilities as far away from each other as Fife and Yakima-NKC's application materials are highly misleading.

NKC should have identified the actual medical director for this proposed facility so that the Department could conduct its usual due diligence with respect to that medical director's credentials and licensing history. NKC should not be permitted to use a "placeholder" medical director to obtain a CON without such review, and then find the real medical director later."

Rebuttal Comments

NKC provided rebuttal comments to DaVita's statements above. It is noted that within its rebuttal comments, NKC refers to DaVita as "*DV*." NKC's rebuttal comments are restated below by topic. [Source: NKC rebuttal comments received July 12, 2017, page 1-11]

"DV attempts to argue that NKC's pro forma financials and utilization projections are unrealistic and unreliable. This is simply not accurate. NKC acknowledges that there were a few formula errors in the pro forma contained in the initial application submittal. These were fully and rightly corrected in our screening responses. For the record, NKC notes that it provided three pro forma financials: l) with the CN application, 2) with the May 15, 2017 screening response and 3) as a supplement to the May 15, 2017 screening response and well within the first 10 days following commencement of review."

Patient and Dialysis Projections

"DV argues that NKC's utilization projections are too high because our average number of treatments per patient, from their perspective, is too high. DV simply misreads our Table 1 (page 8 of the application). Table 1 included only in-center patients but it included all treatments (home and in-center). NKC's utilization is not the 175-179 treatments per patient that DV calculated from the table. DV states that the standard assumption is 148.2 treatments per patient. In fact, as depicted in Table A, this is exactly the same assumption used by NKC.

Reproduced (Table A)
NKC Fife Kidney Center
Patients and Treatment by Modality and Year

FYE 6/30	*Estimated No. of In-center Patients*	*Estimated No. of In-center Treatment*	*Estimated No. of Home Patients*	*Estimated No. of Home Treatments*	*Total Treatments*	*Treatments /Patient*
FYE 2018 (partial year, 1 month only)	*10*	*123.33*	*0*		*123.33*	*12.3*
FYE 2019	*24*	*3,552*	*5*	*740*	*4,292*	*148.0*
FYE 2020	*38*	*5,624*	*7*	*1,036*	*6,660*	*148.0*
FYE 2021	*50*	*7,400*	*10*	*1,480*	*8,880*	*148.0"*

Revenue and Expense Statement Information and Calculations

"DV claims that NKC introduced 'new errors in the revised pro forma.' It appears that DV does not have the final pro forma in its possession.

NKC, in a direct response to the Program's March 31, 2017 screening letter, provided a revised pro forma (Question #7). As requested by the Program, this revised pro forma added a line for the contractual adjustments. NKC also corrected patient census errors in Years 2 and 3 that were in the original submittal. Shortly after submittal of the screening response, NKC notified Program staff that there was a formula error in the net revenue calculation caused by the fact that the contractual adjustments line item was not subtracting from gross revenue. NKC also notified the Program that this error did not impact any other calculations, including net income. Consistent with WAC 246-310-090, a corrected pro forma financial was provided on May 18, 2017. For clarity, Table B provides a reconciliation between the pro forma submitted with the screening response and the pro forma submitted a few days later in order to validate that the only change was related to adding a formula that subtracted contractual from gross patient service revenue.

Reproduced Table B
Reconciliation of Key Pro Forma Line Items

Line Item	***5/15/2017 Pro Forma (2nd Pro forma)***	***5/18/2017 Pro Forma (3rd Pro Forma)***
	FY2022	***FY2022***
Gross Patient Service Revenue	*15,194,577*	*15,194,577*
Contractual Adjustment	*(11,506,075)*	*(11,506,075)*
Bad Debt	*(3,019)*	*(3,019)*
Charity Care	*(11,455)*	*(11,455)*
Net Patient Services Revenue	*15,188,539*	*3,674,028*
Total Direct Expenses	*2,207,780*	*2,207,780*
Excess of Direct Revenue over Direct Expenses	*1,466,248*	*1,466,248*
Overhead	*742,901*	*742,901*
Excess (Deficit) of Revenues	*723,347*	*723,347"*

[Source: NKC rebuttal comment received July 12, 2017, page 3]

"DV attempts to make an argument that the net income or 'bottom line' of the pro forma financial is not accurate. NKC has verified formulas in the pro forma and also reviewed DV's numbers. We are unable to replicate DV's numbers. NKC stands by its pro forma and 'bottom line' calculations. DV's calculations are not accurate".

Lack of Site Control

"Consistent with CN requirements, NKC provided a draft lease agreement for our selected site that includes all terms and conditions. As DV is well aware, a draft lease, as long as it includes all terms and conditions, meets the Program's requirement for site control. For example, NKC provided a draft lease in its recent application proposing to establish a new facility in the King 11 dialysis planning area. This application, containing 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.*

Clearly, DV's criticisms of site control are unfounded and must be disregarded. For the record, it should be noted that NKC has an executed lease with the landlord for the selected site. Included in Attachment 1 is an email from the landlord confirming this fact and that the landlord owns the site."

Medical Director

"DV argues that NKC's 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 and is our Associate Chief Medical Officer (CMO). NKC purposefully selected Dr. Collins to serve as medical director in Fife, as NKC wanted an experienced medical director in Fife 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. DV's comments are without merit."

On May 15, 2017, NKC submitted it second screening responses to the department and the responses along with other documents were mailed to DaVita for public comment. On May 18, 2017 NKC informed the department that the pro forma income statement submitted with screening responses has mathematical errors in it. Because this timeline was within the allowable ten days of the project official beginning of review that an applicant may resubmit information related to screening questions NKC resubmitted an amended pro forma financial income statement. Because this document was resubmitted days after a copy of screening responses were mailed to DaVita, the amended pro forma financial income statement was mistakenly not mailed to DaVita. This mistake was not detected until on August 28, 2017, and as a result, the department declared a Pivotal Unresolved Issue (PUI).

PUI Medical Director Comments

"As we noted in our public comment, NKC's original pro forma (submitted with its February 27 application) and revised pro forma (submitted with its May 15 screening responses) each contained significant errors. NKC's second revised pro forma, which the Department provided with its PUI notice, appears to correct the specific errors that we previously identified. However, NKC's projections are still deficient in two significant respects—and the Department should deny NKC's application based on its failure to satisfy the financial feasibility and cost containment criteria". [Source: PUI comments submitted by DaVita received on September 19, 2017 page 1]

"The medical director fee in NKC's second revised pro forma is unreliable, because NKC has not even identified a medical director for its facility, much less negotiated his or her fee". The medical director identified by NKC—Bonnie Collins, MD –would not be the actual medical director for this facility. Dr. Collins is no longer a practicing nephrologist; she is a senior NKC executive whose name NKC now uses as placeholder in CON applications when it has not yet identified a medical director for a proposed facility. This is confirmed by the fact that NKC also identified Dr. Collins as the medical for its proposed Yakima facility at the same time it was applying for this proposed Fife facility—i.e., according to NKC's CON applications, Dr. Collins would serve, simultaneously, as the medical director for two facilities located 150 miles away from each other". [Source: PUI comments submitted by DaVita received on September 19, 2017 page 1]

"The department historically has permitted a draft medical director agreement to be provided. The problem is not that NKC submitted a draft agreement. The problem is that NKC has not identified the actual medical director for this facility, and therefore the medical director fee in the draft agreement is unreliable". [Source: PUI comments submitted by DaVita received on September 19, 2017 page 1]

PUI Site Control Comments

"NKC had failed to demonstrate site control, because the draft lease submitted with its application is not legally binding on the landlord. The specific issue of NKC failing to demonstrate site control was in DaVita's public comments. Here, we simply add that this also is a reason why NKC's second revised pro forma is not reliable. It identifies rent of $168,850, $207,512, and $212,696 in years 2019, 2020, and 2021 respectively, but the landlord is under no legal obligation whatsoever to lease the property to NKC for that amount of rent. The landlord could demand much higher rent than this to lease the property to NKC". [Source: PUI comments submitted by DaVita received on September 19, 2017 page 2]

"In its rebuttal comments, NKC stated that a lease has been signed[13]. Even if signing a lease after the application was placed under review would be considered timely, NKC did not actually provide a copy of the purported "signed" lease, so it is impossible to verify that it has been signed by all parties or whether the rent in the signed lease is the same as what was identified in the pro forma". [Source: PUI comments submitted by DaVita received on September 19, 2017 page 2]

PUI Rebuttal Comments

"DaVita responded to the PUI on September 19, 2017 and, its response states: NKC's second revised pro forma, which the department provided with its PUI notice, appears to correct the specific errors that we previously identified".

"DaVita's PUI public comments are outside the scope of the PUI and must be disregarded. However, to assure that the record is complete, in Table 1, NKC provides a summary of the irrelevant issues raised by DaVita, along with our brief responses.

Table 1
Summary of Issues Raised Beyond the Scope of PUI

Issues Raised Beyond Scope	***NKC Response***
Medical Director not identified and medical director fees not negotiated	*NKC has identified a medical director and the medical director fees. NKC acknowledged that the medical director agreement is draft, however, any CN issued will contain a condition that NKC provide an executed medical director agreement consistent with the draft. Therefore, the medical director fees provided within the application are accurate and reliable.*
2nd revised pro forma is unreliable because the draft lease is not legally binding.	*NKC's submittal of a draft lease is consistent with the Program's requirements (sic). NKC is well aware that it will be required, upon CN approval, to provide an executed lease agreement to the Program that must be consistent with the draft lease. This executed lease*

[13] NKC's rebuttal comments, received July 12, 2017, page 4.

	agreement will be for the same terms as outlined in the draft lease. Therefore, NKC's draft lease is also reliable". [Source: PUI rebuttal comments submitted by NKC received on October 5, 2017 page 3]

Department Evaluation

The concerns raised by DaVita PUI comments about NKC's medical director and site control were both addressed with the draft documents provided by NKC. As it relates to the draft medical director agreement DaVita stated the fact that NKC provided a draft medical director agreement is not the issue, but the medical director selected for the facility is no longer an active nephrologist because the physician is retired. DaVita also stated that the physician is a senior NKC executive. A review of the information provided in the application shows the physician is an active staff of NKC. In the application NKC provided a listing of its active and courtesy medical staff. Within the list, it was stated that Dr. Bonnie Collins is an active medical staff. [Source: Application Exhibit 5]

DaVita also stated that NKC has not demonstrated site control because the landlord is not obligated to rent to NKC or could charge a much higher rent however, DaVita did not provide any document to support this assertions. A review of the draft lease agreement submitted by NKC show that it identified rent amounts and the amounts were verified in the pro forma financial statement provided by NKC. The department agrees with NKC that if this application is approved, conditions would be attached to the approval requiring NKC to provide its executed medical director and lease agreement consistent with the drafts provided in the application.

NKC anticipates the 10-station Fife Kidney Center would be operational by the end of June 2018. NKC operates on a fiscal year (July 1 through June 30) rather than on a calendar year. Table 4 illustrates the projected revenue, expenses, and net income for years FY 2018 through FY 2021 for NKC Fife Kidney Center.

Table 4
NKC Fife Kidney Center
Projected Revenue and Expenses-Fiscal Years 2018 - 2021

	Partial FY 2018	**FY 1-2019**	**FY 2-2020**	**FY 3-2021**
# of Stations	10	10	10	10
# of Treatments [1]	123	4,292	6,660	8,880
# of Patients [1]	10	24	38	50
Utilization Rate [1]	1.00	2.40	3.80	5.00
Net Patient Revenue [3]	$51,028	$1,775,780	$2,755,522	$3,674,028
Total Expense [2]	$136,357	$1,256,276	$1,763,553	$2,207,779
Net Profit or (Loss)[14]	**($95,647)**	**$160,435**	**$434,793**	**$723,348**

[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/cost allocations. The line item also includes lease costs and medical director costs consistent with the draft agreements

[14] Amounts may not add due to rounding

provided in the application. At NKC's projected volumes, the 10-station facility would make a profit in each of the facility's first three full years of operation.

Related to DaVita's comments regarding NKC's projected patient volumes and dialyses. Those comment were addressed by NKC in its rebuttal. The department concludes NKC's assumptions, projected patients and dialyses are reasonable.

About DaVita's comments related to the proposed facility site, the documentation provided by NKC demonstrated site control. In addition to documentation demonstrating site control, NKC also provided a letter from the landlord confirming the ownership and execution of a lease agreement with contingency language related to issuance of a Certificate of Need. Although the landlord letter dated July 10, 2017 mentioned that fully enforceable lease for the site was signed by Northwest Kidney Centers on February 28, 2017, the department does not have a copy of the document alluded to by the landlord. Base on the documentation submitted in the application, the department concludes that NKC has demonstrated site control. In addition, the department review of the draft lease agreement and site control documentation provided by NKC shows that rent costs[15] identified in the lease are consistent with the financial information summarized in NKC's revenue and expense statement. If NKC's application is approved, the department would attach a condition requiring NKC to provide a copy of its executed lease agreement for review and approval.

For the proposed facility medical director Dr. Bonnie Collins, DaVita stated that Dr. Collins no longer sees dialysis patients outside of a dialysis center because she is retired and not an active nephrologist. In its rebuttal, NKC agreed with DaVita's comments, but stated that as an active employee, Dr. Collins can be assigned as medical director to any of NKC's facility. As previously stated the department confirmed that Dr. Collins is an active employee of NKC.

Given that Dr. Collins is an active employee of NKC, the department can conclude that NKC demonstrated it will have a valid medical director for the Fife Kidney Center. 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. If NKC's application is approved the department would attach a condition requiring NKC to provide a copy of its executed medical director agreement for review and approval.

Based on the information reviewed and with NKC's agreement to the conditions identified above, the department concludes that the immediate and long-range operating costs of the project can be met. **This sub-criterion is met.**

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[15] NKC's lease agreement identified costs associated with the property common areas and taxes.

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

WAC 246-310 does not contain specific 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.

Northwest Kidney Centers

"Northwest Kidney Centers has extensive experience in the design, construction and equipping of dialysis facilities. Northwest Kidney Centers based the construction costs on its recent experience on its recent new construction projects (including Enumclaw Kidney Center and Kirkland Kidney Center)". [Source: Application, page 27]

"The capital costs for the project are detailed in Table 10:

Table 10 (Reproduced)
NKC Fife Capital Expenditures

	NKC Fife	***Landlord Costs***	***Total Project Costs***
TI Building Construction	*$939,200*	*$346,527*	*$1,284,727*
Fixed Equipment	*$148,150*		*$148,150*
Moveable Equipment	*$249,125*		*$249,125*
Architect & Engineering Fees	*$152,745*		*$152,745*
Consulting Fees	*$2,000*		*$2,000*
Sales Tax	*$209,711*		*$209,711*
Misc. Equipment/Signage	*$7,450*		*$7,450*
Real Estate Commission		*$126,010*	
Total Estimated Capital Costs	*$1,708,381*	*$472,537*	*$2,179,918"*

[Source: Application, page 26]

Public Comment

During the review of this project, DaVita provided comments related to the equipment costs identified by NKC. DaVita's comments are restated below. [Source: DaVita June 28, 2017, public comment, page 5]

"DaVita estimated fixed and movable equipment costs, including furniture, for a new 10-station facility in Pierce 4 at $592,217. NKC's stated costs are $441,850. (Table 10 on page 26 of application.) Even assuming 10% sales tax, this is only $486,045. It appears that NKC may have underestimated its equipment costs."

Rebuttal Comments

NKC provided the following statements related to DaVita's comments about equipment costs. [Source: NKC Rebuttal comment received July 12, 2017, pages 4-5]

"NKC undertakes construction of new, expanded or replacement facilities on a regular basis. These projects include the building of new centers or remodels to update equipment and furnishings. We have both in-house and under contract facilities staff with significant experience in

construction and equipment cost estimating. The costs to build and equip each project are calculated specifically for that facility. Our equipment costs for Fife were vetted by our Director of Facilities (with over 25 years' experience here at NKC on similar projects) and our VP of Planning - we stand by the accuracy of these costs. DV claims that these costs of $441,850 (or, $44,185 per station) "may" be underestimated; yet DV provided ***no*** *data or other evidence to substantiate this claim.*

NKC has reviewed several recent DV applications and has found that the average equipment cost per station (in facilities sized between 7 to 11 stations) varied from $34,652 to $65,729. NKC is well within this range for this project and is confident that it can equip NKC Fife with the needed equipment as desclibed in Exhibit 8 of the CN application."

Department Evaluation

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

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 87% of the patients are projected to be Medicare and Medicaid. Revenue from these two sources are projected to equal 53.4%. The remaining 46.6% 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 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, the department concludes **this sub-criterion is met.**

(3) The project can be appropriately financed.

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

Northwest Kidney Centers

"This project will be funded through existing capital reserves of NKC. No financing is necessary." "This is the least costly [financing] *alternative".* [Source: Application, page 27-28]

"A copy of the board commitment letter is included in Exhibit 14." [Source: Application, page 27]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The total cost of the project is $2,179,918. Of this amount, $1,707,381 is NKC's financial responsibility. The remaining $472,537 is the responsibility of the landlord. The letter from the NKC Board of Trustees demonstrates the board's financial commitment to this project. The department also reviewed NKC's audited financial statements for fiscal years 2014, 2015, and 2016. [Source: Application, pages 26-27, Exhibit 14, and Appendix 1] NKC has demonstrated sufficient unrestricted assets to finance the proposed project. The department concludes the NKC Fife Kidney Center can be appropriately financed. **This sub criterion is met.**

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

Based on the source information reviewed and provided the applicant agrees to the conditions identified in the 'conclusion' section of this evaluation, the department concludes Northwest Kidney Centers has met the structure and process of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size.

Northwest Kidney Centers

"NKC offers a competing wage and benefit packages 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, and we do not anticipate any problems with this new Center". [Source: Application, page 30]

"Table 11 details the proposed staffing for this project.

Table 11 (Reproduced)
NKC Fife Kidney Center
Proposed Total Staffing

	FYE 2018	*FYE 2019*	*FYE 2020*	*FYE 2021*
HD Tech	*.69*	*3.33*	*5.27*	*6.94*
RN	*.37*	*1.79*	*2.84*	*3.74*
RN-Home Training (PD & HH)[16]	*0*	*.23*	*.32*	*.45*
Clinical Nurse Manager	*1.00*	*1.00*	*1.00*	*1.00*
Facility System Specialist	*.50*	*.50*	*.50*	*.50*
MSW	*.09*	*.26*	*.41*	*.55*
Dietician	*.08*	*.24*	*.38*	*.50*
Receptionist	*1.00*	*1.00*	*1.00*	*1.00*
Total	*3.73*	*8.35*	*11.72*	*14.68"*

[Source: Application, page 29]

"A complete listing of NKC Medical Staff is included in Exhibit 5 and includes 54 active staff and 43 courtesy staff. The proposed Medical Director for NKC Fife is Dr. Bonnie Collins, MD and the. Physician professional license number is MD00025706. The draft Medical Director agreement with Dr. Collins is included in Exhibit 6." [Source: Application, page 4]

Public Comments

During this review, DaVita provided comments related to the medical director identified in NKC's application. The comments and NKC's rebuttal were addressed in the financial feasibility section of this evaluation. In its financial feasibility review, the department concluded that NKC's medical director could provide services at the new facility and the draft agreement provided by NKC was appropriate. The department will not repeat the information in this section.

Department Evaluation

The majority of the FTEs are expected to be in the categories of nursing and HD Techs that are direct patient care positions. When the new facility opens in 2018, NKC is expected to have 3.73 FTEs and this would increase in the coming years. NKC 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 Bonnie Collins, MD. NKC provided a draft of the medical director agreement between itself and Dr. Collins. The initial term of the agreement is one-year with annual automatic renewals. [Source: Application, page 4, and Exhibit 6]

If this application is approved, the department would attach a condition that prior to providing services NKC 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.**

[16] Peritoneal Dialysis (PD) and Home Hemodialysis (HH)

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

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

Northwest Kidney Center

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	
Medical Staff Credentialing	[Source: Application, page 31]

"*Although NKC Fife will be a new facility Auburn has operated in the adjacent planning area (King 11) since 1997. The proposed new Center is also in proximity to our Centers located at SeaTac (King 4) and Kent (King 10). The new facility will assure that our commitment to the community continues, and NKC will continue to maintain all existing working relationship with physicians in the community. A copy of the existing transfer agreement between NKC and Swedish Medical Center is included in Exhibit 16.*" [Source: Application, page 32]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

NKC provided a listing of the 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 Fife Kidney Center.

NKC also provided a copy of its current transfer agreement between NKC and Swedish Medical Center. This transfer agreement was executed October 2, 2013, as an initial one year term and includes indefinite automatic annual renewals. The department concludes there is reasonable assurance the NKC Fife Kidney Center would have the necessary ancillary and support services. **This sub-criterion is met.**

(3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*
WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2) (a) (i). There are 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.

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

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

Northwest Kidney Centers
"NKC operates all existing programs in conformance with applicable federal and state laws, rules, and regulations. NKC has no history with respect to the actions noted in CN regulations WAC 248-19-390 (5)(a), now codified at WAC 246-310-230(5)(a)." [Source: Application, page 34]

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. With the exception of two dialysis centers that are not yet operational, the remaining 15 centers owned, operated, or managed by NKC are Medicare certified. The department reviewed the compliance history for all 15 centers listed above. 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 NKC

facilities.[17] These surveys revealed minor non-compliance issues typical of a dialysis facility. NKC submitted and implemented acceptable plans of correction. [Source: DOH IIO survey data]

Table 5 below shows the fifteen NKC dialysis centers and the CMS star ratings. [Source: May 25, 2017, CMS compare data]

Table 5
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

As shown in Table 5 above, the facilities operated or owned by NKC have an average rating of 4.3 stars.

NKC identified Dr. Bonnie Collins, MD as the proposed medical director for NKC Fife Kidney Center. A review of Dr. Collins' 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 Fife Kidney Center would be operated in conformance with applicable state and federal licensing and certification requirements. **This sub criterion is met.**

[17] 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) *The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.*

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are 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.

Northwest Kidney Centers

"Although NKC Fife will be a new facility Auburn has operated in the adjacent planning area (King 11) since 1997. The proposed new Center is also in proximity to our Centers located at SeaTac (King 4) and Kent (King 10). The new facility will assure that our commitment to the community continues, and NKC will continue to maintain all existing working relationship with physicians in the community". [Source: Application, page 32]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

If approved, NKC Fife Kidney Center would be NKC's first dialysis facility outside of King or Clallam counties. NKC has been operating in King County for many years, including planning area #11, which is adjacent to Pierce County planning area #4. NKC stated it has been providing services in King County planning area #11 since 1997 and has maintained appropriate relationships with existing healthcare providers in the service area. The department concludes that NKC has the experience and expertise to expand into a new county.

This project would add a fifth dialysis provider to Pierce County ESRD #4, and nothing in the materials reviewed by the department suggests that approval of the NKC Fife Kidney Center will change the relationships NKC has with the existing service area providers. The department concludes **this sub-criterion is met**.

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

This sub-criterion is evaluated in sub-section (3) above and **is met**.

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

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 Northwest Kidney Center's has met the cost containment criteria in WAC 246-310-240.

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230 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 Step three. 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) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Department Evaluation

Step One

The department determined 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

"NKC considered the following options to developing the enclosed proposal:

1) *Purchase land and build a new 10 station treatment center or purchase an existing building and create a new center.*
2) ***Create a new 10 station center within a leased building and install our traditional water room. This application was designed around this option.***
3) *Choose to not apply for the need in this planning area; and*
4) *Apply for need other than the 10 stations specified".* [Source: Application Page 35]

- *"Option 1: While NKC has purchased land or purchased buildings and built treatment centers in the past-doing so within the tight window of a Certificate of Need application is difficult (the time from which notification is provided that an application can be submitted*

and the actual application filling date). We also found that much of the Pierce 4 planning area zoning requires a "Conditional Use Permit" to secure correct zoning, which can take 120 days to confirm. Therefore this option was eliminated." [Source: Application Page 35]

- *"Option 2: **Create a new 10 station center in leased space**. As noted in other sections of this application, the need for 10 stations coupled with the high census of the existing providers led NKC to move forward on the establishment of a new center. Using leased spaced and our traditional water system was deemed most effective (cost effective and cost efficient, based on our NKC standard)".* [Source: Application Page 36]

- *"Option 3: NKC considered not applying for the need in Pierce 4 but doing so would not have met the needs in the community. Further, given the pending sale of CHI Franciscan's dialysis units to Fresenius, NKC wanted to assure that for those patients preferring a non-profit provider that one remained available."* [Source: Application Page 36]

- *"Option 4: Applying for stations that was greater than the need requires an exception, and applying for less than the projected need would be detrimental under the tie-breaker criteria contained in the current rules. For these reasons, this option was ruled out."* [Source: Application Page 36]

- *"Within Pierce 4 planning area we have three (3) patients living in this area. However, within all of Pierce County, we have an additional 20 patients living in communities of Puyallup, Lake Tapps, Sumner, Bonney Lake, other parts of Tacoma, and as far away as Graham and Lakewood. All of these patients would benefit from having an NKC Fife Kidney Center."* [source: NKC screening responses received May 15, page 1]

Public Comment
None

Rebuttal Comment
None

Step Three
This step is applicable only when there are two or more approvable projects. For the ESRD 2017 cycle #1 submission period, NKC's application was the only application accepted and reviewed for the Pierce #4 planning area. Therefore, this step does not apply.

Department Evaluation of Steps One and Two
NKC considered several options before selecting the option to establish a facility in Fife. As noted by NKC, its goal is to improve kidney dialysis access in Pierce County ESRD planning area #4. 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.

Information provided in the application demonstrates that superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable for the patients in Pierce County planning area #4. An additional ten stations in Fife could result in patients having more flexibility scheduling for dialysis.

NKC identified a total cost of $2,179,918 to be expended to establish the new center. Of that amount, NKC is responsible for approximately 78% or $1,707,381. The remaining $472,537 is the responsibility of the landlord.

Given that the other options to this project were either significantly more expensive or no cost—which is do nothing in the planning area—and taking into account the projected need for additional stations in the planning area, the department concludes that the project submitted by NKC is the best available alternative for the community. **This sub-criterion is met.**

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

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

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.

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. The new facility will comply with the State Energy Code, latest edition." [Source: Application pages 36-37]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

NKC proposes to lease space in an existing building. These costs were evaluated in the financial feasibility section of this analysis. There is no information within the application that would cause the department to conclude that the costs of the project are unreasonable. 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.

Northwest Kidney Centers

NKC provided the following statements related to this sub-criterion. [Source: Application, page 36]

"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."

Public Comments

None

Rebuttal Comments

None

Department Evaluation

NKC's project involves construction. With the need for additional stations in Pierce County planning area #4 and the assumptions related to the costs and charges discussed under the Financial Feasibility section of this evaluation, the department does not anticipate an unreasonable impact on the costs and charges to the public as a result of establishing a new dialysis center in the planning area. The department also concludes that NKC **meets this sub-criterion**.

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

Department Evaluation

This project will improve the delivery of health services by locating those services closer to a portion of ESRD Pierce #4 dialysis patients. Additionally, with the projected need for additional dialysis stations with the ESRD Pierce #4 planning area, the construction costs for this will appropriately improve the delivery of health services. The department concludes **this sub-criterion is met**.

APPENDIX A

2016
Pierce County 4 - CORRECTED
ESRD Need Projection Methodology

Planning Area	6 Year Utilization Data - Resident Incenter Patients					
Pierce Four	2010	2011	2012	2013	2014	2015
98402	6	9	11	7	10	12
98403	13	12	10	9	10	7
98404	53	54	69	70	77	81
98405	40	48	52	48	52	51
98406	11	10	14	13	19	14
98407	18	20	18	20	21	17
98408	27	31	34	29	36	42
98409	38	33	33	33	40	43
98416	0	0	0	0	0	0
98418	20	18	17	14	15	16
98421	0	0	1	0	2	1
98422	20	19	17	12	15	15
98424	10	8	8	7	7	10
98443	3	3	6	10	10	6
98465	3	4	6	7	7	10
98466	25	25	26	15	27	24
TOTALS	287	294	322	294	348	349

246-310-284(4)(a)							
	Rate of Change		2.44%	9.52%	-8.70%	18.37%	0.29%
	6% Growth or Greater?		FALSE	TRUE	FALSE	TRUE	FALSE
	Regression Method:	Linear					

246-310-284(4)(c)		Year 1	Year 2	Year 3	Year 4
		2016	2017	2018	2019
Projected Resident Incenter Patients	from 246-310-284(4)(b)	362.20	375.80	389.40	403.00
Station Need for Patients	Divide Resident Incenter Patients by 4.8	75.4583	78.2917	81.1250	83.9583
	Rounded to next whole number	76	79	82	84

246-310-284(4)(d)	subtract (4)(c) from approved stations				
Existing CN Approved Stations		74	74	74	74
Results of (4)(c) above	-	76	79	82	84
Net Station Need		-2	-5	-8	-10

Negative number indicates need for stations

Planning Area Facilities

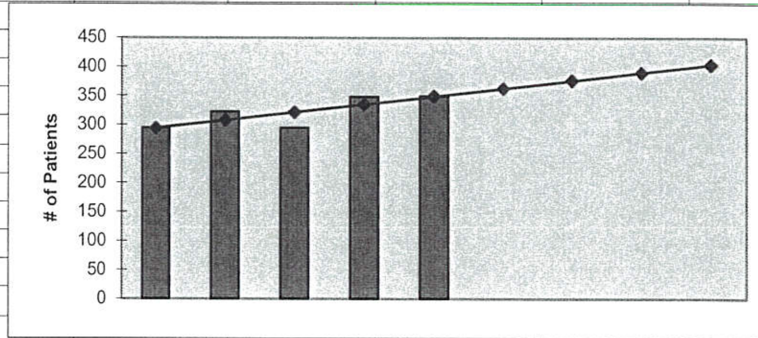
Name of Center	# of Stations
DaVita - Tacoma	13
FHS St. Joseph East	14
FHS South Tacoma	22
FHS St. Joseph Medical	25
Total	74

Source: Northwest Renal Network data 2010-2015
Most recent year-end data: 2015 posted 02/05/2016

Prepared by CN Program Staff - March 2016

2016
Pierce County 4 - CORRECTED
ESRD Need Projection Methodology

x	y	Linear
2011	294	**294**
2012	322	**308**
2013	294	**321**
2014	348	**335**
2015	349	**349**
2016		**362.20**
2017		**375.80**
2018		**389.40**
2019		**403.00**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.788992664
R Square	0.622509424
Adjusted R Square	0.496679232
Standard Error	19.33563205
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	1849.6	1849.6	4.94721826	0.112598582
Residual	3	1121.6	373.8666667		
Total	4	2971.2			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-27055.4	12308.41852	-2.19812155	0.115374355	-66226.28104	12115.48104	-66226.28104	12115.48104
X Variable 1	13.6	6.114463727	2.224234309	0.112598582	-5.858952496	33.0589525	-5.858952496	33.0589525

RESIDUAL OUTPUT

Observation	*Predicted Y*	*Residuals*
1	271.4	-10.4
2	281.5	5.5
3	291.6	2.4
4	301.7	20.3
5	311.8	-17.8