



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

February 1, 2018

CERTIFIED MAIL # 7016 3010 0001 0575 0921

Austin Ross, VP of Planning
Northwest Kidney Centers
700 Broadway
Seattle, WA 98122-4302

RE: Certificate of Need Application #17-41

Dear Mr. Ross:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers proposing establish a new dialysis facility located in King County Planning Area #2 by relocating stations from NKC Seattle and NKC Elliott Bay. 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, 12-station dialysis facility to be located in Seattle within King County planning area #2. The facility would be known as NKC Rainier Beach. Eight of the stations will be relocated from NKC Seattle Kidney Center; the remaining four will be relocated from NKC Elliott Bay Kidney Center. At project completion, the dialysis center is approved to certify and operate 12 dialysis stations. Services to be provided at NKC Rainier Beach include in-center hemodialysis, peritoneal and hemodialysis 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 12 stations is shown below:

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

Following project completion, NKC Elliot Bay would be approved to certify and operate 14 stations and NKC Seattle would be approved to certify and operate 30 stations.

Conditions:

1. Approval of 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. Northwest Kidney Centers will finance the project as described in the application.
3. No later than 30 days following CMS certification of NKC Rainier Beach, Northwest Kidney Centers will request Centers for Medicare and Medicaid Services (CMS) to decertify and cease operation of 8 stations at the NKC Seattle Kidney Center and 4 stations from NKC Elliott Bay Kidney Center
4. 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.
5. Prior to providing services at NKC Rainier Beach, Northwest Kidney Centers will provide an updated transfer agreement listing NKC Rainier Beach as part of the agreement for the department's review and approval

Approved Costs:

The approved capital expenditure for this 12-station facility is \$12,622,415. Of this amount, NKC is responsible for \$12,547,415.

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

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

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

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

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

Austin Ross, Northwest Kidney Centers
CN Application #17-41
February 1, 2018
Page 3 of 3

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

Sincerely,



Nancy Tyson, Executive Director
Health Facilities and Certificate of Need
Office of Community Health Systems

Enclosure

EVALUATION DATED FEBRUARY 1, 2018 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING TO ESTABLISH A 12 STATION KIDNEY DIALYSIS FACILITY IN KING COUNTY END STAGE RENAL DISEASE PLANNING AREA #2

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	Lake City Kidney Center
Broadway Kidney Center	Lake Washington Kidney Center
Elliot Bay Kidney Center	Renton Kidney Center
Enumclaw Kidney Center	Scribner Kidney Center
Federal Way-East Kidney Center ¹	Seattle Kidney Center
Federal Way-West Kidney Center ²	SeaTac Kidney Center
Kent Kidney Center	Snoqualmie Ridge Kidney Center
Kirkland Kidney Center	West Seattle Kidney Center

Clallam County

Port Angeles Kidney Center

PROJECT DESCRIPTION

NKC proposes to construct a 12-station kidney dialysis facility at 4401 South Trenton Street in Seattle [98118] within King County ESRD planning area #2. Eight of the stations would be relocated from NKC Seattle, and four would be relocated from NKC Elliot Bay. Both of these facilities are also located within King County ESRD planning area #2. If approved, this project would not result in an increase in dialysis stations in the planning area. The 12-station facility would be known as NKC Rainier Beach. 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 p2, p7]

The total capital expenditure associated with this project is \$12,622,415. NKC is responsible for all but \$75,000 of this amount. The \$75,000 is solely related to real-estate broker fees, and was paid by the former owner of the site. Of NKC’s amount, 71% is related to land purchase, improvements and building

¹ CN#1593 issued March 10, 2017

² CN#1600 issued May 10, 2017

construction; 7% for fixed and moveable equipment; and the remaining 22% is related to taxes and fees. [Source: Application page 27]

If this project is approved, NKC anticipates the 12 stations would be operational by May 2019. Under this timeline, FYE year 2020 would be the facility's first full year of operation and FYE 2022 would be year three. [Source: Application p7]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as an increase in the number of dialysis stations at a kidney disease center under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

EVALUATION CRITERIA

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

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

- (a) In the use of criteria for making the required determinations, the department shall consider:*
 - (i) The consistency of the proposed project with services or facility standards contained in this chapter;*
 - (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the service or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
 - (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.”*

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

- (b) The department may consider any of the following in its use of criteria for making the required determinations:*
 - (i) Nationally recognized standards from professional organizations;*
 - (ii) Standards developed by professional organizations in Washington State;*
 - (iii) Federal Medicare and Medicaid certification requirements;*
 - (iv) State licensing requirements*
 - (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*
 - (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.*

WAC 246-310-280 through 289 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). NKC must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers-Concurrent Review Cycle #2 for calendar year 2017. No other applications were submitted for the King County planning area #2 during the cycle. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review. Below is a chronologic summary of the review.

APPLICATION CHRONOLOGY

Action	Northwest Kidney Centers
Letter of Intent Submitted	April 28, 2017
Application Submitted	May 31, 2017
Department’s Pre-review Activities including <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant’s 1st Screening Responses Received • DOH 2nd Screening Letter • Applicant’s 2nd Screening Responses Received 	June 30, 2017 August 14, 2017 September 5, 2017 October 20, 2017
Beginning of Review	October 27, 2017
End of Public Comment <ul style="list-style-type: none"> • Public comments accepted through the end of public comment • No public hearing requested or conducted 	December 4, 2017
Rebuttal Comments Received ³	December 19, 2017
Department’s Anticipated Decision Date	February 2, 2018
Department’s Actual Decision Date	February 1, 2018

AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines “affected” person as:

“...an “interested person” who:

- (a) *Is located or resides in the applicant's health service area;*
- (b) *Testified at a public hearing or submitted written evidence; and*
- (c) *Requested in writing to be informed of the department's decision.”*

As noted above, WAC 246-310-010(2) requires an affected person to first meet the definition of an ‘interested person.’ WAC 246-310(34) defines “interested person” as:

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

³ The department did not receive any public comment. As a result, NKC cannot provide rebuttal comments.

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

For this project, no entity requested interested or affected person status.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers’. Certificate of Need application received May 31, 2017
- Northwest Kidney Centers’. 1st screening response received August 14, 2017
- Northwest Kidney Centers’. 2nd screening response received October 20, 2017
- Years 2011 through 2016 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2016 Northwest Renal Network December 31, 2016 (fourth quarter) utilization data released February 15, 2017
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Northwest Kidney Centers website at <https://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

CONCLUSIONS

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers proposing to establish a 12-station dialysis facility located in King County planning area #2 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, 12-station dialysis facility to be located in Seattle within King County planning area #2. The facility would be known as NKC Rainier Beach. Eight of the stations will be relocated from NKC Seattle Kidney Center; the remaining four will be relocated from NKC Elliott Bay Kidney Center. At project completion, the dialysis center is approved to certify and operate 12 dialysis stations. Services to be provided at NKC Rainier Beach include in-center hemodialysis, peritoneal and hemodialysis 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 12 stations is shown below:

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Conditions:

1. Approval of 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.
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5. Prior to providing services at NKC Rainier Beach, Northwest Kidney Centers will provide an updated transfer agreement listing NKC Rainier Beach as part of the agreement for the department's review and approval

Approved Costs:

The approved capital expenditure for this 12-station facility is \$12,622,415. Of this amount, NKC is responsible for \$12,547,415.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the Northwest Kidney Centers project has met the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-280 through 289.

- (1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

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

Northwest Kidney Centers

“There are a total of four dialysis facilities located in King 2; of these four facilities, three are operated by NKC (NKC Broadway, NKC Elliott Bay and NKC Seattle). NKC Broadway is NKC's 'oldest facility' in that it was NKC's first outpatient dialysis facility. Originally called NKC Havilland, it was the largest facility operated by NKC. In 2008, 3 8 stations were relocated to establish NKC Seattle (with 15 stations remaining at NKC Broadway). NKC Elliott Bay was established in 1991 with 15 stations and three additional stations were added in 1994.

NKC is now proposing to take a portion of those stations (8 from NKC Seattle and 4 from NKC Elliott Bay) and establish NKC Rainier Beach. After reviewing patient origin and other demographic data, NKC concluded that locating a facility in South Seattle would improve access to dialysis services for a significant segment of the King 2 dialysis patient population. This facility will be located in the Rainier Valley/Rainier Beach area (zip code 98118). The most recent Northwest Renal Network data indicates that there are 94 patients residing in 98118 and an additional 33 patients residing in the adjacent zip code of 98108. For some of these patients, they may find travel times reduced by driving south to NKC Rainier Beach as opposed to driving north to other King 2 facilities.” [source: Application p14]

“No new stations are being proposed as a result of this project. The establishment of NKC Rainier Beach will bring dialysis services closer to a core segment of our patient population.” [source: Application p20]

NKC provided a table that identifies the distance and approximate drive time between the proposed and the existing facilities in King County ESRD planning area #2. [source: August 14, 2017 screening response p3]

<i>Facility</i>	<i>Distance to NKC Rainier Beach</i>	<i>Travel Time to NKC Rainier Beach</i>
<i>NKC Seattle</i>	<i>7.6 miles</i>	<i>16-35 minutes</i>
<i>NKC Elliot Bay</i>	<i>7.2 miles</i>	<i>16-35 minutes</i>
<i>NKC Broadway</i>	<i>7.2 miles</i>	<i>16-35 minutes</i>
<i>DaVita Olympic View</i>	<i>8.9 miles</i>	<i>20-40 minutes</i>

NKC provided further comments related to travel time and methods within the King # planning area. [source: Application p15]

“Data from American FactFinder indicates that for residents of zip code 98118, 22.1 % are below federal poverty levels (compared to only 11.2% for King County). For lower income residents, having a facility closer to home will mean reduced travel times (particularly for those using public transportation). This is not insignificant as patients often feel unwell following treatment so even a 10-15 minute reduction in travel time will be an improvement. For those patients coming to dialysis by car; NKC Rainier Beach will have its own parking spaces, right outside the front door. Neither NKC Seattle nor NKC Elliott Bay have parking that is as accessible; their parking is located on adjacent property. While this may seem like a small benefit, it can make a difference for dialysis patients to be able to go to and from their car more easily.”

Public Comment

None

Rebuttal

None

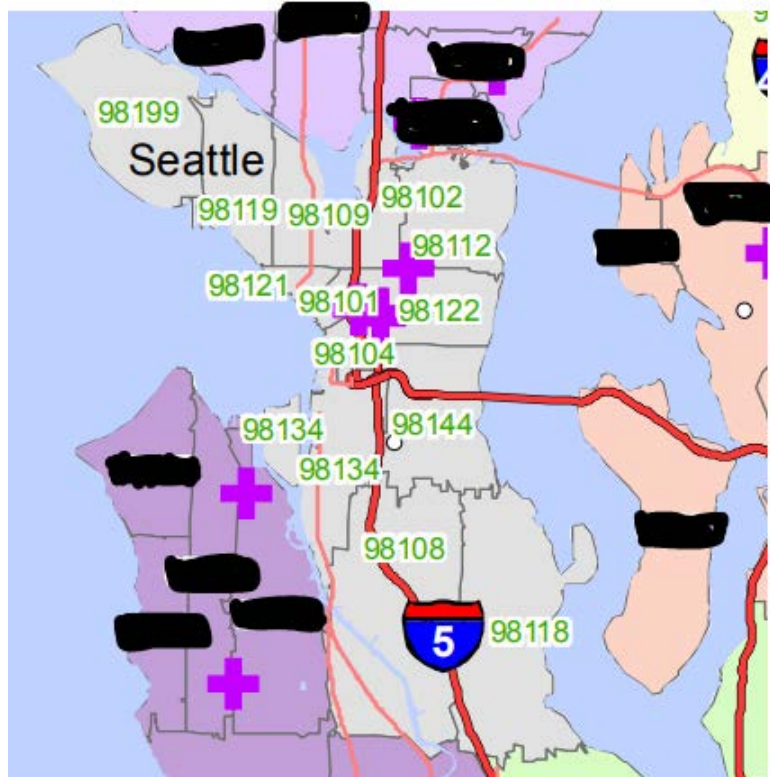
Department Evaluation

In the evaluation of WAC 246-310-210(1), the department must conclude that existing facilities of the same type proposed are not or will not be sufficiently available or accessible to meet the needs of the community. King County ESRD planning area #2 currently has four dialysis facilities in operation, including three owned and operated by NKC. The planning area facilities are shown below:

**Table 1
King County ESRD Planning Area #2 Facilities**

Facility Name	# of Stations	ZIP Code	Community
NKC Elliot Bay	18	98122	Madrona
NKC Seattle	38	98122	Madrona
NKC Broadway	15	98122	Madrona
NKC Olympic View	20	98112	Madison/Capitol Hill

A map of the planning area is shown below in Figure 1. Labels for ZIP codes in adjacent planning areas have been blacked out.



As shown above, ZIP codes 98112 and 98122 – the only two ZIP codes with a dialysis facility – are adjacent to one another, and are effectively in the middle of downtown Seattle. The proposed facility would be located in ZIP code 98118, which is located in the southernmost section of the planning area.

The table below identifies the number of ESRD patients in King County ESRD planning area #2 by ZIP code, with the NKC Rainier Beach ZIP code in bold. [source: NWRN year-end data 2016]

**Table 2
In-Center Patients by ZIP Code**

ZIP Code	Number of In-Center Patients	Percentage of King #2 Patients
98101	11	3.43%
98102	8	2.49%
98104	36	11.21%
98108	34	10.59%
98109	11	3.43%
98112	14	4.36%
98118	94	29.28%
98119	6	1.87%
98121	19	5.92%
98122	40	12.46%
98134	1	0.31%
98144	39	12.15%
98199	8	2.49%
Total	321	100.00%

As shown above, nearly a third of all ESRD patients in King County ESRD planning area #2 live in ZIP code 98118, where the proposed Rainier Beach facility would be located. The two ZIP codes adjacent to 98118 – 98108 and 98144 – contain an additional 22% of the existing ESRD patients in the planning area. In contrast, ZIP codes 98112 and 98122 only contain 16% of existing ESRD patients in the planning area.

Based on the above information, the relocation of 8 stations from NKC Seattle and 4 stations from NKC Elliott Bay could result in increased availability and accessibility to dialysis services for over 50% of King County ESRD planning area #2 patients. In addition to this, the proposed facility would be located 0.2 miles away from the Rainier Beach light rail station.

In summary, the existing dialysis facilities within the planning area may not be sufficiently accessible to patients within the southern portion of the planning area when compared to the proposed Rainier Beach facility. **This sub-criterion is met.**

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 (NRN).⁴

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.⁵

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

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

WAC 246-310-284(5) identifies that for all planning areas except 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

⁴ Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

⁵ WAC 246-310-280 defines base year as “the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report.” For this project, the base year is 2016.

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 projection year, 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)]

The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is a discussion of NKC’s numeric methodology.

Northwest Kidney Centers’ Numeric Need Methodology

“No new stations are proposed as a part of this project. In previous CN decisions wherein a "new" facility is being established via relocation of existing stations, the CN Program has concluded that the need methodology in WAC 246-310-284 is not applicable....For this reason, NKC has not calculated station need for King 2.” [source: Application p19]

Public Comment

None

Rebuttal Comment

None

Department Evaluation of the Numeric Methodology for King County Planning Area #2

Northwest Kidney Centers is correct, this sub-criterion is not applicable to this application as it does not propose the addition of new stations to the planning area.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at a certain utilization before new stations are added. For King County planning area #2, the utilization is 4.8 in-center patients per station.

Northwest Kidney Centers

“...there are four existing facilities in King 2. No new stations are being proposed as a result of this project. The establishment of NKC Rainier Beach will bring dialysis services closer to a core segment of our patient population.” [source: Application, p20]

Public Comment

None

Rebuttal Comment

None

Department Evaluation of WAC 246-310-284(5)

As with the above sub-criterion, Northwest Kidney Centers is correct; this sub-criterion is not applicable to this application as it does not propose the addition of new stations to the planning area.

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 station by the end of the third full year of operation. For King County planning area #2, the requirement is 4.80 in-center patients per approved station. [WAC 246-310-284(6)(a)]

Northwest Kidney Centers

NKC projects the 12-station Rainier Beach facility would be operational by May 2019. NKC uses a fiscal year that ends on June 30th of every year. Using that timeline, fiscal year 2020 would be NKC Rainier Beach’s first full year of operation with 12 stations, and fiscal year 2022 would be year three. Table 3 below shows the projected utilization for year three. [source: Application, p8 and p10]

**Table 3
NKC Rainier Beach
Third Year Projected Facility Utilization**

Year 3	# of Stations	# of In-Center Patients	Patients/Station
2022	12	60	5.00

Public Comment

None

Rebuttal Comment

None

Department Evaluation of WAC 246-310-284(6)

Based on Table 3 above, NKC projected to operate NKC Rainier Beach at or above the 4.8 standard by the end of year 2019—the third full year of operation. **NKC meets this utilization standard under WAC 246-310-284(6).**

WAC 246-310-287

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

- (1) All other applicable review criteria and standards have been met; and*
- (2) One or more of the following have been met:*
 - (a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or*
 - (b) Existing dialysis stations in the dialysis facility are operating at six patients per station. Data used to make this calculation must be from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period; or*
 - (c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and*
- (3) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing.*

Department Evaluation

This sub-criterion is not applicable to this application.

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

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

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

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

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

A facility’s charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources. 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 for all NKC dialysis centers, which would include the proposed Rainier Beach facility. [source: Application, Exhibit 11]

- Admission Policy for all NKC facilities
- Charity Care Policy for all NKC facilities

Medicare and Medicaid Programs

All operational NKC facilities are Medicare and Medicaid certified, including the two facilities from which NKC Rainier Beach would receive stations. NKC provided its projected source of revenues by payer for the proposed Rainier Beach facility, which is shown below in Table 4. [source: Application, p10]

**Table 4
NKC Rainier Beach Sources of Revenue**

Payer Source	Percentage of Patients	Percentage of Revenue
Medicare	64.9%	34.9%
Medicaid	16.2%	8.7%
Other	18.9%	56.4%
Total	100%	100%

Public Comment

None

Rebuttal Comment

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 Rainier Beach facility.

NKC currently provides dialysis services to Medicare and Medicaid eligible patients at its dialysis centers. NKC intends to maintain this status for patients receiving treatment at the NKC Rainier Beach. NKC projects 81.1% of the facility's patients will be on Medicare or Medicaid. A review of the anticipated revenue shows the facility expects to receive 43.6 % 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 Rainier Beach facility. 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 Rainier Beach facility 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 Rainier Beach. **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 sub-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 sub-criterion is not applicable to this application.

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

Department Evaluation

This sub-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 sub-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 sub-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 sub-criterion is not applicable to this application.

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the Northwest Kidney Centers project has **met** the financial feasibility criteria in WAC 246-310-220.

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

Northwest Kidney Centers

Northwest Kidney Centers currently operates NKC Seattle and NKC Elliott Bay with 38 and 18 stations, respectively. The new 12-station facility would be established using 8 relocated stations from NKC Seattle, and 4 relocated stations from NKC Elliott Bay. The project as described in the application would be complete by May of 2019. [source: Application p7]

NKC operates on fiscal years beginning in July and ending in June. NK C provided the projected utilization, revenue, expenses, and net income for partial year 2019 (2 months) and fiscal years 2020 through 2022 for the proposed NK C Rainier Beach facility with 12 stations. [source: Application p7]

NKC provided the assumptions used to project in-center and home treatments and patient volumes for years 2019-2022. Below is a listing of these assumptions, which were based on actual experience of NK C Elliott Bay. [sources: August 14, 2017 screening response p10, Attachment 4]

- *Patient Incenter Census: Assumes 25 patients in start up year (transfer from existing NK C facilities; +15 in FY2019 and +10 per year thereafter*
- *Home Patient Census: Assumed to be 20% of incenter patients based on existing NK C experience*
- *Average Treatments/patients/year: 148*
- *Payer Mix:*

<i>Medicare</i>	<i>64.9% of treatments</i>
<i>Medicaid</i>	<i>16.2% of treatments</i>
<i>Commercial Insurance</i>	<i>18.9% of treatments</i>

- *Charity Care: .05% of Total Revenue*
- *Bad Debt: 02% of Total Revenue*
- *Expenses: Fixed amount per treatment*
- *Interest: Based on bond financing assumptions and interest rate of 2.5% on \$10 million. Term of 20 years has been assumed.*
- *Depreciation: Based on useful life of:*

<i>Land Improvements</i>	<i>25 years</i>
<i>Shell and Core</i>	<i>40 years</i>
<i>Fixed Equipment</i>	<i>15 years</i>
<i>Furniture/Fixtures</i>	<i>7 years</i>
<i>Machines/Moveable Equipment</i>	<i>10 years</i>

Using the assumptions above, NK C projected the number of treatments to be provided in the projection years, as well as the revenue. Table 5 below illustrates this.

**Table 5
NK C Rainier Beach
Projected Utilization, Revenue, Expenses**

	Partial Year: FY2019	Year 1: FY2020	Year 2: FY2021	Year 3: FY2022
# of Stations	12	12	12	12
# of Patients	25	40	50	60
# of Treatments	617	5,920	7,400	8,880
Utilization	2.08	3.33	4.17	5.00
Net Patient Revenue	\$354,090	\$3,399,248	\$4,249,061	\$5,098,873
Total Expenses	\$352,070	\$2,954,383	\$3,510,169	\$4,065,599
Net Profit/(Loss)	\$2,020	\$444,865	\$738,892	\$1,033,274

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.

NKC identified Dr. Bruce O'Neill as the proposed Medical Director for NKC Rainier Beach and provided a draft medical director agreement. The draft agreement identifies a one year term with unlimited automatic renewals, and annual compensation at \$95,000. [source: Application Exhibit 5]

NKC provided the deed to the site, which was purchased outright in March 2017. [source: Application Exhibit 10]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Shown in Table 5 above, based on the projected volumes identified in the application, NKC anticipates that the proposed Rainier Beach facility would be operating at a profit in each of the first three full years of operation with 12 stations.

NKC based their volume, revenues, and expenses on their experience operating other dialysis facilities in King County ESRD planning area #2. This approach is reasonable. The percentage of revenue sources identified by NKC are consistent with percentages the department has reviewed and approved in past applications for dialysis facilities. [source: CN historical files]

There are no lease costs associated with this project, as NKC purchased the site outright.

Compensation for medical director services is identified in Exhibit B attached to the agreement and substantiated in the pro-forma revenue and expense statement. [source: Application, Exhibit 5]

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

- (2) 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

NKC identified the costs for this project, which includes the land purchase, improvements, construction, equipment, and all other associated costs. The capital cost breakdown is shown in Table 6 on the following page.

**Table 6
NKC Rainier Beach Center - Estimated Capital Costs**

Item	Totals
Land Purchase/Improvements	\$2,500,000
Construction/Permitting	\$6,435,837
Equipment	\$855,000
Professional Fees and Inspection	\$1,237,950
Financing	\$229,163
Other	\$485,000
Taxes	\$804,465
Total	\$12,547,415

There is an additional \$75,000 that was expended by the previous owner of the site for real estate fees. [source: Application, p27]

NKC provided the following statements related to the estimated construction costs and equipment costs. [source: Application, p28]

“NKC has extensive experience in the design, construction and equipping of dialysis facilities. However, for this facility, NKC has undertaken an entirely new approach. To begin with, NKC has hired a project management company to guide us through the design, permitting and building of this center. This firm is Spectrum Development and they have significant experience in facilities of this size and in working through the City of Seattle design review process. Spectrum, along with our architectural firm, Mahlum Architects Inc., are helping us create a center that will incorporate a healing environment as the focus for the patient care experience.”

NKC provided the executed development agreement with Spectrum Development. The development agreement includes the responsibilities of NKC and Spectrum Development with respect to the construction of the Rainier Beach facility. [source: scrn 1 Attachment 1]

NKC provided additional statements related to the impact on costs and charges. [source: Application p28]

“The majority of reimbursements for dialysis services flow from Medicare and Medicaid, which are not individually negotiated by the individual provider. As NKC has noted in other CN applications, its charge structure is not based on the capital costs of its projects but is separately set and is based on its contracts with payers. In addition, this project is expected, over the long term, to have lower operating costs as the total depreciation expense for this project is expected to be less than the lease costs would be for a comparable sized building.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Consistent with Certificate of Need Program practices, Northwest Kidney Centers submitted a letter of intent identifying the total costs for the project to be \$12,600,968. The capital costs identified in the application are within 12% of the costs in the letter of intent. [source: Application, p27 and Exhibit 6]

In addition, the cost of the development agreement with Spectrum Development is consistent with the amount identified in the estimated capital expenditure.

Though this project does identify a higher capital expenditure than is typical of dialysis facilities, it should be noted that NKC has purchased the land and will be constructing this proposed facility from the ground up. In most cases, dialysis facilities are constructed within existing space, with construction costs limited to converting space to be appropriate for dialysis. NKC provided a contractors letter attesting to the reasonableness of the costs for this dialysis center.

Information provided by the applicant under WAC 246-310-220(1) shows the Medicare and Medicaid reimbursements are projected to equal 81.1% of the revenue at NKC Rainier Beach. The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility.

Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by NKC about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 18.9% of NKC Rainier Beach's revenue will be derived through a variety of reimbursement sources such as private insurance.

Based on the information, the costs for the project are reasonable. Based on the above information, the department concludes that this station addition project would probably not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #2. **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

NKC identified a capital expenditure of \$12,547,415 to construct NKC Rainier Beach. NKC intends to fund \$10 million of the project using tax exempt bond financing through the Washington Health Care Facilities Administration (WHCFA). The remaining funds would be from corporate reserves. NKC provided a letter from the Chairman of the Board of Trustees committing to funding the remaining \$2.5 million using capital from investments. The letter also includes the provision that NKC would be willing to fund the entire project in the event financing through WHCFA is unsuccessful. [source: screen 1 Attachment 3]

NKC also provided a copy of its audited financial statements for years 2014, 2015, and 2016 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 1]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC intends to finance the project using a combination of tax-exempt financing through WHCFA and corporate reserves and investments. The audited financial statements demonstrate that NKC has sufficient capital available to finance the project – whether wholly or only in part with WHCFA.

Ordinarily, the department would request draft terms from the lending institution to demonstrate the validity of the financial assumptions. However, WHFCA does not provide these draft terms absent a valid Certificate of Need. In lieu of draft terms, NKC provided documentation of past successful financing ventures with WHFCA, and based their assumed interest costs on past experience with WHCFA. This is reasonable. Furthermore, as stated above, NKC is prepared and able to finance the project out of reserves an investments if financing through WHFCA is unsuccessful. Either approach is acceptable.

If this project is approved, the department would attach a condition requiring NKC to finance the project consistent with the financing description provided in the application.

With a financing condition, the department concludes the NKC project **meets this sub-criterion**.

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

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

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

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of full time equivalents (FTEs) that should be employed for projects of this type or size. Therefore, using its experience and expertise the department determined whether the proposed staffing would allow for the required coverage.

Northwest Kidney Centers

NKC provided the following statement related to this sub-criterion:

“8 of the 12 stations for NKC Rainier Beach will be relocated from NKC Seattle and the remaining 4 stations will come from NKC Elliott Bay. NKC does not anticipate any difficulties in staffing NKC Rainier Beach in light of providing additional options for new employees that are outside of Seattle (cost of living in Seattle has continued to rise). The proposed NKC Rainier Beach is located right on the Seattle light rail line which will make access for employees very easy. We also have city provided bike lockers nearby and we adjoin the Chief Sealth trail for staff to enjoy - making this location very appealing. We also plan to invest in new design concepts that will result in a positive experience for both staff and patients. We will first advertise or open the job positions at Rainier Beach internally, and because of the appealing work environment, we do expect that some existing staff will choose to relocate.

We do not expect any concerns or delays in filling any remaining positions.

As noted in other recent NKC applications, NKC has not had to refuse admission to new patients due to staffing shortages.” [source: Application p32]

If this project is approved, NKC expects the additional three stations would be operational by the mid-year 2019. FY 2020 would be the facility’s first full calendar year of operational and FY 2022 would be year three. Table 7 below provides a breakdown of projected FTEs for years 2017 through 2021. [source: Application p31]

**Table 7
NKC Rainier Beach
Projected FTEs for FY 2019 - 2022**

	FY2019 Partial Year	FYE2020 Full Year	FYE2021 Full Year	FYE2022 Full Year
HD Tech	3.47	5.55	6.94	8.33
RN	1.87	2.99	3.74	4.48
RN – home training	0.23	0.36	0.45	0.55
Nurse Manger	1.00	1.00	1.00	1.00
Clinic Director	0.20	0.20	0.20	0.20
Facility System Specialist	0.50	0.50	0.50	0.50
MSW	0.27	0.44	0.55	0.65
Dietician	0.25	0.40	0.50	0.60
Receptionist	1.00	1.00	1.00	1.00
Total	8.79	12.44	14.88	17.31

NKC provided a copy of the draft Medical Director Agreement for this proposed facility between NKC and Dr. Bruce O’Neill. The agreement identifies a term of one year with automatic unlimited renewals. Compensation for medical director services can be found in the agreement and pro forma for \$95,000 per year. [source: Application Exhibit 5]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The majority of the FTEs are expected to be in the categories of nursing and hemodialysis techs that are direct patient care positions. When the new facility opens in 2019, NKC is expected to have 8.79 FTEs. The majority, if not all, of these FTEs are expected to relocate from the other King #2 facilities that will downsize after the NKC Rainier Beach facility opens. Between FY 2019 and FY 2022, NKC expects to add a total of 8.52 FTEs. 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 Dr. Bruce O’Neill. NKC provided a draft of the medical director agreement between itself and Dr. O’Neill. As stated above, the initial term of the agreement is one-year with annual automatic renewals. 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.**

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

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

Northwest Kidney Centers

NKC provided the following information related to this sub-criterion. [Source: Application, page 32]

Ancillary and support services include the following:

- | | |
|---------------------------------------|----------------------------|
| <i>Social Services</i> | <i>Business Office</i> |
| <i>Nutrition Services</i> | <i>Administration</i> |
| <i>Patient Financial Counseling</i> | <i>Information Systems</i> |
| <i>Pharmacy</i> | <i>Human Resources</i> |
| <i>Patient Education</i> | <i>Plant Operations</i> |
| <i>Technical Services</i> | <i>Material Management</i> |
| <i>Visitor Dialysis</i> | <i>Community Relations</i> |
| <i>Informatics Nurses</i> | <i>Public Relations</i> |
| <i>Water Purification Specialists</i> | |
| <i>Medical Staff Credentialing</i> | |

“Each of these departments/functions is based at one of our support offices in Seattle, Lake Forest Park, SeaTac, Rainier Beach (distribution center) or Bellevue, and already provides services daily or on demand at all NKC treatment centers.

A copy of the existing transfer agreement between NKC and Swedish Medical Center is included in Exhibit 14.” [source: Application p33]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC provided a listing 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 Rainier Beach. NKC provided a copy of its current transfer agreement between NKC and Swedish Medical Center. This transfer agreement was executed October 2, 2013 and while the initial term is one year it continues indefinitely after that one year unless the termination clause is invoked. This existing agreement would be amended prior to the opening of the NKC Rainier Beach facility to include the new facility in Schedule 1 of the agreement. If the application is approved, the department would include a condition related to amending the existing transfer agreement to include the new Rainier Beach facility.

The department concludes there is reasonable assurance the NKC Rainier Beach facility 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 no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant’s history in meeting these standards at other facilities owned or operated by the applicant.

The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for these projects, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the ‘star rating’ assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS ‘star ratings’ for Washington State facilities. Finally, the department focused on its own state survey data performed by the Department of Health’s Investigations and Inspections Office. Below is an overview of the CMS star rating review. The department’s Washington State survey data is include in each applicant’s separate review under this sub-criterion.

Centers for Medicare & Medicaid Services (CMS) Star Ratings

On January 22, 2015, the Centers for Medicare & Medicaid Services (CMS) released a media statement with the following information related to its dialysis facility compare website.

“Today, the Centers for Medicare & Medicaid Services (CMS) added star ratings to the Dialysis Facility Compare (DFC) website. These ratings summarize performance

data, making it easier for consumers to use the information on the website. These ratings also spotlight excellence in health care quality. In addition to posting the star ratings, CMS updated data on individual DFC quality measures to reflect the most recent data for the existing measures.

“Star ratings are simple to understand and are an excellent resource for patients, their families, and caregivers to use when talking to doctors about health care choices,” said CMS Administrator Marilyn Tavenner. “CMS has taken another step in its continuous commitment to improve quality measures and transparency.”

DFC joined Nursing Home Compare and Physician Compare in expanding the use of star ratings on CMS websites. The DFC rating gives a one to five-star rating based on information about the quality of care and services that a dialysis facility provides. Currently, nine DFC quality measures are being used collectively to comprise the DFC star ratings. In the future, CMS will add more measures.

In related news, CMS plans to add the Standardized Readmission Ratio (SRR) for dialysis facilities to the publicly reported quality outcome measures available on the Compare website. SRR is a measure of care coordination. SRR is not included in DFC’s star rating at this time.

DFC quality measure data is either updated quarterly or annually. CMS plans to update the DFC’s star rating on an annual basis beginning in October 2015.”

CMS provided the following overview regarding its star rating for dialysis centers. [source: CMS website]

“The star ratings are part of Medicare’s efforts to make data on dialysis centers easier to understand and use. The star ratings show whether your dialysis center provides quality dialysis care - that is, care known to get the best results for most dialysis patients. The rating ranges from 1 to 5 stars. A facility with a 5-star rating has quality of care that is considered ‘much above average’ compared to other dialysis facilities. A 1- or 2- star rating does not mean that you will receive poor care from a facility. It only indicates that measured outcomes were below average compared to those for other facilities. Star ratings on Dialysis Facility Compare are updated annually to align with the annual updates of the standardized measures.”

CMS assigns a one to five ‘star rating’ in two separate categories: best treatment practices and hospitalizations and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

- Best Treatment Practices
This is a measure of the facility’s treatment practices in the areas of anemia management; dialysis adequacy, vascular access, and mineral & bone disorder. This category reviews both adult and child dialysis patients.
- Hospitalization and Deaths
This measure takes a facility’s expected total number of hospital admissions and compares it to the actual total number of hospital admissions among its Medicare dialysis patients. It also takes a facility’s expected patient death ratio and compares it to the actual patient death ratio taking into consideration the patient’s age, race, sex, diabetes, years on dialysis, and any co-morbidities.

The Dialysis Facility Compare website currently reports on 9 measures of quality of care for facilities. These measures are used to develop the star rating. Based on the star rating in each of the two categories, CMS then compiles an ‘overall rating’ for the facility. As with the separate

categories: the more stars, the better the rating. The star rating is based on data collected from January 1, 2012 through December 31, 2015.⁶

The measures used in the star rating are grouped into three domains by using a statistical method known as Factor Analysis. Each domain contains measures that are most correlated. This allows CMS to weight the domains rather than individual measures in the final score, limiting the possibility of overweighting quality measures that assess similar qualities of facility care. The three domains are as follows:

- "Standardized Outcomes (SHR, SMR, and STrR)" – This first domain combines the three outcome measures for hospitalization, mortality and transfusions (SHR, SMR, and STrR).
- "Other Outcomes 1 (AV fistula, tunneled catheter)" – The arteriovenous fistula and catheter measures forms the second domain.
- "Other Outcomes 2 (Kt/V, hypercalcemia)" – The All Kt/V and hypercalcemia measures forms the third domain.

Facilities are rated as long as they have at least one measure in each of the three domains. Because the vascular access measures in the "Other Outcomes 1 (AV fistula, tunneled catheter)" domain do not apply to peritoneal dialysis patients, peritoneal dialysis-only facilities are rated based on the other two domains. They receive ratings as long as they have scores for at least one of the two domains not related to vascular access.

Northwest Kidney Centers

NKC provided the following statements related to this sub-criterion:

"NKC operates all existing programs in conformance with applicable federal and state laws, rules, and regulations". [Source: Application, page 33]

"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 33]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

NKC does not own or operate any out-of-state healthcare facilities. NKC provides dialysis services in Clallam and King counties within Washington State. All NKC's dialysis facilities are Medicare certified. The department reviewed the quality of care compliance history for all 15 kidney dialysis facilities owned, operated, or managed by NKC.

⁶ The information or data on Dialysis Facility Compare comes from two key sources: 1) CMS Statistical Analytical Files (Medicare Claims); and 2) Consolidated Renal Operations in a Web-enabled Network (CROWN). Some ratios are calculated annually based on the information that facilities send Medicare each month; other ratios are calculated quarterly.

The Department of Health's Investigations and Inspections Office (IIO), as the contractor for Medicare, completed 15 compliance surveys facilities own or managed by NKC.⁷ These surveys revealed minor non-compliance issues typical of a dialysis facility. NKC submitted and implemented acceptable plans of correction. [Source: Facility survey data provided by the Investigations and Inspections Office]

The department also 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.

Table 8 on the following page shows the fifteen NKC dialysis centers and the CMS star ratings. [Source: January 24, 2018 Dialysis Facility Compare data]

⁷ Most recent quality of care surveys conducted in year 2010 for Elliot Bay Kidney Center; year 2012 for Broadway Kidney Center, year 2013 for Auburn Kidney Center, Enumclaw Kidney Center, Seattle Kidney Center, and Snoqualmie Kidney Center; year 2014 for Kirkland Kidney Center; year 2015 for Kent Kidney Center, Lake City Kidney Center, Lake Washington Kidney Center, Port Angeles Kidney Center, Scribner Kidney Center, and SeaTac Kidney Center; year 2016 for Renton Kidney Center and West Seattle Kidney Center.

**Table 8
Northwest Kidney Centers Dialysis Facilities CMS Star Rating**

Facilities	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	Bellevue	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
Average Score		4.3

As shown in Table 8, the facilities operated or owned by NKC have an average rating of over 4 stars. Of the 15 dialysis facilities, owned/operated only one facility, NKC West Seattle Center has a rating below 4. It has a three rating. The other 14 facilities have a rating of 4 or above.

NKC identified Dr. Bruce O’Neill as the proposed medical director for NKC Rainier Beach. A review of Dr. O’Neill’s compliance history with the Department of Health’s Medical Quality Assurance Commission did not revealed any recorded sanctions. [Source: DOH Provider Credential Search]

The department concludes there is reasonable assurance that NKC Rainier Beach would be operated in conformance with applicable state and federal licensing and certification requirements. **This sub criterion is met.**

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

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area’s existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Northwest Kidney Centers

NKC provided the following information related to this sub-criterion. [source: Application p33, screen 1 pp5-6]

“Although NKC Rainier Beach will be a new facility, NKC Seattle has operated in the planning area since 2009 and NKC Elliott Bay has operated since 1991. The new facility will assure that our commitment to the community continues, and NKC will continue to maintain all existing working relationships in King 2.”

“A comprehensive list of working relationships that NKC has includes:

All hospitals throughout our market work in collaboration with NKC:

- *Auburn General Hospital*
- *CHI / Highline Hospital*
- *CHI / St. Francis Hospital*
- *Evergreen Hospital*
- *Harborview Medical Center*
- *Multicare*
- *Northwest Hospital*
- *Overlake Hospital*
- *Swedish Edmonds*
- *Swedish Issaquah*
- *Swedish Cherry Hill*
- *Swedish Medical Center*
- *University of Washington*
- *Valley Medical Center*
- *Virginia Mason Medical Center*

Local clinics and Nephrologists in the community strongly support NKC. Here are a few of them (listed by practice name – solo Nephrologists not listed). A copy of our Medical Staff list was provided in our application in Exhibit 4.

- *Cascade Kidney Specialists*
- *CHI Franciscan Nephrology Associates*
- *Eastside Nephrology*
- *Harborview Medical Center*
- *MultiCare Nephrology*
- *Polyclinic, The (and The Polyclinic Madison Center)*
- *Rainier Nephrology*
- *Seattle Nephrology*
- *South Seattle Nephrology Associates*
- *Transplant and Nephrology NW*
- *University of Washington Medical Center*
- *Valley Medical Center Nephrology Services*
- *Virginia Mason Federal Way*

Other partners who are helping to cure kidney disease, slow the onset of kidney disease, which collaborate to help educate and support our patients or help support our system:

- *Northwest Health Response Network (King / Pierce County Healthcare Emergency Services Coalition)*
- *American Diabetes Association – Washington Chapter*
- *Kidney Research Institute*

- *National Kidney Foundation – Washington Chapter*
- *Navos*
- *Washington Dental Society / Access to Dental*

NKC has a strong working relationship in the community and we will continue to foster partnerships that support our patients in this community.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC has been providing services in ESRD King #2 and has maintained appropriate relationships with the service area’s existing healthcare providers. This project would add the service area’s second dialysis facility. Nothing in the materials reviewed by the department suggests that approval of NKC Rainier Beach 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.*

Northwest Kidney Centers

NKC provided the following statements in response to this sub-criterion. [source: Application, p33]

“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).”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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

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

Based on the source information reviewed, the department concludes that the Northwest Kidney has met the cost containment criteria in WAC 246-310-240.

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

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

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in Step three. 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.

Step One

For this project, NKC met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two for this project.

Step Two

For this sub-criterion, NKC considered three alternatives to the project as described in this application, shown below. [source: Application p34]

1. Not to relocate stations to Rainier Beach or any other community
2. Establish a unit with only 8 stations from Seattle Kidney Center
3. To establish a new center in Rainier Beach for 12 stations through a lease of a building

NKC's rationale for rejecting each of these three options is shown below.

“Option 1, that of not relocating stations to Rainier Beach or any other community would not serve the patients in the community. NKC sees this opportunity to create a new center as solving a problem where patients live in one community and need to commute to receive treatment. Today, patients travel through traffic into Seattle or in traffic south to Renton and SeaTac depending on the time of day. NKC believes that having stations closer to where patients reside is very important so this option was rejected.”

“Option 2, establish a unit with only 8 stations from NKC Seattle: We considered doing this as a way to place stations (that are not in use today) to directly meet the need of patient care. Ultimately we decided the need was too great in the Rainier Beach area to only have 8 stations available so we rejected this option”

“Option 3, to establish a new 12 station center through a lease of an already constructed building: Through ongoing searches, no existing buildings in the size and zoning that we needed were found so we rejected this option.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC considered several options before selecting the option to relocate portions of its NKC Seattle and Elliott Bay facilities. As noted by NKC, its goal was to improve access for our patients by reducing drive time and allow them to create better treatment space. NKC also identified the added benefit of locating the facility within a short distance to public transportation. The department did not identify any other alternative that was a superior alternative, in terms of cost, efficiency, or effectiveness that is available or practicable. Therefore, the department moves on to step three for this project.

Step Three

This step is applicable only when there are two or more approvable projects. For the ESRD 2017 cycle #2 submission period, NKC’s application was the only application submitted to add dialysis stations in ESRD King #2 planning area. Therefore, this step does not apply.

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

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

Northwest Kidney Centers

NKC provided the following statements under this sub-criterion. [source: Application, pp35-36]

“We have...integrated the following enhancements to enable long term cost reductions:

- *Use of the Braun Aquaboss heat disinfect water purification system that reduces water consumption by up to 40% and power use by 10% when compared to existing water systems.*
- *A shift in how we approach Supply Chain principles and how supplies are delivered to the unit.*
- *This project is being designed based on required criteria to achieve a USGBC LEED Silver certification. Through this certification we will be meeting the City of Seattle Energy Code requirements. Energy efficiency will be achieved through the use of innovative building envelope design to include:*
 - *Exterior glazing with high performance U=0.34 (or better) rating to meet Seattle energy code requirements.*
 - *Exterior wall and roof assembly designed to maximize thermal insulation*
 - *HVAC mechanical systems to meet requirements of the 2015 Seattle Energy Code (includes central heat recovery ventilation units)*

The new facility will comply with the State Energy Code, latest edition. High efficiency systems, with lower life-cycle operating costs will be used wherever possible.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

As stated under WAC 246-310-210, the costs associated with this project are reasonable. NKC provided detailed information regarding how their facility will meet or exceed energy conservation requirements. 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

“The majority of reimbursements for dialysis services flow from Medicare and Medicaid, which are not individually negotiated by the individual provider. As NKC has noted in other CN applications, its charge structure is not based on the capital costs of its projects but is separately set and is based on its contracts with payers. In addition, this project is expected, over the long term, to have lower operating costs as the total depreciation expense for this project is expected to be less than the lease costs would be for a comparable sized building.” [source: Application p28]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC’s project involves construction. This sub-criterion was evaluated under WAC 246-310-220(2), under which the department substantiated all costs identified for the station relocation. Furthermore, these are existing stations that NKC proposes to relocate to a part of the planning area with the greatest concentration of dialysis patients. With 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 addition stations in the planning area. The department 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.

Northwest Kidney Centers

“NKC will use its existing organizational structure and duplication of systems will be minimized. Economies of scale will also be realized with the sharing of administrative and support staff..” [source: Application p35]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC has demonstrated that this relocation of stations to a new facility in Rainier Beach has the potential to improve delivery of dialysis services to the residents of King County ESRD planning area #2 with the addition of dialysis stations in the planning area. **This sub-criterion is met.**