

STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington 98504

February 21, 2017

CERTIFIED MAIL # 7016 0910 0000 3454 9191

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

RE: CN 16-31

Dear Mr. Ross:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers proposing to construct a new 14-station kidney dialysis facility, within ESRD King County planning area #11. 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 14-station dialysis center in Federal Way within King County planning area #11. Twelve of the stations will be relocated from NKC Auburn Kidney Dialysis Center. The remaining two stations are new to the planning area. At project completion, the dialysis center is approved to certify and operate fourteen dialysis stations. Services to be provided at NKC Federal Way 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 14 stations is shown below:

NKC Federal Way Kidney Dialysis Center

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	12
Total	14

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At completion of the NKC Federal Way dialysis center, the NKC Auburn Kidney Center is approved to operate and certify 12 stations. A breakdown of the approved 12 stations is shown below.

NKC Auburn Kidney Dialysis Center

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

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. Northwest Kidney Centers will finance the project using existing capital reserves of Northwest Kidney Centers as described in the application.
- 3. No later than 30 days following the opening of NKC Federal Way Dialysis Center, Northwest Kidney Centers will request Centers for Medicare and Medicaid Services (CMS) to decertify 12 stations at the NKC Auburn Dialysis 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 commencement Northwest Kidney Centers will provide an executed copy the lease agreement for the department's review and approval. The executed lease agreement must be consistent with the draft provided in the application.
- 6. Prior to providing services at NKC Federal Way, Northwest Kidney Centers will provide an updated transfer agreement listing NKC Federal Way Kidney Center as part of the agreement for the department's review and approval.

Approved Costs:

The total cost of this project is \$4,788,278. Of this amount, \$4,075,787 is NKC's approved cost. The remaining \$712,500 is the amount the landlord will incur.

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.

Austin Ross, Vice President of Planning Northwest Kidney Centers CN Application #16-31 February 21, 2017 Page 3 of 3

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

Mailing Address:

Department of Health

Certificate of Need Program

Mail Stop 47852

Olympia, WA 98504-7852

Physical Address:

Department of Health

Certificate of Need Program

111 Israel Road SE

Tumwater, WA 98501

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

Sincerely,

Bart Eggen, Deputy Director Community Health Systems

Enclosure

EVALUATION DATED FEBRUARY 21, 2017 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING TO ESTABLISH A 14 STATION KIDNEY DIALYSIS FACILITY IN KING COUNTY END STAGE RENAL DISEASE PLANNING AREA #11

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 15 kidney dialysis facilities. Of the 15 facilities, 14 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
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

Northwest Kidney Centers proposes to construct a 14-station kidney dialysis facility in Federal Way by relocating 12 existing stations from its 24 station NKC Auburn Dialysis Center and adding 2 new stations. The new 14 station NKC Federal Way would be located at 33820 Weyerhaeuser Way South, Suite 100 in Federal Way 98001 within King County ESRD planning area #11. Services to be provided 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. [Source: Application, pages 7 and 8, and Exhibit 9]

The total capital expenditure associated with the establishment of the 14-station kidney dialysis center is \$4,788,287. The property owner is responsible for \$712,500 of this amount. NKC's portion of the cost is \$4,075,787. Of that amount 58% is related to building construction; 21% for fixed and moveable equipment; and the remaining 21% is related to taxes and fees. [Source: Application Page 28] If this project is approved, NKC anticipates the 14 new stations would be available by the end of January 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 9]

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 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). 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 #3. No other applications were submitted for the King County planning area #11 during this cycle. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

APPLICATION CHRONOLOGY

Action	Northwest Kidney Centers
Letter of Intent Submitted	April 29, 2016
Application Submitted	May 31, 2016
Department's Pre-review Activities including	
DOH 1st Screening Letter	June 30, 2016
Applicant's Responses Received	August 12, 2016
DOH 2nd Screening Letter	August 30, 2016
Applicant's Responses Received	October 13, 2016
Beginning of Review	October 21, 2016
End of Public Comment	
Public comments accepted through	November 11, 2016
Public hearing conducted ¹	N/A
Rebuttal Comments Received ²	N/A
Department's Anticipated Decision Date	January 27, 2017
Department's Actual Decision Date	February 21, 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;

¹ The department did not conduct a public hearing.

² The department did not receive any public comment therefore no rebuttal comments were submitted

- (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 application no individuals or entities sought "interested person" or "affected person" status.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers application received May 31, 2016
- Northwest Kidney Centers screening responses received August 15, 2016 and October 13, 2016
- Years 2010 through 2015 historical kidney dialysis data obtained from the Northwest Renal Network
- Year end 2015 Northwest Renal Network December 2015 (4th Quarter) Utilization Data released February 5, 2016
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Northwest Kidney Centers website www.nwkidney.org
- Northwest Renal Network website www.nwrn.org
- Centers for Medicare and Medicaid website www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers proposing to establish a new 14-station kidney dialysis center in the city of Federal Way within King County planning area #11 is consistent with applicable criteria of the Certificate of Need Program, provided Northwest Kidney Centers agree to the following in its entirety.

Project Description:

This certificate approves the construction of a new 14-station dialysis center in Federal Way within King County planning area #11. Twelve of the stations will be relocated from NKC Auburn Kidney Dialysis Center. The remaining two stations are new to the planning area. At project completion, the dialysis center is approved to certify and operate fourteen dialysis stations. Services to be provided at NKC Federal Way 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 14 stations is shown below:

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Approved Costs:

The total cost of this project is \$4,788,278. Of this amount, \$4,075,787 is NKC's approved cost. The remaining \$712,500 is the amount the landlord will incur. .

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)

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

criteria is also identified in WAC 246-310-284(5) and (6).

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).³

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

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,

³ 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]

⁴ 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.

Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved incenter 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. King County is broken into 12 sub-planning areas. NKC proposes to add dialysis station capacity to King County planning area # 11. The following five zip codes are included in this planning area.

Zip	City
98001 ⁵	Auburn
98002	Auburn
98010	Black Diamond
98047	Pacific
98092	Auburn

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 station⁶ 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 King 11 is detailed below. A copy of the CN Program's methodology is included in Exhibit 12." [Source: Application, page 17]
- "Table 6 details the year end number of in-center hemodialysis patients in King 11. As Table 6 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 17]
- "Table 7 details the number of projected in-center patients in King 11 in the years 2016-2019

Table 7 (Reproduced)
Projected Year-End Resident In-Center Hemodialysis Patients
Linear Projection

Year	2016	2017	2018	2019
Number of Patients	110.9	115.4	119.9	124.4"

[Source: Application, page 18]

⁵ "Included in Exhibit 1 is documentation from USPS confirming that the primary city in zip code 98001 is Auburn (which is the city listed in the definitions in WAC 246-310-280(9)(A)) as being part of King 11. Per USPS, other cities included within the zip code are Federal Way and Algona". [Source: Application Page 2]

⁶ Defined as in-center hemodialysis and home training patients.

- "Per WAC, the projection year is 2019. For King 11, the appropriate resident in-center patient per station number is 4.8. Assuming 125 patients, 26 stations are calculated as needed in 2019." [Source: Application, page 18]
- "Table 8 demonstrates that there are currently 24 CN approved and/or operational stations in King 11 (at NKC Auburn) which, when total projected need is subtracted, leaves a net need for two stations in 2019. [Source: Application, page 19]

Table 8 (Reproduced)
Analysis of Current Supply vs. Net Station Need

	Stations
Current Supply:	24
TOTAL SUPPLY	24
2019 Projected Need	26
Net Station Need	2"

[Source: Application, page 19]

Public Comments

• None

Rebuttal Comments

None

Department Evaluation

NKC submitted the department's posted methodology for ESRD King #11 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 ESRD King #11 planning area. The department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5). The department's methodology showed a need for two new stations in the planning area by the end of year 2019. The department's methodology is included in this evaluation as Attachment A.

The department concludes NKC meet this numeric methodology standard.

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis station need.⁷ 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

⁷ WAC 246-310-210(1)(b)

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 Federal Way is not an existing facility. However, NKC does operate the only facility in King 11, NKC Auburn. Utilization data for NKC Auburn is included in Table 1.

Table 1 (Reproduced)
NKC Auburn Historical Utilization and Occupancy, FY 2011-10 months 2016

	No. of	No. of	No. of	Patients/	
Year Ending	Patients	Treatments	Stations	Station	Occupancy
6/30/2011	112	17,161	24	4.67	77.8%
6/30/2012	112	17,246	24	4.67	77.8%
6/30/2013	103	16,196	24	4.29	71.5%
6/30/2014	117	16,305	24	4.88	81.3%
6/30/2015	118	16,748	24	4.92	81.9%
6/30/2016	126	15,495 ⁸	24	5.25	88.0%"

[Source: Application, page 5]

• "NKC Auburn is the only existing dialysis facility in King 11, and according to data published by the Northwest Renal Network, NKC Auburn operated at 5.25 patients (126 patients) per station as of December 2015". [Source: Application, page 19]

Public Comments

None

Rebuttal Comments

• None

Department Evaluation

WAC 246-310-284(5) requires the department use the most recent quarterly modality report from the NWRN to calculate the number of patients per station at each of the planning area's dialysis facilities. This application was submitted during the 2016 ESRD concurrent review Cycle 2. The first day of the application submittal period was May 2, 2016. The most recent quarterly modality report as of May 2, 2016 was December 31, 2015 (4th Quarter) posted by the NWRN on February 5, 2016. NKC's Auburn facility is the only dialysis facility located in ESRD King #11. The department calculated the number of patients per station at the NKC Auburn facility to be 5.25. The department concludes **this criterion is met**.

WAC 246-310-284(6)

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

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

⁸ Data for 10 months only (July through April, 2016)

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

Northwest Kidney Centers

• "As table 9 demonstrates, with a total of 14 stations, and our estimated volume, NKC Federal Way will operate in excess of 4.8 in-center patients per station by the 3rd full year of operation (FYE2021)".

Table 9 (Reproduced)
Projected NKC Federal Way Occupancy, FYE2018-2021

	Full or	14 St	ations
Year	Partial Year	Projected Patients	Patients/ Station
FYE 6/30/2018	Partial	50	3.57
FYE 6/30/2019	Full	56	4.00
FYE 6/30/2020	Full	62	4.43
FYE 6/30/2021	Full	69	4.93

[Source: Application Page 20]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

The patients per station standard for ESRD King #11 is 4.8 in-center patients per approved station. The third full year for the NKC Federal Way Kidney Center is FYE 2021. NKC projected the facility would have 4.93 patients per station by that time. The department concludes the standard **is met.**

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

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

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

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

exceptions is Medicare coverage for patients with permanent kidney failure. Patients of any age with permanent kidney failure are eligible for Medicare.

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

A facility's charity care policy should show a willingness of a provider to provide services to patients who do not have private insurance, do not qualify for Medicare, do not qualify for Medicaid or are under insured. With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear.

Northwest Kidney Centers

- "NKC has a long established history of developing and providing services that meet the healthcare needs of the communities it serves. NKC Federal Way, as with all other facilities, will provide services to all regardless of race, color, religious belief, sex, age or lack of ability to pay". [Source: Application Page 21]
- "Copies of the admission policies and procedures and the charity care policy for the proposed NKC Federal Way are included in Exhibit 13." [Source: Application Page 22]
- "The proposed sources of revenue, by payer, for NKC Federal Way were based on the payer mix for NKC Auburn and are:

Payer	% Patients	% Net Revenue
Medicare	68.7%	42.5%
Medicaid	18.2%	10.6%
Other	13.1%	46.9%
Total	100.0%	100.0%"

[Source: Application, page 10 and 30]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

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

NKC currently provides dialysis services to Medicare and Medicaid eligible patients at its dialysis centers. NKC intends to maintain this status for patients receiving treatment at the NKC Federal Way Kidney Center. NKC projects 86.9% of the facility's patients will be on Medicare or Medicaid. A review of the anticipated revenue shows the facility expects to receive 53.1 % of its revenue from Medicare and Medicaid reimbursements. [Source: 2nd screening responses, Attachment 1]

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 Federal Way 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 Federal Way 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 Federal Way 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

• DoH summary of operating revenues and expenses based on Attachment 1, 2nd screening responses.

	Implementation	Project Year 1	Project Year 2	Project Year 3
	Partial Year	Ending	Ending	Ending
STATISTICS	6/30/2018	6/30/2019	6/30/2020	6/30/2021
Total Gross Revenues	\$6,421,388	\$14,379,909	\$15,925,042	\$17,723,030
Total Deductions	(\$4,831,946)	(\$10,823,559)	(\$11,983,226)	(\$13,336,172)
Net Revenues	\$1,589,442	\$3,560,349	\$3,941,815	\$4,386,859
Total Direct Expenses	\$1,266,505	\$2,280,502	\$2,460,721	\$2,669,724
Excess of Direct				
Revenue over Direct				
Expenses	\$322,936	\$1,279,846	\$1,481,094	\$1,717,135
Overhead	\$522,292	\$1,134,836	\$1,218,733	\$1,315,642
Net Profit or Loss	(\$199,356)	\$145,010	\$262,361	\$401,493

• "All revenue, deduction and expenses numbers in the pro forma were based on actual results for our Auburn facility for the first 9 months of our fiscal year. Bad debt has been assumed to be \$1.39 per treatment and charity care is assumed to be \$0.25 per treatment". [Source: 2nd screening responses, Page 1]

• "The proposed sources of revenue, by payer, for NKC Federal Way were based on the payer mix for NKC Auburn and are:

Payer	% Patients	% Net Revenue
Medicare	68.7%	42.5%
Medicaid	18.2%	10.6%
Other	13.1%	46.9%
Total	100.0%	100.0%"

[Source: Application, page 10 and 30]

- A draft lease agreement between DM Ventures Federal Way, LLC ("Landlord") and Northwest Kidney Centers ("Tenant") was provided. [Source: Application, Exhibit 11]
- NKC identified Dr. Frank Fung as the medical director for NKC Federal Way Kidney Center and provided a draft copy of the medical director agreement. [Source: Application, Exhibit 6 and 2nd screening responses, attachment 2]

Public Comments

• None

Rebuttal Comments

• None

Department Evaluation

NKC anticipates the 14-station Federal Way Kidney Center would be operational by the end of January 2018. NKC operates on a fiscal year (July 1 through June 30) rather than on a calendar year. Table 1 illustrates the projected revenue, expenses, and net income for years FY 2018 through FY 2021 for NKC Federal Way Kidney Center.

Table 1 NKC Federal Way Kidney Center Projected Revenue and Expenses-Fiscal Years 2018 - 2021

	Partial FY 2018	FY 1-2019	FY 2-2020	FY 3-2021
# of Stations	14	14	14	14
# of Treatments [1]	3,700	8,288	9,176	10,212
# of Patients [1]	50	56	62	69
Utilization Rate [1]	4.67	4.76	4.85	4.94
Net Patient Revenue [3]	\$1,589,442	\$3,560,349	\$3,941,815	\$4,386,859
Total Expense [2]	\$1,788,797	\$3,415,338	\$3,679,463	\$3,985,366
Net Profit or (Loss) ⁹	(\$199,356)	\$145,010	\$262,361	\$401,493

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

The 'Net Patient Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes such items as salaries and wages, pharmacy, repair & maintenance, depreciation, and overhead. At NKC's projected

⁹ Amounts may not add due to rounding

volumes, the 14-station facility would make a profit in each of the facility's first three full years of operation.

Revenue sources identified by NKC are comparable with previous dialysis applications the department has reviewed and approved ¹⁰. Lease costs for the proposed NKC Federal Way Kidney Center, located at 33820 Weyerhaeuser Way South, Suite 100 in Federal Way, were identified in the draft lease agreement and also verified in the pro-forma operating statement.

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

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

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

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

Northwest Kidney Centers

- "NKC has extensive experience in the design, construction and equipping of dialysis facilities. NKC has based the construction costs on its recent experience in the relocation of its Kirkland facility and Renton Kidney Center. Other capital costs are based on NKC's recent similar dialysis station expansion projects". [Source: Application, page 29]
- "The capital costs for the project are detailed in Table 11:

Table 11 (Reproduced)
Estimated Capital Expenditures

	NKC Federal	Landlord	Total Project
	Way	Costs	Costs
Building Construction	\$2,348,975	\$600,000	\$2,948,975
Fixed Equipment	\$404,100		\$404,100
Moveable Equipment	\$435,131		\$435,131
Architect & Engineering Fees	\$420,073		\$420,073
Sales Tax	\$409,558		\$409,558
Misc. Equipment/Signage	\$57,558		\$57,558
Real Estate Commission		\$112,500	
Total Estimated Capital Costs	\$4,075,787	\$712,500	\$4,788,287"

[Source: Application, Page 28]

• "There are no restrictions (as described above) with regards to the elected site." [Source: Application, page 12]

¹⁰ CN historical files for projects from Franciscan Health System, DaVita Healthcare Partners, and Fresenius Medical Care

- "The site is zoned OP1 zoning district. Included in Exhibit 10 is an email from the City of Federal Way documenting the zoning for the selected site. The zoning, OP1 zoning district, allows for outpatient medical services. Therefore, NKC believes that a dialysis facility is a permissible use." [Source: Application, page 12]
- "A draft lease agreement for the selected site is included in Exhibit 11. The initial term is for 124 months and includes two successive five year renewal options. Included in Exhibit 11 is documentation from the King County Assessor's office that the landlord, DM Ventures Federal Way, LLC is also the property owner." [Source: Application, page 13]
- "The majority of reimbursements for dialysis services flow from Medicare and Medicaid, which are not subject to, or affected by, capital improvements and expenditures by providers. As NKC has noted in other CN applications, its charge structure is not based on the capital costs of its projects but is separately set and is based on its contracts with payers." [Source: Application, page 29]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

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

NKC identified the location of the new dialysis facility as 33820 Weyerhaeuser Way South, Federal Way, Washington. A copy of the draft lease between DM Ventures Federal Way, LLC (landlord) and Northwest Kidney Centers (tenant) was provided. The draft lease identifies the specific facility site, lease costs, terms, and certain requirements for use of the facility by the tenant. The lease outlines roles and responsibilities of both tenant and landlord. When draft leases are submitted, if a project is approved, the department attaches a condition requiring the applicant to provide a copy of the final, executed agreement consistent with the draft lease agreement. If the NKC project is approved, the department would attach a similar condition.

The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the proposed dialysis facility 86.9 % of the patients are projected to be Medicare and Medicaid. Revenue from these two sources are projected to equal 53.1%. The remaining 46.9% 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 and with NKC's agreement to the condition identified above, 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". [Source: Application, page 29]
- "A copy of the board commitment letter is included in Exhibit 14." [Source: Application, page 29]
- "This is the least costly alternative." [Source: Application, page 29]

Public Comments

None

Rebuttal Comments

• None

Department Evaluation

The total cost of the project is \$4,788,278. Of this amount, \$4,075,787 is NKC's financial responsibility. The remaining \$712,500 is the responsibility of the landlord. The letter from Lisa Florence, Vice Chairman, 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 and 2015. [Source: Application pages 28 and 29, Exhibit 14, and Appendix 1] NKC has enough unrestricted assets to finance the proposed project.

The department concludes the NKC Federal Way 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) <u>A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.</u>

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

Northwest Kidney Centers

- "12 of the 14 stations for NKC Federal Way will be relocated from NKC Auburn, and we anticipated that most of the staffing needed for NKC Federal Way will also relocate from the downsized NKC Auburn. In total, we are anticipating only a few FTE's. Therefore, NKC does not anticipates any difficulties in staffing NKC Federal Way". [Source: Application, page 32]
- "Table 12 details the proposed staffing for this project.

Table 12 (Reproduced) NKC Federal Way Proposed Total Staffing

	FYE	FYE	FYE	FYE
	2018	2019	2020	2021
HD Tech	6.94	7.77	8.60	9.57
RN	3.74	4.18	4.63	5.16
<i>RN-Home Training (PD & HH)</i> ¹¹	1.00	1.00	1.00	1.00
Clinical Nurse Manager	1.00	1.00	1.00	1.00
Facility System Specialist	0.50	0.50	0.50	0.50
MSW	0.45	0.51	0.56	0.63
Dietician	0.42	0.47	0.52	0.58
Receptionist	1.00	1.00	1.00	1.00
Total	15.05	16.43	17.31	19.43"

[Source: Application, page 31]

• "A complete listing of NKC Medical Staff is included in Exhibit 5 and includes 48 active staff and 45 courtesy staff. The proposed Medical Director for NKC Federal Way is Frank Fung, MD. Dr. Fung's professional license number is MD00035164. The draft Medical Director agreement with Dr. Fung is included in Exhibit 6." [Source: Application, page 4]

Public Comments

None

Rebuttal Comments

None

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 15.05 FTEs. The majority, if not all, of these FTEs are expected to relocate from the NKC Auburn kidney

¹¹ Peritoneal Dialysis (PD) and Home Hemodialysis (HH)

Center that will downsize after the NKC Federal Way facility opens. Between FY 2018 and FY 2021, NKC expects to add a total of 4.38 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 Frank Fung, MD. NKC provided a draft of the medical director agreement between itself and Dr. Fung. 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.

(2) <u>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.</u>

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

Northwest Kidney Center

• *Ancillary and support services include the following:*

Social Services Business Office Nutrition Services Administration Information Systems Patient Financial Counseling Human Resources Pharmacy Patient Education Plant Operations Technical Services Material Management Community Relations Visitor Dialysis Informatics Nurses Public Relations

Water Purification Specialists

Medical Staff Credentialing [Source: Application, page 32]

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

- "A copy of the existing transfer agreement between NKC and Swedish Medical Center is included in Exhibit 16." [Source: Application, page 32]
- "...upon approval, NKC Federal Way would be added to the transfer agreement prior to opening and seeing the first patient." [Source: 1st screening responses, page 8]

Public Comments

None

Rebuttal Comments

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 Federal Way. NKC provided a copy of its current transfer agreement between NKC and Swedish Medical Center. This transfer agree 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 Federal Way facility to include the new facility. If the application is approved, the department would include a condition related to amending the existing transfer agreement.

The department concludes there is reasonable assurance the NKC Federal Way 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) (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.

Northwest Kidney Centers

- "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.

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. ¹² 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.

• <u>Hospitalization and Deaths</u>

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

Table 2 below shows the fifteen NKC dialysis centers and the CMS star ratings. [Source: December 1, 2016, CMS compare data]

Table2
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	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

¹² 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.

NKC Snoqualmie Kidney Center	Snoqualmie	4
NKC West Seattle Center	Seattle	3

As shown in Table 2, the facilities operated or owned by NKC have an average rating of 4 stars.

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

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

(4) <u>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.</u>

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

Northwest Kidney Centers

• "Although NKC Federal Way will be a new facility, NKC Auburn has operated in the planning area since 1997. The new facility will assure that our commitment to the community continues and NKC will continue to maintain all existing working relationships". [Source: Application Page 33]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

NKC has been providing services in ESRD King #11 since 1997 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 the NKC Federal Way 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) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>. To determine if a proposed project is the best alternative, the department takes a multi-step approach. <u>Step one</u> determines if the application has met the other criteria of WAC 246-310-210 thru 230 including any project type specific criteria. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

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

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

Northwest Kidney Centers

- "NKC considered the following options to developing the enclosed proposal:
 - 1) Add two stations to the existing NKC Auburn facility (for a total of 26 stations;
 - 2) Establish a 12 station facility with relocated stations from NKC Auburn and not add new stations:
 - 3) Add two stations to NKC Auburn after locating 12 stations to NKC Federal Way, or
 - 4) *Undertake the project in this application*". [Source: Application Page 34]
- "Option 1, that of adding additional stations to NKC Auburn, was evaluated but quickly ruled out because the existing NKC Auburn facility does not have the physical capacity to have a total of 26 stations." [Source: Application Page 34]

- "Option 2, the option of establishing a 12-station facility and foregoing the new stations was evaluated closely. However, given the census at NKC Auburn (5.25 patients per station), it did not seem prudent to develop a new facility that will likely be operating close to 4.8 patients per station within the first year of opening. The two new stations will allow for additional patients to be dialyzed weekly. Given the CN Program's dialysis projection methodology, these stations will be fully needed within the next 3 years, so it was determined that it would be in the best interests of our patients to build them at the same time the new facility is being constructed" [Source: Application Page 34]
- "Our goal from the start of this process was improve access for our patients by reducing drive time (with the establishment of a 2nd facility) and allow us to create better treatment space. The option, to do nothing, was not seriously considered because no new stations would be added to NKC Auburn if the status quo was maintained." [Source: 1st Screening responses, page 5]
- "NKC's intent is to create two efficiently operated and organized centers that will replace a single crowded facility. While there are not significant economies of scale to be realized with two facilities vs. a single facility per se, NKC, with two facilities in the planning area, will have the ability to expand capacity in the future. At the same time, the existing NKC Auburn will become less crowded." [Source: 1st screening responses, page 5]
- "...we identified that half of our patients receiving treatment at our Auburn Kidney Center facility live closer to the proposed unit in Federal Way which does improve patient access with reduced driving time, particularly in heavy traffic." [Source: 1st screening responses, page 5]
- "NKC also evaluated the feasibility of relocating the entire 24-station facility and adding two stations. The only space that NKC was able to find in the planning area that was large enough was located in Black Diamond. This location would not be convenient to the majority of King 11 dialysis patients." [Source: 1st screening responses, page 6]

Public Comment

None

Rebuttal

None

Department Evaluation

NKC considered several options before selecting the option to relocate a portion of its NKC Auburn facility and add the two additional projected stations. 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. 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.

Department Evaluation

Step Three

This step is applicable only when there are two or more approvable projects. For the ESRD 2016 cycle #2 submission period, NKC's application was the only application submitted to add dialysis stations in ESRD King #11 planning area. Therefore, this step does not apply.

The department concludes this sub-criterion is met.

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

(a) <u>The costs, scope, and methods of construction and energy conservation are reasonable;</u> 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". [Source: Application Page 35]
- "The new facility will comply with the State Energy Code, latest edition." [Source: Application Page 35]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

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

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

Public Comments

• None

Rebuttal Comments

• None

Department Evaluation

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

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

Department Evaluation

This project will improve the delivery of health services by locating those services closer to a portion of ESRD King #11 dialysis patients. Additionally, with the projected need for additional dialysis stations with the ESRD King #11 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 King County 11 ESRD Need Projection Methodology

	Planning Area	6 Year Utilizat	tion Data Ba	oidant Incante	or Botionto		
	King Eleven (11)	2010	2011	2012	2013	2014	2015
	98001	21	22	24	25	26	32
	98001	42	43	39	33	35	42
	98010	2	2	4	2	33	42
	98047	8	7	11	7	12	9
	98092	22	19	16	20	25	25
	TOTALS	95	93	94	87	101	112
246-310-284(4)(a)	Rate of Change		-2.11%	1.08%	-7.45%	16.09%	10.89%
	6% Growth or Greater?		FALSE	FALSE	FALSE	TRUE	TRUE
	Regression Method:	Linear					
246 240 204(4)(-)				V 4			· · ·
246-310-284(4)(c)				Year 1 2016	Year 2 2017	Year 3 2018	Year 4 2019
Projected Resident							
Incenter Patients	from 246-310-284(4)(b)			110.90	115.40	119.90	124.40
Station Need for							
Patients	Divide Resident Incenter	Patients by 4	4.8	23.1042	24.0417	24.9792	25.9167
	Rounded to next whole n	umber		24	25	25	20
246-310-284(5)	subtract (4)(c) from approv	ed stations					
Existing CN Approved	Stations			24	24	24	24
Results of (4)(c) above)		-	24	25	25	20
Net Station Need				0	-1	-1	-2
Negative number indicates r	need for stations						
Planning Area Fac	ilities						
Name of Center	# of Stations						
NKC Auburn	24						
Total	24						
-							
	al Network data 2010-2015						
Most recent year-end da	ata: 2015 posted 02/05/2016						



2016 King County 11 ESRD Need Projection Methodology

