



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

August 3, 2016

CERTIFIED MAIL # 7008 1830 0002 8022 0878

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

RE: Certificate of Need Application #16-25

Dear Mr. Ross:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers proposing to add dialysis station capacity to Enumclaw Kidney Center located in King County planning area #12. 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 addition of three dialysis stations to Enumclaw Kidney Center located in King County planning area #12. The facility is approved to certify and operate a total of eight stations. Services provided at Enumclaw Kidney Center include in-center hemodialysis, home hemodialysis, and home peritoneal dialysis training. The facility has an isolation area and a permanent bed station. The dialysis facility also provides evening treatments beginning after 5:00pm. A breakdown of all stations at project completion is shown below.

Type	# of Stations
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
Total Stations	8

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 shall finance the project using cash reserves as described in the application.

Approved Capital Costs:

The approved capital expenditure for the addition of three stations is \$42,777 and is solely for moveable equipment.

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

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,



Bart Eggen, Acting Director
Community Health Systems

Enclosure

EVALUATION DATED AUGUST 3, 2016, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY NORTHWEST KIDNEY CENTERS PROPOSING TO ADD DIALYSIS STATION CAPACITY TO ENUMCLAW KIDNEY CENTER LOCATED IN KING COUNTY END STAGE RENAL DISEASE PLANNING AREA #12

APPLICANT DESCRIPTION

Northwest Kidney Centers (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, pp2-3 and Exhibits 1 & 2]

In Washington State, NKC owns and operates the 15 kidney dialysis facilities listed below. NKC does not own or operate any healthcare facilities outside of Washington State. [source: Application, Exhibit 3]

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

This project focuses on Enumclaw Kidney Center identified in bold above. Enumclaw Kidney Center is a five-station facility located at 857 Roosevelt Avenue East in Enumclaw [98022] within King County planning area #12. NKC proposes to add three dialysis stations to the dialysis center, for a facility total of eight stations. [source: Application, p2]

Services provided at Enumclaw Kidney Center include in-center hemodialysis, home hemodialysis, and home peritoneal dialysis training. The facility has an isolation area and a permanent bed station. The dialysis facility also provides evening treatments beginning after 5:00pm. [source: Application, p7 & Exhibit 8 and May 11, 2016, supplemental information, p4]

The capital expenditure associated with the addition of three stations is \$42,777 and is solely for moveable equipment. [source: Application, p25 and May 11, 2016, supplemental information, p3]

If this project is approved, NKC anticipates the additional three stations would become operational by the end of December 2016. Under this timeline, year 2017 would be the facility's first full calendar year of operation with eight stations and 2019 would be year three. [source: Application, p10]

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 the application. WAC 246-310-200(2) provides additional direction in how the department is to make its determinations. It states:

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

(a) In the use of criteria for making the required determinations, the department shall consider:

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

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

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

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

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

To obtain Certificate of Need approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment). 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); WAC 246-310-284 (methodology); and WAC 246-310-287 (exceptions).

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1 for calendar year 2016. No other applications were submitted for the King County planning area #12 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	NKC-Enumclaw Kidney Center
Letter of Intent Submitted	January 29, 2016
Application Submitted	February 29, 2016
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	March 31, 2016 May 11, 2016 N/A ¹ N/A
Beginning of Review	May 18, 2016
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	June 23, 2016
Rebuttal Comments Received ²	July 7, 2016
Department's Anticipated Decision Date	August 22, 2016
Department's Actual Decision Date	August 3, 2016

AFFECTED PERSONS

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

"...an "interested person" who:

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

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;*

¹ NK C waived a second screening, and instead requested that the department begin review regardless of whether the information was complete.

² For this project, the department received three letters of support and no letters of opposition. NK C did not 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.*

DaVita Healthcare Partners, Inc.

On March 25, 2016, DaVita Healthcare Partners, Inc. (DaVita) submitted a letter requesting all correspondence related to NKC's project, to be informed of any public hearing, and to receive a copy of the department's decision. DaVita is a national provider of dialysis services and operates 38 dialysis centers in 17 separate counties, including eight facilities in King County. DaVita does not own or operate a dialysis center in planning area #12 in King County. DaVita does not meet the definition of interested person under (a), (b), (c), (d), (f), and (g) above.

The remaining definition (e) requires DaVita to submit a letter of intent within the 12 months prior to submission of NKC's application—from March 1, 2015 to February 29, 2016. During the 12 months prior to submission of this application, there were four concurrent review cycles for dialysis projects and four opportunities for DaVita to submit a letter of intent for King County planning area #12. Below is a summary of the letters of intent submitted by DaVita during the most recent 12 months prior to February 29, 2016.

Review Cycle /LOI Date	Number of LOIs / Planning Area
Cycle 1 - January 29, 2016	Total of 19 LOIs submitted <ul style="list-style-type: none"> • Pierce #5 - 7 LOIs • King #5 - 5 LOIs • Snohomish #3 - 7 LOIs
Cycle 2 - April 30, 2015	Total of 32 LOIs submitted <ul style="list-style-type: none"> • King #1 - 5 LOIs • King #5 - 5 LOIs • Klickitat - 7 LOIs • Pierce #4 - 10 LOIs • Pierce #5 - 5 LOIs
Cycle 3 - July 31, 2015	Total of 31 LOIs submitted <ul style="list-style-type: none"> • Lewis - 10 LOIs • Pierce #5 - 7 LOIs • Yakima - 14 LOIs
Cycle 4 - October 30, 2015	None

As shown above, DaVita submitted a total of 82 letters of intent for dialysis projects in Washington State. However, none of the letters of intent proposed a project in King County planning area #12 where Enumclaw Kidney Center is located. DaVita does not meet the definition of an 'interested person' and cannot meet the definition of an 'affected person' specific to this application. Even if DaVita met the qualifications for 'interested person', DaVita did not provide any written or oral comments on the Enumclaw Kidney Center application. In summary, no entities received affected person status under WAC 246-310-010(2) for this project.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers' Certificate of Need application received February 29, 2016
- Northwest Kidney Centers' 1st screening responses received May 11, 2016
- Public comments received by 5:00pm on June 23, 2016
- Years 2009 through 2014 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2015 Northwest Renal Network September 30, 2015 (third quarter) utilization data released November 15, 2015
- 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 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

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Northwest Kidney Centers proposing to add three dialysis stations to Enumclaw Kidney Center located in King County planning area #12 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 addition of three dialysis stations to Enumclaw Kidney Center located in King County planning area #12. The facility is approved to certify and operate a total of eight stations. Services provided at Enumclaw Kidney Center include in-center hemodialysis, home hemodialysis, and home peritoneal dialysis training. The facility has an isolation area and a permanent bed station. The dialysis facility also provides evening treatments beginning after 5:00pm. A breakdown of all stations at project completion is shown below.

Type	# of Stations
Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
Total Stations	8

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 shall finance the project using cash reserves as described in the application.

Approved Costs:

The approved capital expenditure for the addition of three stations is \$42,777 and is solely for moveable equipment.

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; WAC 246-310-284; and WAC 246-310-287(2) and (3)³.

(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).

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

³ WAC 246-310-287(1) is evaluated throughout this document and the conclusion is address on the last page.

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 2014.

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 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)]

WAC 246-310-280(9) identifies the ESRD planning areas for the state. NKC proposes to add dialysis station capacity to Enumclaw Kidney Center located in King County planning area #12. There is only one zip code included in this planning area. The zip code is 98022 in Enumclaw.

Northwest Kidney Centers Numeric Need Methodology

NKC proposes to add three dialysis stations to Enumclaw Kidney Center. Based on the calculation of the annual growth rate in the planning area as described above, NKC used the linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. The result of NKC's numeric methodology is shown in Table 1 below. [source: Application, Exhibit 10]

**Table 1
King County Planning Area #12
Numeric Methodology Summary**

4.8 in-center patients per station			
	2018 Projected # of stations	Minus Current # of stations	2017 Net Need or (Surplus)
NKC	3	5	(2)

Public Comments

None

Department Evaluation

Applying the numeric methodology to King County planning area #12, NKC calculated a surplus of two stations.

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project the need for King County dialysis planning area #12. 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 also showed a surplus of two stations in the planning area by the end of year 2017. The department’s methodology is included in this evaluation as Attachment A.

WAC 246-310-284(4) does not demonstrate numeric need for additional stations in King County planning area #12.

WAC 246-310-287

WAC 246-310-287 allows the department to approve new stations in a planning area if the projections in WAC 246-310-284(4) show no net need. Specifically, WAC 246-310-287 states:

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.*

The review criteria referenced in subsection (1) above is evaluated throughout this document. To evaluate subsection (3) above, the department must first evaluate subsection (2).

Northwest Kidney Centers

To demonstrate compliance with the exception criteria under subsection (2), NKC provided the following statements summarized below and supporting documentation. [source: Application, pp12-13, p17 and May 11, 2016, screening response, p1-2 and Attachment 1]

- Enumclaw Kidney Center is the only dialysis provider in the King #12 ESRD planning area.
- The initial application to establish Enumclaw Kidney Center was submitted on November 30, 2010. Projections for patients and number of dialyses in the initial application were for years 2013, 2014, and 2015. For year 2015, a total of 24 patients were projected for the five station center, which calculated to 4.8 patients per stations.
- The facility opened in March 2013 with five stations. September 2015 data obtained from Northwest Renal Network shows the facility is operating with 31 patients which equates to 6.2 patients per station. This calculates to 103% utilization within 2½ years of opening.
- Currently, to accommodate the high utilization of the five stations, NKC has been operating Enumclaw Kidney Center with four patient shifts. The first shift of the day begins at 6:00am and the fourth shift ends at midnight.
- The fourth patient shift is not preferred by most patients because it is disruptive for patients who work or have a family life.
- The fourth shift requires frail dialysis patients to start their treatments very early or complete their treatments very late. These patients are then on the road before 6:00am or after midnight.

- Fourth-shift patients are often newest to dialysis treatment because all of the daytime slots are already taken by other patients. Fourth-shift patients are typically frail and do not have the experience of getting into a dialysis routine. Travelling at midnight after a dialysis treatment can be unnerving for these patients.
- In the King County #12 planning area of Enumclaw, public transportation is limited, and sometimes non-existent, for early morning or after midnight. Dialysis patients often are unable to drive themselves to treatments, so they must arrange for alternative transportation to or from the center.
- Enumclaw Kidney Center is located in King County planning area #12. Table 2 below shows the December 2015 patient origin data for the dialysis center. The total number of patients was 32.

Table 2
Enumclaw Kidney Center
December 2015 Patient Origin Data

ESRD Planning Area	Percentage of Patients	Calculated Number of Patients
King 12	37.5%	12
Pierce 1	18.8%	6
King 11	15.6%	5
Pierce 2	15.6%	5
King 10	6.3%	2
King 4	3.1%	1
Other	3.1%	1
Total	100.0%	32

Public Comments

The department received three letters of support for this project. Two of the letters of support were provided by NKC patients that currently dialyze at Enumclaw Kidney Center. Below are excerpts of statements from the two letters related to WAC 246-310-287.

Sherrie Blalock

"I used to dialyze at Kent because there were not any open spots at Enumclaw. It took me 1 1/2 hours to drive to the unit and back, sometimes longer depending on traffic. I don't feel good often so there were many times I would skip dialysis because of the time it took. I know missing treatments is not good for me but I did not have the energy to do both the long drive and 4 hours of dialysis. I waited for an opening so I could dialyze at Enumclaw for 8 months. My whole life is easier now. My drive is 12 minutes each way. I save \$70 a week in gas. I come to dialysis regularly now that it is fast to get here."

James A. Manning, Colonel (Retired) USA

"In my discussion with both staff and patients, the seemingly crying need is for greater flexibility for the patient wanting either earlier or later hours for the scheduling of treatments. Personally, I know this to be a desirable offering by a center and also making the center more available to patients who reside a great distance in this very rural community."

One letter of support was provided by the clinical director at Enumclaw Kidney Center. This letter focused on need for additional stations from the provider's perspective. Below are excerpts of statements related to WAC 246-310-287.

Debra Marcella, RN, Clinical Director at Enumclaw Kidney Center

"...since opening in March 2013, EKC grew from serving 7 patients to 100% capacity, or 30, in approximately 2.5 years. Because we are at capacity, today we have a waitlist of local area patients who are not able to dialyze here because there are not enough stations available. As EKC's unit manager, I have witnessed the impact EKC has on patients who live in or near this rural community. It is profound. Dialysis is life-sustaining; without it you will die. Coming to treatment 3 times a week for an average of 4 hours each, and the drive to and from, takes its toll on every patient. Before treatment patients often do not feel well because their blood is toxic. The process of dialysis, or cleaning blood, causes fatigue and necessity to rest after treatment. When patients get dialysis close to home, their quality of life is improved. Local non-EKC patients have to drive or take transportation miles away to the next closest unit. It can take an extra 30 or more minutes each way driving. For patients dependent on public transportation the commute is more than double. This time is exhausting for them."

Department Evaluation

Information provided in letters of support from patients of Enumclaw Kidney Center demonstrates compliance with WAC 246-310-287(2)(a).

Information provided in the letter of support from the clinical director indicates that Enumclaw Kidney Center is operating at six patients per station. WAC 246-310-287(2)(b) requires the department to evaluate this sub-criterion using the most recent quarterly modality report or successor report from the Northwest Renal Network (NRN) as of the first day of the application submission period. For this project, the first day of the application submission period is February 1, 2016. The quarterly modality report used is September 30, 2015, released on December 4, 2015.⁶ NRN September 2015 data shows that Enumclaw Kidney Center was operating at 6.2 patients per station. This utilization meets the exception criteria under WAC 246-310-287(2)(a) and (3).

A review of the zip code maps for both Pierce and King counties shows that Enumclaw Kidney Center draws patients from the four planning areas directly adjacent to King County planning area #12. While it is not unusual for patients to cross planning areas to receive dialysis treatment, it is unusual that only 37.5% of Enumclaw Kidney Center's patients reside in planning area #12. This means the majority of the dialysis center's patients reside in planning areas other than King County planning area #12. This practice meets the exception criterion under WAC 246-310-287(3).

Enumclaw Kidney Center is the only dialysis center located in the planning area. The zip code maps shows that King County planning area #12 is the second largest planning area in the county based on square miles.⁷ Because the planning area is more rural than urban, public transportation is limited in Enumclaw. Lack of reliable transportation to and from a dialysis center makes a fourth patient shift undesirable to the patient. The rural nature of the planning area meets the exception criterion under WAC 246-310-287(3).

⁶ The December 31, 2015, quarterly modality report was released on February 15, 2016.

⁷ Based on square miles, the largest planning area in King County is #8. The only dialysis center in that planning area is NKC's Snoqualmie Ridge Kidney Center located in Snoqualmie.

Based on the information summarized above, the department concludes that NKC demonstrated compliance with WAC 246-310-287(2) and (3). The remainder of this evaluation will be used to determine compliance with WAC 246-310-287(1) and the conclusion is addressed following WAC 246-310-240(3).

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 #12, the utilization is 4.8 in-center patients per station.

Northwest Kidney Centers

NKC relied on the NRN quarterly modality report released on September 30, 2015 to demonstrate compliance with this standard. Table 3 below shows the reported utilization of the five stations at Enumclaw Kidney Center as of September 30, 2015.

**Table 3
September 30, 2015 - Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
NKC-Enumclaw Kidney Center	5	31	6.2

Public Comments

None

Department Evaluation

Based on the NRN quarterly modality report released on September 30, 2015, the department concludes **this criterion is met.**

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per station by the end of the third full year of operation. For King County planning area #12, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)]

Northwest Kidney Centers

NKC projects the three additional stations would be operational by the end of December 2016. Using that timeline, calendar year 2017 would be Enumclaw Kidney Center’s first full year of operation with eight stations and 2019 would be year three. Table 4 below shows the projected utilization for year three. [source: Application, p8 and p10]

**Table 4
Enumclaw Kidney Center
Third Year Projected Facility Utilization**

Year 3	# of Stations	# of In-Center Patients	Patients/Station
2019	8	39	4.88

Public Comments

None

Department Evaluation

Based on Table 3 above, NKC projected to operate Enumclaw Kidney Center at or above the 4.8 standard by the end of year 2019—the third full year of operation.

The department also concludes that the current services and facilities of the type proposed are not sufficiently available and accessible to meet the current need in the planning area. **This sub-criterion is met.**

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

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

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

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

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

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

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and whose income is equal to or below 200% of the federal poverty standards, adjusted for family size or is otherwise not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required by a third-party payer.⁸ With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

⁸ WAC 246-453-010(4).

Northwest Kidney Centers

NKC provided copies of the following policies used for all NKC dialysis centers, including Enumclaw Kidney Center. [source: Application, Exhibit 11]

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

Medicare and Medicaid Programs

Enumclaw Kidney Center is currently Medicare and Medicaid certified. NKC provided its projected source of revenues by payer for Enumclaw Kidney Center which is shown below in Table 5. [source: Application, p46]

Table 5
Enumclaw Kidney Center Sources of Revenue

Source	Percentage
Medicare	75.3%
Medicaid	6.1%
Other	18.6%
Total	100.0%

Public Comments

None

Department Evaluation

The Admission Policy outlines the process/criteria that NKC uses to admit patients for treatment and ensures that patients will receive appropriate care at a dialysis center. The 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.

NKC currently provides dialysis services to Medicare and Medicaid eligible patients at its dialysis centers in King and Clallam counties. Information provided in the application demonstrates that NKC intends to maintain this status with the additional stations at Enumclaw Kidney Center. The dialysis center would also maintain its Medicare and Medicaid certification. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare and Medicaid reimbursements. [source: Application, Exhibit 12]

NKC demonstrated its intent to continue to provide charity care to patients receiving treatment by submitting its current "Financial Services-Patient Funding Sources Policy" or charity care policy used for all dialysis centers owned, operated, or managed by NKC. This is the same policy that is used at the Enumclaw Kidney Center. The policy outlines the process a patient would use to access services when they do not have the financial resources to pay for required treatments. [source: Application, Exhibit 11] NKC also include a 'charity care' line item as a deduction from revenue within the pro forma income statements for Enumclaw Kidney Center. [source: Application, Exhibit 12]

Based on the source information reviewed, the department concludes that all residents of the service area would continue to have access to the health services provided at Enumclaw Kidney Center with the addition of three stations. **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 the 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 the application.

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

Department Evaluation

This sub-criterion is not applicable to the 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 the 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 the 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 the 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 determines Northwest Kidney Centers' project has met the financial feasibility criteria in WAC 246-310-220 and the kidney disease treatment centers-exception criteria in WAC 246-310-287(1).

(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

NKC anticipates the additional three stations will be operational at Enumclaw Kidney Center by December 30, 2016. Based on this timeline, NKC determined calendar year 2017 is the facility’s first full year of operation with eight stations. [source: Application, p10]

NKC operates on fiscal years beginning in July and ending in June. NKC provided the projected utilization, revenue, expenses, and net income for fiscal years 2017 through 2020 for Enumclaw Kidney Center with eight stations. Table 6 below illustrates. [source: Application, Exhibit 12]

Table 6
Enumclaw Kidney Center
Projected Revenue and Expenses for Fiscal Years 2017-2020

	FY 1 - 2017	FY 2 – 2018	FY 1 - 2019	FY 1 - 2030
# of Stations	8	8	8	8
# of Treatments [1]	5,180	5,476	5,772	6,068
# of Patients [2]	35	37	39	41
Utilization Rate [2]	4.4	4.6	4.9	5.1
Net Revenue [1]	\$ 2,546,774	\$ 2,692,304	\$ 2,837,833	\$ 2,983,363
Total Expense [1,3]	\$ 2,399,616	\$ 2,485,572	\$ 2,569,796	\$ 2,652,379
Net Profit or (Loss) [1]	\$ 147,158	\$ 206,732	\$ 268,037	\$ 330,984

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

The ‘Net Revenue’ line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The ‘Total Expenses’ line item includes salaries and wages, depreciation, and allocated costs charged to Enumclaw Kidney Center by its parent NKC.

NKC provided Enumclaw Kidney Center's sources of patient revenue shown in Table 7 on the following page. NKC stated it does not anticipate any changes in revenue sources with the additional three stations. [source: Application, p27]

Table 7
Enumclaw Kidney Center
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	75.3%
Medicaid	6.1%
Insurance/HMO	18.6%
Total	100.0%

NKC provided the lease agreement for the site that was executed on January 31, 2011, when Enumclaw Kidney Center was established. The executed lease extends every five years for a total of 25 years. The lease recently extended on January 31, 2016. [source: Application, Exhibit 9]

NKC provided a copy of the existing Medical Director Agreement currently used at the Enumclaw Kidney Center. The agreement was executed on February 1, 2014, and includes roles and responsibilities for NKC and the medical director, Rijuna Menon MD. The agreement is for one year, with automatic renewals each year, with no end date. [source: Application, Exhibit 5]

Public Comments

None

Department Evaluation

Shown in Table 4 above, based on the projected volumes identified in the application, NKC anticipates that Enumclaw Kidney Center would be operating at a profit in each of the first three full years of operation with eight stations.

The percentage of revenue sources identified by NKC is consistent with percentages the department has reviewed and approved in past applications for operational dialysis centers that propose station additions. [source: CN historical files for projects from Franciscan Health System, DaVita Healthcare Partners, and Fresenius Medical Care]

Lease costs for the site at 857 Roosevelt in Enumclaw is identified in the lease agreement and substantiated in the pro-form revenue and expense statement. [source: Application, Exhibit 12]

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 12]

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

The actual costs that NKC will pay for this three station addition is \$42,777 and these costs are solely for moveable equipment. NKC also identified allocation of construction costs that were expended in year 2013 when the five-station facility was established. With \$533,921 in allocated construction costs and associated tax, NKC identified a total cost of \$576,698 for the project. The capital cost breakdown is shown in Table 8 below. [source: Application, p25 and May 11, 2016, screening responses, p3]

Table 8
Enumclaw Kidney Center Estimated Capital Costs

Item	Allocated	Actual
Building Construction costs [allocated]	\$ 490,355	-----
Moveable Equipment [actual costs]	-----	\$ 42,777
Construction Sales Tax [allocated]	\$ 43,566	-----
Total Estimated Capital Costs	\$ 533,921	\$ 42,777

NKC provided the following statements related to this sub-criterion. [source: Application, p26]
"No construction is required to add the three stations. The increase in capital is very minor for this project and will not impact insurance providers or patients."

Public Comments

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 \$576,698. The capital costs identified in the application are consistent with the costs in the letter of intent. [source: Application, p25 and Exhibit 6]

Based on the definition of 'capital expenditure' under WAC 246-310-280(2), NKC identified construction costs already spent, yet allocated to this project. NKC also provided historical documentation to substantiate the total costs expended when the facility was initially established and identified its formula for determining cost allocations for this project. [source: Application, p25 and May 11, 2016, screening responses, pp2-3 and Attachment 1]

Table 5 shows the Medicare and Medicaid reimbursements are projected to equal 81.4% of the revenue at Enumclaw Kidney Center. 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 18.6% of Enumclaw Kidney Center's revenue will be derived through a variety of reimbursement sources such as private insurance.

Based on the information, the costs for the project, including allocated costs 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 #12. **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 the capital costs for the project and included allocation of construction costs that were expended in year 2013 when the five-station facility was established. The actual costs that NKC will pay for this three station addition is \$42,777 and the costs are solely for moveable equipment. [source: Application, p25 and May 11, 2016, supplemental information, p3]

NKC intends to finance the project using existing capital reserves from NKC. No costs will be allocated to, or repaid by, Enumclaw Kidney Center. NKC provided a letter of financial commitment from the NKC board. [Application, p26 and Exhibit 13]

NKC provided audited financial statements for fiscal years 2014 and 2015 to demonstrate availability of funding. [source: Application, Exhibit 13 and Appendix 1]

Public Comments

None

Department Evaluation

The department concludes that the three station addition project at Enumclaw Kidney Center can be appropriately financed with reserves from NKC. If this project is approved, the department would attach a condition requiring NKC to finance the project consistent with the financing description in the application. With the financing condition, the department concludes **this sub-criterion is met.**

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

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 Centers' project has met the structure and process of care criteria in WAC 246-310-230 and the kidney disease treatment centers-exception criteria in WAC 246-310-287(1).

- (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 currently operates Enumclaw Kidney Center with five stations and projects that the additional three stations would become operational by the end of December 2016. Under that timeline, calendar years 2017 through 2019 are the first three full years of operation for Enumclaw Kidney Center as an eight-station facility. Table 9 below shows the current staff (year 2016) and annual incremental increases with the additional three stations. [source: Application, p28]

**Table 9
Enumclaw Kidney Center
Current and Projected FTEs for Fiscal Years 2015-2019**

Staff/FTEs	2016 Current	2017 Increase	2018 Increase	2019 Increase	Total
Medical Director	Contracted Position				
HD Tech	2.50	1.00	0.00	0.00	3.50
Registered Nurses (RN)*	4.10	0.10	0.00	0.00	4.20
Facility System Specialist	0.35	0.00	0.15	0.00	0.50
MSW	0.20	0.10	0.20	0.00	0.50
Dietician	0.20	0.00	0.30	0.00	0.50
Receptionist	0.00	0.50	0.00	0.00	0.50
Total FTEs	7.35	1.70	0.65	0.00	9.70

* The registered nurse category also includes home training and manager RNs.

NKC states it expects the staff increases to be accomplished through increased hours of existing part-time staff at the dialysis center. Further, NKC’s overall current length of service for staff is 9.5 years for all 15 of its dialysis centers. As a result, NKC expects no difficulty recruiting new staff if necessary for Enumclaw Kidney Center. [source: Application, p29]

Public Comments

None

Department Evaluation

As shown in Table 7 above, NKC has the majority of its dialysis staff in place. From current fiscal year 2016 to projection year 2019, NKC expects to add another 2.85 FTEs to Enumclaw Kidney Center. The majority of the additional FTEs would be in the categories of nursing and HD Tech which are direct patient care positions. The table shows that the FTEs would be added incrementally based on the projected utilization and average daily census of dialysis center.

Information provided in the application demonstrates that NKC is a well-established provider of dialysis services in King and Clallam counties. Enumclaw Kidney Center has been in operation since March 2013. NKC provided a practical approach to ensuring adequate staffing at Enumclaw Kidney Center by first considering increased hours for current staff. Based on the above information, the department concludes that NKC has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **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) 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 Centers

NKC states it has been providing dialysis services in King and Clallam counties for many years. This project proposes the expansion of Enumclaw Kidney Center that has been providing dialysis services in King County planning area #12 since March 2013. The project proposes a three station increase in dialysis stations that would result in an eight station facility.

NKC states it currently maintains the appropriate relationships with ancillary and support services Enumclaw Kidney Center. Ancillary and support services such as social services, nutrition, patient education, and some dialysis training services are provided on-site. The remaining ancillary services of financial counseling, pharmacy access, human resources, administration, and plant operations are provided through one of its support offices Seattle, Lake Forest Park, SeaTac, or Bellevue located in King County. [source: Application, p26 and May 11, 2016, screening responses, p4]

The current medical director for the dialysis center is Rijuna Menon, MD. NKC provided a copy of the medical director agreement between itself and Dr. Menon. The agreement was executed on February 1, 2014, and is a one-year term with annual automatic extensions. [source: Application, Exhibit 5]

Public Comments

None

Department Evaluation

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that NKC would continue to maintain the necessary relationships with ancillary and support services to provide dialysis services at Enumclaw Kidney Center. The

department concludes that approval of three additional stations to the dialysis center would not negatively affect existing healthcare relationships. **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.

Northwest Kidney Centers

NKC does not own or operate any out-of-state healthcare facilities and only provides dialysis services in Clallam and King counties within Washington State. [source: Application, pp2-3 and Exhibits 1 & 3]

NKC states it has no history with respect to the actions noted in WAC 246-310-230(5)(a) that states:

"(a) The applicant or licensee has no history, in this state or elsewhere, of a criminal conviction which is reasonably related to the applicant's competency to exercise responsibility for the ownership or operation of a health care facility, a denial or revocation of a license to operate a health care facility, a revocation of a license to practice a health profession, or a decertification as a provider of services in the Medicare or Medicaid program because of failure to comply with applicable federal conditions of participation; or..."

NKC states it operates all existing programs in conformance with applicable federal and state laws, rules, and regulations. [source: Application, p30]

Public Comments

None

Department Evaluation

As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public and in conformance with applicable state licensing requirements and or Medicare/Medicaid certification.⁹ To accomplish this task, the department reviewed the quality of care compliance history for all 15 kidney dialysis facilities owned, operated, or managed by NKC.

For Washington State, the Department of Health's Investigations and Inspections Office (IIO) completed 15 compliance surveys as the contractor for Medicare for the operational facilities own or managed by NKC.¹⁰ These reveals minor non-compliance issues typical of a dialysis facility and

⁹ WAC 246-310-230(5)

¹⁰ 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

NKC submitted and implemented acceptable plans of correction. Enumclaw Kidney Center was surveyed on March 4, 2013, and the survey did not reveal any significant non-compliance issues. [source: facility survey data provided by the Investigations and Inspections Office]

The department also reviewed information on 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-morbidity(ies).

Table 10 below shows the fifteen NKC dialysis centers and the CMS star ratings. [source July 13, 2016, CMS compare data]

Table 10
Northwest Kidney Centers Dialysis Facilities CMS Star Rating

Facilities	City	Star Rating
NKC Auburn Center	Auburn	3
NKC Broadway Kidney Center	Seattle	4
NKC Elliot Bay Kidney Center	Seattle	3
NKC Enumclaw Kidney Center	Enumclaw	4
NKC Kent Kidney Center	Kent	3
NKC Kirkland Kidney Center	Kirkland	3
NKC Lake City Kidney Center	Lake Forest Park	3
NKC Lake Washington	Seattle	4
NKC Port Angeles Kidney Center	Port Angeles	3
NKC Renton Kidney Center	Renton	4
NKC Scribner Kidney Center	Seattle	4
NKC SeaTac	SeaTac	4
NKC Seattle Kidney Center	Seattle	3
NKC Snoqualmie Kidney Center	Snoqualmie	3
NKC West Seattle Center	Seattle	2

Kidney Center, and SeaTac Kidney Center; year 2016 for Renton Kidney Center and West Seattle Kidney Center.

As shown in the table on the previous page, the facilities operated or owned by NKC have an average rating of 3.

The current medical director for Enumclaw Kidney Center is Rijuna Menon, MD and NKC states that Dr. Menon intends to continue as medical director. A review of Dr. Menon'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]

Given the compliance history of the dialysis facilities owned and operated by NKC and the current medical director, there is reasonable assurance that Enumclaw Kidney Center would continue to be operated and managed in conformance with applicable state and federal licensing and certification requirements if this project is approved. **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 submitted documentation intended to demonstrate consistency with WAC 246-310-287(2) and (3) and requested approval of an additional three stations even though numeric need is not demonstrated under WAC 246-310-284. The documentation was provided to demonstrate that approval of three new stations at Enumclaw Kidney Center would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. Further, NKC demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area. [source: Application, p30 and May 11, 2016, supplemental information, pp1-2]

NKC provided a copy of the patient transfer agreement currently used at Enumclaw Kidney Center. The transfer agreement is between NKC and Swedish Medical Center. The patient transfer agreement will continue to be used at the Enumclaw Kidney Center with additional stations. [source: Application, Exhibit 14]

Public Comments

None

Department Evaluation

The department considered NKC's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in the relationship with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of additional stations at Enumclaw Kidney Center would change these

relationships. NKC also submitted documentation that this facility will continue to cooperate with existing healthcare providers.

The department considered the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. The numeric methodology showed a surplus of two stations in King County planning area #12. WAC 246-310-287 allows the department to approve new stations in a planning area if the projections in WAC 246-310-284(4) show no net need. To obtain stations under this exception, NKC must provide specific documentation under sub-section (2) to demonstrate one of the following:

- additional stations are needed to be located reasonably close to the people they serve; or
- existing dialysis stations in the dialysis facility are operating at six patients per station; or
- a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area.

The department concluded under the need section of this evaluation that NKC provided sufficient documentation to warrant approval of the three additional stations under the exception criteria outlined in WAC 246-310-287(2) and (3).

Based on the source documents evaluated, the department concludes approval of this project would promote continuity in provision of healthcare for the planning area, and would not result in an unwarranted fragmentation of services. **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 addressed in sub-section (3) above. **This sub-criterion is met.**

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

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 Centers' project has met the cost containment criteria in WAC 246-310-240 and the kidney disease treatment centers-exception criteria in WAC 246-310-287(1).

- (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, 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.

Step One

Department Evaluation

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

Step Two

Northwest Kidney Centers

Before submitting this application, NKC considered waiting until the need methodology in WAC 246-310-284(4) projected need for additional stations in King County planning area #12. Below is NKC's rationale for rejecting this option. [source: Application, p31]

*"NKC Enumclaw, after only two and a half years of operation, exceeded 6.0 patients per station and a 4th patient shift was added in late summer 2015. As of today, that 4th shift is also at 100% capacity. Despite this very high utilization, the methodology contained in WAC 246-310-284 projects a **surplus** of stations; largely due to the fact that the methodology does not recognize the significant in-migration that is occurring. NKC did not think it was in the best interest of patients to wait until the methodology identified [a numeric need?] (at minimum another 12 months from now, and then a 9 month+ CN review process) and instead elected to proceed with an application and request an exception per WAC 246-310-287." [emphasis included in quote]*

Public Comments

The department received three letters of support for this project. Two of the letters of support were provided by NKC patients that currently dialyze at Enumclaw Kidney Center. Below are excerpts of statements from the two letters related to WAC 246-310-240(1).

Sherrie Blalock

"I used to dialyze at Kent because there were not any open spots at Enumclaw. It took me 1 1/2 hours to drive to the unit and back, sometimes longer depending on traffic. I don't feel good often so there were many times I would skip dialysis because of the time it took. I know missing treatments is not good for me but I did not have the energy to do both the long drive and 4 hours of dialysis. I waited for an opening so I could dialyze at Enumclaw for 8 months. My whole life is easier now. My drive is 12 minutes each way. I save \$70 a week in gas. I come to dialysis regularly now that it is fast to get here."

James A. Manning, Colonel (Retired) USA

"In my discussion with both staff and patients, the seemingly crying need is for greater flexibility for the patient wanting either earlier or later hours for the scheduling of treatments. Personally, I know this to be a desirable offering by a center and also making the center more available to patients who reside a great distance in this very rural community."

One letter of support was provided by the clinical director at Enumclaw Kidney Center. This letter focused on need for additional stations from the provider's perspective. Below are excerpts of statements related to WAC 246-310-240(1).

Debra Marcella, RN, Clinical Director at Enumclaw Kidney Center

"...since opening in March 2013, EKC grew from serving 7 patients to 100% capacity, or 30, in approximately 2.5 years. Because we are at capacity, today we have a waitlist of local area patients who are not able to dialyze here because there are not enough stations available. As EKC's unit manager, I have witnessed the impact EKC has on patients who live in or near this rural community. It is profound. Dialysis is life-sustaining; without it you will die. Coming to treatment 3 times a week for an average of 4 hours each, and the drive to and from, takes its toll on every patient. Before treatment patients often do not feel well because their blood is toxic. The process of dialysis, or cleaning blood, causes fatigue and necessity to rest after treatment. When patients get dialysis close to home, their quality of life is improved. Local non-EKC patients have to drive or take transportation miles away to the next closest unit. It can take an extra 30 or more minutes each way driving. For patients dependent on public transportation the commute is more than double. This time is exhausting for them."

Step Three

This step is applicable only when there are two or more approvable projects. NKC's application is the only application under review to add dialysis stations in King County planning area #12. Therefore this step does not apply.

Department Evaluation

Information provided in the three letters of support demonstrates that superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable for the patients of Enumclaw Kidney Center. Three additional stations at Enumclaw Kidney Center could result in patients having more flexibility for scheduling dialysis at the center.

NKC identified \$42,777 will be expended to add the new stations. The costs are solely for moveable equipment to make the stations available for patients. No construction is required to accommodate the additional stations.

Given that the only other option to this project is to do nothing, taking into account that Enumclaw Kidney Center is operating above 6.0 patients per station as of the September 2015 quarterly data, and documentation provided by NKC to demonstrate that exception circumstances exist at Enumclaw Kidney Center, the department concludes that the project described is NKC and the community's best available alternative.

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

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

Department Evaluation

This sub-criterion is not applicable to the application.

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

Department Evaluation

This sub-criterion is not applicable to the application.

(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 provided the following statements related to this sub-criterion.

"The existing facility was designed and built to meet or exceed all applicable state and local codes and CMS conditions of coverage. The building complies with the State Energy Code, latest edition."

Public Comments

None

Department Evaluation

This project has the potential to improve delivery of dialysis services to the residents of King County planning area #12 and surrounding communities with the addition of three stations at Enumclaw Kidney Center. The department is satisfied the project is appropriate and needed. **This sub-criterion is met.**

WAC 246-310-287(1)

Department Evaluation

WAC 246-310-287 allows the department to approve new stations in a planning area if the projections in WAC 246-310-284(4) show no net need. Subsection (1) requires the applicant to meet all other applicable review criteria and standards. The department concludes that NKC's project meets all applicable review criteria and standards. **WAC 246-310-287(1) is met.**

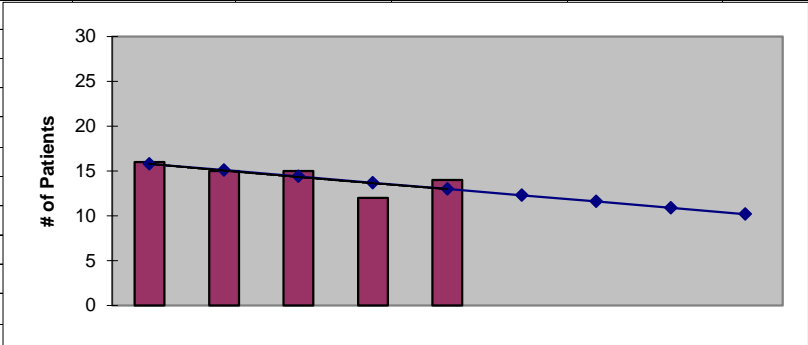
APPENDIX A



**2016
King County 12
ESRD Need Projection Methodology**

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
King Twelve (12)		2010	2011	2012	2013	2014	2015
98022		15	16	15	15	12	14
TOTALS		15	16	15	15	12	14
246-310-284(4)(a)	Rate of Change		6.67%	-6.25%	0.00%	-20.00%	16.67%
	6% Growth or Greater?		TRUE	FALSE	FALSE	FALSE	TRUE
	Regression Method:	Linear					
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)			12.30	11.60	10.90	10.20
Station Need for Patients	Divide Resident Incenter Patients by 4.8			2.5625	2.4167	2.2708	2.1250
	Rounded to next whole number			3	3	3	3
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				5	5	5	5
Results of (4)(c) above			-	3	3	3	3
Net Station Need				2	2	2	2
Negative number indicates need for stations							
Planning Area Facilities							
Name of Center	# of Stations						
NKC Enumclaw	5						
Total	5						
Source: Northwest Renal Network data 2010-2015							
Most recent year-end data: 2015 posted 02/05/2016							

x	y	Linear
2011	16	16
2012	15	15
2013	15	14
2014	12	14
2015	14	13
2016		12.30
2017		11.60
2018		10.90
2019		10.20



SUMMARY OUTPUT

<i>Regression Statistics</i>	
Multiple R	0.729800449
R Square	0.532608696
Adjusted R Square	0.376811594
Standard Error	1.197219
Observations	5

ANOVA					
	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	4.9	4.9	3.418604651	0.161593686
Residual	3	4.3	1.433333333		
Total	4	9.2			

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>
Intercept	1423.5	762.1096881	1.867841365	0.158592261	-1001.873161	3848.873161	-1001.873161	3848.873161
X Variable 1	-0.7	0.37859389	-1.848946903	0.161593686	-1.904854726	0.504854726	-1.904854726	0.504854726

RESIDUAL OUTPUT

<i>Observation</i>	<i>Predicted Y</i>	<i>Residuals</i>
1	14.6	-0.6
2	14.8	0.2
3	15	1
4	15.2	-0.2
5	15.4	-0.4