October 8, 2019

CERTIFIED MAIL # 7018 2290 0001 8591 8155

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

RE: Certificate of Need Application #19-71

Dear Mr. Ross:

We have completed review of the Certificate of Need application submitted by Northwest Kidney Centers. The application proposes to add two dialysis stations to the existing 32-station NKC Renton Kidney Center, located in King County Planning Area #9. 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 two dialysis stations to the 32-station NKC Renton, for a facility total of 34 dialysis stations. Services provided at NKC Renton include in-center hemodialysis, home hemodialysis, home peritoneal dialysis training and support for dialysis patients, hemodialysis for visitors, a private dialysis station (not exempt), a bed dialysis station, and shifts beginning after 5:00 pm.

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<tr>
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<tbody>
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</tr>
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<td>1</td>
</tr>
<tr>
<td>Isolation Station</td>
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<td>1</td>
</tr>
<tr>
<td><strong>Total Stations</strong></td>
<td><strong>34</strong></td>
<td><strong>34</strong></td>
</tr>
</tbody>
</table>

**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 shall finance this project consistent with the financing described in the application.

**Approved Costs:**
The approved capital expenditure for this two-station addition is $31,293. This amount represents the costs for moveable equipment. All costs will be paid by Northwest Kidney Centers.

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:

<table>
<thead>
<tr>
<th>Mailing Address:</th>
<th>Physical Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health</td>
<td>Department of Health</td>
</tr>
<tr>
<td>Certificate of Need Program</td>
<td>Certificate of Need Program</td>
</tr>
<tr>
<td>Mail Stop 47852</td>
<td>111 Israel Road SE</td>
</tr>
<tr>
<td>Olympia, WA 98504-7852</td>
<td>Tumwater, WA 98501</td>
</tr>
</tbody>
</table>

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

Sincerely,

[Signature]

Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure
APPLICATION DESCRIPTION

Northwest Kidney Centers
Northwest Kidney Centers (NKC) is a private, not-for-profit corporation, incorporated in the state of Washington. 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 and is comprised of medical, civic and business leaders from the community. The Board appoints an Executive Committee which oversees operating policies, performance, and approves capital expenditures for all of its facilities. [source: CN historical files and Application, p3 and Exhibits 1 and 2]

NKC provides dialysis services through its facilities located in King, Clallam, Snohomish and Pierce counties and does not own or operate any healthcare facilities outside of Washington State. In Washington State, NKC is approved to own and operated 20 kidney dialysis facilities.1 Below is a listing of NKC’s dialysis facilities in Washington. [source: Application, Exhibit 3 and CN historical files]

<table>
<thead>
<tr>
<th>Clallam County</th>
<th>King County continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Port Angeles Kidney Center</td>
<td>Rainier Beach Kidney Center</td>
</tr>
<tr>
<td></td>
<td>Renton Kidney Center</td>
</tr>
<tr>
<td></td>
<td>Scribner Kidney Center</td>
</tr>
<tr>
<td></td>
<td>Seattle Kidney Center</td>
</tr>
<tr>
<td></td>
<td>SeaTac Kidney Center</td>
</tr>
<tr>
<td></td>
<td>Snoqualmie Ridge Kidney Center</td>
</tr>
<tr>
<td></td>
<td>West Seattle Kidney Center</td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>King County</td>
<td></td>
</tr>
<tr>
<td>Auburn Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Broadway Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Elliot Bay Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Enumclaw Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Federal Way Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Kent Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Kirkland Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Lake City Kidney Center</td>
<td></td>
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<tr>
<td>Lake Washington Kidney Center</td>
<td></td>
</tr>
<tr>
<td>Northwest Everett Kidney Center</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Snohomish County</td>
<td></td>
</tr>
<tr>
<td>Everett Kidney Center</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Pierce County</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fife Kidney Center</td>
</tr>
</tbody>
</table>

PROJECT DESCRIPTION
This project focuses on NKC Renton Kidney Center located at 602 Oakesdale Avenue Southwest in Renton [98057] in King County planning area #9. Currently, NKC Renton is a 32-station facility as shown in the table on the following page.

1 Of the 20 NKC facilities two are recently CN approved and not yet operational. The two facilities are Rainier Beach Kidney Center and Everett Kidney Center.
<table>
<thead>
<tr>
<th>Station Type</th>
<th>CMS Certified Stations</th>
<th>Station Counted for Station Use and Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Use In-Center Stations</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Private Isolation Station</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Permanent Bed Station</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Exempt Isolation Station(^2)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Stations</strong></td>
<td><strong>32</strong></td>
<td><strong>32</strong></td>
</tr>
</tbody>
</table>

This application proposes to add two stations to NKC Renton, resulting in 34 in-center stations. NKC Renton would remain at its current location in Renton and would continue to provide the following services.

- Hemodialysis patients who dialyze in the chronic setting,
- Hemodialysis patients requiring isolation,
- Hemodialysis patients requiring dialysis in a permanent bed station,
- Hemodialysis patients requiring treatment shifts that begin after 5:00 PM,
- Home hemodialysis patients,

Additional services provided will include:

- Back up support for patients of home hemodialysis,
- Back up support for patients of home peritoneal dialysis, and
- Treatment for visiting hemodialysis patients from areas outside the King 9 planning area.

[source: Application, p6]

The capital expenditure associated with the addition of two stations is $31,293 and all costs are associated with the equipment, including sales tax. All costs would be paid by NKC. [source: Application, p14 and Exhibit 9]

Within the application, NKC determined this evaluation would be released in in mid-August 2019. Using that timeline, NKC estimated the additional stations would be operational in September 2019. [source: Application, p5] Under this timeline, full year one is 2020 and full year three is 2022.

**Department Information on Timelines for Completion of the Projects**

NKC identified a timeline for completion of this project based on an August 2019 evaluation release date. Due to delays in releasing this evaluation, NKC’s timeline may not be achievable or accurate. If this project is approved, the department will adjust the operational timeline to account for the additional days of delay of the release of this evaluation.

**APPLICABILITY OF CERTIFICATE OF NEED LAW**

NKC’s application proposes to add two dialysis stations to an existing dialysis center. This application is subject to review as an increase in the number of dialysis stations in a kidney disease center under provisions of RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

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\(^2\) In screening responses dated June 14, 2019, NKC Renton explained it prefers the flexibility of using an isolation station that does not fit the definition of “exempt isolation station” consistent with WAC 246-310-800(9).
EVALUATION CRITERIA
WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determination. It states:

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

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

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

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

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

NKC must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. For kidney dialysis applications submitted under WAC 246-310-818 ‘Special Circumstance One- or Two-Station Expansion,’ the following review criteria do not apply and will not be discussed in this evaluation.

- WAC 246-310-809 One-time exempt isolation station reconciliation
- WAC 246-310-812 Kidney disease treatment facilities—Methodology
- WAC 246-310-821 Kidney disease treatment facilities—Standards for planning areas without an existing facility
- WAC 246-310-830 Kidney disease treatment facilities—Relocation of facilities
- WAC 246-310-833 One-time state border kidney dialysis facility station relocation
**WAC 246-310-803**

WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2019 concurrent review cycle, the data must be received before February 16, 2019. NKC submitted its data elements on February 12, 2019.

**TYPE OF REVIEW**

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Special Circumstances Concurrent Review Cycle #1 for calendar year 2019. Even though applications submitted under WAC 246-310-806 are reviewed under a concurrent review cycle, the applications are not reviewed competitively. Below is the chronologic summary of the application’s review.

**APPLICATION CHRONOLOGY**

<table>
<thead>
<tr>
<th>Action</th>
<th>NKC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Intent Submitted</td>
<td>April 1, 2019</td>
</tr>
<tr>
<td>Application Submitted</td>
<td>May 1, 2019</td>
</tr>
<tr>
<td>Department’s Pre-review Activities including</td>
<td></td>
</tr>
<tr>
<td>• DOH 1st Screening Letter</td>
<td>May 15, 2019</td>
</tr>
<tr>
<td>• Applicant’s 1st Screening Responses Received</td>
<td>June 14, 2019</td>
</tr>
<tr>
<td>Beginning of Review</td>
<td>June 24, 2019</td>
</tr>
<tr>
<td>End of Public Comment</td>
<td>July 24, 2019</td>
</tr>
<tr>
<td>• Public comments accepted through the end of public comment</td>
<td></td>
</tr>
<tr>
<td>• No public hearing requested or conducted</td>
<td></td>
</tr>
<tr>
<td>Rebuttal Comments Deadline</td>
<td>July 31, 2019</td>
</tr>
<tr>
<td>Department’s Initial Anticipated Decision Date</td>
<td>August 15, 2019</td>
</tr>
<tr>
<td>Department's Anticipated Decision Date with a 60-day extension</td>
<td>October 13, 2019</td>
</tr>
<tr>
<td>Department’s Actual Decision Date</td>
<td>October 8, 2019</td>
</tr>
</tbody>
</table>

**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;

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3 Public comments were accepted through July 24, 2019, however no public comments were submitted for this project. As a result, NKC did not provide rebuttal comments.

4 Thirty-day extension letters were sent to NKC on August 14, 2019 and September 13, 2019.
(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.

One entity sought affected person status, DaVita, Inc. During this review DaVita did not provide public comments, and therefore do not qualify for affected person status.

SOURCE INFORMATION REVIEWED

- NKC Certificate of Need application received May 1, 2019
- NKC 1st screening response received June 14, 2019
- Years 2013 through 2018 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health’s ESRD Need Projection Methodology for King County planning area #9 posted to its website March 2019
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Compliance history obtained from the Washington State Department of Health Office of Health Systems Oversight
- NKC website at https://www.nwkidney.org/
- Northwest Renal Network website at www.nwrn.org
- Northwest Renal Network modality data
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSION

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted by NKC proposing to add two dialysis stations to NKC Renton located in King County planning area #9, is consistent with applicable criteria of the Certificate of Need Program, provided that the applicant agrees to the following in its entirety.

Project Description:

This certificate approves the addition of two dialysis stations to the 32-station NKC Renton, for a facility total of 34 dialysis stations. Services provided at NKC Renton include in-center hemodialysis, home hemodialysis, home peritoneal dialysis training and support for dialysis patients, hemodialysis for visitors, a private dialysis station (not exempt), a bed dialysis station, and shifts beginning after 5:00 pm.

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</table>
As required under Washington Administrative Code 246-310-818(10), the additional stations requested must be operational within six months of approval, otherwise this Certificate of Need is revoked.

Conditions:
1. Approval of the project description as stated above. NKC 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. NKC shall finance this project using existing capital reserves, as described in the application.

Approved Costs:
The approved capital expenditure for this two-station addition is $31,293. This amount represents the costs for moveable equipment. All costs will be paid by NKC.
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 this NKC project has met the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-800 through 833.

(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 246-310-818

WAC 246-310-818(1) - (13) outline the review requirements for dialysis projects submitted under the special circumstance review criteria. For this project, NKC must demonstrate compliance with the following sub-sections of WAC 246-310-818.

WAC 246-310-818(1) The department will approve one or two additional special circumstance stations for an existing kidney dialysis facility (facility) if it meets the following criteria, regardless of whether the need methodology in WAC 246-310-812 projects a need for additional stations in the planning area:

(a) For 4.8 planning areas, the facility has operated at or above an average of 5.0 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; or

(c) The facility can accommodate one or two additional stations within its existing building, which may include shelled space. If renovation is needed to accommodate the additional station(s), renovation must be within the existing building.

Northwest Kidney Centers

To demonstrate compliance with this sub-criterion, NKC provided the following documents:

- Six month utilization ‘raw’ utilization data from Northwest Renal Network.; and
- Single line drawing showing the current stations and support areas of the dialysis center as well as where the stations would be added.

[source: Application, p11 and exhibit 5]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

For this project, the six months preceding the letter of intent submission period for the Special Circumstance Concurrent Review Cycle #1 for King County planning area #9 is October 2018 through March 2019. NKC used data from the same timeframe for this project. The data provided in the application and confirmed by data produced by the Northwest Renal Network, shows that NKC Renton was operating at an average of 6.02 patients per station.

The single line drawing shows the two additional stations will be set up in existing space within the facility. Based on the information reviewed the department concludes the sub-criterion is met.
WAC 246-310-818(5) For 4.8 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 4.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

Northwest Kidney Centers
To demonstrate compliance with this sub-criterion, NKC provided the following documents:
- Six month utilization ‘raw’ utilization data from Northwest Renal Network. This data focuses on NKC Renton located in King County.
[source: June 14, 2019, screening response, Appendix 1]

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The only dialysis facility owned, operated, or affiliated with NKC in King County Planning area #9 is the facility under review – NKC Renton. As discussed under the previous sub-criterion, utilization at this facility exceeds 5 patients per station. This sub-criterion is met.

WAC 246-310-818(7) For 4.8 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would fall below a calculated 4.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.

Northwest Kidney Centers
To demonstrate compliance with this sub-criterion, NKC provided the following documents:
- Six month utilization ‘raw’ utilization data from Northwest Renal Network. This data focuses on NKC Renton located in King County.
[source: June 14, 2019, screening response, Appendix 1]

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The six months preceding the letter of intent submission period for the Special Circumstance submission cycle #1 for King County planning area #9 is October 2018 through March 2019. The data to be used by NKC for this project is the same time frame. If this project is approved, NKC Renton would be operating 34 in-center dialysis stations. The data provided in the application shows that the 34-station center would be operating at an average of 5.67 patients per station. This exceeds the 4.5 patient per station minimum. This sub-criterion is met.
WAC 246-310-818(10) Station(s) approved under this section must be operational within six months of approval, otherwise the approval is revoked.

Northwest Kidney Centers
To demonstrate compliance with this sub-criterion, NKC provided the following table showing the projected timeline for operation of the additional station. [source: Application, p5]

<table>
<thead>
<tr>
<th>Event</th>
<th>Month/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Complete</td>
<td>May 2019</td>
</tr>
<tr>
<td>Construction Commenced</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Construction Completed</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Facility Prepared for Survey</td>
<td>September 1, 2019</td>
</tr>
<tr>
<td>Additional Stations Operational</td>
<td>September 1, 2019</td>
</tr>
</tbody>
</table>

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The timeline identified in NKC’s Table 1 above projects the new dialysis station would be operational at NKC Renton within one month of approval. NKC identified a timeline for completion of this project based on an August 15, 2019 evaluation release date. Due to delays in releasing this evaluation, NKC’s timeline could not be achievable, so the department recalculated an operational date for this project. Using the actual October 2019 decision date, plus one month is November 2019. Given that WAC 246-310-818(10) requires additional stations to be operational within six months of approval, 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. One of the
exceptions is Medicare coverage for patients with permanent kidney failure. Patients of any age with permanent kidney failure are eligible for Medicare coverage.

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

A facility’s charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, 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.\(^5\) With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

**Northwest Kidney Centers**

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

“NKC has a long-established history of developing and providing services that meet the dialysis needs of the communities it serves. NKC Renton, as with all other NKC facilities, is committed to providing services to all patients regardless of race, color, ethnic origin, religious belief, sex, age or lack of ability to pay.

Copies of the admission policies and procedures and the charity care policy for the existing NKC Renton are included in Exhibit 8.”  [source: Application, p12]

NKC provided copies of the following policies for this project. [source: Application, Exhibit 8]

- New Patient Admission Policy
- Patient Compliance
- Charity Policy

**Medicare and Medicaid Programs**

NKC Renton is currently Medicare and Medicaid certified and NKC provided the facility’s Medicare and Medicaid provider numbers. NKC also included a table showing the current percentages of revenues by payer, and revenues by patient for NKC Renton. The information is summarized below. [source: Application, p8 and p17]

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage of Revenue by Payer</th>
<th>Percentage of Patients by Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>44.2%</td>
<td>71.7%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>7.6%</td>
<td>15.0%</td>
</tr>
<tr>
<td>Commercial</td>
<td>48.2%</td>
<td>13.3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.00%</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

\(^5\) WAC 246-453-010(4).
Department Evaluation

NKC has been providing dialysis services to the residents of Washington State for many years. The New Patient Admissions Policy provides the assurance that NKC would provide treatment to adults without regard to “race, color, religion, sex, national origin, or age...” provided that the patient is a candidate for dialysis services.

All NKC dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that NKC Renton would continue both Medicare and Medicaid certifications. NKC projected the Medicare revenues for NKC Renton to be 44.2% of total revenues. Pro forma financial data provided in the application shows continued Medicare revenues. NKC’s Medicaid revenues are currently and are projected to be 7.6% of total revenues. Pro forma financial data provided in the application shows continued Medicaid revenues.

NKC provided a policy titled “Charity” which provides the necessary information and process a patient would use to obtain charity care at NKC Renton. NKC further demonstrated its intent to provide charity care for patients by including a ‘charity’ line item as a deduction from revenue within the pro forma income statement.

Given that NKC currently operates NKC Renton and uses these policies and procedures at this center, the policies provided in the application are executed policies. No draft policies were provided by NKC. The department concludes NKC’s project meets this sub-criterion.

(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.

(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.

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

(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.

(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.

(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
WAC 246-310-210(3), (4), and (5) do not apply to this dialysis project under review.

B. Financial Feasibility (WAC 246-310-220)
Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that this NKC Renton project has met the financial feasibility criteria in WAC 246-310-220 and WAC 246-310-815.

(1) The immediate and long-range capital and operating costs of the project can be met.
WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, NKC must demonstrate compliance with the following sub-sections of WAC 246-310-815(1). 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.

WAC 246-310-815(1)
(1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.
(a) The calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.
(b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payer mix and current expenses.
(c) New facilities.
   (i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.
   (ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.
   (iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.
   (iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.
   (v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities.

Given that NKC Renton is currently operational, sub-sections (1)(a) and (b) above apply to this project.

Northwest Kidney Centers
As previously stated, NKC proposes the two additional stations would be operational September 2019 based on an August 2019 evaluation release date. [source: Application, p5] Under this timeline, calendar year one of this project is 2019 and full year one is 2020; calendar year three is 2022.
Once the additional stations are added, NKC Renton would be operating with 34 in-center dialysis stations, which includes a permanent bed station and one isolation station. NKC provided the assumptions used to project in-center treatments and patients for calendar years 2019, referenced as the ‘implementation year’ and full calendar years 2020 through 2022. The assumptions are restated below. [source: Application, Exhibit 6]

1. Volumes
   a. Patient In-Center Census: Census is expected to reach 204 by June 30, 2023. The Renton Kidney Center has been operating at near capacity for the past 3 years with a steady referral base. It is anticipated that the new stations will provide more desirable time slots and that historic referral patterns will continue throughout the pro forma period.
   b. Treatments are calculated based on 13 treatments per month and a 5% no-show rate.

Using the assumptions stated above, NKC’s projected number of in-center dialyses and patients for the 34-station facility in years 2019 through 2022 is shown in the table below. [source: Application, p11]

<table>
<thead>
<tr>
<th>Department’s Table 1</th>
<th>NKC Renton Kidney Center</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Projected Patients and Dialyses for Years 2019 – 2022</strong></td>
<td></td>
</tr>
<tr>
<td>Number of Stations</td>
<td>CY 2019</td>
</tr>
<tr>
<td>Total In center Patients</td>
<td>193</td>
</tr>
<tr>
<td>Total In center Treatments</td>
<td>27,225</td>
</tr>
</tbody>
</table>

NKC provided the following assumptions for its projected financial statements, which are restated below. [source: Application, Exhibit 6]

1. The Pro forma is completed based on a June 30 fiscal year. The implementation year is assumed to be the 12 months ending June 30, 2020.
2. Gross Revenue
   a. Medicare: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the existing facility for the first 9 months of fiscal year 2019.
   b. Medicaid: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the existing facility for the first 9 months of fiscal year 2019.
   c. Medicaid: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the existing facility for the first 9 months of fiscal year 2019.
   d. Total Gross Revenue is the weighted average of the above gross revenue relative to the patient payer mix which is reflective of the actual average payer mix for the existing facility for the first 9 months of the fiscal 2019.
3. Deductions from Gross Revenue
   a. Total Contractual Deductions is the weighted average is reflective of the actual average payer mix for the existing facility for the first 9 months of fiscal year 2019.
b. Bad Debt is reflective of the actual average bad debt write-off for the existing facility per treatment for the first 9 months of fiscal year 2019.
c. Charity is reflective of the actual average bad debt write-off for the existing facility per treatment for the first 9 months of fiscal year 2019.

Specific to various line items in the revenue and expense statement, NKC provided the following clarification. [source: Application, Exhibit 6]

1. Direct Expenses: All direct expenses are modeled based on the actual average amount per treatment for the existing facility for the first 9 months of fiscal year 2019.
   a. No inflation has been assumed in the forecast period
   b. Medical Director is based on contracted amount
   c. Depreciation has been increased to reflect the addition on equipment needed for the project.
   d. Other Supplies refers to office supplies, janitorial supplies, building and plant supplies
   e. Other Purchased Services refers to language interpretation services, freight, landscaping, window washing and pest control.
   f. Facility Rent expense is based on the terms of the existing lease. The current negotiated term expires in fiscal year 2022. The current lease rate escalator is 2.75% and the proforma assumes that this would continue should be remain a lessee vs. owner of the facility. See note 7.

2. Overhead: is based on the organization-wide operating budget for fiscal year 2019. Overhead included administrative and support services.

3. It should be noted that NKC has entered into a purchase and sale agreement to acquire the land and existing clinic building from the current owner. The sale has not been executed, thus the proforma assumes that the sale will not close and NKC continues to lease the current facility. If the sale were to occur, there would be an overall positive impact to the proforma as the capital depreciation on the building would be less than the current lease rate.

Specific to the lease expense category, NKC provided lease costs that match the revised proforma. [source: June 14, 2019, screening response, p2, attachments 2 and 3]

Based on the assumptions above, NKC projected the revenue, expenses, and net income for years 2020 through 2023. A summary of the projections are shown in the table below. [source: Application, Exhibit 6]

<table>
<thead>
<tr>
<th></th>
<th>CY 2019</th>
<th>CY 2020</th>
<th>CY 2021</th>
<th>CY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenue</td>
<td>$15,722,448</td>
<td>$15,960,668</td>
<td>$16,335,012</td>
<td>$16,743,388</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$11,756,258</td>
<td>$11,927,173</td>
<td>$12,190,026</td>
<td>$12,476,186</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
<td>$3,966,190</td>
<td>$4,033,495</td>
<td>$4,144,986</td>
<td>$4,267,202</td>
</tr>
</tbody>
</table>

The ‘Net Revenue’ line item is gross in-center and training revenue, minus deductions for commercial contractual allowances, bad debt, and charity care.
The ‘Total Expenses’ line item includes all expenses related to the projected operation of the 34-station facility in years 2019 through 2022. The expenses also include allocated costs as described above. Medical director costs are $117,000 annual and consistent with the executed Medical Director Agreement provided in Exhibit 10, Amendment – Exhibit B, Medical Director Compensation and Log.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
NKC Renton is currently operating with 32 dialysis stations. NKC based its projected utilization of NKC Renton on its current utilization, plus two additional stations. This approach for an existing facility is reasonable.

As a special circumstance application, WAC 246-310-815(1)(b) requires an applicant to base its revenue projections on the current payer mix and base its expense projections on current expenses. NKC provided both revenue and expense projections and based them on current operations.

Since NKC Renton is currently operational, the facility has an existing lease agreement. The costs identified in the lease agreement can be substantiated in the revenue and expense statement. NKC has the exclusive right to purchase their current site, and identified that they are in the early stages of doing so. NKC expects the transaction would close prior to the expiration of the lease. [source: Application Exhibits 6 and 11]

NKC provided a copy of the executed Medical Director Agreement with an amendment effective October 1, 2018. The agreement is currently effective and includes automatic annual renewals. The costs identified in the Medical Director Agreement can be substantiated in the revised revenue and expense statement submitted in screening.

Based on the above information provided by the applicant, the department concludes that NKC’s projected revenue and expense statement is reasonable. 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 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, NKC must demonstrate compliance with the following sub-sections of WAC 246-310-815(2). Using its experience and expertise the department compared the proposed project’s costs with those previously considered by the department.

**WAC 246-310-815(2)**
An applicant proposing to construct finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC 246-310-800(11) will be determined to have an unreasonable impact on costs and charges and the application will be denied. This does not preclude an applicant from constructing shelled space.
Northwest Kidney Centers
For this sub-criterion, NKC states that this project requires equipment, but no construction, to add two stations to NKC Renton. NKC provided its capital cost breakdown shown below. [source: Application, p16]

<table>
<thead>
<tr>
<th>Item</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moveable Equipment (including dialysis machines)</td>
<td>$31,293</td>
</tr>
<tr>
<td><strong>Total Estimated Capital Costs</strong></td>
<td><strong>$31,293</strong></td>
</tr>
</tbody>
</table>

Specific to costs and charges for health services, NKC provided the following statements. [source: Application, p17]

“This project will have no impact on the costs and charges for services. The capital costs for this project are relatively minor and will not impact payers or patients. NKC’s charges for services are not determined by capital expenditures. The pro forma operating assumptions and statement, which include the impact of the incremental depreciation expense on operations, is included in Exhibit 6.”

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The costs for adding two stations to the 32-station NKC Renton is $31,293. The costs are comparable to those reviewed in past applications for similar size station addition. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the revised proforma shows that NKC Renton currently has Medicare and Medicaid reimbursements that equal 51.8% of the revenue at the dialysis center. This amount is reasonable and consistent with percentages reviewed and approved in past NKC projects.

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 facilities 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 48.2% of net revenue is commercial.

Based on the above information provided by the applicant, the department concludes that NKC’s projected costs associated with the two-station addition to NKC Renton would probably not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #9. This sub-criterion is met.

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

Northwest Kidney Centers
NKC identified a capital expenditure of $31,293 to add two stations to NKC Renton. NKC intends to fund the project using corporate reserves. NKC provided a letter from its corporate vice president of finance and chief finance officer to demonstrate an operational and financial commitment to the project. [source: Application, p18 and Exhibit 9]

NKC also provided a copy of its audited financial statements for years 2015, 2016, and 2017 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 1]

Public Comment
None

Rebuttal Comment
None

Department Evaluation
NKC intends to finance the project with reserves and demonstrated the funds are available. If this project is approved, the department would attach a condition requiring NKC to finance the project consistent with the financing description provided in the application.

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

C. Structure and Process (Quality) of Care (WAC 246-310-230)
Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the NKC project has met the structure and process of care criteria in WAC 246-310-230.

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

**Northwest Kidney Centers**

If this project is approved, NKC expects the additional stations would be operational by September 1, 2019. Year 2020 would be the facility’s first full calendar year of operation and 2022 would be year three. The table below provides a breakdown of projected FTEs for historical year 2018, and projected years 2020 through 2022. [source: Application, p19]

<table>
<thead>
<tr>
<th>FTE by Type</th>
<th>CY 2018 Historical</th>
<th>CY 2019 Increase</th>
<th>CY 2020 Increase</th>
<th>CY 2022 Increase</th>
<th>CY 2022 Increase</th>
<th>Total FTEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Director</td>
<td>0.20</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.20</td>
</tr>
<tr>
<td>Nurse Manager/Care Manager</td>
<td>2.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>2.00</td>
</tr>
<tr>
<td>Tech</td>
<td>24.96</td>
<td>0.56</td>
<td>1.29</td>
<td>0.21</td>
<td>0.49</td>
<td>27.51</td>
</tr>
<tr>
<td>RN-In Center/PD/HHD</td>
<td>13.44</td>
<td>0.30</td>
<td>0.70</td>
<td>0.11</td>
<td>0.26</td>
<td>14.81</td>
</tr>
<tr>
<td>RN Home Training</td>
<td>2.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>2.00</td>
</tr>
<tr>
<td>Facility System Specialist</td>
<td>1.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
</tr>
<tr>
<td>MSW</td>
<td>1.46</td>
<td>0.08</td>
<td>0.00</td>
<td>0.03</td>
<td>0.03</td>
<td>1.60</td>
</tr>
<tr>
<td>Dietician</td>
<td>1.46</td>
<td>0.08</td>
<td>0.00</td>
<td>0.03</td>
<td>0.03</td>
<td>1.60</td>
</tr>
<tr>
<td>Receptionist</td>
<td>1.63</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>1.63</td>
</tr>
<tr>
<td><strong>Total FTEs</strong></td>
<td><strong>48.15</strong></td>
<td><strong>1.02</strong></td>
<td><strong>1.99</strong></td>
<td><strong>0.38</strong></td>
<td><strong>0.81</strong></td>
<td><strong>52.35</strong></td>
</tr>
</tbody>
</table>

NKC’s medical director is under contract at a total of $117,000 annually, but is not an employee and is not included in the table above. [source: Application, Exhibit 10 and June 14, 2019, screening response, p2 and Attachment 2] The agreement was executed in October 1, 2018 and is currently effective and includes automatic annual renewals.

NKC provided the following statements related to recruitment and retention of staff. [source: Application, p21]

“NKC is proactive in its efforts to assure quality staffing. NKC offers a competitive wage and benefit package as well as numerous other recruitment and retention strategies. Specific strategies include:

- NKC offers competitive wage and benefit packages. To ensure that its wages and benefits remain competitive, NKC conducts an annual market survey to benchmark its compensation package.
- NKC remains active on various job board including but not limited to indeed.com, nursing associations, Health e-careers, and other local resources.
- NKC also has contacts with colleges and universities throughout the Puget Sound area to both recruit staff as well as to serve as a clinical rotation site.
- NKC staff participate, at least monthly, in job fairs in and around the Puget Sound area.
- NKC also offers a substantial tuition reimbursement program for existing staff. Typically, in an average year, 15-20 employees take advantage of this program. Primarily, dialysis technician staff use this program to become registered nurses.
- NKC human resources staff are active in various boards and councils that focus on sharing of recruitment and retention strategies.
NKC human resources staff also work with agency personnel as needed for the use of temporary filling of staff positions.
NKC has a highly successful employee referral program that incentivizes current employees to refer colleagues from outside the organization for open positions.
NKC will, as needed, work with outside recruiters if a position has been challenging to fill.

Recent history demonstrates that NKC has been successful in staffing our new facilities. The most recent examples include NKC Federal Way East (located in King 11) and NKC Federal Way West Campus (located in King 5) and NKC Fife Kidney Center (located in Pierce 4). These new units were staffed with a combination of individuals that chose to transfer from other locations and new hires to the organization. In addition, NKC likely has part time staff that would be willing to expand their work hours.

The record will further demonstrate that in those rare circumstances in which we have faced staffing shortages (due to extended leave of absences or other issues), we have successfully used our roster of per diem staff or staff from other facilities nearby to supplement. The proximity of NKC Renton to NKC SeaTac, and NKC Kent also allows for sharing with those facilities in the event we have a situation that requires additional staffing."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
Information provided in the application demonstrates that NKC is a well-established provider of dialysis services in Washington State and in King County. NKC Renton Kidney Center has been operational since approximately April of 1987.  

For this project, NKC is proposing to add two stations to the existing center. The two station increase will require addition of approximately four FTEs by the end of the third full year of operation, 2022.

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) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

---

6 The facility was initially established as Mount Rainier Kidney Center.
**Northwest Kidney Centers**

NKC provides dialysis services throughout Washington State, including its NKC Renton Kidney Center in King County. If this project is approved, NKC Renton Kidney Center’s in-center stations will increase from 32 to 34. NKC states that the following ancillary and support services would be provided on site: nutrition services, patient education, patient financial counseling, pharmacy, plant operations, technical services, visitor dialysis, and water purification specialists.

Additional services are coordinated through NKC’s four support centers (a fifth one will be opening in the fall of 2019). [source: Application, p23]

NKC also provided a listing of the entities it currently has working relationships with for NKC Renton. [source: Application, p22, pp24-25, and Exhibit 15]

**Public Comment**
None

**Rebuttal Comment**
None

**Department Evaluation**

NKC Renton has been operating in King County approximately April of 1987. All ancillary and support services have been established for the dialysis center. NKC states that no new agreements or revisions to existing agreements are necessary for this project.

The department concludes that all required ancillary and support agreements and relationships are already in place. **This sub-criterion is met.**

(3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant’s history in meeting these standards at other facilities owned or operated by the applicant.

The evaluation of WAC 246-310-230(5) is also evaluated under this sub-criterion, as it relates to facility compliance history. Compliance history is factored into the department’s determination that an applicant’s project would be operated in compliance with WAC 246-310-230(3).

**Northwest Kidney Centers**

NKC provided the following statements in response to this sub-criterion. [source: Application p26 and p28]

“NKC has no history with respect to the actions noted in CN regulation WAC 246-310-230(5)(a).”

---

7 The facility was initially established as Mount Rainier Kidney Center.
NKC operates all existing programs in conformance with applicable federal and state laws, rules and regulations."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for this project, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the ‘star rating’ assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS ‘star ratings’ for Washington State facilities.

Centers for Medicare & Medicaid Services (CMS) Star Ratings
CMS provides the following overview regarding its star rating for dialysis centers.

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

CMS Star Rating for Washington State Centers
NKC is approved to own, operate, or manage 20 facilities, and of those, 18 are currently operational. Of the 18 facilities reporting to CMS by NKC, three facilities do not have the necessary amount of data to compile a star rating. For the remaining 15 facilities with a star rating, the average rating is 4.47. [source: CMS data July 2019]

The department also focused on its own state survey data performed by the Department of Health’s Office of Health Systems Oversight.

Washington State Survey Data
While 18 of the 20 NKC facilities are operational, in the most recent three years, 11 facilities have been surveyed. All surveys resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, NKC provided its Medical Director Agreement identifying the physician Frank Fung, M.D., associated with Valley Medical Group. Using data from the Medical Quality Assurance Commission, the department found this physician is compliant with state licensure and has no enforcement actions on his license.
The department also researched the compliance history of all known staff working at NKC Renton, which includes: fifteen registered nurses, five licensed practical nurses, twenty hemodialysis technicians, four dieticians\(^8\), and one medical social worker. None of the licensed employees had any enforcement action.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by NKC. The department also considered the compliance history of the physician that would be associated with the facility. The department concludes that NKC has been operating in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the addition of two new stations to NKC Renton would not cause a negative effect on NKC’s compliance history. The department concludes that NKC’s project \textit{meets this sub-criterion}.

\(4\) \textit{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.

\textbf{Northwest Kidney Centers}

NKC provided the following statements in response to this sub-criterion. [source: Application p26-27]

\begin{quote}
“NKC has operated outpatient dialysis services since 1962 (the very first in the Country); growing from 9 patients to over 1,700 today. NKC has, and continues to be, committed to providing optimal health, quality of life and independence for people with kidney disease. Further, NKC has experienced firsthand, and to the direct benefit of our patients that fragmentation is reduced or eliminated, when services are highly coordinated. NKC strives to provide services that deliver dialysis care that is coordinated via multiple entities including, but not limited to, physicians, other health care providers (nursing homes, assisted living facilities), home health care, hospitals, etc. as dialysis patients frequently have multiple providers and entities from which they receive services. For example, for nursing home or assisted living patients, NKC will report any care needs or issues identified during dialysis (as well as inform the patient’s physician, if appropriate). As patients are admitted and discharged from the hospital, NKC staff follow their care needs to ensure that the facility is prepared to provide dialysis to these patients upon discharge from the hospital.

In addition, NKC filed an application and secured a Comprehensive ESRD Care (CEC) accountable care organization designation from CMS. This entity, known as the Northwest Kidney Care Alliance is designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with End-Stage Renal Disease (ESRD). The premise is that a new payment and service delivery model that provides Medicare beneficiaries with person-centered, high-quality and non-fragmented care
\end{quote}

\(^8\) Two of the four dieticians are licensed, known as certified dieticians – the other two are registered nationally with the Commission on Dietetic Registration. The CN program received documentation that the two non-certified dieticians are current in their national registration. The CN program confirmed with the dietitian licensing program that licensure does not exclude nationally registered dietitians from working with a limited scope of practice.
that reduces costs and improves outcomes is better for patients. This is the only such entity in Washington State.

NK C Renton has been providing outpatient dialysis services in the King 9 Dialysis Planning Area since 1986. Growth has continued, and today it operates above full capacity, more than 6.0 patients per station and a 4th patient shift. NKC Renton’s current occupancy means that its patients have difficulty receiving timely access to services. The additional stations will assure that our commitment to the community to provide timely access and high quality remains.

Because of our longevity and our commitment to patient centered care, NKC enjoys longstanding established relationships with area health care providers, including but not limited to hospitals, physicians, nursing homes, assisted living facilities and adult family homes. In addition, NKC has mechanisms in place to assure that coordination of services is in place and fragmentation is avoided. In fact, as a long standing provider in the planning area, NKC is well positioned to assure that fragmentation is avoided.

NK C Renton through its Nurse Manager, Dietician, Social Worker and support through Admitting and Patient Services staff, routinely coordinate and communicate with the patients’ physicians, families or other relevant care providers for any changes that might impact their care.

NKC Renton has all of the ancillary and support agreements and a comprehensive array of in-house services already in place that help to assure that continuity of care is in place for patients.”

Public Comment
None

Rebuttal Comment
None

Department Evaluation
NK C has been a provider of dialysis services in Washington State for many years. NKC also has a history of establishing relationships with existing healthcare networks in King County for NKC Renton. Additionally, NKC’s project would promote continuity in the provision of healthcare services in King County planning area #9 by increasing the number of stations at NKC Renton.

NK C provided sufficient rationale in the application to demonstrate that the project would promote continuity in the provision of health care services in the community and not result in unwarranted fragmentation.

Based on the information above, the department concludes that NKC’s project meets this sub-criterion.

(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.

Department Evaluation for Northwest Kidney Centers
This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.
D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the NKC project has met the cost containment criteria in WAC 246-310-240.

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

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

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

If there are multiple applications, the department’s assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in **Step three**. Under WAC 246-310-818(11) this step does not apply Special Circumstance applications.

**Step One**

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

**Step Two**

For this sub-criterion, NKC discussed the benefits of adding stations through this special circumstances application, below is NKC’s discussion. [source: Application, p31]

“WAC 246-310-818 allows dialysis facilities to request up to two additional stations based on internal utilization; regardless if there is need in the planning area. Given the high census at NKC Renton, the shortened timeline for the +2 Special Circumstances concurrent review cycle will provide for some relief to the continued census pressures at NKC Renton. Therefore, no other alternative was considered.”

Public Comment
None

Rebuttal Comment
None

**Department Evaluation**

NKC provided a comprehensive discussion of why adding stations in this planning area is the appropriate alternative. Specifically, NKC operates only one center in King County planning area #9 and asserts it is a highly utilized facility.
Special circumstance applications are designed to quickly bring stations online in highly utilized facilities. The department is satisfied that the applicant appropriately chose to submit a special circumstance application for NKC Renton in order to promote immediate access to services.

The department concludes that the project submitted by NKC is the best available alternative for the community. **This sub-criterion is met.**

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

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

(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**

Since NKC’s capital expenditure is solely related to dialysis equipment, this sub-criterion does not apply to this project.

(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 response for this sub-criterion. [source: Application, p32]

“WAC 246-310-818 allows dialysis facilities to request up to two additional stations based on internal utilization; regardless if there is need in the planning area. Given the high census at NKC Renton, the shortened timeline for the +2 Special Circumstances concurrent review cycle will provide for some relief to the continued census pressures at NKC Renton. Therefore, no other alternative was considered.”

**Public Comment**

None

**Rebuttal Comment**

None

**Department Evaluation**

NKC’s project has the potential to improve delivery of dialysis services to the residents of King County planning area #9 with the addition of two stations in the planning area. Consistent with the special circumstance rules, NKC would be operating the additional stations within six months of approval. **This sub-criterion is met.**