



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
*Olympia, Washington 98504*

July 10, 2019

CERTIFIED MAIL # 7016 3010 0001 0575 1218

Rudy Lai - Director, Special Projects  
DaVita Healthcare Partners Inc. - North Star Division  
32275 32nd Ave S  
Federal Way, WA 98001

RE: Certificate of Need Application #18-59

Dear Mr. Lai:

We have completed review of the Certificate of Need application submitted by DaVita, Inc. The application proposes the establishment of a 23-station dialysis facility in King County planning area #11. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a 23-station dialysis center in King County planning area #11 is consistent with applicable criteria of the Certificate of Need Program, provided DaVita, Inc. agrees to the following in its entirety.

**Project Description:**

This certificate approves the establishment of a 23-station dialysis center to be located at the intersection of O Street and 115th St SW, King County Parcel ID #0301500090, #0301500280, and #0301500110 in Auburn [98001], within King County planning area #11. The table below provides a breakdown of the total number of stations at project completion.

	<b>CMS Certified Stations</b>	<b>Stations Counted in Methodology</b>
General Use In-Center Stations	21	21
Permanent Bed Station	1	1
Private Isolation Station	1	0
<b>Total Stations</b>	<b>23</b>	<b>22</b>

Services to be provided at the new dialysis center include in-center hemodialysis, isolation capabilities, and a permanent bed station. There will also be a patient shift starting after 5pm.

**Conditions:**

1. Approval of the project description as stated above. DaVita, Inc. 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. DaVita, Inc. shall finance this project consistent with the financing described in the application.
3. Prior to providing services at the new dialysis center, DaVita, Inc. will provide a copy of the executed Patient Transfer Agreement consistent with the draft provided in the application.

**Approved Capital Expenditure:**

The total capital expenditure for this project is \$3,386,554, which includes construction costs, equipment, and associated fees and taxes.

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:

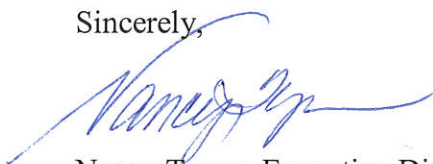
Department of Health  
Certificate of Need Program  
Mail Stop 47852  
Olympia, WA 98504-7852

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 the Certificate of Need Program at (360) 236-2955.

Sincerely,



Nancy Tyson, Executive Director  
Health Facilities and Certificate of Need

Enclosure

**YEAR 2018 CYCLE 1 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED JULY 10, 2019 FOR DAVITA, INC. PROPOSING TO ADD DIALYSIS STATION CAPACITY IN KING COUNTY PLANNING AREA #11**

**APPLICANT DESCRIPTION**

**DaVita, Inc.**

DaVita submitted this application under its subsidiary of Total Renal Care, Inc. For Certificate of Need purposes, DaVita, Inc. is the applicant. DaVita is a national provider of dialysis services operating in 45 states and the District of Columbia.<sup>1</sup> In Washington State, DaVita is approved to own and operate a total of 42 dialysis centers in 19 separate counties. Listed below are the names of the operational facilities owned or operated by DaVita in Washington State. [source: CN historical files and Application, pdf6-9]

**Benton**

Chinook Dialysis Center  
Kennewick Dialysis Center

**Clark**

Vancouver Dialysis Center  
Battle Ground Dialysis Center

**Chelan**

Wenatchee Valley Dialysis Center

**Douglas**

East Wenatchee Dialysis Center

**Franklin**

Mid-Columbia Kidney Center

**Island**

Whidbey Island Dialysis Center

**King**

Bellevue Dialysis Center  
Federal Way Dialysis Center  
Kent Dialysis Center  
Olympic View Dialysis Center  
Renton Dialysis Center  
Redondo Heights Dialysis Center  
Westwood Dialysis Center

**Kittitas**

Ellensburg Dialysis Center

**Pierce**

Graham Dialysis Center  
Lakewood Community Dialysis Center  
Parkland Dialysis Center  
Puyallup Community Dialysis Center  
Rainier View Dialysis Center  
Tacoma Dialysis Center

**Skagit**

Cascade Dialysis Center

**Snohomish**

Everett Dialysis Center  
Lynnwood Dialysis Center  
Mill Creek Dialysis Center  
Pilchuck Dialysis Center

**Spokane**

Downtown Spokane Renal Center  
North Spokane Renal Center  
Spokane Valley Renal Center

**Stevens**

Echo Valley Dialysis Center

**Thurston**

Olympia Dialysis Center  
Tumwater Dialysis Center

**Whatcom**

Mount Baker Kidney Center

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<sup>1</sup> DaVita operates in 45 states and the District of Columbia. The five states where DaVita is not located are: Alaska, Delaware, Mississippi, Vermont, and Wyoming.

**Lewis**  
Cooks Hill Dialysis Center

**Mason**  
Belfair Dialysis Center

**Pacific**  
Seaview Dialysis Center

**Yakima**  
Mt. Adams Dialysis Center  
Union Gap Dialysis Center  
Wapato Dialysis Center  
Yakima Dialysis Center  
Zillah Dialysis Center

## **PROJECT DESCRIPTION**

Within its application, DaVita refers to a 22-station need in King County planning area #11 and frequently refers to this figure. Based on WAC 246-310-800(9), exempt isolation stations are not counted in the methodology. Shortly following the department's first screening, the department sent out a supplemental screening asking DaVita to clarify whether the isolation station would meet the definition under WAC 246-310-800(9), and DaVita confirmed that it would meet the definition. As a result, this evaluation will consistently refer to a 22-station need in the planning area. However, if this project is approved, the approval will reflect one additional exempt isolation station as identified by DaVita in response to screening.

### **DaVita, Inc.**

DaVita proposes to establish a new 23-station dialysis center at the intersection of O Street and 115th St SW, King County Parcel ID #0301500090, #0301500280, and #0301500110 in Auburn [98001], within King County planning area #1. The new center would be known as DaVita Auburn Valley Dialysis Center. Services to be provided at the new dialysis center include:

- 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.

Additional services provided will include:

- Treatment for visiting hemodialysis patients from other areas outside King #11, and
- Community education for patients recently diagnosed with Chronic Kidney Disease (CKD).  
[source: Application, pdf9, 11]

If approved, DaVita expects the 23-station dialysis center would be operational and prepared for survey by May 2021. [source: Application, pdf11]

The total capital expenditure for this project is \$3,386,554, which includes construction costs, equipment, and associated fees and taxes. [source: Screening 1 pdf10]

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

DaVita identified a timeline for completion of this project based on a December 2019 evaluation release date. Due to delays in releasing this evaluation, DaVita'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**

DaVita's project is subject to Certificate of Need review as the construction, development, or other establishment of a new health care facility under the provisions of RCW 70.38.105(4)(a) and WAC 246-310-020(1)(a).

## **EVALUATION CRITERIA**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction 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).

DaVita must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. For this application submitted under WAC 246-310-806 Nonspecial Circumstance, 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 246-310-818	Special circumstances one- or two-station expansion—Eligibility criteria and application process
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an existing facility
WAC 246-310-824	Kidney disease treatment centers—Exceptions
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 2018 concurrent review cycle, the data must be received before February 16, 2018. Each applicant submitted the data elements on February 15, 2018. This data is used to calculate superiority in the event that more than one application meets the applicable review criteria. Consistent with WAC 246-310-827, these data elements are the only means by which two or more applications may be compared to one another.

WAC 246-310-803 and WAC 246-310-827 allow for public review and correction to data submissions prior to any concurrent review cycle. Therefore, if the department receives public comments related to data submission under WAC 246-310-803 or WAC 246-310-827 during a review, the comments will not be considered and discussed.

**TYPE OF REVIEW**

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle #1 for calendar year 2018. DaVita’s application was the only project submitted for King County planning area #11. Consistent with sub-section WAC 246-310-806(8), the department converted the review to a regular review timeline. Below is the chronological summary of the review timelines.

**APPLICATION CHRONOLOGY**

<b>Action</b>	<b>DaVita, Inc.</b>
Letter of Intent Submitted	May 1, 2018
Application Submitted	June 1, 2018
Department’s pre-review activities <ul style="list-style-type: none"> <li>• DOH 1<sup>st</sup> Screening Letter</li> <li>• Applicant's Responses Received</li> <li>• DOH 2<sup>nd</sup> Screening Letter</li> <li>• Applicant's Responses Received</li> </ul>	June 29, 2018 August 13, 2018 September 4, 2018 October 19, 2018
Beginning of Review	October 22, 2018
End of Public Comment <sup>2</sup> <ul style="list-style-type: none"> <li>• Public comments accepted through the end of public comment</li> <li>• No public hearing requested or conducted</li> </ul>	November 30, 2018
Rebuttal Comments Submitted	December 14, 2018
Department's Initial Anticipated Decision Date	January 28, 2019
Department's Actual Decision Date	July 10, 2019

<sup>2</sup> Public comments were accepted through November 30, 2018, however no public comments were submitted for this project. As a result, DaVita did not provide rebuttal comments.

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

For this project, several entities sought interested person status or requested to receive copies of the application. Only one of these entities qualified for affected person status – Northwest Kidney Centers (NKC). NKC first qualified as an interest person under WAC 246-310-010(34)(b), as they operate a dialysis facility in King County Planning Area #11. NKC then qualified as an affected person by meeting all of the criteria under WAC 246-310-010(2).

## **SOURCE INFORMATION REVIEWED**

- DaVita, Inc. Certificate of Need application received June 1, 2018
- DaVita, Inc. 1<sup>st</sup> screening response received August 13, 2018
- DaVita, Inc. 2<sup>nd</sup> screening response received October 19, 2018
- Years 2012 through 2017 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health’s ESRD Need Projection Methodology for King County planning area #11 posted to its website March 2018
- 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
- Centers for Medicare and Medicaid website at [www.medicare.gov/dialysisfacilitycompare](http://www.medicare.gov/dialysisfacilitycompare)
- Certificate of Need historical files

## CONCLUSION

### DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a 23-station dialysis center in King County planning area #11 is consistent with applicable criteria of the Certificate of Need Program, provided DaVita, Inc. agrees to the following in its entirety.

### Project Description:

This certificate approves the establishment of a 23-station dialysis center to be located at the intersection of O Street and 115th St SW, King County Parcel ID #0301500090, #0301500280, and #0301500110 in Auburn [98001], within King County planning area #11. The table below provides a breakdown of the total number of stations at project completion.

	<b>CMS Certified Stations</b>	<b>Stations Counted in Methodology</b>
General Use In-Center Stations	21	21
Permanent Bed Station	1	1
Private Isolation Station	1	0
<b>Total Stations</b>	<b>23</b>	<b>22</b>

Services to be provided at the new dialysis center include in-center hemodialysis, isolation capabilities, and a permanent bed station. There will also be a patient shift starting after 5pm.

### Conditions:

1. Approval of the project description as stated above. DaVita, Inc. 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. DaVita, Inc. shall finance this project consistent with the financing described in the application.
3. Prior to providing services at the new dialysis center, DaVita, Inc. will provide a copy of the executed Patient Transfer Agreement consistent with the draft provided in the application.

### Approved Capital Expenditure:

The total capital expenditure for this project is \$3,386,554, which includes construction costs, equipment, and associated fees and taxes.



## **CRITERIA DETERMINATIONS**

### **A. Need (WAC 246-310-210)**

Based on the source information reviewed, the department concludes that DaVita has **met** the need criteria in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-812(5).

- (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 246-310-812 requires the department to evaluate kidney disease treatment centers applications based on the population's need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology is applied and detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria and also identified in WAC 246-310-812(5) and (6).

#### WAC 246-310-812 Kidney Disease Treatment Center Numeric Methodology

WAC 246-310-812 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network (NWRN).<sup>3</sup>

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 246-310-812(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.<sup>4</sup>

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

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NWRN data, again concluding with the base year. [WAC 246-310-812(4)(b) and (c)]

[WAC 246-310-812(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

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<sup>3</sup> NWRN was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [Source: Northwest Renal Network website]

<sup>4</sup>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 2017.

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

Finally, once station need has been calculated for the project years, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-812(4)(d)] The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is a discussion of the numeric methodology submitted by DaVita.

**DaVita, Inc.**

DaVita proposes to establish a 23-station dialysis center to be located in Auburn. DaVita relied on the numeric methodology posted to the department’s website for King County planning area #11. The methodology projected need for 22 stations in projection year 2022.

Public Comment

None

Rebuttal Comment

None

**Department Evaluation of the Numeric Methodology for King County Planning Area #11**

The department calculates the numeric methodology for each of the 57 ESRD planning areas in Washington and posts each of the results to its website. The department’s year 2018 numeric methodology was posted in March 2018.

Based on the calculation of the annual growth rate in the planning area, the department used the linear regression to determine numeric need. The number of projected patients was divided by 4.5 to determine the number of stations needed in King County planning area #11. A summary of the department’s numeric methodology is shown in Table 1 below.

**Department’s Table 1  
King County Planning area #11 Numeric Methodology Summary**

	4.5 in-center patients per station		
	2022 Projected # of stations	Minus Current # of stations	2022 Net Need or (Surplus)
DOH Methodology Post to Website	48	26	22

As shown in the table above, once the 26 existing stations are subtracted from the projected need, the result is a net need of 22 stations. The department’s methodology is included in this evaluation as Appendix A. DaVita’s proposed isolation station would not be counted. The department concludes DaVita **met the numeric methodology standard**.

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis station need.<sup>5</sup> The department uses the standards in WAC 246-310-812(5) and WAC 246-310-812(6).

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<sup>5</sup> WAC 246-310-210(1)(b).

**WAC 246-310-812(5)**

*Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:*

*(a) All stations for a facility have been in operation for at least three years; or*

*(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.*

*...Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.*

For King County planning area #11, WAC 246-310-812(5) requires all CN approved stations in the planning area be operating at 4.5 in-center patients per station. DaVita provided the following table showing utilization in the planning area. [source: Application, pdf14]

*Applicant’s Table 5*

Table 5 Existing Dialysis Facilities in King 11	Quarterly Utilization of Existing Stations			
	Provider	Approved Stations (as of 12/31/2017)	NWRN 12/31/2017	
Patients			Patients Per Station	
NKC AUBURN 502520	NKC	12 (24)	143	11.92
NKC Federal Way East	NKC	14 (0)	0	0

\*note, at the time, NKC Auburn had not relocated its stations and was operating with 24 approved stations, or 5.96 patients per station.

DaVita provided the following information regarding the lack of utilization at the NKC’s Federal Way East facility. [source: Application, pdf14-15]

*WAC 246-310-812(5)(b) provides that [the department will consider the 4.5 in-center patients per station standard met for those facilities when] “Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.” NKC Auburn Kidney Center, with 24 stations, has historically been the sole dialysis facility in the King 11 planning area. Under CN #1593, Northwest Kidney Centers was approved to relocate twelve (12) stations from NKC Auburn to a new facility, NKC Federal Way East, and add two additional stations to NKC Federal Way East. In its application, NKC represented the following: “This project will commence immediately upon CN approval (assuming Q1 2017). The proposed facility will be operational by January 1, 2018.” CN approval was on February 21, 2017. Therefore, the approval was within the first quarter (hereafter, “Q1”) of 2017, as NKC projected, and NKC Federal Way East should have become operational by January 1, 2018 per the timeline represented in the application. It did not.*

*NKC claimed in its progress reports that it would open by February, 2018. This would not have been operational within the timeline claimed in its application. And yet NKC did not meet the February timeline, either, despite clear patient need for the additional stations provided by CN #1596. NKC*

staff informed DaVita staff, on March 2, 2018, that the facility was not yet open, and it would be another one to two weeks before it was.

*NKC Federal Way East did not open in the timeline presented in its application. According to WAC 246-310-812(5), NKC Federal Way East is therefore seen to meet the 4.5 patients per standard, regardless of its census. As NKC Auburn would appropriately be at 5.96 patients per station, or 99.31% six-shift utilization, with 24 chairs as of 12/31/2017, both facilities with approved stations in the King 11 planning area meet the 4.5 patients per station utilization standard.*

*Finally, it is worth noting the exceptional utilization and patient demand seen in King 11 at NKC Auburn. If all 24 operational stations as of 12/31/2017 are allocated just to NKC Auburn, in addition to the two (2) stations granted under CN #1593 to be added to NKC Federal Way East as a partial relocation and expansion, a 26-station NKC Auburn with all approved stations in the planning area would have operated at 5.50 patients per station as of 12/31/2017, well in excess of the 4.5 patients per station threshold.”*

#### Public Comment

Northwest Kidney Centers provided the following comments related to this application:

***NKC Federal Way East Applied for and Received an Exception to its Timeline as Allowed in WAC 246-310-812 (5)(b). NKC Federal Way East was operationalized timely. DaVita’s application was predicated on NKC Federal Way East being late. This is false.***

*As the CN Program is aware, NKC Federal Way East became “operational” (as defined in WAC 246-310-800(12)) on March 12, 2018. On September 4, 2018, NKC submitted a request for an exception to its timeline and outlined the reasons for the delay. This letter, as required by WAC 246-310-812(5)(b), documented the delays in the timeline that were beyond NKC’s control. On October 26, 2018, the CN Program provided a response to NKC’s September 2018 letter and found:*

*‘For the reasons stated below, the Department is granting your request.....Based on the totality of the information considered, the department concludes NKC was prevented from meeting the timeline submitted in the application due to circumstances beyond its control.’*

*More importantly, the letter notes that NKC’s length of time to construct the facility was 28 days longer than originally described in the application, however, 42 of these days were related to a late issuance of the CN decision, and therefore were beyond NKC’s control.*

*A copy of NKC’s letter to the CN Program and the CN Program’s subsequent response are included in Exhibit B. DaVita was incorrect in assuming a late operational date and its application is not timely. Consistent with WAC 246-310-812(5), DaVita’s application must be rejected.*

***DaVita’s Application was Premature. NKC Federal Way East (King 11 Planning Area) Operated Below 4.5 Patients Per Station Based on Northwest Renal Network Data Available at the time of DaVita’s Submittal.***

*DaVita’s application proposing to establish a new 22 station facility in Auburn submitted in the Cycle 1 Non-Special Circumstances was premature given that NKC operationalized its new facility timely.*

*NKC was approved to establish a new 14 station facility in February 2017 (to be known as NKC Federal Way East). This facility was to be established with both relocated and new CN approved stations. At the time that DaVita's application was submitted, the most recent Northwest Renal Network data available was for 12/31/2017. As DaVita acknowledged in Table 5 of its application, NKC Federal Way East had reported no data as of 12/31/2017. Therefore, its utilization was below the 4.5 patients per station utilization threshold that must be met before new stations can be approved (WAC 246-310-812(5)(a)).*

#### Rebuttal Comment

DaVita rebutted NKC's comments, below.

*"NKC projected an approximately 11-month timeline for its Federal Way East project. Its project actually took approximately 12-13 months. NKC's facility opened on March 12, 2018.*

*At no point during this year-long project did NKC ever seek a modification of its project schedule. By NKC's own admission, the permitting delay was resolved by July 31, 2017, the date the building permit was approved. Also by NKC's own admission, the construction delay was resolved by approximately January 1, 2018, when construction was complete.*

*NKC also did not seek a modification of its project schedule during the approximately three months between the completion of construction around January 1 and the facility opening on March 12.*

*Most importantly, NKC did not seek a modification of its project schedule during the approximately three months between the March 12 facility opening and the June 1 deadline for Cycle 1 applications.*

*Therefore, **on June 1, 2018**, the deadline for dialysis providers to file applications to meet the need for twenty-two additional stations in this planning area, **WAC 246-310-812(5) was satisfied**. It is undisputed that NKC's new stations "had not become operational within the timeline as represented in the approved application" and that the Department had not "approve[d] a ... modification of the timeline[.]" Indeed, NKC had not even requested a modification of the timeline, even though construction was completed five months earlier and the facility had been open and serving patients for approximately three months.*

*The deadline to obtain a Section 812(5)(b) modification of the project timeline for stations that did not become operational within the timeline as represented in the approved application must be, at the latest, the application deadline for the new application at issue. Otherwise, Section 812(5) becomes unworkable. It would mean that dialysis providers would have to file applications for which it is undisputed that Section 812(5) is met as of the application deadline, or else miss the opportunity to meet the identified need, but then could have those applications denied because the existing provider later obtains a retroactive modification of its timeline to change whether Section 812(5) is met, after the application already has been filed.*

*In other words, dialysis providers could not know, at the time they file their applications, whether all prerequisites for an application are satisfied. Specifically, whether an application can satisfy Section 812(5) would depend on what happens after the application is filed. This would be, at minimum, deeply unfair to applicants. It also would be inconsistent with fundamental principles of agency law and potentially raises due process concerns.*

*Applicants must be able to determine, before they file their applications, whether or not a planning area is “open,” i.e., whether Section 812(5) and the other regulatory prerequisites to filing an application are met.*

*The present situation illustrates this perfectly.*

*NKC’s facility opened on March 12, 2018. It is undisputed that this was not “within the timeline as represented in the approved application.” Yet NKC did not seek a modification of that timeline, either before or after opening its facility. On May 1, DaVita filed a letter of intent to file a CON application to meet the 22-station need in this planning area. Yet NKC still did nothing. On June 1, DaVita determined – correctly – that Section 812(5) was satisfied because NKC’s facility did not open within the timeline as represented in the approved application and NKC did not seek, and the Department did not grant, a modification of that timeline. This is the key point: **On the day DaVita filed its application, and paid the \$25,054 filing fee, it is undisputed that DaVita’s application satisfied Section 812(5).***

*NKC then apparently recognized that DaVita might be approved to meet the need for twenty-two additional stations in this planning area and it had better manufacture a basis for denial of DaVita’s application. So in July 2018 – more than six months after construction was complete – NKC obtained letters from its contractor and architect stating that the project was delayed. NKC then used these letters to ask the Department, on September 4, for a modification of its project timeline. By this time, construction had been complete for eight months, and the facility had been open for six months. DaVita was never given any notice of NKC’s request or any opportunity to comment, even though DaVita’s application was pending. On October 26, the Department granted NKC’s request.*

*But NKC’s delay in requesting this modification – until six months after its facility opened – meant that DaVita’s application already was filed, screened, and complete before the modification was granted.*

*Whether or not NKC’s timeline modification is effective for future application cycles, i.e., application deadlines after the modification was made, it cannot be used retroactively to change whether Section 812(5) was met for an application filed on June 1, five months before the modification was made.*

*Finally, if the Department were to permit a CON holder like NKC to retroactively change whether Section 812(5) is satisfied for applications already filed by a competing dialysis provider, the Department will be creating a process that undermines the Department’s mission and guarantees litigation. First, the overriding purpose of the CON Program is to ensure access to healthcare services. But this process would allow need for dialysis stations to go unmet, even when the rules dictate that as of the application deadline new stations should be approved, based on later actions of an existing provider. Second, applicants would not know when applying whether a planning area is “open” because whether the planning area is open may not be determined until long after the application is filed, and even after the application is screened, if an the existing provider later chooses to request a modification of its project timeline in light of the fact that a competitor has now applied. The denied applicant undoubtedly will appeal in these circumstances, and attack the basis for the timeline modification while also challenging any other grounds for denial of its application: although the Department has, by regulation, the “sole discretion” to grant modifications, the CON holder’s request still must meet the standard that “the applicant was prevented from meeting the initial timeline due to circumstances beyond its control” before the Department may exercise that*

*discretion, and in exercising its discretion, the Department is governed by the Administrative Procedure Act and other applicable laws.*

*In the interest of fairness, and to ensure a CON application process that works, a modification to a project timeline can be effective only for future applications, and not apply to applications already filed. DaVita’s application satisfies Section 812(5) because as of the application deadline NKC’s stations “had not become operational within the timeline as represented in the approved application” and that the Department had not “approve[d] a ... modification of the timeline[.]”*

**Department Evaluation**

WAC 246-310-812(5) states that the “*data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.*” The date of the letter of intent is May 1, 2018. The data available as of May 1, 2018, is December 31, 2017, end of year data that was available on February 15, 2018. The utilization of the three existing dialysis centers located in King County planning area #11 is shown below.

**Department’s Table 2  
December 31, 2017, Utilization Data for King County Planning Area #11**

<b>Facility Name</b>	<b># of Stations</b>	<b># of Patients</b>	<b>Patients/Station</b>
NKC Auburn	12	143	11.92
NKC Federal Way East	14	0	0.00

As shown in the table above, one of the three centers meet and far exceeded the utilization requirement. For the NKC Federal Way East facility, DaVita asserts that the facility did not meet the timeline in their application and WAC 246-310-815(5)(b) should apply to this project.

WAC 246-310-815(5)(b) states:

*“Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:*

- (a) All stations for a facility have been in operation for at least three years; or*
- (b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, the department, at its sole discretion, may approve a one-time modification of the timeline for purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.*

*Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.”*

Within public comment, NKC provided information related to their timeline modification request. In return, DaVita argued that NKC’s timeline modification request should only apply moving

forward – that is for cycles following their request. The sequence of events surrounding this issue is summarized below:

- On March 10, 2017, CN #1593 was issued to Northwest Kidney Centers (NKC) approving the establishment of a new 14-station dialysis facility in the King 11 planning area.
- Within NKC’s application, they identified the facility would be operational by January 1, 2018.
- The department issued their decision on this application 42 days later than anticipated in the CN application, which shifts the applicant’s operational timeline.
- Based on the date of the uncontested CN (March 10, 2017), NKC’s expected operational date would shift 42 days, from January 1, 2018 to February 12, 2018.
- NKC’s approved facility offered their first treatment on March 12, 2018 – one month later than the expected operational date based on the date of the uncontested CN.
- On June 1, 2018, DaVita submitted an application to submit a new dialysis facility in the King 11 planning area.
- At the time of DaVita’s application, NKC had not met the timeline represented in their application, which allowed anyone to submit applications for the planning area under WAC 246-310-812(5)(b).
- Following the submission of DaVita’s application, NKC submitted a request to the department to modify the timeline for CN #1593.
- The timeline for DaVita’s application and NKC’s involvement is captured below:

**Department’s Table 3  
Event Chronology**

<b>Entity Involved</b>	<b>Action</b>	<b>Date</b>
DOH	New ESRD rules become effective	January 1, 2018
NKC	PROJECTED Operational Date for CN #1593 based on decision timing	February 12, 2018
NKC	ACTUAL Operational Date for CN #1593	March 12, 2018
DOH	DOH posts methodology identifying 22 station need in King 11	March 20, 2018
DaVita	CN Application Received	June 1, 2018
DaVita	First Screening Questions Sent	June 29, 2018
DaVita	First Screening Responses Received	August 13, 2018
DaVita	Second Screening Questions Sent	September 4, 2018
NKC	Request to Department for Timeline Modification Received	September 4, 2018
DaVita	Second Screening Responses Received	October 19, 2018
NKC	Response Approving Timeline Modification Sent	October 26, 2018
DaVita	Beginning of Review	October 26, 2018
DaVita/NKC	Public Comment Due	December 3, 2018
DaVita/NKC	Rebuttal Due	December 13, 2018

- As shown above, DaVita submitted their application in compliance with WAC 246-310-812(5), because NKC had not met the timeline represented in their application.
- NKC submitted a request to the department in September 2018 to modify the timeline in their application.
- The CN program approved NKC’s request in October 2018.



Per WAC 246-310-815(5)(b), the department has sole discretion surrounding these types of requests. Northwest Kidney Centers' request was granted, however it should not be viewed as retroactive, given that DaVita's project was already under review by the time the request was granted. As noted in the timeline above, NKC provided their first treatment in March 2019, before the numeric need methodology was published. The department would consider NKC's timeline modification effective for future cycle applications from the date it was granted. If NKC had not achieved the utilization threshold by the second concurrent review cycle in 2019, their timeline modification request would have effectively prevented applications in the planning area. This was not the case. NKC currently has an application pending for the King 11 planning area submitted on December 3, 2019, which is within Cycle 2. It would be unfair and damaging to the Certificate of Need process to allow a timeline modification request to negatively impact an approvable project.

Considering the timing of the request and the review schedule, the department exercises its discretion in this decision, that the timeline modification request should not be the barrier to this project when there is such significant numeric need in the planning area.

Based on the information above, the department concludes that the NKC project did not meet the timeline represented in their application, WAC 246-310-812(5) applies to this project, and **the standard is met for DaVita's King 11 Dialysis project.**

- (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.<sup>6</sup> 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.

**DaVita, Inc.**

DaVita provided the following information for this sub-criterion. [source: Application, pdf18]

*“DaVita’s history of providing dialysis services at numerous locations throughout Washington State shows that all persons, including the underserved groups identified in WAC 246-310-210(2), have adequate access to DaVita’s facilities, as required by the regulation. We have provided as Appendix 14 copies of the applicable admission, patient financial evaluation, and patient involuntary transfer policies. Additionally, the pro forma the funds that have been budgeted to provide charity care.”*

DaVita also provided the following policies for this project. [source: Application, Exhibit 14]

- Accepting End State Renal Disease Patients for Treatment
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer
- Patient Financial Evaluation Policy
- Patient Rights

**Public Comment**

None

**Rebuttal Comment**

None

**Department Evaluation**

DaVita provided copies of the necessary policies used at all DaVita dialysis centers, including the proposed Auburn facility. They include the required non-discrimination language and are consistent with those approved by the department in the past.

**Medicare and Medicaid Programs**

DaVita currently participates in the Medicare and Medicaid programs for its operational dialysis centers. As directed WAC 246-310-815, DaVita based its payer mix on DaVita’s three closest facilities. Two facilities are located in King County and one is located in Pierce County, including DaVita Federal Way Community Dialysis Center, DaVita Kent Dialysis Center, and DaVita Puyallup Dialysis Center. [source: Application, pdf30]

For the proposed Auburn facility, DaVita provided a table showing the proposed percentages of revenues by payer and revenues by patient for the new facility. The information is summarized on the following page. [source: Application, pdf23]

**Department’s Table 4  
DaVita Projected Payer Mix**

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	30.67%	56.74%

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<sup>6</sup> WAC 246-453-010(4).

Medicaid	1.01%	2.18%
Other: Commercial	68.32%	41.08%
<b>Total</b>	<b>100.00%</b>	<b>100.0%</b>

Based on the information above, the department concludes that **DaVita’s application 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)**

**DaVita, Inc.**

Based on the source information reviewed the department concludes that DaVita, Inc. 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, each applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(1).

**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.*

**DaVita, Inc.**

For DaVita's project, sub-sections (a) and (c) of WAC 246-310-815(1) apply. DaVita provided the following information related to this sub-criterion.

*In order to reach net revenue per treatment, DaVita first identifies each comparable facility per WAC 246-310-815 (in this case, DaVita Federal Way, Kent, and Puyallup). Each facility's net revenue is divided by its total treatments for the last full year of data available (1/1/2017-12/31/2017). This produces three net revenue per treatment figures. These three net revenue per treatment figures are averaged to produce the projected net revenue per treatment figure. In the case of other [operating] expenses, DaVita first identifies each comparable facility per WAC 246-310-815, listed above (excluding Redondo Heights due to its exemption status). Each facility's other expenses categories are divided by its total treatments for the last full year of data available (1/1/2017-12/31/2017). This produces a per-treatment estimate of each "other expense" category, such as medical supplies, for each comparable facility. These three "other expense" category figures are averaged to produce the projected "other expense" per treatment for each category, which increases at 2% annually. The three exceptions are the medical director, lease, and depreciation expenses. The Medical Director and Lease are based on the contractually-outlined expenses, while the depreciation is based on the relevant depreciation schedules for the project's capital expense. The medical director, lease, and depreciation expenses are for 8 months of 2021 given the May 3 timing of the partial year start. Tax and CAM is estimated separately, in a methodology similar to that highlighted above. Annual Tax and CAM for each comparable facility in 2017 is divided by the square footage of each facility, to reach a per-square foot figure for each comparable. The average of those three figures is the baseline for CAM in the projected facility, inflated by 2% annually (in this case, starting as a 2017 figure at \$4.91/square foot). CAM for 2021 is, similarly, for 8 months." [source: Screening 1 pdf6-7]*

**First Full Year:** 2022, based on a first patient date in May 2021.

**Total Stations:** CON Approved stations. One CON-exempt isolation station is also included in driving relevant category calculations (bio-med FTE, depreciation).

**Total Chronic Capacity:** 6 shift capacity of CON-approved stations is assumed to be 100% utilization.

**Patient Census Projections:** Census projections are based on a 5-year projection of planning area patients using a regression of 5 years historical data and DaVita's own experience and expertise. This is the same trend line (based on the Department's methodology as applied through 2022), but extended out through 2024 to project planning area census through the projection period. DaVita uses projected planning area census, existing planning area capacity, and additional market and experiential knowledge to project new facility census.

**Total Treatments:** Total Treatment Volume is assumed to be based on average yearly census, a 5% missed treatment rate consistent with DaVita's own experience and expertise, and three treatments weekly for 52 weeks per year. For partial year 2021, this is the average census for the May 3-Dec 31 time period, a 5% missed treatment rate, and three treatments weekly for 34.71 weeks remaining in the year.

**Revenue per treatment:** No inflation is applied to revenue per treatment, which is based on the last full year of operation, 2017 and its payor mix, as an average of comparable facilities for in-center modality only. It is calculated as the blended revenue per treatment for each comparable, averaged.

**General expenses:** Based on an average of comparable facilities (cost per treatment) for the last full calendar year (2017) by category, on a per treatment basis. This excludes lease expenses (noted below), depreciation expense (based on projected capital expenditures), medical director expense (noted below), and labor costs (noted below).

**Cost inflation:** DaVita does not assume inflation in any expense category – no current contract cost increases are known, and thus none are included.

**Medical Director Expense:** based on contracted, known expenses in latest medical director agreements that run through the extent of the three-year projection window. This includes post-certification ICHD compensation only, given the uncertainty of actual certification date – this makes 2021 a conservative projection.

**Lease Expense:** base rent is directly pulled from the lease contract for each calendar year, per clause 3 of the Building Lease, with the payment term projected to start in April 2021, per clause 2 (the pro forma begins with the projection period in May, 2021). Tax and CAM are calculated based on average cost per square foot of comparable facilities in 2017.

**Labor Assumptions:** Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits, taxes, and non-base pay are assumed at a rate of 59.96% of wages based on comparable facilities. [source: Screening 2 pdf7]

*Other Revenue includes ancillary supply revenue, primarily administered pharmaceuticals. It is estimated as the average per treatment of the three comparable facilities based on the 2017 full year, with no inflation.*

*Other Purchased Services includes (1) pre-employment screening and time keeping services and (2) employment advertising. It is estimated as the average per treatment of the three comparable facilities (based on the 2017 full year, with 2% inflation).*

*Other Direct Expenses includes (1) telephone, (2) travel, (3) freight & postage, (4) dues & subscriptions, and (5) insurance. It is estimated as the average per treatment of the three comparable facilities (based on the 2017 full year, with 2% inflation).*

*Depreciation includes 1) depreciation of tenant leasehold improvements, 2) depreciable services and fees included in the capital expenditure, including architecture and engineering as well as permits, 3) depreciation of furniture, fixtures, and equipment, and 4) depreciation of dialysis machines. The whole of this depreciation amounts to \$318,538 per year, consistent with the detailed projected operating statement.*

G&A is allocated on a per-treatment basis. It is projected based on the average of the three comparables' G&A allocation per treatment in 2017, inflated at 2% annually. This means each comparable assigned G&A allocation for 2017 is divided by its total number of treatments. The average of these three per-treatment figures is used as the base projection G&A allocation, with inflation accounted for on an annual basis in the projection. [source: Screening 1 pdf7]

Table 11 provides expected payor mix for the Auburn Valley Dialysis Center, projected using DaVita's comparable facilities and aligned with the pro forma operating statement.

Applicant's Table 11

<b>Table 11 DaVita Auburn Dialysis Center Projected Payor Mix</b>	<b>Percentage by Revenue</b>	<b>Percentage by Patient</b>
Medicare	30.67%	56.74%
Medicaid	1.01%	2.18%
Commercial, HMO, Other Government, and Other	68.32%	41.08%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Using the assumptions stated above, DaVita projected the end-of-year number of in-center dialyses and patients for years 2021 through 2024, which are shown in Table 4. [source: October 19, 2018, screening response, Appendix 9B Revised]

**Department's Table 5  
DaVita Auburn Valley Dialysis Center  
Projected Patients and Dialyses for Fiscal Years 2021 – 2024**

	<b>FY 2021 Partial Year</b>	<b>FY 2022 Full Year 1</b>	<b>FY 2023 Full Year 2</b>	<b>FY 2024 Full Year 3</b>
Number of Stations*	22	22	22	22
Total In center Patients	20	48	80	117
Total In center Treatments	1,046	5,030	9,435	14,553

\*excluding CON-exempt isolation station

DaVita also projected the revenue, expenses, and net income for fiscal years 2021 through 2024, which are shown in the table below. [source: October 19, 2018, screening response, Appendix 9B Revised]

**Department's Table 6  
DaVita Auburn Valley Dialysis Center  
Projected Revenue and Expenses for Fiscal Years 2021- 2024**

	<b>FY 2021 Partial Year</b>	<b>FY 2022 Full Year 1</b>	<b>FY 2023 Full Year 2</b>	<b>FY 2024 Full Year 3</b>
Net Revenue	\$475,253	\$2,284,933	\$4,286,003	\$6,610,766

Total Expenses	\$975,639	\$2,298,699	\$3,362,324	\$4,598,002
<b>Net Profit / (Loss)</b>	<b>(\$500,386)</b>	<b>(\$13,766)</b>	<b>\$923,679</b>	<b>\$2,012,764</b>

The ‘Net Revenue’ line item is gross in-center revenue, minus deductions for bad debt and charity care.

The ‘Total Expenses’ line item includes all expenses related to the operation of the projected facility in years 2021 through 2024. The expenses also include allocated costs consistent with historical DaVita percentages. Medical director costs are \$70,000 annual and consistent with the executed agreement in the application.

Public Comment

NKC provided the following comments under this sub-criterion:

***DaVita Auburn Valley’s Pro Forma Contains Errors and Questionable Assumptions. It’s Conformance to WAC 246-310-220, WAC 246-310-240 and WAC 246-310-815 Cannot Be Confirmed***

*For its King 11 application, DaVita provided three sets of pro forma financials (Exhibit 9, application, Exhibit 9A, screening response #1 and Exhibit 9B, screening response #2). In both 9A and 9B, contrary to the specific instructions provided by the CN Program in its March 2018 ESRD application, DaVita included inflation in its assumptions. In fact, DaVita included inflation in each of the nine applications that it submitted in Cycle 1 Non-Special Circumstances Concurrent Review Cycle. When those providing public comment pointed out that DaVita had erroneously included inflation, DaVita wrote that it confirmed with the CN Program that “inflation is permitted in cost projections” (see page 10 of DaVita King 1 October 5, 2018 rebuttal). However, DaVita provided no documentation in support of the CN program making such a statement. For this application at least, DaVita, in its 2nd screening response, submitted a 3rd pro forma financial in which it removed inflation from its expenses.*

*The removal of inflation results in an overall decrease in costs per treatment. However, DaVita reduced its costs per treatment even on line items that are primarily variable (such as salaries and wages). DaVita provided no explanation for these changes, and these late changes are simply not reliable.*

***DaVita’s proposed project is complex in that it includes developing “wetlands.” NKC’s experience suggests that the timeline and costs in its CN application are not reliable, as there are too many unknowns associated with the site.***

*DaVita outlined “site control” and its proposed structure on page 18 of its application as follows:*

- A. The property is owned by Southern Financial Group LLC and will remain under their ownership.*
- B. DaVita (via Total Renal Care, Inc) has leased the land from Southern Financial Group and states that this confirms site control.*
- C. DaVita declares it will lease the building – and not own it.*
- D. Once the project is approved, Total Renal Care, Inc. will **assign** the ground lease to Genesis KC Development LLC.*
- E. Genesis KC Development LLC. will construct a “gray shell building of certain specifications”.*

- F. *Genesis KC Development LLC. will then lease the space proposed to DaVita via Total Renal Care.*
- G. *DaVita will then complete TI improvements within the space provided.*

*DaVita's proposed location is considered 100% "wetlands" (see Exhibit C that was included in DaVita's application) and, more importantly, is considered "100% unusable" by the King County Assessor's Office (see Exhibit D). What if Genesis KC Development LLC finds that the City of Auburn does not approve of their wetland relocation mitigation efforts and denies the permits or delays them until an acceptable mitigation plan is found? If a separate property has already been located (for wetland mitigation relocation), why has DaVita not disclosed this detail? Wetland development also typically requires special easements, environmental impact statements and public comment periods all of which can delay or end the project and/or increase costs.*

*The timeline within the application assumes the Project will commence construction on January 17th, 2020. The CN Program should be informed as to all coordination efforts with the Department of Ecology and related City of Auburn oversight that would allow construction in a wetland during the wet season – (October to May). Simply from a "breaking ground" perspective, how would the Developer be able to be on the site in the winter on land that is declared 100% wetland? Even if the project was viable, the timeline is not realistic due to the issues cited above. The DaVita application is too speculative and too underdeveloped from a timing and cost perspective.*

#### Rebuttal Comment

DaVita's rebuttal is quoted below:

#### ***DaVita's pro forma is reliable.***

*DaVita's pro forma included inflation in its projection of costs not set by contract. It was DaVita's understanding that this was permitted.*

*Some other providers have argued that inflation is not permitted in cost projections. NKC makes that argument in its comments here. However, in screening DaVita provided a new pro forma which removes inflation. This is stated clearly in the "assumptions" accompanying the revised pro forma: "DaVita does not assume inflation in any expense category[.]"*

*Therefore, NKC's comment does not make any sense. NKC criticizes DaVita for including inflation in its initial pro forma, yet also criticizes DaVita for correcting this by removing inflation from its revised pro forma. NKC cannot have it both ways. Either including inflation in cost projections is permitted (in which case DaVita's August 13 pro forma (Ex. 9A) was accurate) or including inflation in cost projections is not permitted (in which case DaVita's October 19 pro forma (Ex. 9B) was accurate).*

*NKC also points out that "[t]he removal of inflation results in an overall decrease in costs per treatment."<sup>13</sup> Of course it does. If costs are decreased (by removing inflation), but the number of treatments remains constant, cost per treatment by definition will decrease. Therefore, DaVita's revised pro forma which omits inflation (i.e., has lower cost projections) obviously reflects lower cost per treatment than DaVita's initial pro forma which includes inflation (i.e., has higher cost projections).*

*DaVita's August 13 pro forma (Ex. 9A, including inflation) is a reliable projection of costs for this facility, because it is reasonable to assume that prices will increase over time (i.e., that there will be*



*inflation). However, DaVita understands that for CON purposes, the Department may wish for applicants to assume no inflation. Therefore, DaVita's October 19 pro forma (Ex. 9B) assumes no inflation. Both approaches are fully documented, and therefore whichever approach the Department determines to be correct (including inflation or assuming no inflation), DaVita's application materials are complete and demonstrate the financial feasibility of DaVita's project.*

***DaVita's has selected an excellent site for this project.***

*DaVita chose an excellent site for its facility, conveniently located on a commercial street in Auburn just off the 167 highway and less than a mile from a Walmart and other businesses.*

*NKC wildly speculates about what could go wrong with DaVita's project and then summarily concludes that NKC's unsupported speculation ("What if ...?") means that "DaVita's application is too speculative[.]"<sup>14</sup> But NKC provides no evidence supporting its claims that DaVita will have difficulty opening its facility on schedule at the identified site.*

*As the Department would expect, DaVita carefully selected its proposed site and did its due diligence before filing its application. In fact, it provided the relevant documentation in its application—which NKC apparently overlooked.*

*The parcels at issue are zoned C-3 (Heavy Commercial).<sup>16</sup> This is appropriate for a project of this type.<sup>17</sup> DaVita provided with its application a May 21, 2018 letter from Cecile Malik, Planner, City of Auburn, confirming that "[p]ermitted uses with the C-3 zone include 'Medical Clinics' and 'Hospitals,' therefore a kidney dialysis center would be a permitted use."<sup>18</sup> The City also stated in its letter that this wetlands site could be developed but this "would require off-site mitigation[.]"<sup>19</sup> The City identified no obstacle to this project. The City's letter provided by DaVita is consistent with what the Department historically has found to be adequate for CON purposes.*

*NKC ignores the letter from the relevant municipality, the City of Auburn, and instead appears to suggest that certain language ("100% unusable") on the King County assessor's website means that nothing can be built on this site. If so, either NKC is being disingenuous or does not know what it is talking about.*

*First, the usability information on the county assessor's website does not reflect any actual land-use determinations. It simply shows the information in the county's property database used to set property-tax rates. Why the county assessor's database says that the property is "unusable" is unclear, but this plainly is not accurate. It is even contradicted by the other information on the county assessor's website, in the line-items immediately before and after the cell NKC has highlighted: "Unbuildable: NO"; "Zoning: C3" (heavy commercial); as well as a crucial land allocation that is rooted in an actual determination, and which NKC conveniently forgets to highlight – "Environmental type: Wetland (to be fair, NKC does highlight "Wetland")," "Percentage affected: 63."<sup>20</sup> In this context, on a total site of 7.06 acres, this means that 2.61 acres of the site is considered unaffected by wetlands using the assessor's own reported data. DaVita needs approximately one acre for its proposed site plan, meaning its entire proposed site fits on the acreage that is not considered wetlands in the assessor's own data.*

*Second, the City of Auburn, the actual land-use decision maker at issue, confirmed that the site is appropriately zoned for a dialysis clinic, but off-site mitigation likely would be required due to the presence of wetlands.<sup>21</sup> However King County wishes to characterize the property for purposes of*

*setting property-tax rates, the City of Auburn has confirmed that a dialysis facility may be built at this location in its jurisdiction.*

*Additionally, NKC's suggestion that DaVita's project timeline is unrealistic also is baseless. DaVita projected a project timeline of approximately 2.5 years from CON approval to facility opening.<sup>22</sup> This is a very reasonable timeline for a project of this type in this location, and includes sufficient time allotted for the proper permitting process under the USACE Nationwide Permitting Program (NWP), which allows for development of up to 2.55 acres and typically takes just 6-12 months. DaVita does not anticipate any difficulty in meeting its stated 2.5-year timeline.*

*DaVita chose an appropriate site for this project. It submitted the same type of information that CON applications historically have provided to demonstrate the likelihood that it can proceed at this site. While NKC offers only speculation ("What if..."), DaVita has provided detail and documentation showing that its project meets all CON requirements, including a letter from the City of Auburn planning department."*

### **Department Evaluation**

DaVita proposes a new 23-station dialysis center in King County planning area #11. DaVita based its projected utilization of the new Auburn Valley facility consistent with WAC 246-310-815(1)(a) and (c). Based on a review of the assumptions used for projecting utilization of the 23-station dialysis center, the department concludes they are reasonable.

NKC provided comments identifying problems with inclusion of inflation in the application. As DaVita correctly pointed out in rebuttal, inflation was removed in response to screening. Consistent with long-standing practice, documentation provided in screening effectively replaces the original pro forma. Therefore, comments related to the original pro forma provided in the application or the revised statements will not be considered – only comments related to the pro forma provided in response to second screening will be evaluated.

One line item of concern in NKC's comments are the salaries and wages. The FTE table provided in response to first screening included assumptions for salaries and wages. When the department "tested" these figures (average wages per FTE category), they were generally consistent with the pro forma provided in response to second screening. Since these are an average figure, the department does not expect a one to one match, unlike the department would expect in Medical Director agreements or Lease agreements.

The department is satisfied that inflation was properly removed from the projections, and that the assumptions provided with the pro forma satisfy CN requirements.

DaVita provide a copy of the executed Lease Agreement for the site to demonstrate site control. Since DaVita will be leasing the site, rent/lease costs must be included in pro forma revenue and expense statement. Consistent with the department's expectations, inflation was excluded, and the department was able to substantiate the lease costs in the pro forma with the lease agreement.

NKC expressed concerns regarding the site in Auburn, particularly regarding a categorization from the King County Assessor's website. The department reviewed information from the King County Assessor's website – though there is a line item that says "percentage unusable – 100," this appears to conflict with several other pieces of information on the King County Assessor's website. For example, the line immediately beneath asks the question if the site is "unbuildable" – the answer is

“no.” Per the district reports for each of these parcels, much of the land use information is delegated to the authority-having jurisdiction – the City of Auburn. The City of Auburn confirmed that the site is properly zoned for this use, and that only off-site mitigation would be required. Based on communication from the authority-having jurisdiction in the application, the department is satisfied that the site is appropriate.

DaVita also provided a copy of the executed Medical Director Agreement that substantiates the costs identified in the pro form revenue and expense statement.

For DaVita’s project, the department concludes **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, DaVita must demonstrate compliance with the following sub-sections of WAC 246-310-815(2).

**WAC 246-310-815(2)**

*An applicant proposing to construct a 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.*

**DaVita, Inc.**

DaVita provided the following information under this sub-criterion. [source: Application, pdf22]

*“WAC 246-310-815(2) requires that applicants limit the costs of facility projects by creating a test of reasonableness in the construction of finished treatment floor area square footage. The treatment floor area must not exceed the maximum treatment floor area square footage defined in WAC 246-310-800(11). As outlined in response to Question Eleven under the Project Description, DaVita does not propose to construct treatment floor space in excess of the maximum treatment floor area square footage, and thus, under the WAC 246-310-815(2) test, this project does not have an unreasonable impact on costs and charges.”*

DaVita provided a copy of its proposed line drawings for the new dialysis center. [source: Screening 1, Appendix 16A]

Consistent with WAC 246-310-800(11), DaVita Indian Trail Dialysis Center’s maximum allowable square footage for 22 stations (including one permanent bed station and 2 future stations) and one isolation station is 6,737.5. DaVita’s project will use 5,891 square feet. [source: Screening 1 pdf12]

Specific to the costs and charges for health services, DaVita provided the statements below. [source: Application, pdf21]

*“Additionally, as noted in response to question seven, reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area.”*

**Public Comment**

None

Rebuttal Comment

None

**Department Evaluation**

The estimated costs for this project is \$3,386,554, which includes all costs associated with DaVita finishing out a “gray shell” that would be built by Genesis KC Development, LLC in order to establish the dialysis center. The costs are comparable to those reviewed in past applications for similar type projects and similar sized facilities. The department does not consider the capital expenditure to be excessive for this project.

DaVita Auburn Valley Dialysis Center’s projected Medicare and Medicaid reimbursements will be approximately 31% of revenue, with the rest coming from commercial and other payer sources. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, the percentages above appear to be unusual. That being said, nearly 60% of patients would be reimbursed by Medicare or Medicaid.

Regardless of the number of patients projected, under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment and that 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 payors 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 the department’s understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information provided by DaVita indicates that this project would not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement.

To be compliant with WAC 246-310-800(11), Auburn Valley Dialysis Center’s maximum floor space for a 23-station facility is 6,737.5 square feet.. DaVita calculated that its actual floor space will be 5,163 which includes the one isolation station that is not counted at the center.

Based on the above information provided in the application, the department concludes that DaVita’s projected costs associated with the this project would not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #11. **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 applicant’s projected source of financing to those previously considered by the department.

**DaVita, Inc.**

DaVita provided the following information about financing the \$3,386,554 costs for this project. [source: Application pdf19-20, Screening 1 pdf10]

*“In the interest of transparency, we also would note that DaVita ultimately will lease, not own, the building in which the dialysis center will be located. This will be accomplished by (1) after CN approval, DaVita, via Total Renal Care, assigning the ground lease to Genesis KC Development, LLC; (2) Genesis constructing a gray shell building of certain specifications that matches the requirements described in the project description and single line drawings; (3) Genesis leasing the space to DaVita via Total Renal Care; and (4) Davita, via Total Renal Care, taking possession as tenant, competing construction, and beginning to provide dialysis services. A copy of an executed lease agreement between Genesis and Total Renal Care is provided in Appendix 15 following the ground lease. DaVita’s rent payments to Genesis include the payments owed to Southern under the ground lease. In other words, Genesis is expected to start making the rent payments under the Appendix 15 ground lease after it takes over that lease as DaVita’s assignee, but Genesis will pass those payments on to DaVita through the Appendix 15 lease.*

*Therefore, the ground lease provided as Appendix 15 demonstrates that Total Renal Care has control over the site now, and the lease provided as Appendix 15 demonstrates that Total Renal Care will continue to have control over the site even after it assigns the ground lease to Genesis as planned.”*

**Department’s Table 7  
Capital Expenditure Breakdown**

<b>Item</b>	<b>Amount</b>
Utilities to Lot Line	\$2,000
Building Construction	\$2,082,091
Fixed Equipment (not in construction contract)	\$237,022
Moveable Equipment	\$706,127
Architect / Engineering Fees	\$174,000
Supervision & Inspection of Site	\$91,000
Washington State Sales Tax	\$94,315
<b>Total Capital Expenditure</b>	<b>\$3,386,555</b>

**Public Comment**

None

**Rebuttal Comment**

None

**Department Evaluation**

DaVita 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 DaVita to finance the project consistent with the financing description provided in the application. With a financing condition, the department concludes the DaVita project **meets this sub-criterion**.

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

**DaVita, Inc.**

Based on the source information reviewed the department concludes that DaVita, Inc. 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.

**DaVita, Inc.**

DaVita provided the following staffing table showing projected staff for the new dialysis center. [source: Screening 1 pdf4]

**Department’s Table 8  
Full Time Equivalent (FTE) Breakdown**

<b>FTEs</b>	<b>2021 Partial</b>	<b>2022 Full Year</b>	<b>2023 Full Year</b>	<b>2024 Full Year</b>
Administrator	1.00	1.00	1.00	1.00
Administrative Assistant	1.00	1.00	1.00	1.00
Medical Social Worker	0.09	0.28	0.53	0.82
Dietician	0.09	0.28	0.53	0.82
RN-In Center/PD/HHD	0.29	0.94	1.77	2.73
Patient Care Tech	0.88	2.83	5.31	8.18
BioMed Technician	0.58	0.55	0.55	0.55
Other	0.13	0.42	0.80	1.23
<b>FTE Totals</b>	4.06	7.30	11.49	16.33
<b>Change</b>	--	3.24	4.19	4.84

*“DaVita anticipates no difficulty in recruiting the necessary personnel to staff DaVita Auburn Valley Dialysis Center. Based on our experience operating facilities in the western Washington area, DaVita anticipates that staff from geographically adjacent facilities will serve patients at the new DaVita Auburn Valley Dialysis Center, and some new staff may also be required. DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer (davita.com/about/awards) and offers a competitive wage and benefit package to employees. DaVita posts openings nationally both internally and external to DaVita..”* [source: Application pdf26]

Focusing on recruitment and retention of necessary staff, DaVita provided the following information. [source: Screening 1 pdf5]

*“DaVita does not expect any significant barriers to recruiting staff for DaVita Auburn Valley Dialysis Center. As outlined in its application, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer and offers a competitive wage and benefit package to employees, and posts openings nationally. However, in the unlikely event Auburn Valley Dialysis Center faces any barriers to recruiting staff, DaVita would take a multi-faceted approach, utilizing those methods necessary to ensure timely patient care. These methods may include, but are not*

*limited to, selective use of signing bonuses and incentives for select staff recruitments, cross-staffing with nearby DaVita facilities where possible, and if absolutely essential, limited use of agency temporary staff, with a continued focus on recruitment and retention of permanent teammates as soon as possible. As mentioned, however, DaVita does not expect any significant barriers to recruiting staff, especially given its existing expertise with operating dialysis facilities in south King County.”*

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that DaVita is a well-established provider of dialysis services in Washington State and in King County, though they do not yet have a presence in King County planning area #11..

With an establishment of a 23-station dialysis center, DaVita expects to need approximately 16 FTEs by the end of year three (2024). DaVita intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable.

Based on the above information, the department concludes that DaVita has the ability and expertise to recruit and retain 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.

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: Application, pdf26]

*“Ancillary services such as social services, nutrition services, financial counseling, pharmacy access, patient education, staff education, information services, material management, administration and biomedical technical services will be provided on site. Additional services are coordinated through DaVita’s main office in Denver, Colorado, and support offices in Federal Way and Tacoma, Washington, and elsewhere. These ancillary and support services provided centrally include the Guest Services Program that provides assistance in locating other dialysis facilities for patients wishing to travel or relocate. In addition, DaVita offers centralized revenue cycle, management services, quality improvement services, biomedical equipment maintenance and a number of other high-value off-site programs.*

*DaVita anticipates establishing working relationships with local hospitals, both for emergency patient transfer as well as coordinated discharge and acceptance of patients. DaVita also anticipates*

*continuing its relationships with area physician practices to ensure the highest quality coordinated care for patients. Finally, DaVita anticipates establishing relationships with local nursing homes to provide care for their resident ESRD patients, many of which it already collaborates with in other area dialysis facilities.*

DaVita provided a draft Patient Transfer Agreement for the new dialysis center. [source: Application, Appendix 12]

DaVita also provided a copy of the executed Medical Director Agreement that identifies a specific physician associated with Pacific Nephrology Associates, PS. The physician identified in the agreement is Di Zhao, MD. In addition to Dr. Zhao, the following four physicians are identified in the agreement as 'pre-approved' to provide medical director services. Zheng Ge, Yajuan He, Ho Won Lee, and Young Ho Kim. The agreement identifies roles and responsibilities for both DaVita and Dr. Zhao and all costs are identified in the agreement. [source: Application, Appendix 3]

#### Public Comment

None

#### Rebuttal Comment

None

#### Department Evaluation

While DaVita's Auburn Valley Dialysis Center will be a new center in King County planning area #11, it is not DaVita's only center in King County or in Washington State. Consistent with the approach used in applications where a new dialysis center would be established, the department accepts either draft agreements or a listing of ancillary and support services. For this project, DaVita provided a listing of ancillary and support services expected to be use for the new dialysis center. This approach is acceptable.

DaVita provided a copy of the executed Medical Director Agreement for the 23-station dialysis center. The agreement is between Total Renal Care (a subsidiary of DaVita) and Pacific Nephrology Associates, PS. The agreement outlines all roles and responsibilities for each entity, includes all costs associated with the agreement, and has an initial term of ten years. At the end of ten years, the agreement automatically renews annually unless either entity notifies the other of an intent to terminate the agreement. This agreement is acceptable.

DaVita provided a draft Patient Transfer Agreement between itself and an undisclosed hospital. While the department generally requires draft agreements to identify both entities, since there are no costs associated with Patient Transfer Agreements, applicants are not required to identify the hospital in the draft agreement. If this project is approved, the department would attach a condition to the approval requiring DaVita to provide a copy of an executed Patient Transfer Agreement consistent with the draft provided in the application.

The department also concludes that all other required ancillary and support agreements and relationships can be established.

Based on the information above, the department concludes that DaVita demonstrated that it would have the necessary ancillary and support services at its Auburn Valley Dialysis Center. **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).

### **DaVita, Inc.**

DaVita provided the following statements related to this sub-criterion. [source: Application, pdf28-29]

*“DaVita and the United States Department of Health and Human Services, Office of Inspector General entered into a Corporate Integrity Agreement (“CIA”) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs and, in particular, included the appointment of an Independent Monitor to prospectively review DaVita’s arrangements with nephrologists and other health care providers for compliance with the Anti-Kickback Statute (collectively, “Federal Health Care Programs and Laws”). That Independent Monitor completed the prospective review process in the fall of 2017. Each arrangement is now reviewed by the Risk Rating team to ensure that it is compliant with these Federal Health Care Programs and Laws. A full copy of the Corporate Integrity Agreement is included with this application in Appendix 20.*

*The applicant has no adverse history of license revocation or decertification in Washington State. DaVita has no criminal convictions related to DaVita’s competency to exercise responsibility for the ownership or operation of its facilities. As previously reported, a DaVita facility in Tennessee was decertified and closed ten years ago (2007) and DaVita voluntarily temporarily shut down a facility in Texas nine years ago (2008). DaVita has also supplied, in Appendix 13, a list of all state regulatory agencies with which it interacts.”*

### **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.

### CMS Star Rating for Out-of-State Centers

In the application, DaVita reports dialysis services to CMS for approximately 2,728 facilities in 46 states and the District of Columbia. Of the 2,728 facilities reporting to CMS by DaVita, 371 do not have the necessary amount of data to compile a star rating. For the remaining 2,357 facilities with a star rating, the national average rating is 3.71.

### CMS Star Rating for Washington State Centers

For Washington State, DaVita owns, operates, or manages 42 facilities in 19 separate counties. All of the 42 centers are operational, however, three do not have the necessary amount of data to compile a star rating.<sup>7</sup> For the remaining 39 centers with a star rating, the Washington State average rating is 4.08

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 all 42 of DaVita facilities are operational, in the most recent three years, 24 facilities have been surveyed. All surveys resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

DaVita provided an executed Medical Director Agreement with Pacific Nephrology Associates, PS. The agreement identifies Di Zhao as the medical director and the following four physicians as pre-approved physician for medical director services:

Zheng Ge    Yajuan He    Ho Won Lee    Young Ho Kim

Using data from the Medical Quality Assurance Commission, the department found that all five physicians are compliant with state licensure and have no restrictions on their licenses. Given that DaVita proposes a new facility, other staff have not been identified.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by DaVita. The department also considered the compliance history of the five physicians that would be associated with the facility. The department concludes that DaVita has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of a new dialysis center would not cause a negative effect on DaVita's compliance history. The department concludes that DaVita's project **meets this sub-criterion.**

- (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

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<sup>7</sup> The three centers are: Belfair Dialysis Center in Mason County, Cooks Hill Dialysis Center in Lewis County, and Renton Dialysis Center in King County.

and size. Therefore, using its experience and expertise the department assessed the materials in the application.

**DaVita, Inc.**

DaVita provided the following information for this sub-criterion. [source: Application, pdf27-28]

*“Appendix 17 provides a summary of quality and continuity of care indicators used in DaVita’s quality improvement program. The DaVita Continuous Quality Improvement (CQI) program incorporates all areas of the dialysis program. The program monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Dialysis-specific statistical tools (developed by DaVita) are used for measurement, analysis, communication, and feedback. Continuing employee and patient education are integral parts of this program. Appendix 17 includes an example of DaVita Quality Index (DQI) data.*

*Appendix 18 includes an example of DaVita’s Physician, Community and Patient Services offered through DaVita’s Kidney Smart Education Program. Appendix 12 includes a draft copy of a patient transfer agreement with an area partner. DaVita has been honored as one of the World’s Most Admired Companies® by FORTUNE® magazine since 2006, confirming its excellence in working effectively with the communities it serves (DaVita.com/about/awards).*

*The proposed DaVita Auburn Valley Dialysis Center will have an appropriate relationship to the service area’s existing health care system. DaVita Auburn Valley Dialysis will be a key component of the expanded health care system in the service area, and the project will enable enhanced patient access in the King 11 planning area with highly utilized facilities meeting the 4.5 patients per station threshold and NKC Auburn at 5.96 patients per station in December 2017. Furthermore, DaVita has a long track record of working with area providers and collaborating with them to provide the highest quality care for patients.”*

**Public Comment**

None

**Rebuttal Comment**

None

**Department Evaluation**

DaVita has been a provider of dialysis services in Washington State for many years. DaVita also has a history of establishing relationships with existing healthcare networks in King County. Additionally, DaVita’s project would promote continuity in the provision of healthcare services in the planning area by establishing a new facility in a planning area where additional dialysis stations are needed.

DaVita provided documentation 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 DaVita’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**

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, the department concludes that the DaVita, Inc. 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. Since DaVita submitted the only application for King County planning area #11 for year 2018 Cycle 1, step three does not apply to this project.

**Step One**

**DaVita, Inc.**

For this project, DaVita asserts it meets the applicable review criteria under WAC 246-310-210, 220, and 230.

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

DaVita’s application met the review criteria under WAC 246-310-210, 220, and 230. The department will review this application under step two below.

**Step Two**

**DaVita, Inc.**

DaVita identified the following two alternatives before submitting this application. [source: Application, pp28]

***Alternative 1: Do nothing. That is, do not apply for additional stations in the King 11 planning area.***

*King 11 is growing in ESRD population, with a three-year annualized in-center ESRD census growth rate of 13.33% and demonstrated need for twenty-two (22) stations. NKC Auburn has little additional capacity, with utilization of 5.96 patients per station when it had double the stations, and NKC Federal Way East has not become operational within its projected timeline. With strong demand for access to dialysis services but no application, patients will be forced to dialyze at less convenient times, locations, or even out of the planning area entirely. This alternative was rejected.*

***Alternative 2: Apply for twenty-two (22) stations in the King 11 planning area. As summarized above, King 11 shows substantial need for dialysis services. DaVita will offer high-quality dialysis services to patients in the King 11 planning area, additional provider choice, and additional, centrally located access. This alternative was selected.***

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

DaVita currently operates several dialysis centers in King County. DaVita provided a comprehensive discussion of alternatives considered. After reviewing the information, the department concludes that DaVita appropriately rejected all other alternatives before submitting its application. **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 for DaVita, Inc.**

This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and **is considered met.**

(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.*

**DaVita, Inc.**

DaVita provided the following information related to this sub-criterion. [source: Application, pdf31]

*“DaVita Auburn Valley Center will meet all current energy conservation standards required. Furthermore, DaVita design standards, reflected in the single-line drawing, are planned to promote energy efficiency, create efficient workflows, clean sightlines and a safe and welcoming environment for patients. When possible, this may be reflected in locating patients away from the exterior envelope for optimal HVAC layout, providing southern exposure for daylighting and solar comfort, and minimizing process piping length.”*

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

DaVita's project could have the potential to improve delivery of dialysis services to the residents of King County planning area #11 with the addition of 23 dialysis stations. **This sub-criterion is met.**