



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

May 8, 2019

CERTIFIED MAIL # 7018 2290 0001 8591 8308

Evan Moore, Director Special Projects
DaVita Inc., North Star Division
32275 – 32nd Avenue South
Federal Way, Washington 98001

RE: CN Application #18-62 – DaVita Sumner Dialysis Center

Dear Mr. Moore:

We have completed review of the Certificate of Need application submitted by DaVita, Inc. proposing to establish a new 9-station dialysis center in Pierce County planning area #1. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. 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 9-station dialysis center to be located at 16290 Auto Lane in Sumner [98390] within Pierce County planning area #1. The table below provides a breakdown of the total number of stations at project completion.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	8	8
Permanent Bed Station	1	1
Private Isolation Station	1	0
Total Stations	10	9

Services to be provided at the new dialysis center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training, 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 \$2,821,498, 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:

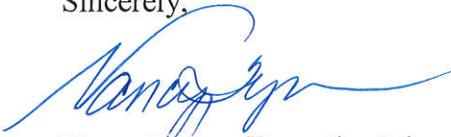
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

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 MAY 8, 2019, FOR DAVITA, INC. PROPOSING TO ADD DIALYSIS STATION CAPACITY IN PIERCE COUNTY PLANNING AREA #1

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.¹ In Washington State, DaVita is approved to own and operate a total of 42 dialysis centers in 19 separate counties.² Listed below are the names of the facilities owned or operated by DaVita in Washington State. [source: CN historical files and Application, pp5-8]

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

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

¹ 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.

² The department acknowledges that DaVita has submitted applications to establish additional dialysis centers in the counties of Cowlitz (#19-37), King (#18-59 & #19-39), Kitsap (#19-38), Snohomish (#18-63), Spokane (#18-62), and Thurston (#18-60). As of the writing of this evaluation, final decisions on these projects have not been released.

Kittitas

Ellensburg Dialysis Center

Lewis

Cooks Hill Dialysis Center

Mason

Belfair Dialysis Center

Pacific

Seaview Dialysis Center

Whatcom

Mount Baker Kidney 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 9-station need in Pierce County planning area #1 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 9-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 9-station dialysis center at 16290 Auto Lane in Sumner [98390], within Pierce County planning area #1. The new center would be known as DaVita Sumner 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 Pierce 1, and
- Community education for patients recently diagnosed with Chronic Kidney Disease (CKD).

[source: Application, p8 & p10]

If approved, DaVita expects the 9-station dialysis center would be operational and prepared for survey by January 2021. [source: Application, p10]

The total capital expenditure for this project is \$2,821,498, which includes construction costs, equipment, and associated fees and taxes. [source: October 19 ,2018, screening response, pdf3]

Department Information on Timelines for Completion of the Projects

DaVita identified a timeline for completion of this project based on a January 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 Pierce County planning area #1. 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

Action	DaVita, Inc.
Letter of Intent Submitted	May 1, 2018
Application Submitted	June 1, 2018
Department’s pre-review activities <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant's Responses Received • DOH 2nd Screening Letter • Applicant's Responses Received 	June 29, 2018 August 13, 2018 September 4, 2018 October 19, 2018
Beginning of Review	October 22, 2018
End of Public Comment ³ <ul style="list-style-type: none"> • Public comments accepted through the end of public comment • No public hearing requested or conducted 	November 30, 2018
Rebuttal Comments Submitted	December 14, 2018
Department's Initial Anticipated Decision Date	January 28, 2019

³ 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.

Action	DaVita, Inc.
Department's Anticipated Decision Date with a 120-day extension ⁴	May 28, 2019
Department's Actual Decision Date	May 8, 2019

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, two entities sought interested person status, but none sought affected person status.

SOURCE INFORMATION REVIEWED

- DaVita, Inc. Certificate of Need application received June 1, 2018
- DaVita, Inc. 1st screening response received August 13, 2018
- DaVita, Inc. 2nd 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 Pierce County planning area #1 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
- Certificate of Need historical files

⁴ Thirty day extension letters were sent to DaVita on January 31, 2019, February 27, 2019, April 2, 2019, and May 1, 2019.

CONCLUSION

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a 9-station dialysis center in Pierce County planning area #1 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 9-station dialysis center to be located at 16290 Auto Lane in Sumner [98390] within Pierce County planning area #1. The table below provides a breakdown of the total number of stations at project completion.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	8	8
Permanent Bed Station	1	1
Private Isolation Station	1	0
Total Stations	10	9

Services to be provided at the new dialysis center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training, 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 \$2,821,498, 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).⁵

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.⁶

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 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.

⁵ 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]

⁶WAC 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.

DaVita, Inc.

DaVita proposes to establish a 9-station dialysis center to be located in Sumner. DaVita relied on the numeric methodology posted to the department’s website for Pierce County planning area #1. The methodology projected need for 9 stations in projection year 2022.

Public Comment

None

Rebuttal Comment

None

Department Evaluation of the Numeric Methodology for Pierce County Planning Area #1

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 and updated in May 2018. The updated methodology posted in May will be used for evaluating this project.

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 Pierce County planning area #1. A summary of the department’s numeric methodology is shown in Table 1 below.

**Department’s Table 1
Pierce County Planning area #1 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	45	36	9

As shown in the table above, once the 36 existing stations are subtracted from the projected need, the result is a net need of 9 stations. The department’s methodology is included in this evaluation as Appendix A. 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.⁷ The department uses the standards in WAC 246-310-812(5) and WAC 246-310-812(6).

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.*

⁷ WAC 246-310-210(1)(b).

...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 Pierce County planning area #1, 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 that two of the three centers currently operating in the planning area were above the 4.5 standard. [source: Application, p13]

Applicant's Table 5

Table 5		Quarterly Utilization of Existing Stations			
Existing Dialysis Facilities in Pierce 1	Provider	Approved Stations	NWRN 12/31/2017		Standard Met? 4.5 Patients Per Station
			Patients	Patients Per Station	
FMC PUYALLUP 502587	FMC	12 (+2 spec. circs app.)	70	5.83	Yes
DVA PUYALLUP 502534	DVA	19	108	5.68	Yes
CHI Franciscan Health Bonney Lake	CHI FH	3	0		No

DaVita provided the following information regarding the lack of utilization at the CHI Franciscan's Bonney Lake facility. [source: Application, p14]

“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.” CHI FH was granted CN #1574 for its Bonney Lake via settlement agreement, dated April 11, 2016. In its application, CHI FH represented that Bonney Lake would be operational in December 2015, for an award anticipated by the Department in February 2015, or roughly 11 months. Per WAC 246-310-812(5)(b), this timeline starts from the date of uncontested Certificate of Need approval, or April 11, 2016. By this standard, CHI FH Bonney Lake Dialysis Center should have opened by the first quarter of 2017. It did not, and actually began construction in 2018. It is currently under construction, and is not yet operational.

According to WAC 246-310-812(5), CHI FH Bonney Lake Dialysis Center is therefore meets the 4.5 patients per standard, regardless of its census. As FMC Puyallup and DVA Puyallup were both above 4.5 patients per station on 12/31/2017 for their approved stations, Pierce 1 has met the 4.8/4.5 patients per station standard.”

Public Comment

None

Rebuttal Comment

None

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 Pierce County planning area #1 is shown below.

**Department’s Table 2
December 31, 2017, Utilization Data for Pierce County Planning Area #1**

Facility Name	# of Stations	# of Patients	Patients/Station
Fresenius Kidney Care Puyallup	18	93	5.16
DaVita Puyallup Community Dialysis Center	22	129	5.86
CHI Bonney Lake	3	0	0.00

As shown in the table above, two of the three centers meet the utilization requirement. For the CHI Bonney Lake facility, DaVita asserts that the facility did not meet its timeline for opening 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.”

To evaluate DaVita’s assertions, the department reviewed the following documents associated with the CHI Bonney Lake project.

- The department’s evaluation dated February 20, 2015. This initial evaluation resulted in a denial of CHI Franciscan Health’s establishment of a 6-station dialysis center in Bonney Lake.
- The April 11, 2016, Settlement Agreement among CHI Franciscan, DaVita, Inc. and CHI Franciscan.⁸
- Certificate of Need #1574 issued on April 29, 2016, and associated quarterly progress reports. It is noted that the initial application requested 6 dialysis station and CN #1574 approved a 3-

⁸ The executed Settlement Agreement allowed for a dismissal of the Adjudicative Service Unit case number M2015-386.

station dialysis center in Bonney Lake. CN #1574 was issued consistent with the settlement agreement.

February 20, 2015, Evaluation

The department's evaluation identified an anticipated decision date of February 2, 2015. The decision was released on February 20, 2015—18 days behind schedule. CHI Franciscan identified that the facility would become operational 11 months later or by the end of December 2015.

April 11, 2016, Settlement Agreement

Consistent with the agreement, CN #1574 was issued on April 29, 2016. Applying an 11 month timeline to that date results in a revised operational date March 2017.

CN #1574 and quarterly progress reports

The most recent quarterly progress report submitted by CHI Franciscan shows that the facility is expected to be open in March/April 2019.⁹ WAC 246-310-812(5)(b) allows a certificate holder to request a one-time modification of the timeline if the operational date identified in the application is not met. CHI Franciscan did not submit such a request.

Based on the information above, the department concludes that even though CHI Bonney Lake is not operational, WAC 246-310-812(5) applies to this project and the standard is met for DaVita's Sumner 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

⁹ December 2018 progress report received February 21, 2019.

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.¹⁰ 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, pp16-17]

“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 Sumner facility.

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 Pierce County and one is in King County. They are: DaVita Puyallup Dialysis Center in Puyallup and DaVita Graham Dialysis Center in Graham, both in Pierce County. The King County facility is DaVita Federal Way Community Dialysis Center located in Federal Way. [source: Application, p28]

For the proposed Sumner 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, p21]

¹⁰ WAC 246-453-010(4).

**Department's Table 3
DaVita Projected Payer Mix**

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare (includes managed care)	27.72%	56.82%
Medicaid	0.81%	1.92%
Other: Commercial	71.47%	41.26%
Total	100.00%	100.0%

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. [source: August 13, 2018, screening response, pdf5 and October 19, 2018, screening response, pdf5-6]

“Per WAC 246-310-815(1)(c), the three closest facilities used are DaVita Puyallup Dialysis Center, Federal Way Community Dialysis Center, and Graham Dialysis Center. Where applicable, in-center-only values are used (i.e., blended revenue per treatment is for in-center treatments, and expenses are based on comparables' in-center expense per treatment).

In order to reach net revenue per treatment, DaVita first identifies each comparable facility per WAC 246-310, noted above. Each facility's net in-center revenue is divided by its total in-center 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. 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 12 months of 2021 given the January 4 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 \$4.89/square foot). CAM for 2021 is, similarly, for 12 months."

First Full Year: 2022, based on a first patient date in January 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 expertise, and three treatments weekly for 52 weeks per year. For partial year 2021, this is the average census for the Jan 4-Dec 31 time period, a 5% missed treatment rate, and three treatments weekly for 51.71 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 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, apart from those payment increases outlined in the lease, noted below.

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 May 2019, per clause 2 (NTP in January 2019, possession in February, 120 days post-possession = payments). 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 59.00% of wages based on comparable facilities.

'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).

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.

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

Applicant's Table 11

Table 11 DaVita Sumner Dialysis Center Projected Payor Mix	Percentage by Revenue	Percentage by Patient
Medicare	27.72%	56.82%
Medicaid	0.81%	1.92%
Commercial, HMO, Other Government, and Other	71.47%	41.26%
Total	100.00%	100.00%

Using the assumptions stated above, DaVita projected the end-of-year number of in-center dialyses and patients for fiscal years 2020 through 2023, which are shown in Table 4.¹¹ [source: October 19, 2018, screening response, Appendix 9B Revised]

**Department's Table 4
DaVita Sumner Dialysis Center
Projected Patients and Dialyses for Fiscal Years 2021 – 2024**

	FY 2021 Partial Year	FY 2022 Full Year 1	FY 2023 Full Year 2	FY 2024 Full Year 3
Number of Stations	9	9	9	9
Total In center Patients	16	25	35	45
Total In center Treatments	1,221	2,976	4,387	5,869

¹¹ DaVita's fiscal years begins January 1 and ends December 31. [source: Application, Appendix 10]

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 5
DaVita Sumner Dialysis Center
Projected Revenue and Expenses for Fiscal Years 2021- 2024

	FY 2021 Partial Year	FY 2022 Full Year 1	FY 2023 Full Year 2	FY 2024 Full Year 3
Net Revenue	\$597,814	\$1,457,437	\$2,148,055	\$2,873,750
Total Expenses	\$1,178,889	\$1,605,689	\$1,959,243	\$2,330,586
Net Profit / (Loss)	(\$581,075)	(\$148,252)	\$188,812	\$543,164

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 9-station facility in fiscal years 2021 through 2024. The expenses also include allocated costs consistent with historical DaVita percentages. Medical director costs are \$65,000 annual and consistent with the executed agreement in the application.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita proposes a new 9-station dialysis center in Pierce County planning area #1. DaVita based its projected utilization of the new Sumner Dialysis Center consistent with WAC 246-310-815(1)(a) and (c). Based on a review of the assumptions used for projecting utilization of the 9-station dialysis center, the department concludes they are reasonable.

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. DaVita’s provided a ‘crosswalk’ of the costs as listed in the lease agreement to substantiate the costs listed in the pro forma revenue and expense statement.

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, p20]

“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: August 13, 2018, screening response, Revised Appendix 16]

Consistent with WAC 246-310-800(11), DaVita Sumner Dialysis Center’s maximum allowable square footage for 9 stations and one isolation station is 3,325. DaVita’s project will use 2,984 square feet. [source: August 13, 2018, screening response, pdf 11 and Revised Appendix 16]

Specific to the costs and charges for health services, DaVita provided the statements below. [source: Application, p20]

“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 \$2,821,498, which includes all costs associated with the establishment of the dialysis center, including \$1,821,367 for building out the space in an existing building. 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 Sumner Dialysis Center's projected Medicare and Medicaid reimbursements is 28.52% of revenue and commercial/other is 71.48%. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, the percentages above appear to be unusual.

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), Sumner Dialysis Center's maximum floor space for a 9-station facility is 3,325. DaVita calculated that its actual floor space will be 2,984 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 Pierce County planning area #1. **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 \$2,821,498 costs for this project. [source: Application, pp18-19 and August 13, 2018, screening response, pdf7]

“DaVita, Inc., via its wholly-owned subsidiary Total Renal Care, Inc., is solely responsible for the capital costs identified above.

The DaVita Sumner Dialysis Center executed lease, with a term extending at least five years beyond project completion, is included in Appendix 15.

The zoning map in Appendix 15 identifies the site for DaVita Sumner Dialysis Center as zoned “Interchange Commercial.” Chapter 18.16 of the Sumner Zoning Code, provided, creates “Interchange Commercial” under clause 18.16.010(A)(4), otherwise known as “IC.” Under “18.16.020 Principal and conditional uses”, row 29 of the table, “Medical and Dental Services”, including dialysis centers, IC permits use – see the last column. In addition, Appendix 23 is provided with a zoning letter documenting this permissive use.

Construction cost is estimated based on the non-binding contractor estimate presented in response to Question 6. Construction cost number includes sales tax. Sales tax is assumed at the Sumner, Pierce County rate of 9.3% for all fixtures, furnishings, and equipment, and where else applicable.”

**Department’s Table 6
Capital Expenditure Breakdown**

Item	Amount
Utilities to Lot Line	\$2,000
Building Construction (includes sales tax)	\$1,821,367
Fixed Equipment (not in construction contract)	\$234,453
Moveable Equipment	\$474,812
Architect / Engineering Fees	\$156,000
Supervision & Inspection of Site	\$81,001
Washington State Sales Tax	\$51,865
Total Capital Expenditure	\$2,821,498

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: August 13, 2018 screening response, pdf4]

**Department’s Table 7
Full Time Equivalent (FTE) Breakdown**

FTEs	FYE 2021 Partial Yr	FYE 2022 Increase	FYE 2023 Increase	FYE 2024 Increase	FYE 2024 Totals
Administrator	1.00	0.00	0.00	0.00	1.00
Administrative Assistant	1.00	0.00	0.00	0.00	1.00
Medical Social Worker	0.07	0.10	0.08	0.08	0.33
Dietician	0.07	0.10	0.08	0.08	0.33
RN-In Center/PD/HHD	1.02	1.21	1.06	1.11	4.40
BioMed Technician	0.25	0.00	0.00	0.00	0.25
Other	0.10	0.15	0.12	0.13	0.50
FTE Totals	3.51	1.56	1.34	1.40	7.81

DaVita provided the following clarification regarding the staffing table above. [source: Application, p23 and August 13, 2018, screening response, pdf4]

“DaVita projects FTEs based on staffing ratios for patients per shift, combined with clinical expertise. Standard ratios are noted in Table 18. Overall census estimates are based on the assumptions describing the pro forma in Appendix 9.

Aggregated salary, wage, and benefit rates for each FTE category are noted in Table 18, based on actual rates from 2017 comparable facilities. Benefits are based on comparable facilities at 59% of wage rates.

‘Other’ includes, among other miscellaneous categories, patient education and inventory management roles, as well as staff training.”

Focusing on recruitment and retention of necessary staff, DaVita provided the following information. [source: Application, p24 and August 13, 2018, screening responses, pdf5]

“DaVita anticipates no difficulty in recruiting the necessary personnel to staff DaVita Sumner 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 Sumner 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.

DaVita does not expect any significant barriers to recruiting staff for DaVita Sumner 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 Sumner 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 extensive existing expertise with operating dialysis facilities in east Pierce 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 Pierce County, including planning area #1.

With an establishment of a 9-station dialysis center in the Sumner area, DaVita expects to need approximately 8 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, p25]

“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 located in Tacoma. The physician identified in the agreement is Young Ho Kim, MD. In addition to Dr. Kim, the following four physicians are identified in the agreement as ‘pre-approved’ to provide medical director services. Zheng Ge, MD; Yajuan He, MD; Ho Wo Lee, MD; and Di Zhao, MD. The agreement identifies roles and responsibilities for both DaVita and Dr. Kim and all costs are identified in the agreement. [source: Application, Appendix 3]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

While DaVita’s Sumner Dialysis Center will be a new center in Pierce County planning area #1, it is not DaVita’s only center in Pierce 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 9-station dialysis center. The agreement is between Total Renal Care (a subsidiary of DaVita) and Pacific Nephrology Associates. 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 Sumner 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, p26-27]

“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.¹² 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. The agreement identifies Young Ho Kim, MD as the medical director and the following four physicians as pre-approved physician for medical director services:

Xheng Ge, MD Yajuan He, MD Ho Won Lee, MD Di Zhao, MD

Using data from the Medical Quality Assurance Commission, the department found that all five physicians are compliant with state licensure and have no enforcement actions on the license. Given that DaVita proposes a new facility, 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-

¹² The three centers are: Belfair Dialysis Center in Mason County, Cooks Hill Dialysis Center in Lewis County, and Renton Dialysis Center in King County.

200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: Application, pp26-27]

“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 Sumner Dialysis Center will have an appropriate relationship to the service area’s existing health care system. DaVita Sumner 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 Pierce1 planning area with highly utilized facilities meeting the 4.5 patients per station threshold. 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 Pierce 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 Pierce County planning area #1 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 three alternatives before submitting this application. [source: Application, pp27-28]

“Alternative 1: Do nothing. That is, do not apply for additional stations in the Pierce 1 planning area. Pierce 1 is growing in ESRD population, with a three-year annualized in-center ESRD census growth rate of 9.99% and demonstrated need for nine (9) stations. FMC Puyallup and DVA Puyallup have little additional capacity for growth, even with FMC’s additional two special circumstances stations, and CHI FH Bonney Lake has not become operational within its projected timeline, nor will three additional stations significantly reduce projected patient demand. 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: Expand DaVita Puyallup Dialysis Center. As summarized above, Pierce 1 shows substantial need for dialysis services. DaVita considered attempting to meet this need by applying to expand DaVita Puyallup Dialysis Center, but this was found to be infeasible from a design perspective and less efficient than a new site that could also be located so as to provide enhanced access in a different part of the Pierce 1 planning area. This alternative was rejected.

*Alternative 3: Apply for nine (9) stations in Sumner in the Pierce 1 planning area. As summarized above, Pierce 1 shows substantial need for dialysis services. DaVita will offer high-quality dialysis services to patients in the Pierce 1 planning area and additional, centrally located access in a new geography. **This alternative was selected.**”*

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita currently operates one dialysis center in Pierce County planning area #1. DaVita provided a comprehensive discussion of alternatives considered, including not submitting this application. After reviewing the information, the department concludes that DaVita appropriately rejected all other alternatives before submitting its application.

- (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, p28]

“DaVita Sumner 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.”

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 Pierce County planning area #1 with the addition of 9 dialysis stations in the planning area. **This sub-criterion is met.**

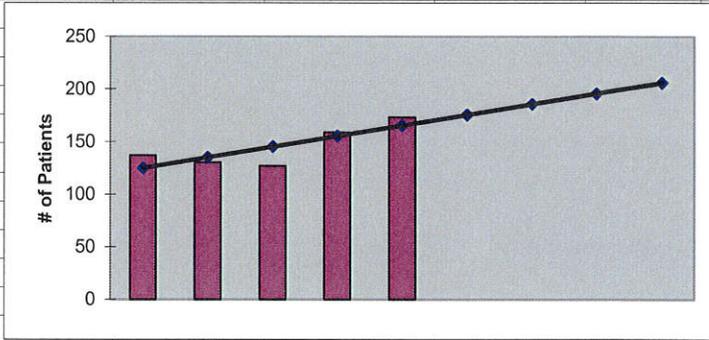
APPENDIX A



2018
Pierce County 1-Adjusted
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Pierce 1	2012	2013	2014	2015	2016	2017	
98354	4	4	4	5	5	9	
98371	15	17	13	17	23	25	
98372	17	29	26	21	23	23	
98373	21	23	23	18	27	21	
98374	16	20	24	26	39	31	
98375	9	20	15	19	20	30	
98390	7	9	6	3	5	7	
98391	20	15	19	18	17	27	
TOTALS	109	137	130	127	159	173	
246-310-812(4)(a)	Rate of Change		25.69%	-5.11%	-2.31%	25.20%	8.81%
	6% Growth or Greater?		TRUE	FALSE	FALSE	TRUE	TRUE
	Regression Method:	Linear					
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	Year 5
			2018	2019	2020	2021	2022
Projected Resident Incenter Patients	from 246-310-812(4)(b)		175.50	185.60	195.70	205.80	215.90
Station Need for Patients	Divide Resident Incenter by 4.8		36.56	38.67	40.77	42.87	44.98
	Rounded to next whole number		37	39	41	43	45
246-310-812(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations	Total		36	36	36	36	36
Results of (4)(c) above			37	39	41	43	45
Net Station Need			-1	-3	-5	-7	-9
Negative number indicates need for stations							
Planning Area Facilities							
Name of Center	# of Stations						
FKC Puyallup	14						
DaVita Puyallup	19						
Franciscan Bonney Lake	3						
Total	36						
Source: Northwest Renal Network data 2012-2017							
Most recent year-end data: 2017 posted 02/07/2018							

x	y	Linear
2013	137	125
2014	130	135
2015	127	145
2016	159	155
2017	173	165
2018		175.50
2019		185.60
2020		195.70
2021		205.80
2022		215.90



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.800277764
R Square	0.6404445
Adjusted R Square	0.520592667
Standard Error	13.81665661
Observations	5

ANOVA					
	df	SS	MS	F	Significance F
Regression	1	1020.1	1020.1	5.343635411	0.103875908
Residual	3	572.7	190.9		
Total	4	1592.8			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-20206.3	8803.961235	-2.295137321	0.105457748	-48224.4339	7811.833905	-48224.4	7811.834
X Variable 1	10.1	4.369210455	2.311630466	0.103875908	-3.804777669	24.00477767	-3.80478	24.00478