

STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington 98504

May 15, 2019

CERTIFIED MAIL # 7018 2290 0001 8591 8469

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

RE: CN Application #18-63 – DaVita Stillaguamish Dialysis Center

Dear Mr. Moore:

We have completed review of the Certificate of Need application submitted by Charemont Dialysis, LLC a subsidiary of DaVita, Inc., proposing to establish a 10-station dialysis center in Snohomish County planning area #1. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Washington Administrative Code 246-310-240

Cost Containment

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision 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

Evan Moore, Special Projects Director DaVita, Inc.-North Star Division Office Certificate of Need Application #18-63 May 15, 2019 Page 2 of 2

Appeal Option 2:

You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:
Department of Health
Adjudicative Service Unit
Mail Stop 47879

Olympia, WA 98504-7879

Physical Address
Department of Health
Adjudicative Service Unit

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

2018 CYCLE 1 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED MAY 15, 2019, FOR THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD KIDNEY DIALYSIS CAPACITY IN SNOHOMISH COUNTY PLANNING AREA #1.

- CHAREMONT DAILYSIS, LLC A SUBSIRADY OF DAVITA, INC., IS PROPOSING TO ESTABLISH A NEW 10-STATION DAILYSIS CENTER IN ARLINGTON WITHIN SNOHOMISH COUNTY PLANNING AREA #1.
- PUGET SOUND KIDENY CENTER IS PROPOSING TO ESTABLISH A NEW 10-STATION DIALYSIS FACILITY IN ARLINGTON WITHIN SNOHOMISH COUNTY PLANNING AREA #1.

APPLICANT DESCRIPTIONS

Charemont Dialysis, LLC.

Charemont Dialysis, LLC is a wholly owned subsidiary of Total Renal Care, Inc. an entity that also wholly owned by DaVita, Inc., information in this application states that Charemont Dialysis, LLC would be doing business as DaVita Stillaguamish Dialysis Center. Charemont Dialysis, LLC's UBI number is 604-280-358.

DaVita, Inc. the parent company of Charemont Dialysis, LLC and Total Renal Care, Inc. is a private for-profit corporation. DaVita, Inc. is a national provider of dialysis services operating in 45 states and the District of Columbia. In Washington State, DaVita, Inc. is approved to own and operate a total of 42 dialysis centers in 19 separate counties. Listed below are the names of the facilities owned or operated by DaVita, Inc. in Washington State [Source: CN historical files and Application, pages 5-8]

Benton	Pacific

Chinook Dialysis Center

Kennewick Dialysis Center

Seaview Dialysis Center

Pierce Clark Grahan

ClarkGraham Dialysis CenterVancouver Dialysis CenterLakewood Community Dialysis CenterBattle Ground Dialysis CenterParkland Dialysis CenterPuyallup Community Dialysis Center

Rainier View Dialysis Center

Chelan
Wenatchee Valley Dialysis Center
Tacoma Dialysis Center

DouglasSkagitEast Wenatchee Dialysis CenterCascade Dialysis Center

Snohomish Everett 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), Pierce (#18-62), 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.

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

Lewis

Cooks Hill Dialysis Center

Mason

Belfair 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

Yakima

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

Puget Sound Kidney Centers

Puget Sound Kidney Centers is a not-for-profit entity that provides kidney dialysis services in Washington State. Puget Sound Kidney Centers was established in 1981 as a community-based provider in northern Snohomish County, and is governed by a board of directors and 5-member executive team that includes the president/CEO, chief financial officer, chief operating officer, chief medical officer, and an executive director for the Puget Sound Kidney Centers Foundation. [Source: Puget Sound Kidney Centers website and application, page 5]

PSKC provides dialysis services through its facilities located in Island, Skagit, Pierce, and Snohomish counties and does not own or operate any healthcare facilities outside of Washington State. In Washington State, PSKC is approved to own and operate a total of seven dialysis facilities³. Of the seven facilities, one is located in Island County, one in Pierce County⁴, one in Skagit County, and four are in Snohomish County. Puget Sound Kidney Centers also operates a mobile dialysis service that provides dialysis services to patients in area hospitals. Below is a listing of the Puget Sound Kidney Centers dialysis facilities in Washington. [Source: CN historical files and Application, page 2]

³ The department acknowledges that PSKC has submitted applications to establish additional dialysis centers in the counties of Thurston (#19-31) Kitsap (#18-52), King (#18-53), and another center in Snohomish (#18-55). As of the writing of this evaluation, final decisions on these projects have not been released

⁴ Of the seven Puget Sound Kidney Center facilities, PSKC Lakewood is recently CN approved and not yet operational

Snohomish

PSKC Everett

PSKC South

PSKC Smokey Point

PSKC Monroe

Skagit

PSKC Anacortes

Pierce

PSKC Lakewood

Island

PSKC Whidbey

PROJECT DESCRIPTIONS

Note – each application refers to a 10-station need in Snohomish County planning area #1. Per 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 all applicants to clarify whether their isolation stations would meet the definition under WAC 246-310-800(9). Though this evaluation will consistently refer to a 10-station need, the approved project(s) would reflect one additional exempt isolation station, if identified by the applicant in response to screening.

DaVita, Inc.

DaVita, Inc. is proposing to establish a ten-station kidney dialysis facility in Arlington within Snohomish County planning area #1. The new ten-station dialysis center will be known as DaVita Stillaguamish Dialysis Center. The proposed DaVita Stillaguamish Dialysis Center would be located at the intersection of Highway 9 and Olympic Place within the City of Arlington. The Snohomish County assessor parcel identification number is #00893800002800. Services to be provided at DaVita Stillaguamish Dialysis Center includes in-center hemodialysis, peritoneal dialysis, backup dialysis, permanent bed station, and dedicated isolation/private room and treatment shifts beginning after 5:00 p.m. [Source: Application, page 10]

The capital expenditure associated with the ten station facility is \$2,144,780. Of that amount 60% or \$1,284,040, is related to building construction improvement; 28% or \$605,858 is for fixed and moveable equipment, 12% or \$254,882; is for taxes and consulting fees. [Source: Screening response July 31, 2018, page 10]

If this project is approved, DaVita, Inc. anticipates the ten-station facility would be operational by June 2021. Under this timeline, year 2022 would be DaVita Stillaguamish Dialysis Center first full calendar year of operation and year 2024 the third year of operation. [Source: Application page 10]

For ease of reference in this evaluation DaVita, Inc., will be referred to as ("DaVita") and the ten-station DaVita Stillaguamish Dialysis Center will be referred to as ("DaVita Stillaguamish").

Puget Sound Kidney Centers

Puget Sound Kidney Centers proposes to establish a ten-station kidney dialysis facility in Arlington within Snohomish County planning area #1. The new nine-station dialysis center will be known as Puget Sound Kidney Centers Arlington. The proposed Puget Sound Kidney Centers Arlington would be located at 74th Avenue SE within the City of Arlington. The Snohomish County assessor parcel identification number for the property is #00793300001201. Services to be provided at Puget Sound Kidney Centers Arlington includes in-center hemodialysis, home hemodialysis training, peritoneal dialysis training and home backup, a permanent bed station, and dedicated isolation/private room and treatment shifts beginning after 5:00 p.m. [Source: Application, pages 5 and 6]

The total capital expenditure associated with the establishment of the nine-station kidney dialysis center is \$4,638,758. Of that amount 62.5% or \$2,899,720, is related to building construction improvement; 19.1% or \$886,122 is for fixed and moveable equipment, 18.4% or \$852,916; is for taxes and consulting fees. [Source: Application Page 18]

If this project is approved, Puget Sound Kidney Centers anticipates the ten-station facility would be operational by the end of January 2021. Under this timeline, year 2021 would be the facility's first full year of operation and calendar year 2023 would be year three. [Source: Application, Page 5]

For ease of reference in this evaluation Puget Sound Kidney Centers would be referred to as ("PSKC") and the proposed ten- station Puget Sound Kidney Centers Arlington would be referred to as ("PSKC Arlington").

APPLICABILITY OF CERTIFICATE OF NEED LAW

These projects are subject to Certificate of Need review as the construction, development, or other establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

EVALUATION CRITERIA

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

Each application must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. For these two applications 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 <u>before</u> 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 these applications under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle #1 for calendar year 2018. Below is the chronological summary of the two applications review timelines.

APPLICATION CHRONOLOGY

Action	DaVita, Inc.	PSKC
Letter of Intent Submitted	May 1, 2018	May 1, 2018
Application Submitted	June 1, 2018	June 1, 2018
Department's pre-review activities		
 DOH Screening Letter 	June 29, 2018	June 29, 2018
 Applicant's Responses Received 	July 31, 2018	July 31, 2018
Beginning of Review	August 6, 2018	

Action	DaVita, Inc.	PSKC	
Public Hearing Conducted	None Requested or Conducted		
Public Comments accepted through the end of public comment	Septembe	er 5, 2018	
Rebuttal Comments Submitted	October 5, 2018		
Department's Anticipated Decision Date	December 19, 2018		
Department's Anticipated Decision Date with 150-day extension ⁵	May 20), 2019	
Department's Actual Decision Date	May 15	5, 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 these two projects each applicant is an affected person to the competing application. The followings persons or entity sought interested person status to these projects.

Health Facilities Planning & Development

Health Facilities Planning & Development (HFPD) located in King County, is a consultation firm hired by applicants to prepare and submit Certificate of Need applications on their behalf. Health Facilities Planning & Development requested interested person status to the two applications, and to be informed of the department's decision. Health Facilities Planning & Development does meet the definition of an "interested person" under WAC 246-310-010(34). HFPD did not provide independent written or oral comment on this application. Therefore, it does not meet the definition of an "affected person" under WAC 246-310-010(2).

⁵ Thirty day extension letters sent to the applicants on December 20, 2018, January 18, 2019, February 20, 2019; March 20, 2019; and April 26, 2019.

Northwest Kidney Centers

Northwest Kidney Centers is an end stage kidney dialysis provider and it owns and operates dialysis facilities in Island, King and Clallam counties. Northwest Kidney Centers submitted an application to establish a dialysis facility in Snohomish County planning area #2. Northwest Kidney Centers sought and received interested person status under WAC 246-310-010(34) for both projects. However, Northwest Kidney Centers did not submit written comments to the department so it cannot qualify as an affected person under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- DaVita, Inc. Certificate of Need application received June 1, 2018
- DaVita, Inc. screening response received July 31, 2018
- Puget Sound Kidney Centers Certificate of Need application received June 1, 2018
- Puget Sound Kidney Centers screening response received July 31. 2018
- Public comments accepted through September 5, 2018
- Rebuttal comments received on October 5, 2018
- Years 2012 through 2017 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health's ESRD Need Projection Methodology for Snohomish 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 and Oversight
- DaVita, Inc. website at www.davita.com
- DaVita Medical Group website at www.davitamedicalgroup.com
- Puget Sound Kidney Centers website at www.pskc.net
- Northwest Renal Network modality data
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSIONS

Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers proposing to establish a new ten-station kidney dialysis center in Arlington within Snohomish County planning area #1 is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Kidney Centers agrees to the following in its entirety.

Project Description:

This certificate approves the construction of a ten nine-station dialysis center in Arlington within Snohomish County planning area #1. At project completion, the dialysis center is approved to certify and operate 11 dialysis stations. 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	9	9
Permanent Bed Station	1	1
Private Isolation Station	1	0
Total Stations	11	10

Services to be provided at Puget Sound Kidney Centers Arlington includes in-center hemodialysis, home hemodialysis training, peritoneal dialysis training and home backup, a permanent bed station, and dedicated isolation/private room and treatment shifts beginning after 5:00 p.m.

Conditions:

- 1. Puget Sound Kidney Centers agrees with the project description as stated above. Puget Sound Kidney Centers further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Prior to providing services, Puget Sound Kidney Centers will provide an executed copy of the medical director agreement for the department's review and approval. The executed medical director agreement must be consistent with the draft provided in the application.
- 3. Prior to providing services at Puget Sound Kidney Centers Arlington, Puget Sound Kidney Centers will provide an executed copy of the patient transfer agreement for the department's review and approval. The executed patient transfer agreement must be consistent with the draft provided in the application.
- 4. Puget Sound Kidney Centers shall finance this project consistent with the financing described in the application.

Approved Costs:

The approved capital expenditure for this project is \$4,638,758.

CONCLUSIONS

DaVita, Inc.

For the reasons stated in this evaluation, the department has concluded that the DaVita, Inc. project is not consistent with the Certificate of Need review, and a Certificate of Need is denied.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

DaVita, Inc.

Based on the source information reviewed, the department concludes that DaVita Inc. 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) and (6).

Puget Sound Kidney Centers

Based on the source information reviewed the department concludes that Puget Sound Kidney Centers 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) and (6).

(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).⁶

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 incenter patients for each of the previous six consecutive years, concluding with the base year.⁷

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

⁶ 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]

⁷WAC 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.

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 the discussion of the two applicant's numeric methodology.

DaVita

DaVita is proposing to establish a ten station kidney dialysis facility in Arlington within Snohomish County planning area #1. The new ten-station dialysis center will be known as DaVita Stillaguamish Dialysis Center. DaVita submitted the numeric methodology posted to the department's website for Snohomish County ESRD planning area #1. The methodology projected need for ten new stations in year 2018.

Public Comment

None

Rebuttal Comment

None

PSKC

PSKC proposes to establish a ten station dialysis center to be located in Arlington. PSKC relied on the numeric methodology posted to the department's website for Snohomish County planning area #1. The methodology projected need for ten new stations in year 2018.

Public Comment

None

Rebuttal Comment

None

Department Evaluation of the Numeric Methodology for Snohomish 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 it will be used for evaluating these two projects.

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

Department's Table 1 Snohomish 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 Posted to Website	38	28	10

As shown in the table above, once the 28 existing stations are subtracted from the projected need, the result is a net need of 10 stations. The department's methodology is included in this evaluation as Appendix A. The department concludes all three applicants **meet 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.⁸ 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 incenter 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 incenter 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 Snohomish County planning area #2, WAC 246-310-812(5) requires all CN approved stations in the planning area be operating at 4.5 in-center patients per station. Below is a discussion of the information submitted by each applicant for this standard.

DaVita

Currently there is one kidney dialysis facility operational in Snohomish County ESRD planning area #1 DaVita provided a table showing the facility is operating above the 4.5 standard. [Source: Application Page 13]

Public	Commen
None	

Rebuttal Comment None

⁸ WAC 246-310-210(1)(b).

PSKC

There is one kidney dialysis facility operational in Snohomish County ESRD planning area #1 and the facility is owned by PSKC. PSKC provided a table showing the facility was operating above the 4.5 standard. [Source: Application, page 12]

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 existing PSKC Smokey Point dialysis center utilization is shown below.

Department's Table 2

December 31, 2017, Utilization Data Snohomish County ESRD planning area #1

Facility	# of Stations	# of Patient	Patients/Station
Puget Sound Kidney Centers Smokey Point	28	126	4.50

As shown in the table above, both DaVita and PSKC meet the utilization requirement and this standard is met for all the applicants.

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

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

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

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

In response to this sub-criterion, DaVita provided the following statement.

"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." [Source: Application, page 16]

DaVita also provided copies of the following policies for this project. [Source: Application page 16, Appendix 14]

- Admission policy/ Accepting End Stage Renal Disease Patients for Treatment
- Patient Behavior Agreements Discharge, Involuntary Discharge of Involuntary Transfer
- Patient Financial Evaluation Policy

The department received public comments from PSKC related to DaVita's compliance with this sub-criterion. The comments are restated below.

DaVita should be denied for directing Patients from Medicaid to Commercial Insurance

"As the data collected by the CN Program in early 2018 demonstrates, the State's two for profit providers, including DaVita, have the highest net revenues per treatment, by far, and DaVita in particular, treats a significantly lower percentage of Medicaid patients. Increasingly over the past 18 months or so, various States, including Washington, have found that DaVita was providing premium assistance so that Medicaid patients remain in, or transfer to commercial plans, including Affordable Care Act expansion plans.

Also, on May 5, 2017, the Washington State Office of the Insurance Commissioner (OIC) issued an Order to Cease and Desist against DaVita for selling health insurance without a license. While DaVita argued and denied that it engaged in any conduct that requires licensure or registration with the OIC, it agreed to settle the matter, and the settlement is dated November 8, 2017. In summary, DaVita agreed to, for a term of two years:

1. When DaVita insurance counselors advise DaVita dialysis patients about insurance options, they will advise each such patient about all public and private insurance options then known

⁹ WAC 246-453-010(4).

to DaVita and that satisfy the patient's expressed needs and preferences regarding their insurance needs.

- 2. DaVita counselors will not ask or urge dialysis patients to enroll in any particular kind of insurance from any particular insurer.
- 3. DaVita will obtain a written acknowledgement from patients that the information counselors provided is consistent with subparagraphs 4 (a) and (b) above.
- 4. DaVita counselors will not accept commissions from insurers for their counsel in services.
- 5. DaVita will not pay its insurance counselors any commission, bonus, or other compensation contingent on patient insurance enrollment.
- 6. If DaVita personnel sell, solicit or negotiate insurance, such person will first obtain licensure as an insurance producer.

"Regardless and separate from the OIC settlement, the data collected by the CN Program for purposes of concurrent review in Cycle 1 dialysis applications—including the Snohomish 1 Planning Area and data that PSKC secured from the other Non-Special Circumstances Cycle 1 applications, demonstrates that DaVita operates with the lowest percentage of Medicaid patients and the highest "other" insurance percentage, and the highest net revenues of any applicant". [Source: Public comments received September 5, 2018, page 3]

In response to PSKC's public comments, DaVita provided the rebuttal comments restated below.

DaVita's payor mix is consistent with other providers

"At every one of its facilities in Washington, including those used as comparable for this application, DaVita accepts all patients regardless of insurance status or ability to pay. Although DaVita accepts all patients, PSKC attempts to make the case that DaVita has an inordinate number of commercially-insured patients. But this is not accurate.

PSKC's primary tactic is to make unreliable comparisons between payor-mix statistics. The reason they are unreliable is that dialysis providers define the payor-mix categories differently. For example, it is unclear how PSKC categorizes patients covered by government-based programs other than Medicare and Medicaid. Also, PSKC apparently bundles managed Medicaid with fee-for-service Medicaid, whereas DaVita includes managed Medicaid in its "Other" category. Comparing differently-defined payor mix categories may serve PSKC's efforts to mislead the Department, but it is not helpful for a real analysis.

That said, a rough comparison can be made by combining PSKC's Medicare and Medicare Advantage categories, so that PSKC has only "Medicare," "Medicaid," and "Commercial" categories, and contrasting these with the corresponding company-wide figures reported in DaVita's Form 10-K, which as a public company DaVita is required to file with the U.S. Securities and Exchange Commission and that is attached as an appendix to DaVita's application. In its annual report for 2017, DaVita disclosed that approximately 89.5% of its total dialysis patients are covered by government-based programs. This is almost identical to PSKC's 89.1% projection for its proposed facility. The remaining 10.5% of DaVita's total dialysis patients are associated with commercial payors.7 Again, this is almost identical to PSKC's 10.8% projection.

But it is not even necessary to look at DaVita's company-wide payor-mix figures. In response to PSKC's criticism, we have gone back to the data for the comparable facilities (Everett, Cascade, and Pilchuck) specifically, to determine how much of the "Commercial, HMO, Other Government, and Other" category is attributable to Medicare Advantage and managed Medicaid. Here is a payor mix with the categories adjusted to be more similar to PSKC's categories:

DaVita's Reallocated Table 11

Table 11 –Reallocated	Percentage by	Percentage by	
Stillaguamish Dialysis Center	Revenue	Patient	
Projected Payor Mix			
Medicare (including Medicare Advantage)	35.38%	72.22%	
Medicaid (including Managed Medicaid)	3.26%	6.98%	
Commercial, HMO, Other Government, and Other	61.37%	21.80%	
Total	100.00%	100.00%	
Note: VA (included in Other Government)	2.66%	4.36%	

As can be seen in the above table, the percentage of DaVita's patients covered by Medicare (including Medicare Advantage), Medicaid (including managed Medicaid), and the VA adds up to 83%, which is comparable to PSKC's 87.7% projection.

DaVita accepts all patients regardless of insurance status or ability to pay. PSKC provides no evidence whatsoever for its false claims to the contrary. [Source: Rebuttal comments received October 5, 2018, pages 2 and 3]

DaVita does not sell insurance

"The comments also reference an Office of Insurance Commissioner ("OIC") cease and desist order issued to DaVita in 2017. But DaVita had done nothing wrong in counseling patients regarding available insurance options, and after investigating the OIC rescinded and withdrew its order. Either DaVita's competitors are uninformed about what actually happened, or they know exactly what happened and their reliance on the OIC order is disingenuous. DaVita suspects it's the latter. But in any event there is no merit to this criticism". [Source: Rebuttal comments received October 5, 2018, pages 4 and 5]

DaVita provides insurance counselling to patients

"DaVita's dialysis facilities are Medicare-certified and accept Medicare and Medicaid patients. As a result, they are required to comply with federal conditions for coverage. Based on these conditions of coverage, DaVita employs multidisciplinary teams to assess and address its patient's medical requirements and-because ESRD is a tremendous psychological and financial burden on patients-their psychosocial needs, including financial concerns.

Among the team members who help meet patient's needs are insurance counselors. The insurance counselors serve DaVita's patients by, among other things, helping them navigate the healthcare payment labyrinth so that they understand their options and may make an informed choice about insurance. The insurance counselor's present patients with information about both public and private insurance options and provide assistance to patients during the enrollment process, when needed, after a patient has chosen an insurer. For patients who elect to proceed with private insurance and need assistance with their premiums, the insurance counselors may help the patients apply for premium support from third-party entities, such as the American Kidney Fund or the

Washington State Health Care Authority's Premium Payment Program, which subsidizes the cost of private insurance for Washington residents enrolled in Apple Health, Washington's Medicaid program.

The decision on an insurance option is the patient's choice. DaVita's insurance counselors do not choose plans for patients, and they do not urge patients to choose private insurance or to choose a particular carrier. The patient alone makes the choice whether to obtain a commercial plan or a government plan. Similarly, if the patient prefers private insurance, the insurance counselors do not choose a particular commercial plan. The decisions about private or government insurance, and about which particular plan to choose, are made by the patient alone. [Source: Rebuttal comments received October 5, 2018, page 5]

DaVita's insurance counselling is consistent with CMS requirements and guidance

The Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers both Medicare and Medicaid, mandates that dialysis facilities inform patients of their rights and account for patient's psychosocial needs. Among other things, CMS specifies certain "patient's rights" for dialysis facilities, including that "I have the right to be told about any financial help available to me."

CMS regulations further require that dialysis facilities have an interdisciplinary team that provides each patient with "an individualized and comprehensive assessment of his or her needs" that "must be used to develop the patient's treatment plan and expectations for care." 42 C.F.R. § 494.80. That assessment must include, among other things, an "evaluation of psychosocial needs by a social worker." 42 C.F.R. § 494.80(a)(7). The CMS manual for certification of dialysis facilities makes clear that the evaluation of psychosocial needs should address, among other things, the patient's "financial capabilities and resources," "access to available community resources," and "eligibility for Federal, State or local resources." [Source: DaVita's rebuttal comment received October 5, 2018, pages 5 and 6]

Department Evaluation

PSKC provided public comment that questioned the appropriateness of DaVita's payer mix for DaVita Stillaguamish and linked several applications submitted by DaVita in 2018 to support its assertions. PSKC introduced data from other dialysis facilities in Snohomish and King Counties to suggest that DaVita has an organization-wide history in which Medicaid patients are inappropriately steered into commercial insurance plans.

The two articles provided by PSKC, while full of information regarding steps that are being taken to request action from the Department of Health and Human Services, does not include or point to conclusive evidence that DaVita denied access to any patients based on payer source. The payer mix table above identifies that approximately 3.26% of revenue is from Medicaid, representing approximately 6.98% of patients. There were approximately 801,633 Snohomish County residents in 2018, of which approximately 109,022 were enrolled in some form of Medicaid program – approximately 13.6% of the population. While 13.6% is more than the 6.98% identified in the application, this has not been adjusted for age or any other factors and is not concerning to the CN program.

PSKC did not provide sufficient evidence for the department to conclude that DaVita patients on Medicaid have been inappropriately steered into commercial plans. The department found no evidence to support that DaVita is not accessible to Medicaid patients. Insofar as the reimbursement

is concerned, this issue is addressed under WAC 246-310-827 – superiority. This analysis can be found under WAC 246-310-240 towards the conclusion of this evaluation. DaVita provided copies of the necessary policies that will be used at DaVita Stillaguamish and at all DaVita dialysis centers.

Medicare and Medicaid Programs

The applicant states, "DaVita Stillaguamish Dialysis Center will be certified by Medicare and Medicaid upon completion." [Source: Application page 12]

Furthermore, DaVita also provided the following statements, "Table 11 provides expected payor mix for the DaVita Stillaguamish Dialysis Center, projected using DaVita's comparable facilities and aligned with the pro forma operating statement". [Source: Application pages 20 and 21]

DaVita's Table 11

Table 11 Stillaguamish Dialysis Center Projected Payor Mix	Percentage of Patients	Percentage by Payer	
Medicare	23.72%	52.03%	
Medicaid	1.30%	3.40%	
Commercial, HMO, Other Government, and Other	74.98%	44.57%	
Total	100.00%	100.00%	

DaVita did not provide a policy specifically entitled "Charity Care." However, DaVita's Patient Financial Evaluation Policy provides the necessary information and process a patient would use to obtain charity care at a DaVita facility. DaVita further demonstrated its intent to provide charity care for patients treating at DaVita Stillaguamish by including a 'charity' line item as a deduction from revenue within its pro forma income statement.

Given that DaVita currently operates dialysis centers in Washington State and uses the same policies and procedures at each center, and the same policy would be used at DaVita Stillaguamish, as a result, no draft policies were provided by in this application. The department concludes DaVita's project **meets this sub-criterion**.

PSKC

In compliance with this sub-criterion, PSKC provided the following statements.

"As noted above, all individuals in need of dialysis services have access to PSKC's dialysis centers. PSKC's Community Service Statement policy, attached as Exhibit 4, prohibits discrimination on the basis of race, income, ethnicity, sex, or handicap.

Copies of the requested policies are included in <u>Exhibit 4</u>". [Source: Application Page 14 and 15]

PSKC provided copies of the following policies used at all PSKC's dialysis centers. [Source: Application page 14, Exhibit 4]

- Policy and Procedure/New Patient Admission
- Policy and Procedure/Patient Transfer and Discharge
- Policy and Procedure/Community Service Statement

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC provided copies of the necessary policies that would be used at proposed PSKC Arlington. The same documents are used all existing PSKC dialysis centers.

Medicare and Medicaid Programs

As directed by WAC 246-310-815, PSKC based its payer mix on PSKC's three closest facilities. All three facilities are located in Snohomish County. They are: PSKC Everett located in Everett; PSKC South located in Mountlake Terrace; and PSKC Monroe located in Monroe. PSKC Arlington is not existing facility. However, all PSKC's facilities currently operational in Washington provides Medicare and Medicaid. In the application, the applicant states, "PSKC Arlington will be certified by Medicare and Medicaid". For the proposed PSKC Arlington facility, PSKC provided a table showing the proposed percentages of revenues by payer and revenues by patients for the new facility. The information is summarized below. [Source: Application pages 8 and 20]

PSKC's Table 10 PSKC's Arlington Kidney Center Projected Payer Mix

Payer Mix	Percentage by Revenue	Percentage by Patients	
Medicare	51.0%	61.4%	
Medicare Managed Care	15.6%	15.8%	
Medicaid	7.9%	11.9%	
Other: Commercial	25.5%	10.8%	
Total	100.0%	100.0%	

Based on the information above, the department concludes that PSKC's application meets this subcriterion.

- (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.
- (c) 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 any of the three dialysis projects 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.

Puget Sound Kidney Centers

Based on the source information reviewed and agreement to the conditions identified in the "conclusion" section of this evaluation, the department concludes that Puget Sound Kidney Centers has meet he 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 the two projects, DaVita and PSKC must demonstrate compliance with the following sub-sections of WAC 246-310-815(1). Using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

WAC 246-310-815(1)

- (1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.
- (a) The calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.
- (b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payer mix and current expenses.
- (c) New facilities.
 - (i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.
 - (ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.

- (iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.
- (iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.
- (v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities.

DaVita

DaVita Stillaguamish is not operational, sub-sections (1)(a) and (c) above apply to this project. As previously stated, DaVita stated the new ten station dialysis facility would be operational in June 2021. Under this timeline, calendar year one of the project is 2022 and calendar year three is 2024. [Source: Screening response received July 31, 2018, page 3]

DaVita provided the assumptions used to project in-center patients and home patients treatments for partial calendar years 2021, and full calendar years 2022 through 2024. The assumptions are restated below. [Source: Screening response received July 31, 2018, page 4, Appendix 9A]

- First Full Year: 2022, based on a first patient date in June 2021.
- Total Stations: CON Approved stations.
- Total Chronic Capacity: 6 shift capacity 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.
- 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.

Using the assumptions stated above, DaVita's projected the number of in-center and home dialyses and patients for the 10-station DaVita Stillaguamish in years 2021 through 2024 is shown in Table 3. [Source: Screening response received July 31, 2018, Appendix 9A]

Department's Table 3
DaVita Stillaguamish Dialysis Center
Projected Patients and Dialyses for Years 2021 – 2024

	Partial Year 2021	Full Year 1- 2022	Full Year 2- 2023	Full Year 3- 2024
Number of Stations	10	10	10	10
Total In center Patients	7	29	41	52
Total In center Treatments	335	2,668	5,180	6,854
Total Home Patients	1	2	4	6
Total Home Treatments	87	222	445	741
Total All Patients	8	31	45	58
Total All Treatments	422	2,890	5,625	7,595

DaVita provided the following assumptions used to project revenue, expenses, and net income for the 10-station DaVita Stillaguamish. [Source: Screening response received July 31, 2018, Appendix 9A]

- 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.
- Expenses: Based on an average of comparable facilities for the last full calendar year (2017).
- Cost inflation: DaVita's experience and expertise leads to an assumption that non-medical director or lease costs (which are previously contracted and based on actual contract costs) are likely to inflate at ~2% per year, and each category is assumed as such.
- 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 and PD compensation consistent with planned services.
- Lease Expense: base rent is directly pulled from the lease contract for each calendar year, per clause 3 of the Development Agreement, with the payment term projected to start in May 2021. Tax and CAM are calculated based on available average cost per square foot of comparable facilities in 2017, inflated at 2% annually.
- Labor Assumptions: Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits are assumed at a rate of 64% of wages based on historical precedent. Salaries and wages are projected to inflate at 2% annually.

Specific to the base rent reference under the lease expense category, DaVita provided the following clarification. "Please see the lease assumptions outlined below – the total row at the bottom will match Appendix 9A. Note that partial year 2021 is projected from June 1, 2021. The actual payment begin date for the lease is May 2021, based on a start date 30 days after the certificate of occupancy date per the terms of the lease. Tax and CAM is estimated on a per square foot basis using the comparable facilities (2017 tax and CAM/facility square feet). The average of the three comparable facilities' tax and CAM expense is \$2.94, which is the base for the projection, inflated at 2% annually". [Source: Screening response received July 31, 2018, page 7 and Appendix 20]

DaVita's Lease Expenses Base Rent Table

Lease Years				Monthly Amounts		
From To		Го	Rent	Tax + CAM		
Year	Month	Year	Month			
2021	5	2022	4	\$21,928	\$1,715	
2022	5	2023	4	\$21,928	\$1,749	
2023	5	2024	4	\$21,928	\$1,784	
2024	5	2025	4	\$21,928	\$1,820	

	PY FY21	FY22	FY23	FY24
Base Rent	\$153,492.50	\$263,130	\$263,130	\$263,130
Tax & CAM	\$12,003.03	\$20,851	\$21,268	\$21,693
Total	\$165,496	\$283,981	\$284,398	\$284,823

Based on the assumptions above, DaVita projected the revenue, expenses, and net income for years 2021 through 2024. A summary of the projections are shown in Table 4. [Source: Screening response received July 31, 2018, Appendix 9A]

Department's Table 4 DaVita Stillaguamish Dialysis Center

Projected Revenue and Expenses for Years 2021 - 2024

÷	Partial Year 2021	Full Year 1- 2022	Full Year 2- 2023	Full Year 3- 2024
Net Revenue	\$236,794	\$1,619,393	\$2,184,192	\$2,696,072
Total Expenses	\$567,616	\$1,665,439	\$2,496,254	\$3,125,928
Net Profit / (Loss)	(\$330,822)	(\$46,046)	\$655,334	\$1,130,169

The 'Net Revenue' line item is gross in-center treatments and home treatments minus deductions for bad debt and charity care. The 'Total Expenses' line item includes all expenses related to the projected operation of the projected 10-station facility in years 2021 through 2024. The expenses also include allocated costs per treatment which is multiplied by the projected number of treatments. Medical director costs are \$95,000 annually and is consistent with the executed medical director agreement provided in the application.

The department received public comments from PSKC related to DaVita's compliance with this sub-criterion. The comments is restated below.

DaVita's charges for healthcare costs

"...DaVita states that its proposed new Stillaguamish facility will have no effect on the costs and charges for health care services. It goes on further to state that the revenue assumptions were based on the three closest facilities as required by the Program. PSKC has compared the projected net revenue per treatment for this application as well as the two 19 station applications (King 1 – Green Lake and Thurston – Lacey) and questions how this 10 station facility would have a higher net income than the 19 station Green Lake facility.

As one might expect, DaVita Stillaguamish has higher net expenses per treatment; not surprising given the smaller size of the facility. However, what is puzzling is that the average net revenue per treatment is \$80 to \$100 higher than either Green Lake or Lacey.

PSKC's Table 2 Comparison of Three DaVita Applications (Green Lake, Lacey and Stillaguamish)

Facility	Net Revenue/ Treat (3 Closet)	Net Revenue/ Treatment (Year3)	Average Expenses/ Treatment (Year 3)	Net Income/ Treatment (Year 3)
DaVita Stillaguamish	Everett: \$613.59 Cascade: \$392.15 Pilchuck: \$626.09	\$560.38	\$354.98	\$148.80
DaVita Green Lake	Olympic View: \$389.34 Westwood: \$425.79 Bellevue: \$591.71	\$480.74	\$331.41	\$103.11
DaVita Lacey	Olympia: \$546.12 Tumwater: \$601.41 Lakewood: \$358.15	\$460.16	\$319.50	\$74.34

DaVita Stillaguamish's pro forma financial assumptions include:

- 2% annual inflation for most expenses despite instructions from the CN Program to exclude inflation (see instructions for March 2018 ESRD application).
- Table 13A of the screening response provided the average wage rate and FTEs for DaVita Stillaguamish. PSKC cannot tie the FTEs and wage rates to the salaries and wages line item in the pro forma financial (Appendix 9A". [Source: Public comments received September 5, 2018, pages 4 and 5]

The department received rebuttal comments from DaVita in response to the public comments submitted PSKC. The comments is restated below.

DaVita's pro forma is accurate

"PSKC claims to be confused as to why DaVita's Snohomish 1 application projects higher net revenue per treatment than DaVita's King 1 or Thurston applications. The answer is simple: they used different comparable facilities. The Department's regulations require use of "the applicant's three closest dialysis facilities. "WAC 246-310-815(1)(c)(i). The three facilities closest to DaVita's Snohomish 1 location are completely different than the three facilities closest to DaVita's King 1 or Thurston locations.

As the Department knows, net revenue per treatment will vary between individual facilities for a number of reasons, including the payor mix and payment rates. Therefore, it can hardly be a surprise that applications relying on distinct sets of comparable will have different net revenue per treatment rates. DaVita's net revenue per treatment calculation here is completely accurate, based on the three comparable facilities that DaVita is required to use under the rules". [Source: Rebuttal comments received October 5, 2018, page 8]

Inflation is permitted in cost projections

"As PSKC notes, the Program's application form contains guidance stating that an applicant should not include inflation in cost projections. But omitting inflation makes the cost projections less accurate. Therefore, DaVita asked the Program whether it would be permissible to include inflation, and the Program confirmed that it would be permissible if it were a reasonable estimate. DaVita accordingly included it.

If the Program tells DaVita in a future application cycle that it is forbidden to include inflation in cost projections, even though it makes those projections more accurate, DaVita of course will abide by the Program's instructions. In any event, if inflation is removed from the cost projections, it improves the financial feasibility of DaVita's facility". [Source: Rebuttal comments received October 5, 2018, page 8]

DaVita's projected staffing costs are accurate

"Finally, PSKC claims that it "cannot tie" DaVita's staffing table and pro forma. But DaVita's staffing table and pro forma match exactly. PSKC simply has not accounted for the fact that salaries and wages from the staffing table are based on 2017 full-year actuals, and projections from that date include inflation (i.e., 2021 would be the fourth year from the 2017 data used, and shown in the staffing table wage rates), as noted in DaVita's assumptions. If these factors are accounted for, the staffing table and pro forma match exactly..." [Source: Rebuttal comments received October 5, 2018, page 10]

Department Evaluation

DaVita Stillaguamish is currently not operational so the applicant based its projected utilization for the proposed ten station facility on its three closest facilities. The department considers this approach reasonable. WAC 246-310-815(1)(b) requires a new facility to base revenue projections on the net revenue per treatment of the applicant's three closest dialysis facilities. DaVita provided both its revenue and expense projections and based them on DaVita Pilchuck Dialysis Center, DaVita Everett Dialysis Center and DaVita Cascade Dialysis Center operations. PSKC asserted that DaVita's net revenue per treatment is higher when compared to other providers. The comparable data that PSKC used for its assertions did not show that DaVita's revenue per treatment is significantly higher when compared to similar size facilities revenue per treatments.

PSKC stated that DaVita's application assumed 2% inflation annually. The department noted that DaVita's application did mentioned that it assumed 2% inflation for negotiated contracts. DaVita referred to this 2% as "inflation," but this doesn't accurately capture what DaVita is doing and is not consistent with the type of inflation that the department precludes in CN applications. DaVita's application states that 2% is based on past experience in those categories.

The application form specifies that non-inflated **dollars** should be used. If a general inflation rate had been applied to all dollars in all line items (including revenues, deductions and contracted costs), this would be problematic and contrary to application instructions. However, DaVita is not applying a general inflation rate to their pro forma. Rather, they are using their past experience operating dialysis centers to predict that expenses not tied to agreements/contracts have historically gone up at approximately that rate.

The department regularly provides technical assistance to applicants and advises that when known, known expenses should be included. Again, consistent with WAC 246-310-815 DaVita based its revenue and expense projections on performance at their closest three facilities. Because this 2% is consistent with DaVita's experience operating dialysis facilities, this is a reasonable approach.

Within the application, DaVita provided an executed lease between Genesis KC Development, LLC ("landlord") and Charemont Dialysis ("Tenant"). The lease agreement was executed in May 2018 and is valid for 180 months or 15 years. The costs identified in the lease agreement can be substantiated in the revenue and expense statement.

DaVita provided a copy of an executed Medical Director Agreement between Charemont Dialysis, LLC (DaVita), The Everett Clinic, PLLC and the four nephrologists associated with the Everett Clinic, PLLC (Contractor). The Medical Director Agreement and a joinder agreement was executed with the Everett Clinic, PLLC on May 31, 2018 and is valid through May 31, 2023. The costs identified in the medical director agreement can be substantiated in the revenue and expense statement.

Based on the above information provided in the application, the department concludes that DaVita's projected revenue and expense statement is reasonable. **This sub-criterion is met.**

PSKC

Given that PSKC Arlington is not an existing facility sub-sections (1)(a) and (c) is applicable to this project. As previously stated, PSKC proposes to establish 10-station kidney dialysis facility and it would be operational by the end of January 2021. Under this timeline, year 2021 would be the

dialysis facility first full year of operation and calendar year 2023 would be year three. [Source: Application, Page 5]

PSKC provided the assumptions used to project in-center patients treatments and home patients treatments for calendar years 2021 through 2023. The assumptions are restated below. [Source: Application, Exhibit 6]

1. Volumes

- A. <u>Patients In-Center</u>. Census was based on the assumptions outlined below: PSKC has assumed that 10 patients transfer from PSKC Smokey Point upon opening; and an additional 15 new patients are added (due to the increase projected, in part, from application of the methodology). In 2022, an additional 13 patients are added and in 2023, 10 new patients are expected.
- B. <u>Patients Home Program</u>. Increases in patient census by modality were projected based upon PSKC's historical experience.
- C. <u>Treatments In-Center</u>. Treatments were assumed to average 148 treatments per patient annually to account for missed treatments.
- D. <u>Treatments Home Program</u>. Treatments were based on PSKC experience and assumed an average.

Department's Table 5
PSKC's Arlington Kidney Center
Projected Revenue and Expense Yr. 2021-2023

	Full Year 1- 2021	Full Year 2- 2022	Full Year 3- 2023
In-center Station	10	10	10
In-center Treatments Patients	25	38	48
In-center Treatments	3,700	5,624	7,104
Home Treatment- HHD	290	368	446
Home Treatments -PD	1,060	1,770	2,480
Home Training – HHD	22	22	22
Home Training –PD	20	30	40
Total Treatments	5,092	7,814	10,092

PSKC provided the following assumptions used to project revenue, expenses, and net income for the 10-station kidney dialysis center. [Source: Application, Exhibit 6]

2. Revenues

- A. Revenues and current payer mix were based on the current experience of three closest PSKC facilities (PSKC Everett, PSKC Smokey Point, and PSKC Monroe) for all modalities. Payer mix by patient and revenue was provided in Table 10 of the application. Net revenue per treatment is assumed to be \$308.94 for in-center treatments and per WAC 246-310-812 (c)(i) is the average of the three closest facilities. Net revenue per treatment for home treatments is based upon the net revenue by modality for home hemodialysis (\$307.52) and peritoneal dialysis treatments (\$189.23).
- B. Charity care is assumed to be 0.88% of net revenue based on the three closest facilities.
- C. Bad debts are assumed to be 1.1% of net revenue based on the three closest facilities.

3. Direct Expenses

Per the requirement of WAC 246-310-815 (1)(iii) unless otherwise stated, 'all other expenses' have been calculated based on the average cost per treatment of the three closest facilities (total expenses/total treatments) to the proposed PSKC Arlington.

- A. Salaries and wages: information regarding the number of FTEs and average salary was provided in Table 12.
- B. Benefits were assumed to be 24.41%, which is based on the average benefit percentages of the three closest facilities.
- C. Medical Director fees are based on medical director agreement applicable to PSKC Arlington (see Exhibit 7 of the application; \$40,000/year).
- D. Medical supplies: average cost per treatment based on the three closest facilities (\$30.39 for incenter and \$57.93 for home treatments).
- E. Pharmacy and EPO: based on the average cost per treatment of the three closest facilities.
- F. Office and miscellaneous expenses include office supplies, small equipment, information technology expenses (including licenses, software maintenance, and IT-related supplies), equipment rent, and other miscellaneous expenses. These expenses were based on the cost per treatment experience for PSKC's three closest facilities. In year 2021, the first year of operation for PSKC Arlington, the expense was increased to include the cost of small equipment not eligible for capitalization.
- G. Repairs and Maintenance include maintenance agreements and parts for various operating equipment. These expenses were based on the cost per treatment experience of PSKC's three closest facilities.
- H. Housekeeping: These expenses were based on the cost per treatment experience of PSKC's three closest facilities.
- I. Building repairs and maintenance, and utilities. Building maintenance was estimated using the cost per square foot average of PSKC's three closest facilities.
- J. Utilities were based on the cost per treatment experience of PSKC's three closest facilities.
- K. Communication expenses include telephone (both land and cell), postage, connectivity, and internet costs. They were based pm the average costs of PSKC's three closest facilities.
- L. Laboratory expenses were based on the rate charged for each bundled patient and was assumed to be \$750/patient.
- M. Training: These expenses were based on the cost per treatment experience at PSKC's three closest facilities.
- N. Interest: PSKC intends to finance the proposed facility construction. The required interest expense incurred for this project has been reflected according to the terms of the bank letter.
- O. Depreciation expenses were estimated based on the actual useful lives PSKC assigned to certain equipment classifications. Classifications are as follows:

- 1. Building 40 years
- 2. Building improvements 15 years
- 3. Medical equipment 7 years
- 4. Furniture and office equipment 7 years

4. Overhead

- A. Indirect expenses are allocated based on a cost per patient treatment (equivalent in-center treatments) for the proposed PSKC Arlington using 2017 actuals.
- B. The Corporate Medical Director fees are allocated based on a cost per patient treatment (equivalent in-center treatments).

Based on the assumptions above, PSKC projected the revenue, expenses, and net income for calendar year 2021 through 2023. A summary of the projections are shown in Table 6. [Source: Screening response received July 31, 2018, Attachment 1]

Department's Table 6 PSKC Arlington Kidney Center Projected Revenue and Expenses for Year 2021-2023

	Full Year 1- 2021	Full Year 2- 2022	Full Year 3- 2023
Net Revenue	\$1,414,813	\$2,154,506	\$2,759,742
Total Direct Expenses	\$1,604,152	\$2,039,142	\$2,475,201
Net Profit/(Loss)	(\$189,339)	\$115,364	\$284,541

The 'Net Revenue' line item is gross in-center treatments and home treatments minus deductions for bad debt and charity care. The 'Total Direct Expenses' line item includes all expenses related to the projected operation of the projected ten station facility in year 2021 through 2024. The expenses also include overhead allocated costs for administrative and support services. Medical director costs is \$40,000 annually and is consistent with the draft medical director agreement provided in the application.

The department received public comments from DaVita related to PSKC's compliance with this subcriterion. The comments are restated below.

PSKC's financing is unreliable

"PSKC has not successfully demonstrated that it can finance the projects it has proposed. As a preliminary matter, PSKC's application includes a typo regarding the cost of its project. On page 16 of its Application, PSKC states that it "will debt-finance \$6,500,000 of the approximately \$7.4 million of the proposed project." However, the stated project costs are \$4,638,758. Presumably PSKC meant to write that it will debt-finance \$3,500,000 of the approximately \$4.6 million. Assuming this to be the case, PSKC has, in total, proposed simultaneous projects that require commercial debt financing for \$25.5 million (see the below table).

Planning Area	PSKC Project	Proposed	Financing Amount
Snohomish 1	Arlington	\$	3,500,000
King 1	Richmond Beach	\$	8,500,000
Kitsap	Silverdale	\$	-
Thurston	Lacey	\$	6,500,000
Clark	Vancouver	\$	7,000,000
Total		\$	25,500,000

While the year-end financial statements in its Application for 2016 show \$7,837,464 in cash reserves, essentially all of those are committed to an existing project. As condition #3 of CN #1598 for its 29-station Lakewood facility, PSKC is committed to \$8,957,745 in capital expenditure solely from its capital reserves, more than it had extant on December 31, 2016. Assuming PSKC even has \$8,957,745 in capital reserves, this means that PSKC is essentially solely reliant on debt financing for any of the above projects.

PSKC has provided a letter in Exhibit 5 from Banner Bank to demonstrate its ability to qualify for a loan to fund this project. This letter is inadequate to demonstrate that PSKC will obtain the loan, and is not conditionable. As an analogy, if you were to purchase a home, you would obtain a preapproval letter for at least the amount in question, then when entering contract on the home, would almost certainly have a financing contingency. That contingency protects you from having to proceed on the contract if you are not actually approved. The same is true, at a larger scale, in this case. PSKC provides a letter from Banner Bank that amounts to a pre-approval letter. While it contains general terms, without having gone through underwriting, there is absolutely no guarantee those terms will remain consistent or the funding will even be granted and PSKC has no control over that outcome.

Furthermore, as outlined above, PSKC is not attempting to finance this project in a vacuum. Not only are all of PSKC's existing cash reserves committed to another project, but it is proposing financing a further four projects at a total of \$25.5 million. Although the bank letter suggests, in a footnote, that Banner Bank will lend to PSKC on multiple projects, Banner Bank does not commit to doing so. It notes that each project "would be considered and underwritten on its own merits," and for good reason. Its client, PSKC, is proposing not just this project, but five (four of which require financing). Its language in the footnote about not anticipating multiple projects materially affecting its willingness to fund those projects is simply not reliable nor credible.

Based on current commercial lending standards, the upper limit on borrowing for PSKC would be Net Debt of roughly 3-4 times annual EBITDA. EBITDA stands for Earnings Before Interest, Taxes, Depreciation and Amortization. In essence, it is calculated by adding back the income taxes, debt-service interest, and depreciation & amortization to earnings. Net Debt is a company's current cash reserves plus its outstanding debt.

In its 2016 financial statements, PSKC had \$2,823,804 in revenues over expenses, including unrealized gains on investments (Application, 2016 Financial Statements, p.4). As a non-profit, PSKC does not pay income taxes of note, and its financial statements do not indicate material debt service payments. It had depreciation and amortization of \$1,474,096. This yields an estimate of 2016 EBITDA of \$4,297,900.

As PSKC's cash reserves are more than 100% spoken for as an obligation to fulfilling the Department's condition for financing of its Lakewood facility (essentially, a debt PSKC owes to itself and is required to spend over a certain time period), but its outstanding debt in 2016 was \$0, DaVita charitably assumes that PSKC's Net Debt is \$0. As PSKC has indicated it will also cash-finance its proposed Silverdale facility in Kitsap County with cash it does not appear to have, this is a more than generous assumption.

If this is the case, given a generous assumed upper limit of four times Net Debt to EBITDA for PSKC to borrow, this gives \$17,191,600 as a limit to PSKC's borrowing (EBITDA of \$4,297,000 * 4). PSKC proposes to finance \$25,500,000 worth of projects. There is no way that PSKC can claim security in its financing for those projects, nor is that financing reliable for Certificate of Need purposes. Moreover, the closer PSKC were to come to its borrowing limit, the less likely it would be that it could obtain financing terms as generous as those identified in its application—and in this application cycle, PSKC unrealistically proposes to blow through the ceiling on its potential borrowing under current commercial lending standards...". [Source: Public comments received September 5, 2018, pages 5-6]

In response to DaVita's public comments, PSKC provided its rebuttal comments. The comments are restated below.

PSKC's financing is reliable and meets all CN requirements

"DaVita states, and PSKC agrees, that CN guidelines require an applicant to identify the source of financing for a project and provide supporting documentation. Years of prior CN approvals demonstrate that a letter from a lender meets these requirements. PSKC has done exactly this.

DaVita's public comment cites a total of \$25.5 million in proposed financing for PSKC projects in Cycle 1, and another nearly \$9 million for PSKC's currently under development (and already funded) Pierce 5 project. The nearly \$9 million for Pierce 5 is already committed and, as noted below, the correct dollar amount for the remaining three applications in Cycle 1 is less than \$25 million. Each of the Cycle 1 applications include a letter of preliminary commitment from our long-standing banking partner, Banner Bank, thus meeting CN requirements.

Understanding the financial support that Banner Bank is willing to provide PSKC is critical to understanding the overall financial feasibility of our CN applications. We provided separate letters from Banner Bank in connection with each of our application filings. The amount of financing that Banner Bank is willing to provide for each project identified below is as follows:

Recreated PSKC's Table

Richmond Beach	\$8,500,000
Arlington	\$4,000,000
Lacey	\$6,500,000
Total	\$19,000,000

[Source: Rebuttal comments received October 5, 2018, page 7]

"... DaVita has attempted to define and place a borrowing capacity on PSKC based upon its own interpretation of commercial lending practices - utilizing a simplified multiplier of EBIDTA. DaVita provides no foundation for its assumption that 3-4X EBIDTA is an industry standard for asset-poor companies like itself, much less that such a standard is applicable to PSKC's asset-rich circumstances. Whatever the source of DaVita's formula, it does not take into consideration the

strength of PSKC's balance sheet that has accumulated due to its financial discipline and decision to defer the use of debt financing in the past, and the willingness of its current lender to provide the necessary financing for proposed projects". [Source: Rebuttal comments received October 5, 2018, page 9]

Department Evaluation

PSKC Arlington is currently not operational so the applicant based its projected utilization for the proposed 10-station facility on its three closest facilities. The department considers this approach reasonable. WAC 246-310-815(1)(b) requires a new facility to base revenue projections on the net revenue per treatment of the applicant's three closest dialysis facilities. PSKC provided both revenue and expense projections and based them on its PSKC Smokey Point, PSKC Monroe and PSKC Everett operations. DaVita raised concerns that PSKC may be financially overextended with the applications it has submitted during the 2018 cycle 1 reviews. DaVita states that PSKC is proposing to debt finance \$25,500,000 worth of projects that it cannot claim security in its financing for those projects. A review of PSKC's application for this project, shows that it provided two financing letters.

A letter from PSKC's chief financial officer and another letter from Banner Bank. The letter from PSKC's chief financial officer stated the applicant will use a combination of debt financing and reserve as finance for this project. The letter from Banner Bank states that PSKC currently has \$3,000,000 unsecured revolving line credit and that PSKC will qualify for secured long-term financing. The department notes that PSKC withdrew two of its five applications submitted during this review cycle and was refunded portions of the review fee. DaVita did not provide documentation to show that PSKC is unable to obtain financing or that the financing letters provide PSKC are deficient. However, PSKC provided information in its rebuttal comment to assure that it was not financially overextended now, nor would PSKC take that risk in the future. The department considers the two financial letters provided by PSKC to be adequate for this project.

PSKC provided a copy of the draft Medical Director Agreement that substantiates the costs identified in the pro form revenue and expense statement. PSKC provided a commercial and investment real estate purchase and sale agreement dated March 5, 2018 and it's between Puget Sound Kidney Centers ("buyer") and Jensens Kent Prairie Farm, LLC ("seller"). PSKC states that it used reserve to purchase the real estate property. Within the application, PSKC provided a letter from its Chief Financial Officer. The letter states the cost for the real estate property has already be expensed by PSKC. If this application is approved, the department will attached conditions requiring that PSKC finance this project consistent with the information provided in the application.

Based on the information reviewed and with PSKC's agreement to the conditions identified above, the department concludes that the immediate and long-range operating costs of the project can be met. This sub-criterion is met.

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

WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, DaVita and PSKC must demonstrate compliance with the following sub-sections of WAC 246-310-815(2). Using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

WAC 246-310-815(2)

An applicant proposing to construct a finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC <u>246-310-800(11)</u> 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

For this sub-criterion, DaVita provided the following information.

"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". [Source: Application, page 20]

Specific to the costs and charges for health services, DaVita provided the statements below.

"No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project. PSKC Smokey Point currently meets the 4.5 patients per station threshold, and serves a geographically distant community centered on the Smokey Point area. The proposed facility will operate at utilization levels consistent with a 4.8 patients per station standard within three years. Finally, 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, and will actually increase patient choice of provider from one provider to two in the planning area". [Source: Application, page 20]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The estimated costs for this project is \$2,126,106, which includes all costs associated with the establishment of the dialysis center, including \$1,282,040 for building out the space. 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. Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. For the proposed DaVita Stillaguamish facility, the applicant projected that 25.02% of its

patients would be Medicare and Medicaid. Revenue from these two sources are projected to equal 55.43%. The remaining 44.57% of revenue will come from a variety of sources including private insurance.

The department notes that CMS has implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment and the rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary.

Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by DaVita about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 44.57% of revenue is combined commercial and other revenues.

To be compliant with WAC 246-310-800(11), DaVita Stillaguamish maximum floor space for a 10 station facility is 4,199 DaVita calculated that its actual floor space will be 3,325. DaVita's project does not exceed the maximum treatment floor area square footage allowable. However, the department notes above that DaVita did not take into consideration the one isolation station that is not counted at the center.¹⁰ Rather DaVita calculated its floor plans using 10 in-center stations instead of 11. When recalculated, DaVita's floor space does not exceed the 4,199 maximum space.

Based on the above information provided in the application, the department concludes that DaVita's projected costs associated with the establishment of ten-station dialysis center would probably not have an unreasonable impact on the costs and charges for healthcare services in Snohomish County planning 1. **This sub-criterion is met.**

PSKC

For this sub-criterion PSKC provided the following statement.

"As noted in response to Question 8, PSKC's charges are not determined by capital costs for new facilities. PSKC's charges are the same at each of its facilities. The development of PSKC Arlington will not result in an unreasonable impact on the costs and charges for health services in Snohomish 1". [Source: Application, page 19]

PSKC provided a copy of its proposed line drawings for PSKC Arlington. [Source: Application, Exhibit 3]

¹⁰ Consistent with WAC 246-310-809, if a new dialysis center will be established and it will provide isolation services, the isolation is not counted in the numeric need methodology, but is counted in the floor plan space for calculations.

Consistent with WAC 246-310-800(11), PSKC Arlington's maximum allowable square footage for 10 stations and one isolation station is 4,199. PSKC's project will use 2,652 square feet. [Source: Application, page 7]

Specific to the costs and charges for health services, PSKC provided the statements below.

"PSKC does not expect the project to affect the charges for its services and importantly, this project will have no effect on billed rates to patients, providers, or payers. PSKC's charges for dialysis services are not determined by its capital expenditures for new facilities". [Source: Application, page 19]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The estimated costs for PSKC Arlington is \$4,638,758, which includes all costs associated with the establishment of the dialysis center, including \$2,414,720, for building out the space. The costs are comparable to those reviewed in past applications for similar type projects and similar sized facilities. For this project, PSKC states that it relies on Botesch, Nash & Hall Architects, P.S. experience which has supported the applicant on several recent new facilities, and renovations, and it has significant cost estimating experience.

For the proposed PSKC Arlington facility, PSKC projected that 89.1% of its patients would be Medicare and Medicare Managed Care and Medicaid. Revenue from these three sources are projected to equal 74.5%. The remaining 25.5% of revenue will come from a variety of sources including private insurance.

The department notes that CMS has implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment and the rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary.

Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by PSKC about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 25.5% of revenue is combined commercial and other revenues.

Based on the above information provided in the application, the department concludes that PSKC's projected costs associated with the establishment of ten station dialysis center would probably not

have an unreasonable impact on the costs and charges for healthcare services in Snohomish 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 DaVita and PSKC's projected source of financing to those previously considered by the department.

DaVita

DaVita identified a capital expenditure of \$2,144,780 associated with the construction of the 10-station DaVita Stillaguamish. Within the application, DaVita states, "The project will be funded from DaVita's capital expenditures budget. Capital budgeting reflects appropriate allocations of funds for projects in the Pacific Northwest. A letter from Mike Staffieri, Chief Operating Officer, committing to these funds is included as Appendix 6". [Source: Application page 22]

DaVita also provided a copy of its audited financial statements for years 2015, 2016, and 2017 to demonstrate sufficient reserves to finance the project. [Source: Application, Appendix 10]

Specific to the costs and charges for health services, DaVita provided the statements below.

"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 Arlington, Snohomish County rate of 9.1% for all fixtures, furnishings, and equipment, and where else applicable". [Source: Application, page 19]

Department's Table 7
DaVita Stillaguamish Dialysis Center Estimated Capital Costs

Item	Total
Building Construction	\$1,282,040
Fixed & moveable equipment	\$605,858
Washington State sales taxes and fees	\$254,882
Total Estimated Capital Costs	\$2,144,780

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita intends to fund the project using corporate reserves and it provided a letter from its chief operating officer for kidney care to demonstrate an operational and financial commitment to the project. 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**.

PSKC

PSKC provided the following information about financing the \$4,638,758 associated with the construction of the 10-station PSKC Arlington facility.

Within the application, "PSKC will debt-finance \$6,500,000 of the approximately \$7.4 million of the proposed project. Included in Exhibit 5 is a letter from Banner Bank outlining the terms of the financing. The remaining costs (\$843,636) will be funded from reserves. These reserves were already expended for the land purchase. Also included in Exhibit 5 is a letter from Mr. Ken Kouchi, CFO, confirming the use of reserves for the remaining project cost". [Source: Application, pages 16 and 18]

"Botesch, Nash & Hall Architects, P.S. provided the estimated costs for building construction, fixed equipment and architectural and engineering fees. Botesch, Nash & Hall Architects, P.S. has supported PSKC on several recent new facilities, and renovations, and has significant cost estimating experience. PSKC was responsible for providing the estimated capital expenditure related to the "Moveable Equipment" and "Other" items". [Source: Application, page 18]

Department's Table 8 PSKC Arlington Kidney Center Estimated Capital Costs

Item	Total
Building Construction	\$2,899,720
Fixed & moveable equipment	\$886,122
Washington State sales taxes and fees	\$852,916
Total Estimated Capital Costs	\$4,638,758

PSKC also provided a copy of its financial statements/audited financial statements for years 2014, 2015; and 2017 to demonstrate sufficient reserves to finance the project. [Source: Application, Appendix 1]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC intends to debit finance this project with bank loan and reserves. PSKC provided two letters that demonstrated that funds needed for this project, would be available. If this project is approved, the department would attach a condition requiring PSKC to finance the project consistent with the financing description provided in the application. With a financing condition, the department concludes the PSKC's 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.

Puget Sound Kidney Centers

Based on the source information reviewed and agreement to the conditions identified in the "conclusion" section of this evaluation, the department concludes that Puget Sound Kidney Centers has the financial feasibility 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

To comply with this sub-criterion DaVita provided the following statements.

"Table 13 presents the staffing for DaVita Stillaguamish Dialysis Center. The salary and wage and benefit costs for the facility are detailed below". [Source: Application page 22]

DaVita's Proposed Staffing Table 13A

FTE by Type	FY 21	FY 22	FY 23	FY 24
Administrator	0.75	1.00	1.00	1.00
Administrative				
Assistant	0.75	1.00	1.00	1.00
Medical Social Worker	0.03	0.15	0.29	0.39
Dietician	0.03	0.15	0.29	0.39
RN-In-Center	0.11	0.50	0.97	1.28
LPN		-	-	-
PCT	0.32	1.50	2.91	3.85
RN-PD	0.06	0.08	0.17	0.28
RN- HHD	-	-	-	-
Biomed Tech	0.28	0.28	0.28	0.28
Other	0.06	0.24	0.47	0.64
Total FTEs	2.39	4.9	7.38	9.39

DaVita provided the following clarification regarding the staffing table above.

"Other" includes, among other miscellaneous categories, patient education and inventory management roles, as well as staff training. DaVita also notes that the existing FTE table did not show data for partial year 2021 separately requested, and provides the amended Table 13A with that

information below. Table 13A also reflects the responses to the Department's questions dated July 16, 2018". [Source: Screening response received July 31, 2018, page 4]

Focusing on recruitment and retention of necessary staff, DaVita provided the following information.

"DaVita does not expect any significant barriers to recruiting staff for Stillaguamish 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 Stillaguamish 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 the Snohomish County area". [Source: Screening response received July 31, 2018, page 4]

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 Snohomish County. A review of DaVita's projected FTE increase for DaVita Stillaguamish shows that most of the increase is expected to occur by year 2024. By that year, DaVita anticipates it will have a total of 9.39 FTEs. DaVita expects that the most increase in FTEs will occur in the PCT category which is projected to increase by 3.53 between year 2021 and year 2024. The in-center RN would increase by 1.17 in the same time period. For the other category consisting of FTEs who provide patient education, inventory management roles, and training hours this category would increase slightly.

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**.

PSKC

PSKC provided the following staffing table showing projected staff for the new dialysis center.

"Table 12 details the proposed staffing for the new facility". [Source: Application page 22]

PSKC's Table 12
Puget Sound Kidney Centers Proposed Staff

FTEs	2021	2022	2023
Staffing Needs	FTE	FTE	FTE
Stations	10	10	10
Clinical Service			
Direct Care Manager	0.60	1.00	1.00
Home RN	0.20	0.30	0.50
Registered Nurse	2.00	2.00	3.00
Dialysis Techs	3.00	4.50	5.25
Technical Services			
BioMed Tech	0.40	0.60	0.80
Computer Technician	0.10	0.10	0.10
Social Services			
Social Worker	0.30	0.40	0.50
Nutrition Services			
Dietitian	0.30	0.40	0.50
Administrative Services			
Administrative Asst.	0.60	0.80	1.00
FTE Totals	7.50	10.10	12.65

PSKC also provided the following clarification regarding the staffing table above.

"The staffing was based on PSKC's actual experience. PSKC schedules direct patient care staff to maintain a safe and efficient level of care. General patient staffing ratios are:

- Dialysis Technician 4:1 (Isolation 1:1)
- Registered Nurse 16-20:1
- Social Worker 100:1
- Renal Dietitian 100:1
- Home Registered Nurse 18-22:1
- Care Coordinator 80-100:1

All other personnel are determined by days and hours in operation. The average wage/FTE identified is based on PSKC's known average labor cost and the years of employment/step at which the majority of staff work. Consistent with WAC 246-310-815(c), which states that new facilities should use known expenses, PSKC based its staffing on empirical experience. We believe this accurately identifies labor cost". [Source: Application, page 22]

Focusing on recruitment and retention of necessary staff, PSKC provided the following information.

"In addition to providing exceptional patient care, PSKC offers a competitive wage and benefit package for staff, a positive and supportive work environment, and a philosophy that encourages

existing staff to receive training and additional education. For each of these reasons, PSKC has not experienced difficulty recruiting and retaining qualified staff in any facility. PSKC's goal is to "grow" its own, and PSKC's training, education and flexible human resource policies have allowed PSKC to excel with this strategy.

Based on our historical record and performance, we do not anticipate any significant difficulties recruiting the staff needed for this new facility". [Source: Application, page 22]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that PSKC is a well-established provider of dialysis services in Washington State and in Snohomish County. Many of its Snohomish County dialysis centers have been operational for many years

A review of PSKC's projected FTE increase for PSKC Arlington shows that most of the increase is expected to occur by year 2023. By that year, PSKC anticipates it will have a total of 12.65 FTEs. PSKC expects that the most increase in FTEs will occur in the dialysis techs category which is projected to increase by 2.25 between year 2021 and year 2023. The in-center RN position would increase by 1.00 FTE in the same time period. For the other category consisting of FTEs who provide patient education, inventory management roles, and training hours this category would increase slightly.

Based on the above information, the department concludes that PSKC's 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

DaVita provided the following information for this sub-criterion.

"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". [Source: Application, page 25]

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 with a physician associated with The Everett Clinic, PLLC known as Oliver Tai, MD. The agreement also identifies Dr. Katrina G. Carle and Dr. Noemie Juaire as preapproved physicians who can provide services at the facility. The medical director agreement identifies roles and responsibilities for both DaVita and Dr. Oliver Tai. Additionally, all costs are identified in the agreement. [Source: Application, page 24 and Appendix 3]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

While DaVita Stillaguamish will be a new center in Snohomish County planning area #1, it is not DaVita's only center in Snohomish County or in Washington State. Consistent with the approached used in applications where a new dialysis center would be established, the department accepts either draft agreements or 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 10 station dialysis center. The agreement is between Charemont Dialysis Center, LLC (a subsidiary of DaVita) and The Everett Clinic, PLLC. The agreement outlines all roles and responsibilities for each entity, includes all costs associated with the agreement, and has an initial term of five years. At the end of five 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 for the new facility. The department also concludes that all other required ancillary and support agreements and relationships can be established.

Based on the information, the department concludes that DaVita demonstrated that it would have the necessary ancillary and support services at DaVita Stillaguamish Dialysis Center. This subcriterion is met.

PSKC

To comply with this sub-criterion, PSKC provided the following information.

"Table 13 provides a listing of the proposed ancillary and support services required for PSKC Arlington. While vendor(s) are identified for several of these services (current PSKC vendors), no specific agreements have been entered into at this time. [Source: Application page 22]

"PSKC Arlington will provide the full range of Medicare required ancillary and support services including:

Administration	Patient Financial Counseling
Information Systems	Plant Operations
Material Management	Social Services
Nursing Services	Staff Education
Nutrition Services	Technical Services
Patient Education"	

[Source: Application page 25]

"Table 14 details the ancillary and support services and indicates which would be provided onsite and which would be provided offsite through PSKCs Corporate.

PSKC's Table 14 Proposed Ancillary and Support Services for PSKC Arlington

Services	Offered Onsite/Offsite
Administration	Offsite
Human Resource	Offsite
Information Systems	Offsite
Materials Management	Offsite
Nursing Services	Onsite
Nutrition Services	Onsite
Patient Education	Onsite
Patient Financial Counseling	Offsite
Plant Operations	Onsite
Social Services	Onsite
Staff Education	Offsite
Technical Services	Onsite

"PSKC will expand its long-standing relationships in Snohomish County, to include, at minimum, the health care facilities/providers/organizations identified in Table 15". [Source: Application page 26]

"Per PSKC's July 10, 2018, conversation with CN Program Staff, we understand that this question should include information about how PSKC's existing or proposed relationships will promote continuity in the provision of health care services. Therefore, to respond fully, we elected to replicate Table 15 of the CN application, and add two columns: the first documents the current status of the relationship; the second how the relationship promotes continuity of care.

PSKC Revised Table 15

PSKC's Arlington Proposed Working Relationships

Category	Organization/Scope	Status of PSKC	How relationship support continuity
		Relationship (Existing or to be established)	
Hospitals	Providence Everett Regional Medical Center Skagit Valley Hospital, Mount Vernon Cascade Valley Hospital Arlington	Existing executive and clinical relationships with area hospitals	Coordination with care managers and discharge staff to ensure that PSKC has information about discharge timing and need for dialysis. In addition, PSKC provides acute dialysis at the Providence hospitals.
Public Health	Snohomish Health District for supportive health services for patients	Existing relationship to be expanded to include PSKC Arlington	Supportive services including public health notices related to infectious diseases are provided
Emergency Planning	Northwest Kidney Centers & Olympic Peninsula Kidney Centers - "Mutual Aid Agreement" for dialysis services during emergencies	Existing agreement to be expanded to include PSKC Arlington.	Emergency and disaster planning assures capacity is in place.
Clinicians	 Western Washington Medical Group, North Sound Kidney Physicians DaVita Medical Group, aka The Everett Clinic PolyClinic Kaiser Permanente Many other independent physician group practices 	Existing relationship to be expanded to include PSKC Arlington	Coordination with physicians/staff to ensure that information regarding dialysis patients is communicated with PSKC's patient's individual physicians. In addition, invitations to PSKC's continuing education monthly sessions are extended to all physician groups as well.
Transportation	 Community Transit – DART bus service in Snohomish County TAP – Bus service for rural areas of North Snohomish County Paratransit services – Medicaid transportation broker DSHS Home and Community Services DSHS Department of Vocational Rehabilitation 	Existing relationships will be expanded to include PSKC Arlington	PSKC staff work with transportation staff to set up and coordinate individual patient transportation needs.

Category	Organization/Scope	Status of PSKC Relationship (Existing or to be established)	How relationship support continuity
	Stillaguamish Senior Center		
Long-Term	■ Golden Villa Care Center,	Existing relationships	For nursing home
Care	Marysville	will be expanded to	patients needing
	 Marysville Care Center, 	include PSKC	dialysis, PSKC works
	Marysville	Arlington	with nursing home staff
	 Josephine Caring 		to set up and coordinate
	Community, Stanwood		a dialysis schedule. In
	Parkway Nursing Center,		addition, PSKC keeps
	Snohomish	×	nursing home staff
	Madeleine Villa Health Care		informed of the
	Center, Marysville		patient's dialysis care.
	 Arlington Health and 		
	Rehabilitation, Arlington		
	 Regency Care of Arlington 		
	Brookdale Assisted Living,		
	Stanwood		28
	Mountain View		
TT: 1	Rehabilitation, Marysville		
Higher	• Everett Community	Existing	As noted in earlier
Education	College	relationships will be	sections, PSKC
	 Skagit Valley College 	expanded to include	currently serves as a
	Bastyr University,	PSKC Arlington.	clinical site.
	Kenmore	PSKC Arlington will	
	University of Washington	be offered as a	
	School of Public Health	clinical training site.	

PSKC provided the following information about a Patient Transfer Agreement for the new dialysis center. "In addition, a copy of an existing transfer agreement with Providence Regional Medical Center, Everett is included in Exhibit 14. This agreement will be modified to include PSKC Arlington." [Source: Application, page 27 and Exhibit 14]

PSKC also provided a copy of a draft Medical Director Agreement with Dr. Mark Gunning, MD. The draft agreements identifies roles and responsibilities for both PSKC and Dr. Mark Gunning. Additionally, all costs are identified in the agreement. [Source: Application, page 23 and Exhibit 7]

The department received public comments from DaVita related to PSKC medical director for the proposed PSKC Arlington. The comments are restated below.

PSKC's draft medical director agreement is unreliable

"The Department requires a Medical Director Agreement ("MDA") that, if in draft form, may be conditioned for signature by time of facility opening, in keeping with CMS regulation. That is, the MDA must have been fully negotiated by the parties, and be ready for signature at time of submission to the Department.

It logically continues that if the medical director named in the draft agreement is one whom the ESRD provider has no intent of using as its medical director in the facility for the projection period

that agreement cannot have been fully negotiated with the actual intended medical director, and is unreliable for Certificate of Need purposes.

PSKC names Dr. Mark Gunning as the proposed medical director for PSKC Arlington in its draft medical director agreement, Exhibit 7 of the Application. Dr. Gunning, according to PSKC's organizational chart from Exhibit 1 of its application (18-55), replicated below and circled in red, is the Corporate Medical Director for PSKC (he also holds Hospital medical directorship duties).

The Department actually has a history with PSKC and Dr. Gunning. When PSKC applied for stations in Pierce County ESRD Planning Area #5 in in 2016 (an application that ultimately resulted in the decision to grant PSKC a 29-station dialysis facility in Lakewood, WA), its original named medical director was Dr. Paramita Mukherjee. In PSKC's screening question responses for its Lakewood application, dated July 27, 2016, PSKC replaced Dr. Mukherjee with Dr. Gunning and submitted a signed medical director agreement in his name – no longer a draft agreement. In its responses, PSKC averred, "Dr. Gunning also serves as PSKC's Corporate Medical Director. The Corporate Medical Director position is an independent contractor position, and as such Dr. Gunning has sufficient time, and is highly qualified to assume the medical directorship of PSKC-Lakewood." (PSKC Lakewood Screening Responses, July 27, 2016, Question #26).

One would expect that if PSKC actually intended to contract with Dr. Gunning as a medical director in Lakewood consistent with the signed medical director agreement it submitted to the Department in 2016 and its representations to his qualifications, Dr. Gunning would be the medical director when Lakewood opened (scheduled for Summer 2019). Dr. Gunning will not be, and the Department need not take DaVita's word for it. Going back to the organizational chart in Exhibit 1 of the Arlington Application, see the medical director section enlarged for clarity below.



Dr. Añel is slated to be the PSKC Lakewood medical director when the facility opens, which would violate his existing non-compete agreement with DaVita in his MDA at Cooks Hill.2 PSKC never intended to use Dr. Gunning as Medical Director in Lakewood, even though it submitted a signed MDA to the Department. All one has to do is look at the non-compete clause PSKC submitted with Dr. Gunning's signed Lakewood MDA in the Screening Responses dated July 27, 2016. Its text reads as follows:

11. <u>Practice Commitment.</u> Mark Gunning, M.D. will not serve as Medical Director or related role with other dialysis organizations, facilities or programs operating in Snohomish, Skagit, or Island Counties without prior written consent of the PSKC President and CEO.

What rational provider, believing its quality improvement programs and intellectual property were valuable and worth protecting, would sign an agreement it intended to honor with a physician to provide medical director services in its facility that allowed that physician to take those programs and intellectual property to a competitor that was literally located next door? There is not one.

PSKC never intended to use Dr. Gunning as its medical director in Lakewood, and PSKC does not intend to use Dr. Gunning as its medical director in Arlington. PSKC was so desperate to not use Dr. Gunning in Lakewood that it replaced his signed agreement with an agreement with a physician, Dr. Ramon Añel, who has an existing non-compete in effect for the location. PSKC has an established practice of using Dr. Gunning via his existing financial relationship with PSKC as Corporate Medical Director as a placeholder in its Certificate of Need applications to the Department, nothing more.

A placeholder does not indicate a negotiated agreement. It does not indicate that PSKC has even identified its planned actual medical director, much less had a conversation with that individual. It does not indicate that the compensation, term, non-compete, or any other terms, have been discussed with that individual. It does not indicate that PSKC's medical director compensation of \$40,000, tied with one other PSKC application for the lowest proposed or current medical director compensation identified in any of the 29 special and non-special circumstances applications submitted in 2018 Cycle 1, is acceptable to any other possible medical director in the region given its lack of market competitiveness.

PSKC's proposed draft medical director agreement is unreliable for Certificate of Need purposes. Its terms have not been negotiated with whomever PSKC actually plans to use as medical director in Arlington. PSKC has shown a history of using placeholder medical directors, even in signed agreements, for CON purposes. It will show no compunction in doing the same with a draft agreement. The Department is not able to rely on PSKC's draft medical director agreement to satisfy both structure and process of care or financial feasibility". [Source: Public comments received September 5, 2018, pages 2-4]

In response to DaVita's public comments, PSKC provided its rebuttal comments. The comments are restated below.

PSKC's draft medical director agreement is reliable and meets all CN requirements

"PSKC agrees with DaVita that an Agreement in draft form is acceptable. We note for the record, an agreement is acceptable in draft form when it meets the four requirements identified in the CN guidelines related to draft agreements. These guidelines, included on page 2 of the CN application packet for dialysis applications state:

If any of the documents provided in the application are in draft form, a draft is only acceptable if it includes the following elements:

- a. identifies all entities associated with the agreement,
- b. outlines all roles and responsibilities of all entities,
- c. identifies all costs associated with the agreement, and
- d. includes all exhibits that are referenced in the agreement.

The PSKC draft Agreement meets each of these requirements. Further the CN guidelines require:

At B1:

- 1. Provide the following agreements/contracts:
 - Management agreement.
 - Operating agreement
 - Medical director agreement
 - Development agreement
 - Joint Venture agreement

Note, all agreements above must be valid through at least the first three full years following completion or have a clause with automatic renewals

And, at C4:

4. Provide the name and professional license number of the current or proposed medical director. If not already disclosed under 210(1) identify if the medical director is an employee or under contract.

The draft Agreement PSKC submitted met the requirements of both B1 and C4.

DaVita questions the sincerity of PSKC's plan to contract with Dr. Gunning as the Medical Director of the new facility, dismissing him as a "placeholder" because (1) as of the time of the original CN application of June 2018, Dr. Gunning was serving as the Corporate Medical Director for PSKC, (2) he was replaced as medical director for our under-construction Lakewood unit prior to its opening, and (3) the non-compete clause in the draft Agreement is for different counties than DaVita would require of "its own" medical directors. DaVita has no knowledge of Dr. Gunning's current medical directorship roles, responsibilities and time commitments, and its speculations are without merit. PSKC is fully prepared to finalize the Medical Director agreement with Dr. Gunning, and have Dr. Gunning sign the agreement as drafted.

First, Dr. Gunning has been a trusted colleague of PSKC for many years. He has served capably in a number of roles with PSKC, including Corporate Medical Director through August 2018. While serving in that role, Dr. Gunning also served as medical director in one or more capacities, including MD of our Anacortes unit (as evidenced by Exhibit 1

to our Application). He previously served as medical director for other units, too, and beginning in September 2018 is serving in that role for our Everett unit. In short, Dr. Gunning is a well-qualified and experienced medical director with a demonstrated capacity to provide medical direction in multiple roles for PSKC. We believe he is an exceptional choice to serve in that same capacity for our proposed Arlington facility. Notwithstanding DaVita's breathless conjectures, Dr. Gunning is no mere placeholder. PSKC fully expects that Dr. Gunning will serve as PSKC Arlington's medical director upon the opening of its operations.

Second, DaVita raises an issue, totally unrelated to this application, regarding the proposed medical director of PSKC's new Pierce 5 Lakewood unit. As it notes, PSKC negotiated and executed a medical director agreement with Dr. Gunning during screening for Lakewood, when the original proposed medical director, Dr. Mukherjee, became unexpectedly unavailable because she moved and changed practices. That signed agreement was fully enforceable, but less than ideal given the travel times involved for Dr. Gunning. We later identified another possible medical director for Lakewood, Dr. Ramon Añel. At the time Dr. Añel agreed to be medical director of our Lakewood unit, he had forgotten that he had entered into a non-compete with DaVita. He has attested to this fact in an email included in Attachment 1. We fully expect that confusion to be resolved well before that facility opens in 2019. In any event, DaVita is completely mistaken in its suggestion that the events in Lakewood somehow prove that Dr. Gunning is unable or unwilling to serve as medical director at PSKC Arlington.

Third, it is PSKC's business decision when and how to negotiate a non-compete clause in its agreements. PSKC is fully prepared to enter into a Medical Director agreement with Dr. Gunning and have Dr. Gunning sign the agreement as drafted. DaVita's speculations to the contrary are without merit. Indeed, DaVita's objection here is chiefly notable for what it demonstrates about DaVita's own competitive philosophy. Given the rapidly growing dialysis population in the State, and the documented shortage of nephrologists, DaVita's expansive and restrictive non-compete requirements are burdensome on the entire delivery system...

In any event, nonessential changes to a draft agreement (that is, changes to terms other than the roles and responsibilities, costs, and exhibits) are permitted; the CN rules and prior CN Program decisions require only that the final signed agreement be consistent with the draft, not that it be identical.

Even were the final agreement between PSKC and Dr. Gunning to include amendments to minor details from the draft, such as the geographical extent of the non-compete clause as raised by DaVita, it would not change the essential terms of the agreement as contemplated by the draft. DaVita's concerns, even if valid, would thus be fully addressed by a condition on PSKC's CN that the final Medical Director Agreement be submitted prior to opening, and that the final signed document be consistent with the draft submitted with our application.

Even if DaVita's objections had any merit (and they do not), it would have no bearing on the strength and completeness of our Application. The Program has regularly allowed changes to applicant's medical directors between CN application approval and time of opening, including for DaVita. Notably, CN guideline C4 does not require nor state that there be no future modification regarding the proposed medical director, whether before or after facility opening. Given the years-long

development cycle for most medical facilities, a strict rule requiring no changes to staffing between application and opening would be entirely unworkable. Moreover, the Department's HLJ clarified in a 2012 Final Order that naming a specific medical director is not a core CN requirement, and that in fact the medical director requirement is merely a proxy for the requirement that the applicant demonstrate qualified staffing:

...PSKC fully intends to engage Dr. Gunning as the Medical Director. PSKC has met all requirements, including showing its capacity to enlist sufficient qualified staff for PSKC Arlington. DaVita's argument is again, at its core, a desperate effort to have the PSKC application rejected before superiority". [Source: Rebuttal comments received October 5, 2018, pages 2-6]

Department Evaluation

As previously stated, PSKC has been operating dialysis facilities in Snohomish County for many years and has established ancillary and support agreements in place for its Snohomish County facilities. PSKC states it would use the same strategies to establish ancillary and support agreements for the proposed facility.

PSKC provided a draft Medical Director Agreement between itself and Dr. Mark Gunning, MD. The draft agreement identifies all roles and responsibilities for both entities and includes all costs associated with the agreement. DaVita expressed concerns about the draft agreement and states that PSKC did not engage the medical director it purported it would use in previous applications. DaVita implies that PSKC provided the same draft agreement in each of its applications submitted during this review cycle and suggests that the agreement is merely a 'place-holder' by PSKC to obtain CN approval. DaVita further implies that PSKC may not even implement the Medical Director Agreement with Dr. Mark Gunning. After reviewing the agreement, staff does not come to the same conclusion as DaVita. The agreement is valid and typical of agreements that are conditioned if the project is approved.

Because of the many comments provided by PSKC and DaVita, department is compelled to clarify information provided in PSKC's rebuttal. Below is an excerpt of the many rebuttal comments provided by PSKC in response to DaVita's public comment.

"...Much time was spent arguing this issue in motions and at hearing. However, as indicated, the whole issue of identifying the Medical Director by name is a non-issue. There is no requirement in statute or CN regulation that the actual Medical Director be named in the CN Application. The requirement in WAC 246-310-230 "Criteria/or Structure and Process of Care" is that the applicant demonstrate that there is a sufficient supply of qualified staff that can be recruited and that the proposed service has appropriate organizational structure..."

PSKC appears to consider the identification of the medical director to be 'non-issue.' The department does not. While there are unforeseen circumstances where a medical director may change after the project is approved, this action is not considered to be standard. None of the Washington State dialysis providers, including PSKC, have a history of changing the medical director on a regular basis after approval. If this project is approved the department would attach a condition to the approval requiring PSKC to provide a copy of the executed Medical Director Agreement consistent with the draft agreement.

PSKC provided a copy of the draft Medical Director Agreement that substantiates the costs identified in the pro form revenue and expense statement. However, DaVita provided public comment that calls into question the validity of this agreement. DaVita first argued that the medical director agreement is simply a template. The department recognizes that like-type agreements from the same provider will often bear a number of similarities. Because the focus of this application, is for the proposed PSKC Arlington project, the department disagreed with DaVita's assertion that the draft agreement submitted by PSKC is not proper.

A review of the draft medical director agreement shows that the costs and terms of the agreement are consistent with draft documents the department normally accepts from applicants. The costs identified in the draft medical director agreement can be substantiated in the revenue and expense statement submitted by PSKC. If this project is approved, the department would attach a condition requiring PSKC to provide its executed medical director agreement consistent with the draft provided in the application.

PSKC's existing Patient Transfer Agreement is with Providence Regional Medical Center in Everett. If this project is approved, PSKC intends to expand the current agreement to include PSKC Arlington. Since there are no costs associated with Patient Transfer Agreements, applicants are not required to identify the hospital in the draft agreement. This approach by PSKC is acceptable. If this project is approved, the department would attach a condition to the approval requiring PSKC to provide a copy of the executed Patient Transfer Agreement with the new facility included.

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

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

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

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

DaVita

DaVita provided the following statement in response to this sub-criterion.

"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." [Source: Application pages 26-27]

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 these projects, 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

DaVita reports dialysis services to CMS for approximately 2,728 facilities in 45 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. 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]

In this application, DaVita provided its medical Director Agreement with The Everett Clinic. The agreement identifies Dr. Oliver Tai, MD as the medical director and Katrina Carli, MD and Noemie Juaire, MD, as the pre-approved physicians for medical director services. Using data from the

¹¹ The three centers are: Belfair Dialysis Center in Mason County, Cooks Hill Dialysis Center in Lewis County, and Renton Dialysis Center in King County.

Medical Quality Assurance Commission, the department found the 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 two 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.

PSKC

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

"PSKC has no history with respect to the actions noted in CN regulation WAC 246-310-230(5) (a). In fact, and as detailed in the cost containment section, PSKC has documented high quality per the CN Program's new superiority indicators (WAC 246-310-827).

In its most recent CN approval for PSKC, the Program reviewed PSKC's quality and compliance with state and federal requirements. As part this review, the CN Program considered the CMS star ratings for each of PSKC's six operational facilities. In that review, the CN Program found that each of the facilities had a 3 star or better rating. PSKC has updated the CMS Star Ratings and as noted in Table 16, all facilities now rate as a 4 or 5." [Source: Application, Page 28-29]

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 these projects, 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

PSKC does not operate any out of state facilities.

CMS Star Rating for Washington State Centers

PSKC owns, operates, or manages 7 facilities, and of those, 6 are currently operational. For the 6 facilities with a star rating, the average rating is 4.33.

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 6 of the 7 PSKC facilities are operational, in the most recent three years, three facilities have been surveyed. All surveys resulted in no significant non-compliance issues. [Source: DOH OHSO survey data]

In this application, PSKC identified Mark Gunning, MD as the proposed medical director for PSKC Arlington. Using data from the Medical Quality Assurance Commission, the department found that the medical director is compliant with state licensure and has no enforcement actions on the license. Given that PSKC 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 PSKC. The department also considered the compliance history of the medical director associated with the facility. The department concludes that PSKC 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 PSKC's compliance history. The department concludes that PSKC'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 and size. Therefore, using its experience and expertise the department assessed the materials in the application.

DaVita

To comply with this sub-criterion DaVita provided supporting documentation to demonstrate compliance with this sub-criterion. The documents focuses on DaVita's Continuous Quality Improvement (CQI) program and the April 2018 press release for Top Clinical Outcomes. [Source: Application, page 25 & Appendix 17]

"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 copy of a draft transfer agreement between DaVita Green Lake Dialysis Center and an area care hospital 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 Stillaguamish Dialysis Center will have an appropriate relationship to the service area's existing health care system. DaVita Stillaguamish 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 Snohomish 1 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." [Source: Application, page 25-26]

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 Snohomish 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.

PSKC

PSKC provided the following information for this sub-criterion.

"As with all PSKC facilities, PSKC Arlington will provide a collaborative, comprehensive, and patient-centered approach to the provision of dialysis services. In addition, PSKC's unrelenting focus on high-quality, compassionate care, coupled with respect for the patients, staff, and other providers has served the community well. Without dispute, PSKC's quality is outstanding as evidenced by publicly available metrics and the CN Program's own superiority indicators. With the establishment of this new facility, PSKC will continue to maintain all existing working relationships that support care in Snohomish 1". [Source: Application, page 28]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC has been a provider of dialysis services in Washington State for many years and it has a history of establishing relationships with existing healthcare networks in Snohomish and Clallam counties. Additionally, PSKC'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.

PSKC 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 PSKC's project meets this sub-criterion.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

Department Evaluation for DaVita

This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.

Department Evaluation for Puget Sound Kidney Centers

This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.

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

DaVita, Inc.

Based on the source information reviewed, the department concludes that the DaVita, Inc. project did not meet the cost containment criteria in WAC 246-310-240.

Puget Sound Kidney Centers

Based on the source information reviewed, the department concludes that the Puget Sound Kidney Centers project meet the cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives</u>, 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. <u>Step one</u> 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 <u>step two</u>, 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 <u>Step three</u>. The department completes step three under WAC 246-310-827.

Step One

DaVita

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

PSKC

For this project, PSKC met the applicable review criteria under WAC 246-310-210, 220, and 230

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Both applicant's met the review criteria under WAC 246-310-210, 220, and 230. The department will review both applications under step two below.

Step Two

DaVita

For this sub-criterion, DaVita provided the statements below.

"Alternative 1: Do nothing. That is, do not apply for additional stations in the Snohomish 1 planning area. Snohomish 1 is growing in ESRD population, with a three-year annualized in-center ESRD census growth rate of 10.49% and demonstrated need for ten (10) stations. Census projections covering the first three full years of operation provide evidence that continued planning area census growth will necessitate additional capacity for dialysis patients. With strong demand for access to dialysis services but no application, patients may be forced to dialyze at less convenient times, locations, or even out of the planning area entirely. This alternative was rejected.

Department Evaluation

DaVita currently operates a dialysis facility in Snohomish County. DaVita provided a comprehensive discussion of alternative of not submitting an application. After reviewing the information, the department concludes that DaVita appropriately rejected the alternative before submitting its application.

PSKC

PSKC identified the following options before submitting this application.

"PSKC evaluated three options:

- Acquire property and design a facility such that PSKC would be prepared to submit a CN application,
- Expand the existing PSKC Smokey Point facility; or
- Do nothing.

"Given the need for additional stations in Snohomish 1, and while PSKC Smokey Point was initially plumbed for 36 stations, PSKC chose to establish a new facility for the following reasons:

- Between our Smokey Point, Everett, and Monroe facilities, we have approximately 35-40 patients that reside in or around our proposed location in Arlington, and many of these patients have requested a PSKC option that involves less travel.
- Cascade Valley Hospital, Arlington has encouraged PSKC to consider placing a facility closer to residents in and around Arlington.
- While PSKC Smokey Point has space to expand, it is PSKC's desire to build and operate facilities in locations convenient for patients, facilities that are warm and inviting.

In the end, improving access for patients was the determinant. Some patients will realize more than 20 minutes/day in time saved, or nearly 50 hours per year. PSKC is confident in our ability to build and staff the facility, while maintaining operational efficiency and significantly lower patient charges. In addition, the new facility, PSKC Arlington, will be located on a site owned by PSKC and designed and custom built from the ground up. This gives us the unique opportunity to consider patient comfort and amenities, quality, safety, staff efficiency and support at every decision point. PSKC Arlington will be architecturally and aesthetically pleasing to patients and staff, and the community will be proud of the facility PSKC will build and operate. PSKC is confident the dialysis community will reap the benefits of our unrelenting focus on improved access to care, quality of care, and cost of care". [Source: Application, page 31]

Public comment

None

Rebuttal

None

Department Evaluation

PSKC currently operates many dialysis facilities in Snohomish County. PSKC provided a comprehensive discussion of alternatives considered, including not submitting an application. After reviewing the information, the department concludes that PSKC appropriately rejected all other alternatives before submitting its application.

Step Three

WAC 246-310-827 states: For purposes of determining which of the competing applications should be approved, the criteria in this section will be used as the only means for comparing two or more applications to each other. No other criteria or measures will be used in comparing two or more applications to each other under any of the applicable sub-criteria within WAC <u>246-310-210</u>, <u>246-310-220</u>, <u>246-310-230</u> or <u>246-310-240</u>.

WAC 246-310-827(3)-(10) outline the process for identifying a superior project if more than one application met the applicable review criteria discussed above. As stated in the introduction section of this evaluation, the data submitted under WAC 246-310-803 is collected and scores are calculated prior to the submission of any applications. Per WAC 246-310-827(5), providers had the opportunity to comment and submit corrections during the development of the scores. The dataset was final as of the first working day of April in 2018. Public comment or rebuttal to update or correct this data during the review of these projects is not accepted.

Using the superiority workbook posted April 2, 2018, the department has identified the final scoring of each applicant. The worksheet is attached in Appendix B to this evaluation. The summary is below.

Applicant	Score
DaVita, Inc.	23.17
Puget Sound Kidney Centers	25.50

As shown in the table, DaVita had a score of 23.17 and PSKC had a score of 25.00. WAC 246-310-827(9) provides the following direction.

"The application with the highest total score will be the superior alternative for the purpose of meeting WAC <u>246-310-240(1)</u>."

Based on WAC 246-310-827(9) above, PSKC is considered the best available alternative for the community and meets this sub-criterion. DaVita did not meet the sub-criterion.

- (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

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

Department Evaluation for PSKC

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

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC capital expenditure involves constructions, equipment and associated sales tax, this sub-criterion is met

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

PSKC

In compliance with this sub-criterion, the applicant states,

"While PSKC Arlington will not obtain official LEED certification, PSKC Arlington will utilize energy efficient lighting and mechanical systems, as well as building materials (ex: carpeting) that use recycled material content and finishes. In addition, PSKC Arlington will be designed to meet or exceed current energy code requirements. High efficiency systems, including water infiltration systems, with lower life-cycle operating costs will be used wherever possible. Finally, in terms of operational efficiency, the building will be designed to maximize site lines for caregivers, the viewing of the patients, by the providers and minimize the number of steps providers need to take care of patients; resulting in overall operational efficiency". [Source: Application page 33]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC's project could have the potential to improve delivery of dialysis services to the residents of Snohomish County planning area #1 with the establishment of a 10 station kidney dialysis stations in the planning area. **This sub-criterion is met**

DaVita, Inc.

DaVita provided the following information for this sub-criterion.

"DaVita Stillaguamish Dialysis 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." [Source: Application, page 28]

Public Comment

None

Rebuttal Comment

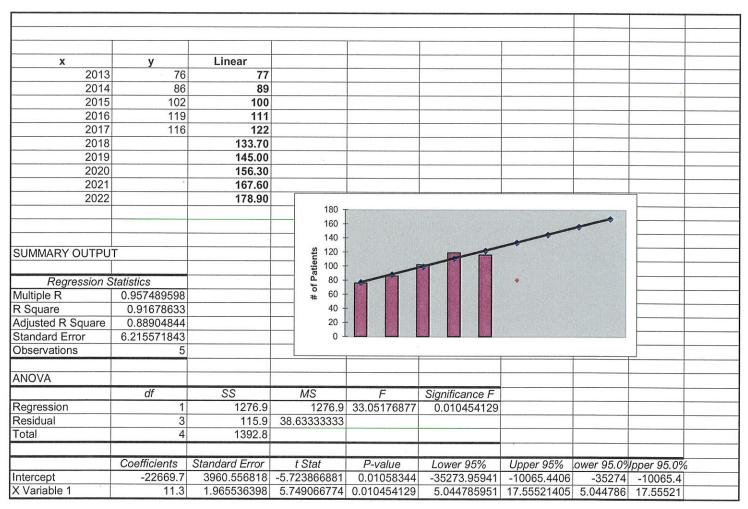
None

Department Evaluation

DaVita's project could have the potential to improve delivery of dialysis services to the residents of Snohomish County planning area #1 with the addition of 10 dialysis stations in the planning area. **This sub-criterion is met.**



2018 Snohomish County 1 ESRD Need Projection Methodology



Snohomish #1 Superiority Review

Data Element	DV Pilchuck	DV Everett	DV Cascade	Average
Home Training	0.00	1.00	0.00	0.33
Shift after 5:00	1.00	1.00	1.00	
Nursing Home Score	2.00	2.00	3.00	
Comorbidity Score	2.50	3.75	6.25	4.17
SMR	2.00	2.00	2.00	
SHR	2.00	2.00	2.00	2.00
Total Performance Score	10.00	6.00	10.00	8.67
Net Revenue Per Treatment	1.00	3.00	4.00	2.67
Total				23.17

Data Elemenț	PSKC Smky Pt	PSKC Monroe	PSKC Everett	Average
Home Training	1.00	1.00	1.00	1.00
Shift after 5:00	1.00	1.00	1.00	1.00
Nursing Home Score	3.00	5.00	3.00	3.67
Comorbidity Score	5.00	5.00	2.50	4.17
SMR	2.00	2.00	2.00	2.00
SHR	2.00	2.00	2.00	2.00
Total Performance Score	4.00	10.00	6.00	6.67
Net Revenue Per Treatment	5.00	5.00	5.00	5.00
Total				25.50

Applicant	Score
DaVita, Inc.	23.17
Puget Sound Kidney Centers	25.50