



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

September 28, 2016

CERTIFIED MAIL # 7008 1830 0002 8022 0816

Amanda Crain, Chief Operating Officer
Puget Sound Kidney Centers
1019 Pacific Avenue
Everett, Washington 98201

RE: Certificate of Need Application #16-27

Dear Ms. Crain:

We have completed review of the Certificate of Need application submitted by Puget Sound Kidney Centers proposing to add dialysis stations to PSKC-South in Mountlake Terrace, within Snohomish County planning area #3. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Puget Sound Kidney Centers agrees to the following in its entirety.

Project Description

This certificate approves the addition of four dialysis stations to PSKC-South, for a facility total of 31 dialysis stations. At completion of the station addition, Puget Sound Kidney Centers is approved to certify and operate 31 stations at PSKC-South. Services provided at PSKC-South include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	29
Total	31

Conditions

1. Approval of 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. Puget Sound Kidney Centers shall finance the project using cash reserves as described in the application.

Approved Costs

Puget Sound Kidney Centers identified a capital cost for the seven-station addition to be \$377,823 and is related to minor remodeling and construction, equipment, and associated fees. The department expects the costs for the four station addition to be similar to the costs identified, therefore the approved capital costs were not reduced.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

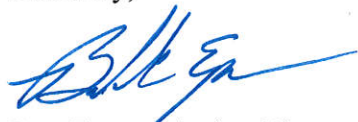
Send your written response to the Certificate of Need Program, at one of the following addresses.

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

Physical Address:
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

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

Sincerely,



Bart Eggen, Acting Director
Community Health Systems

Enclosure

EXECUTIVE SUMMARY

EVALUATION DATED SEPTEMBER 28, 2016 FOR TWO CERTIFICATE OF NEED APPLICATIONS, EACH PROPOSING TO ADD DIALYSIS STATION CAPACITY TO SNOHOMISH COUNTY PLANNING AREA #3

- **PUGET SOUND KIDNEY CENTERS PROPOSING TO ADD SEVEN STATIONS TO PSKC-SOUTH IN MOUNTLAKE TERRACE**
- **DAVITA HEALTHCARE PARTNERS, INC. PROPOSING TO ESTABLISH A SEVEN-STATION DIALYSIS CENTER IN LYNNWOOD**

BRIEF APPLICANT AND PROJECT DESCRIPTIONS

Puget Sound Kidney Centers

Puget Sound Kidney Centers (PSKC) is a not-for-profit entity that provides kidney dialysis services in Washington State. Currently, PSKC owns and operates six dialysis facilities in three separate counties. [source: PSKC website and application, p1 & p3]

This project focuses on PSKC-South located at 21309 – 44th Avenue West in Mountlake Terrace [98043], within Snohomish County planning area #3. PSKC proposes to add seven stations to the existing 27 station center, for a facility total of 34. [source: Application, p1 & p3]

If approved, PSKC-South would be operating all 34 stations by the end of December 2016. [source: Application, p9]

The estimated capital expenditure for the project is \$377,823. The costs are for minor remodeling and construction, equipment, and associated fees. [source: Application, p30, and April 29, 2016, screening response, pp2-3]

DaVita HealthCare Partners, Inc.

In late 2012, DaVita, Inc. a for-profit end stage renal care provider was acquired by HealthCare Partners Holding, Inc. To reflect the combination of the two companies, DaVita, Inc. changed its name to DaVita HealthCare Partners Inc. Throughout this evaluation, DaVita HealthCare Partners Inc. will be referenced as ‘DaVita.’ [source: CN historical files]

DaVita’s application proposes to establish a seven-station dialysis center in Lynnwood, within Snohomish County planning area #3. The new facility would be located at 13619 Mukilteo Speedway, #D1 in Lynnwood [98087]. [source: Application, p5]

If approved, the new seven-station facility would be operational by the end of December 2017. [source: Application, p14]

The estimated capital expenditure for the project is \$1,720,865. The costs are for remodeling and construction, equipment, and associated fees. [source: Application, p23, and Appendix 7]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Puget Sound Kidney Centers

This project is subject to Certificate of Need review as an increase in the number of dialysis stations at a kidney disease center under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

DaVita HealthCare Partners, Inc.

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

CONCLUSIONS

Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers proposing to add dialysis station capacity to PSKC-South located in Snohomish County planning area #3 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 addition of four dialysis stations to PSKC-South, for a facility total of 31 dialysis stations. At completion of the station addition, Puget Sound Kidney Centers is approved to certify and operate 31 stations at PSKC-South. Services provided at PSKC-South include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	29
Total	31

Conditions:

1. Approval of 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. Puget Sound Kidney Centers shall finance the project using cash reserves as described in the application.

Approved Costs:

Puget Sound Kidney Centers identified a capital cost for the seven-station addition to be \$377,823 and is related to minor remodeling and construction, equipment, and associated fees. The department expects the costs for the four station addition to be similar to the costs identified, therefore the approved capital costs were not reduced.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to add dialysis station capacity to Snohomish County planning area #3 is consistent with applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners, Inc. agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a three station dialysis center in Snohomish County planning area #3. At completion of the project, DaVita HealthCare Partners, Inc. is approved to certify and operate three stations at the new dialysis center. Services provided at the new dialysis center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	1
Total	3

Conditions:

1. Approval of the project description as stated above. DaVita HealthCare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. DaVita HealthCare Partners, Inc. shall maintain compliance with the terms and conditions outlined in the October 22, 2014, Corporate Integrity Agreement with Department of Health and Human Services.
3. DaVita HealthCare Partners, Inc. shall finance the project using cash reserves as described in the application.
4. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed medical director agreement. The executed agreement must be consistent with the draft agreement provided in the application.
5. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed transfer agreement with a local hospital. The executed agreement must be consistent with the draft agreement provided in the application.

Approved Costs:

DaVita HealthCare Partners, Inc. identified a capital cost for the seven-station dialysis center to be \$1,720,865, which includes all construction, equipment, fees, and sales tax. The department expects the costs for the three-station dialysis center to be similar to the costs identified, therefore the approved capital costs were not reduced.

EVALUATION DATED SEPTEMBER 28, 2016 FOR TWO CERTIFICATE OF NEED APPLICATIONS, EACH PROPOSING TO ADD DIALYSIS STATION CAPACITY TO SNOHOMISH COUNTY PLANNING AREA #3

- **PUGET SOUND KIDNEY CENTERS PROPOSING TO ADD SEVEN STATIONS TO PSKC-SOUTH IN MOUNTLAKE TERRACE**
- **DAVITA HEALTHCARE PARTNERS, INC PROPOSING TO ESTABLISH A SEVEN-STATION DIALYSIS CENTER IN LYNNWOOD**

APPLICANT DESCRIPTIONS

Puget Sound Kidney Centers

Puget Sound Kidney Centers (PSKC) is a not-for-profit entity that provides kidney dialysis services in Washington State. PSKC 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 PSKC Foundation. [source: PSKC website and application, p1]

Currently, PSKC owns and operates six dialysis facilities in three separate counties. PSKC also operates a mobile dialysis service that provides dialysis services to patients in area hospitals. Below is a listing of the six dialysis facilities owned or operated by PSKC. [source: Application, p3]

Skagit	Snohomish
PSKC – Anacortes	PSKC – Everett
	PSKC – Monroe
Island	PSKC – South
PSKC – Whidbey Island	PSKC – Smokey Point

DaVita HealthCare Partners, Inc.

DaVita, Inc. is a for-profit end stage renal care provider that was acquired by HealthCare Partners Holding, Inc. in late 2012. To reflect the combination of the two companies, DaVita, Inc. changed its name to DaVita HealthCare Partners Inc. Throughout this evaluation, DaVita HealthCare Partners Inc. will be referenced as ‘DaVita.’

Currently DaVita operates or provides administrative services in approximately 2,197 outpatient dialysis centers located in the United States. [source: Application, p6] In Washington State, DaVita owns or operates 40¹ kidney dialysis facilities in 18 separate counties. Listed on the following page are the names of the facilities owned or operated by DaVita in Washington State. [source: CN historical files and Application, p7]

¹ As of the writing of this evaluation, four of DaVita’s CN approved dialysis facilities are not yet state surveyed and operational. The four facilities are: Centralia Dialysis Center [CN #1572 issued on April 15, 2015]; Elk Plains Dialysis Center [CN #1568 issued on March 23, 2015]; Redondo Heights Dialysis Center [CN #1528 issued on May 19, 2014]; and Renton Dialysis Center [CN #1501R issued on December 3, 2015].

Benton

Chinook Dialysis Center
 Kennewick Dialysis Center

Clark

Vancouver Dialysis Center
 Battle Ground Dialysis Center

Chelan

Wenatchee Valley Dialysis Center

Douglas

East Wenatchee Dialysis Center

Franklin

Mid-Columbia Kidney Center

Island

Whidbey Island Dialysis Center

King

Bellevue Dialysis Center
 Federal Way Dialysis Center
 Kent Dialysis Center
 Olympic View Dialysis Center (management only)
 Renton Dialysis Center
 Redondo Heights Dialysis Center
 Westwood Dialysis Center

Kittitas

Ellensburg Dialysis Center

Lewis

Centralia Dialysis Center

Mason

Belfair Dialysis Center

Pacific

Seaview Dialysis Center

Pierce

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

Skagit

Cascade Dialysis Center

Snohomish

Everett 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

Yakima

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

PROJECT DESCRIPTIONS**Puget Sound Kidney Centers**

This project focuses on PSKC-South located at 21309 – 44th Avenue West in Mountlake Terrace [98043], within Snohomish County planning area #3. PSKC proposes to add seven stations to the existing 27 station center, for a facility total of 34. [source: Application, p1 & p3]

Services currently provided at PSKC-South include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training. The facility has an isolation area. The dialysis facility also provides

evening treatments beginning after 5:00pm. [source: Application, pp2-3, Exhibit5, and April 29, 2016, screening responses, p1]

If this project is approved, PSKC would add seven stations to PSKC-South, for a facility total of 34 stations. One of the additional stations would be a permanent bed station to be used for those patients unable to tolerate dialyzing in a chair. [source: Application 8 and April 29, 2016, screening responses, p1]

If this project is approved, PSKC-South would be operating all 34 stations by the end of December 2016. [source: Application, p14]

The estimated capital expenditure for the project is \$377,823. The costs are for minor remodeling, equipment, and associated fees. [source: Application, p30, and April 29, 2016, screening response, pp2-3]

DaVita HealthCare Partners, Inc.

DaVita proposes to establish a seven station dialysis center 13619 Mukilteo Speedway, #D in Lynnwood [98087] in Snohomish County planning area #3. The facility would be known as Lynnwood Dialysis Center. [source: Application, p5]

Services to be provided at DaVita-Lynnwood include in-center hemodialysis, backup dialysis service, home hemodialysis and home peritoneal dialysis training, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: Application, p12]

If this project is approved, DaVita-Lynnwood would be operating all seven stations by the end of December 2017. [source: Application, p9]

The estimated capital expenditure for the project is \$1,720,865. The costs are for remodeling, equipment, and associated fees. [source: Application, p23, and Appendix 7]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Puget Sound Kidney Centers

PSKC's project is subject to Certificate of Need review as any increase in the number of dialysis stations at a kidney disease center under the provisions of RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

DaVita HealthCare Partners, Inc.

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

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction in how the department is to make its determinations. It states:

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

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

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

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

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

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

WAC 246-310-280 through 289 contain service or facility specific criteria for dialysis projects and must be used to make the certain determinations. Specific to these two projects, in order to obtain Certificate of Need approval, each 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). Additionally, each applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 (definitions); WAC 246-310-282 (concurrent review cycle); WAC 246-310-284 (methodology and standards); and WAC 246-310-287 (exceptions).

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted these two projects under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1 for calendar year 2016. A chronological summary of the review is shown on the following page.

APPLICATION CHRONOLOGY

Action	PSKC	DaVita
Letter of Intent Submitted	January 29, 2016	January 29, 2016
Application Submitted	February 29, 2016	February 29, 2016
Department’s pre-review activities <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant's Responses Received 	March 31, 2016 April 29, 2016	March 31, 2016 April 29, 2016
Beginning of Review	May 16, 2016	
Public Hearing Conducted	None Requested or Conducted	
Public Comments accepted through the end of public comment	July 15, 2016	
Rebuttal Comments Submitted	August 15, 2016	
Department's Anticipated Decision Date	September 28, 2016	
Department's Actual Decision Date	September 28, 2016	

AFFECTED PERSONS

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

“...an “interested person” who:

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

As noted above, WAC 246-310-010(2) requires an affected person to first meet the definition of an ‘interested person.’ WAC 246-310-010(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.*

Under concurrent review, each applicant is an affected person for the other application.

No other entities requested interested or affected person status for either of the two projects.

SOURCE INFORMATION REVIEWED

- Puget Sound Kidney Centers Certificate of Need application received February 29, 2016
- Puget Sound Kidney Centers screening responses received April 29, 2016
- DaVita HealthCare Partners Certificate of Need application received February 29, 2016
- DaVita HealthCare Partner’s screening responses received April 29, 2016

SOURCE INFORMATION REVIEWED (continued)

- Public comments accepted through July 15, 2016 for both dialysis applications
- Puget Sound Kidney Centers’ rebuttal responses received August 15, 2016
- DaVita HealthCare Partners’ rebuttal responses received August 15, 2016
- Licensing and/or survey data provided by the Department of Health’s Investigations and Inspections Office
- Licensing data provided by the Medical Quality Assurance Commission
- Puget Sound Kidney Centers website at www.pskc.net
- DaVita HealthCare Partners website at www.davitahealthcarepartners.com
- Northwest Renal Network website at www.nwrn.org
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Geographic Map of Snohomish County Planning Area #3 at www.usnaviguide.com
- 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 add dialysis station capacity to PSKC-South located in Snohomish County planning area #3 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 addition of four dialysis stations to PSKC-South, for a facility total of 31 dialysis stations. At completion of the station addition, Puget Sound Kidney Centers is approved to certify and operate 31 stations at PSKC-South. Services provided at PSKC-South include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	29
Total	31

Conditions:

1. Approval of 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. Puget Sound Kidney Centers shall finance the project using cash reserves as described in the application.

Approved Costs:

Puget Sound Kidney Centers identified a capital cost for the seven-station addition to be \$377,823 and is related to minor remodeling and construction, equipment, and associated fees. The department expects the costs for the four station addition to be similar to the costs identified, therefore the approved capital costs were not reduced.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to add dialysis station capacity to Snohomish County planning area #3 is consistent with applicable criteria of the Certificate of Need Program, provided DaVita HealthCare Partners, Inc. agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a three station dialysis center in Snohomish County planning area #3. At completion of the project, DaVita HealthCare Partners, Inc. is approved to certify and operate three stations at the new dialysis center. Services provided at the new dialysis center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	1
Total	3

Conditions:

1. Approval of the project description as stated above. DaVita HealthCare Partners, Inc. further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. DaVita HealthCare Partners, Inc. shall maintain compliance with the terms and conditions outlined in the October 22, 2014, Corporate Integrity Agreement with Department of Health and Human Services.
3. DaVita HealthCare Partners, Inc. shall finance the project using cash reserves as described in the application.
4. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed medical director agreement. The executed agreement must be consistent with the draft agreement provided in the application.
5. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed transfer agreement with a local hospital. The executed agreement must be consistent with the draft agreement provided in the application.

Approved Costs:

DaVita HealthCare Partners, Inc. identified a capital cost for the seven-station dialysis center to be \$1,720,865, which includes all construction, equipment, fees, and sales tax. The department expects the costs for the three-station dialysis center to be similar to the costs identified, therefore the approved capital costs were not reduced.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Puget Sound Kidney Centers **met** the applicable need criteria in WAC 246-310-210.

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that DaVita HealthCare Partners, Inc. **met** the applicable need criteria in WAC 246-310-210.

- (1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

WAC 246-310-284 requires the department to evaluate kidney disease treatment center applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

WAC 246-310-284 Kidney Disease Treatment Center Numeric Methodology

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network (NRN).²

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need [WAC 246-310-284(4)(a)]. This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.³

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

² Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

³ WAC 246-310-280 defines base year as “*the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the Northwest Renal Network's Modality Report or successor report.*” For these projects submitted on February 29, 2016, the base year is 2014. [Year end 2015 data was available on February 5, 2016.]

on the planning area’s previous five consecutive years NRN data, again concluding with the base year [WAC 246-310-284(4)(b) and (c)].

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the projection year, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

WAC 246-310-280(9) identifies the 57 separate ESRD planning areas for the state. Snohomish County is broken into three sub-planning areas. PSKC and DaVita propose to add dialysis station capacity to Snohomish County planning area #3. The following nine zip codes are included in this planning area.

Zip	City
98012	Mill Creek/Bothell
98020	Edmonds/Woodway
98021	Bothell
98026	Edmonds

Zip	City
98036	Lynnwood/Brier
98037	Lynnwood
98043	Mountlake Terrace
98087	Lynnwood
98296	Snohomish

The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website.

Puget Sound Kidney Centers Numeric Methodology

[source: Application, pp19-21]

PSKC proposes to add seven dialysis stations to PSKC-South located in the Mountlake Terrace zip code of 98043. PSKC submitted the numeric methodology posted to the department’s website for Snohomish County planning area #3. The methodology projected need for seven new stations in year 2018.

Public Comments

None

Rebuttal Comments

None

The department’s evaluation of the PSKC’s numeric methodology will be discussed below, concurrently with the DaVita’s project.

DaVita HealthCare Partners, Inc. Numeric Methodology

[source: Application, pp18-21]

DaVita proposes to establish a seven-station dialysis center in the Lynnwood zip code of 98087. DaVita submitted the numeric methodology posted to the department’s website for Snohomish County planning area #3. The methodology projected need for seven new stations in year 2018.

Public Comments

None

Rebuttal Comments

None

Department Evaluation of the Numeric Methodology for the Applications

Each applicant submitted the department’s posted methodology for Snohomish County dialysis planning area #3 as part of their application. Neither produced another methodology.

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project the need for Snohomish County dialysis planning area #3. The department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5). The department's methodology also showed a need for seven stations in the planning area by the end of year 2018.

Table 1 below is a summary of the projected net need provided by each applicant and the department for Snohomish County planning area #3. For these two projects, both PSKC and DaVita used the numeric methodology posted to the department’s website for Snohomish County planning area #3. The department’s methodology is included in this evaluation as Attachment A.

**Table 1
Snohomish County Planning Area #3
Numeric Methodology Summary**

	4.8 in-center patients per station		
	2018 Projected # of stations	Minus Current # of stations	2018 Net Need or (Surplus)
PSKC	43	36	7
DaVita	43	36	7
DOH	43	36	7

Table 1 above shows that both applicants and the department projected a need for seven stations in the planning area. As a result, the net station need for Snohomish County planning area #3 is seven for year 2018.

The department concludes PSKC and DaVita **meet this numeric methodology standard**. For this standard, each application is equivalent to the other.

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.⁴ The department uses the standards in WAC 246-310-284(5) and WAC 246-310-284(6).

WAC 246-310-284(5)

Before the department approves new in-center kidney dialysis stations, all certificate of need approved stations in the planning area must be operating at 4.8 in-center patients per station 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. For these exception planning areas all certificate of need approved stations in the planning area must be operating at 3.2 in-center patients per station. Both resident and nonresident patients using the dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period.

For Snohomish County planning area #3, all approved stations in the planning area must be operating at 4.8 in-center patients per station before new stations can be added. The 4.8 patients per station represents 80% of the maximum number of patients that can receive dialysis per station in a facility that operates three patient shifts. If existing providers are operating either at or above the 4.8 standard, then the department considers the providers are effectively and appropriately serving the population. The 4.8 standard also means that the existing providers are approaching an occupancy level where stations are not or will not be sufficiently available to meet future need. WAC 246-310-284(5) identifies the data to be used to evaluate this sub-criterion.

Puget Sound Kidney Centers

[source: Application, pp21-22]

PSKC used data from the most recent quarterly modality report from the Northwest Renal Network (NRN) as of the first day of the application submission period. The first day of the application submission period is February 1, 2016. The most recent quarterly modality report from NRN as of February 1, 2016, contains data through September 30, 2015, released on December 4, 2015.⁵

There are two existing facilities operating in the planning area. Table 2 below shows a summary of the utilization calculated by PSKC.

**Table 2
Puget Sound Kidney Centers Facility Utilization Calculations**

Facility Name	# of Stations	# of Patients	Patients /Station
PSKC-South	27	146	5.41
DaVita Mill Creek Dialysis Center	9	44	4.89

PSKC concluded both facilities were operating above the 4.8 standard.

⁴ WAC 246-310-210(1)(b).

⁵ The December 31, 2015, quarterly modality report was released on February 15, 2016.

Public Comments

- *“I have at least four patients ready to start dialysis, and several more waiting to begin, and I would want them to be treated at PSKC-S. I was informed recently that PSKC-S would not be able to accommodate my patients because their patient schedule is completely full on an almost daily basis. This is very troubling and disappointing. PSKC-S offers such a high quality service, but because of rules, these patients may have to dialyze in their Everett facility instead of a center closer to their residence. The patients now must add more time and distance to their travel for their dialysis services, and this is not the first time I have had difficulty referring patients at PSKC-S due to its full schedule. For the record, I am not affiliated with PSKC in any way, but I believe that patients deserve access to the highest quality care available, and the facility of their choice.”* [source: Jung H. Joh, MD, Seattle Nephrology]
- *“...there are a number of grounds on which the department could determine that DaVita’s application is superior to PSKC’s application. I will highlight one particularly important one: that DaVita’s proposed facility would improve access to care for Snohomish 3 residents. DaVita’s proposed location is a testament to our commitment to treat patients where they live and work. PSKC is correct that many patients reside around its current facility. However, this population represents only a portion of the need in Snohomish 3 and patients should not be required to travel considerable distances on the congested I-5 in order receive great care. This planning area currently has no option for patients who reside on the northern end, namely those who reside in zip code 98087 which has grown by nearly 15% in the past five years. DaVita proposes to bring its services and many additional benefits to that community at a location that was specifically chosen at the juncture of the 525 Mukilteo Speedway and Highway 99, **providing access to both urban and more rurally based patients.**”* [bold emphasis in original] [source: DaVita July 15, 2016, comments, pp4-5]

PSKC Rebuttal Comments [source: August 15, 2016, rebuttal comments, p6]

- *As noted in our application, PSKC has operated with 27 stations since 2001, and has consistently operated at or above 90% occupancy since 2011. Today, we operate effectively at 100% occupancy. In 2008—8 years ago—DV secured CN approval to establish a new dialysis facility in Snohomish 3. This facility became operational in December of 2009. ...even with the opening of DV’s nine-station facility, PSKC’s occupancy never fell below 88%. ...The bottom line is that DV Mill Creek has greatly underperformed in the Snohomish 3 market, denying patient access for patients desiring to dialyze at our PSKC-S facility. Granting more stations to DV does not increase access to care. Quite the contrary, if more stations are awarded to DV, patients and payers desiring care at PSKC will be denied. Even with the award of 7 stations to PSKC-S, our current occupancy only decreases to 4.6 patients per station, and we have already achieved our 2017 estimated patient census. At this growth rate, we would be approaching 4.8 patients per station before DV even proposes to open its stations.”* [underline emphasis in original]

The department’s evaluation of PSKC’s existing facility utilization standard under WAC 246-310-284(5) will be discussed below, concurrently with the DaVita’s project.

DaVita HealthCare Partners, Inc.

[source: Application, pp20-21]

DaVita also relied on the September 30, 2015 NRN quarterly modality report to demonstrate compliance with this standard. Table 3 below shows a summary of the utilization calculated by DaVita.

Table 3
DaVita HealthCare Partners Facility Utilization Calculations

Facility Name	# of Stations	# of Pts	Pts/Station
PSKC-South	27	146	5.41
DaVita Mill Creek Dialysis Center	9	44	4.89

DaVita also concluded both facilities were operating above the 4.8 standard.

Public Comments

- *“As discussed in PSKC-S’s CN application, since 2011, PSKC-S has consistently operated at or above 90% occupancy. In fact, as of July 12, 2016, us [sic] in-center census is 157 patients, or 97% of WAC-defined capacity. The other facility in Snohomish 3, DV Mill Creek opened in 2009. In its 2007 CN application, DV proposed to: 1) open by November 2008 and 2) be operating at 80% of capacity within 3 years of opening or by 2011. The reality is DV did not open until December of 2009 (13 months longer than anticipated), and then took nearly six (6) years to achieve 80% utilization. [underline emphasis in original] While allowing for the submittal of these two CN applications, DV Mill Creek’s 4.8 patients per station utilization was short-lived. As noted in Table 1 [included in the public comments], in the subsequent two quarters, DV Mill Creek’s census has fallen below 80% again. (NRN data from March 31st shows DV Mill Creek at only 72% occupancy.) The bottom line is that DV Mill Creek has greatly underperformed in the Snohomish 3 market, denying PSKC an opportunity to increase capacity all to the detriment of dialysis patients.” [source: PSKC – July 15, 2016, comments, pp1-2]*
- *“...in five of the past six years, there has been need for additional stations in Snohomish 3. In addition, PSKC-S has been above 90% occupancy and has been positioned to add stations, but has been prohibited from doing so because of DV’s poor market performance. At our current 97% occupancy level, every single day we are challenged to accommodate new patients in general, and especially those desiring or in need of certain dialysis shifts and times. Without additional stations, PSKC-S will basically be ‘closed’ to new patients, and patients seeking care at our unit will need to travel elsewhere, or be forced into dialysis times, shifts (4th shift) and providers not of their choosing. Either option is untenable, both for the patients we serve and for us, because our nonprofit mission is to enhance the quality of life for those with kidney disease.” [source: PSKC – July 15, 2016, comments, pp1-2]*

Rebuttal Comments

- *“Much of PSKC’s superiority analysis emphasizes that (1) DaVita Mill Creek took longer than anticipated to reach an 80% utilization rate, and (2) PSKC-South historically has had a high utilization rate, higher than DaVita Mill Creek. As a preliminary matter, we note that DaVita is not proposing to add stations in Mill Creek. DaVita is proposing to build a new facility in Lynnwood. The zip code in which DaVita proposes to build its facility,*

98087, is one of the fastest growing in the planning area, having experienced an average ESRD growth rate of 14.2% over the past 5 years, compared to 4.3% for the planning area as a whole during the same time period. Therefore, PSKC’s repetitive comparisons of utilization statistics at PSKC-South and Mill Creek are not comparisons of the two facilities under review here. Instead, they are a comparison of PSKC South to one of DaVita’s existing facilities, rather than the new facility that DaVita proposes to build in Lynnwood.”
 [source: DaVita August 15, 2016, p5]

Department Evaluation of WAC 246-310-284(5) for both PSKC and DaVita

The department used the September 30, 2015, NRN quarterly modality report to evaluate compliance with this standard. Table 4 below shows a summary of the utilization of both dialysis centers operating in Snohomish County planning area #3.

**Table 4
 Department’s Facility Utilization Calculations**

Facility Name	# of Stations	# of Pts	Pts/Station
PSKC-South	27	145	5.37
DaVita Mill Creek Dialysis Center	9	44	4.89

It is noted that both PSKC and DaVita counted 146 patients for PSKC-South, rather than 145. The September 30, 2015, quarterly modality report shows one patient in the category of CAPD—or continuous ambulatory peritoneal dialysis. While patient training for CAPD is provided in the dialysis center, CAPD services are provided in the patient’s home.⁶ Patients under this category are not counted for the utilization standard.

With the corrected information, Table 4 above shows that both existing facilities satisfy this standard. Meeting this standard indicates that the two existing facilities are effectively and appropriately serving the population. Meeting this standard also indicates stations are not or will not be sufficiently available to meet future need. **This standard is met.**

Within their respective comments, both PSKC and DaVita agree that the existing facilities are operating above the 4.8 standard based on the September 30, 2015, NRN quarterly modality report. PSKC and DaVita disagree on who should receive the seven stations projected to be needed in the planning area.

PSKC asserts that the seven stations should be added to its PSKC-South facility because the facility is operating well above the 4.8 standard, and has been operating above that standard for the most recent five years. PSKC states that even though the planning area has shown numeric need for stations, DaVita’s low utilization at its Mill Creek center has prevented any expansion in the planning area, including at PSKC-South.

The department reviewed historical numeric methodology for Snohomish County planning area #3. A summary of the information is provided in Table 5 on the following page. [source: CN Program historical numeric methodologies]

⁶ Based on August 19, 2016, e-mail exchange between NRN staff and CN Program staff.

**Table 5
Snohomish County Planning Area #3 Numeric Need Projections**

Year	Station Need	Minus Current Stations	Net Need (Surplus)	Projection Year
2007	36	27	9	2010
2008	42	27	15	2011
2009	40	36	4	2012
2010	38	36	2	2013
2011	34	36	(2)	2014
2012	35	36	(1)	2015
2013	41	36	5	2016
2014	44	36	8	2017
2015	43	36	7	2018

Table 5 shows that PSKC-South was the only operational dialysis center in the planning area through year 2008. In 2009, DaVita’s Mill Creek facility was approved. In years 2011 and 2012, the numeric methodology calculated a surplus of stations in the planning area. As a result, applications for additional stations in the planning area could not be submitted, regardless of PSKC-South utilization. Beginning in year 2013, the planning area showed numeric need for additional stations. These two applications were submitted in year 2016, based on year 2015 methodology.

PSKC also states that its facility—PSKC-South in Mountlake Terrace—has been operating well above the 4.8 standard. DaVita’s Mill Creek Dialysis Center was approved in April 2008 and operational in mid-year 2010. With two centers in the planning area, under this standard, both must be operating above the 4.8 standard before any new stations could be added. Table 6 below shows a review of the two Snohomish County planning area #3 dialysis centers number of patients as reported to NRN in each of the four quarters for years 2013, 2014, and 2015. [source: Historical NRN quarterly modality reports]

**Table 6
PSKC-South and DaVita-Mill Creek Utilization**

PSKC-South			DaVita-Mill Creek		
Quarter	# of Patients	Patients/Station	Quarter	# of Patients	Patients/Station
2013-1	142	5.3	2013-1	23	2.6
2013-2	144	5.3	2013-2	24	2.7
2013-3	142	5.3	2013-3	30	3.3
2013-4	147	5.4	2013-4	35	3.9
2014-1	150	5.6	2014-1	37	4.1
2014-2	152	5.6	2014-2	38	4.2
2014-3	151	5.6	2014-3	35	3.9
2014-4	147	5.4	2014-4	38	4.2
2015-1	146	5.4	2015-1	36	4.0
2015-2	142	5.3	2015-2	40	4.4
2015-3	145	5.4	2015-3	44	4.9
2015-4	147	5.4	2015-4	42	4.7

As shown in Table 6, quarterly NRN data for years 2013, 2014, and 2015 substantiate PSKC’s claim that PSKC-South has consistently operated above the 4.8 standard. The data shows that DaVita’s Mill Creek facility operated below the 4.8 standard, with the exception of the third quarter of year 2015.

DaVita asserts that adding stations to PSKC-South located in the Mountlake Terrace zip code of 98043 does not improve access for dialysis services for patients residing in the rural areas of Snohomish County planning area #3.

To evaluate DaVita’s statement, the department reviewed the historical number of patients by zip code for Snohomish County planning area #3. Table 7 below is a summary of the five-year patient growth by zip codes for years 2009 through 2014.

Table 7
Snohomish County Planning Area #3 Percentage of Patient Growth by Zip Code

Zip Code	2009	2010	2011	2012	2013	2014	5-Year Average
98037	-15.8%	25.0%	15.0%	-17.4%	5.3%	-5.0%	1.2%
98036	30.8%	-11.8%	20.0%	-22.2%	-28.6%	-20.0%	-5.3%
98026	16.7%	28.6%	11.1%	30.0%	30.8%	-17.6%	16.6%
98012	-15.4%	-18.2%	5.6%	-5.3%	-16.7%	20.0%	-5.0%
98043*	0.0%	-4.8%	50.0%	-3.3%	41.4%	-4.9%	13.1%
98020	-11.8%	-3.3%	6.9%	-3.2%	-16.7%	0.0%	-4.7%
98087***	-21.4%	72.7%	-26.3%	35.7%	-15.8%	6.3%	8.5%
98296	0.0%	0.0%	42.9%	-15.0%	35.3%	21.7%	14.1%
98021**	-8.3%	-18.2%	22.2%	9.1%	-8.3%	-9.1%	-2.1%

*=PSKC-South **=DaVita Mill Creek Dialysis Center ***=DaVita proposed center

PSKC-South is located in the Mountlake Terrace zip code of 98043 [shown in bold above]. This zip code has experienced a moderate growth in patients for the most recent five years. DaVita’s Mill Creek Dialysis Center is located in the Bothell zip code of 98021 [in bold above]. This zip code has experienced a decrease in growth for the most recent five years. DaVita proposes to establish a facility in a Lynnwood zip code of 98087 [shown in bold above]. This zip code has experienced moderate to high growth in patients over the most recent five years.

Though not shown in the historical data above, for years 2002 through 2005, there were no patients residing in the 98087 zip code. Beginning in year 2006, the zip code had 3 patients, which increased to 28 in 2014. This equates to a 9 year average growth of 42.6%.

Based on Tables 5 and 6 above, the department concludes that PSKC-South has been consistently operating above the 4.8 standard since at least January 2013. PSKC’s assertion that additional stations located at PSKC-South in Mountlake Terrace would improve availability and accessibility to dialysis services in the Snohomish County #3 planning area can be substantiated.

The data also substantiates DaVita’s argument that adding stations to PSKC-South may not improve patient access for patients residing in the rural areas of the planning area. Table 7 above substantiates that DaVita’s proposed site in the planning area zip code of 98087 could improve

availability and geographic accessibility to dialysis services in the Snohomish County #3 planning area. A zip code map of the planning area showing the location of the existing and proposed dialysis centers is included as Appendix B to the evaluation.

The department does not have the data to measure which is more valuable—increasing access to dialysis services in an existing facility vs creating a new facility to increase geographic access to dialysis services. The department concludes PSKC and DaVita **meet the standard under WAC 246-310-284(5)**. For this standard, each application is equivalent to the other.

WAC 246-310-284(6)

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

Puget Sound Kidney Centers

[source: Application, p9 and p22]

PSKC proposes the addition of seven stations to the 27 station PSKC-South. The seven stations are projected to be operational in December 2016. Year 2017 will be the first full year of operation at PSKC-South with 34 stations and year three is 2019. Table 8 below shows the projected utilization of PSKC-South with 34 stations.

Table 8
PSKC-South Projected Utilization Calculations

PSKC-South-34 Stations	# of Pts	Pts/Station
Year One - 2017	157	4.62
Year Two - 2018	162	4.76
Year Three - 2019	168	4.94

Public Comments

None

Rebuttal Comments

None

The department’s evaluation of PSKC’s projected utilization standard under WAC 246-310-285(6) will be discussed below, concurrently with the DaVita’s project.

DaVita HealthCare Partners, Inc.

[source: Application, p14 and Appendix 9]

DaVita proposes the establishment of a seven-station dialysis center in Lynnwood. The new center is expected to be operational by the end of December 2017. Year 2018 will be the first full year of operation for the new facility and year three is 2020. Table 9 on the following page shows the projected utilization of DaVita Lynnwood with seven stations.

Table 9
DaVita Lynnwood Projected Utilization Calculations

DaVita Lynnwood -7 Stations	# of Pts	Pts/Station
Year One - 2018	12	1.71
Year Two - 2019	25	3.57
Year Three - 2020	34	4.86

Public Comments

- *“While DV and PSKC concur that seven additional stations are needed in Snohomish 3, simply adding them to any provider to the planning area will not address the current access problems at PSKC-S. These stations are needed at PSKC-S to ensure that patients choosing to dialyze at our facility will have access to the facility of their choice. Giving stations to DV will perpetuate access problems as DV’s documented history in this market shows that it has struggled to perform and absolutely nothing in its application suggests that a new location in Lynnwood will enhance its performance.”* [source: PSKC – July 15, 2016, comments, pp1-2]

DaVita Rebuttal Comments [source: August 15, 2016, p5]

- *“Much of PSKC’s superiority analysis emphasizes that (1) DaVita Mill Creek took longer than anticipated to reach an 80% utilization rate, and (2) PSKC-South historically has had a high utilization rate, higher than DaVita Mill Creek. As a preliminary matter, we note that DaVita is not proposing to add stations in Mill Creek. DaVita is proposing to build a new facility in Lynnwood. The zip code in which DaVita proposes to build its facility, 98087, is one of the fastest growing in the planning area, having experienced an average ESRD growth rate of 14.2% over the past 5 years, compared to 4.3% for the planning area as a whole during the same time period. Therefore, PSKC’s repetitive comparisons of utilization statistics at PSKC-South and Mill Creek are not comparisons of the two facilities under review here. Instead, they are a comparison of PSKC South to one of DaVita’s existing facilities, rather than the new facility that DaVita proposes to build in Lynnwood.”*

Department Evaluation of WAC 246-310-284(6) for both PSKC and DaVita

Both PSKC and DaVita project to be operating above the 4.8 standard in their respective third year of operation. PSKC’s projections rely, in part, on its current utilization and wait list of patients at PSKC-South. PSKC states that the addition of seven stations to PSKC-South would bring its current occupancy to 4.6 patients per station.

To date, DaVita has established 40 separate dialysis centers in Washington State, and of those, three are in Snohomish County, and one of the three is in Snohomish County planning area #3. While DaVita’s projections reasonably show a slow ramp-up for services and reach 4.86 patients per station by the end of year three (2019), DaVita did not identify the specific basis for its projected occupancy at the new Lynnwood facility.

PSKC requests that the department take into consideration that DaVita’s Mill Creek center became operational several months after the projected operational timeline identified in the Mill Creek

application.⁷ PSKC further suggests the department take into consideration that the Mill Creek center did not meet the projected utilization of 4.8 patients per station in the third year of operation (2012) as projected by DaVita. The claims by PSKC can be substantiated; however, these are not standards under the current dialysis rules.

As shown in Tables 8 and 9 above, each facility is projected to operate at or above the 4.8 standard by the end of the third full year of operation. PSKC's projections are determined to be reliable because they are based on the facility's current high utilization and a wait list of patients. DaVita's projections are based on its history of establishing dialysis centers in Washington State and the ramp up time generally experienced by DaVita for new centers. Each applicant relied on different assumptions to project utilization in year three and each applicant's assumptions are reliable.

The department concludes PSKC and DaVita **meet this sub-criterion**. Further, each application is equivalent to the other.

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

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

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

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

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

Charity care shows a willingness of a provider to provide services to individuals who do not have private insurance, do not qualify for Medicare, or do not qualify for Medicaid, or under insured. With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear.

Puget Sound Kidney Centers

PSKC provided copies of the following policies used at all PSKC dialysis centers, including PSKC-South. [source: Application, Exhibit 7]

- Community Service Statement for the Puget Sound Kidney Centers - Approved October 2010

⁷ Certificate of Need Application #08-11 submitted August 31, 2007, and the decision was released on April 18, 2008.

PSKC also provided the following statements regarding admission for all PSKC dialysis centers. [source: Application, p23]

“All individuals in need of dialysis services have access to PSKC’s dialysis centers. PSKC’s Community Service Statement policy, attached as Exhibit 7, prohibits discrimination on the basis of race, income, ethnicity, sex, or handicap. PSKC reinvests into the community and does not turn patients away on the basis of income or payment resources. PSKC is committed to caring for the underserved, and is truly a nonprofit provider in every sense of the word. Our policy differentiates us from many other dialysis providers in that we identify patients prospectively and qualify them as eligible for charity care (as opposed to re-categorizing bad debt). We are proud of our policy and are aware of how it has benefited dialysis patients over the years.”

PSKC-South is currently Medicare and Medicaid certified. PSKC provided its projected source of revenues by payer for PSKC-South which is shown below in Table 10. [source: Application, p9]

Table 10
PSKC-South Sources of Revenue

Source	Percentage
Medicare	69.0%
Medicaid	6.0%
Commercial	25.0%
Total	100.0%

PSKC did not specifically provide a policy entitled “Charity Care Policy.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-210(2) for PSKC

PSKC has been providing dialysis services to the residents of Skagit Island, and Snohomish counties for many years. The Community Service Statement for the Puget Sound Kidney Centers provides the assurance that PSKC-South would accept patients for treatment without regard to “age, race, color ethnicity, sex or sexual orientation, religious or political beliefs, medical disease, disorder or disability, or on the basis of income or payment resources.”

All PSKC dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that PSKC-South would maintain its certifications. For PSKC-South, the Medicare revenues are 69.0% of total revenues. The addition of seven stations is not expected to change the percentage. Pro forma financial data provided in the application shows Medicare revenues. [source: Application, p9 and Exhibit 8]

PSKC-South’s Medicaid revenues are projected remain at 6.0% of total revenues, and are not expected to change with the addition of seven stations. Pro forma financial data provided in the application shows Medicaid revenues. [source: Application, p9 and Exhibit 8]

PSKC did not provide a policy specifically entitled “Charity Care” for PSKC or PSKC-South. However its Community Service Statement for the Puget Sound Kidney Centers provides the assurance that PSKC would provide services to all patients requiring dialysis services without regard to ability to pay. In Washington State, most dialysis patients qualify for either Medicare or Medicaid services. Charity care is generally not used by dialysis providers. PSKC further demonstrated its intent to provide charity care to its PSKC-South patients by including a ‘charity’ line item as a deduction from revenue within the pro forma income statement. [source: Application, Exhibit 8]

The department concludes PSKC’s project **meets this sub-criterion.**

DaVita HealthCare Partners, Inc.

DaVita provided copies of the following policies used at all of its dialysis centers. [source: Appendix 14]

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

DaVita also provided the following statements regarding admission to its dialysis centers. [source: Application, p21]

“Appendix 14 [of the application] includes a copy of the admission, patient financial evaluation, and patient involuntary transfer policies which together demonstrate that patients will not be denied access to care due to indigence, racial or ethnic identity, gender, or handicapped status. Further, DaVita is a for-profit organization and contributes tax revenues to support a broad array of social services state wide.”

DaVita’s dialysis centers are Medicare and Medicaid certified. Specific to this new facility, DaVita provided its sources of revenues by payer which is shown in Table 11 below. [source: Application, p13]

**Table 11
DaVita-Lynnwood Sources of Revenue**

Source	Percentage
Medicare	56.70%
Medicaid	4.5%
Insurance/HMO	38.8%
Total	100.0%

DaVita also did not specifically provide a policy entitled “Charity Care Policy.”⁸

Public Comments

None

⁸ While Appendix 14 attached to DaVita’s application is entitled “Accepting Patients for Treatment, Indigent Care Policy, Involuntary Transfer Procedure.” The Indigent Care Policy is not included in the appendix.

Rebuttal Comments

None

Department Evaluation of WAC 246-310-210(2) for DaVita

DaVita has been providing dialysis services to the residents of Washington State and Snohomish County for many years. The Accepting End Stage Renal Disease Patients for Treatment provides the assurance that DaVita would accept patients for treatment without regard to “*race, color, national origin, gender, sexual orientation, age, religion, or disability...*” provided that the patient is a candidate for dialysis services.

All DaVita dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that DaVita-Lynnwood would also obtain both certifications. DaVita projected the Medicare revenues for the new center to be 56.7% of total revenues. Pro forma financial data provided in the application shows Medicare revenues. [source: Application, p13 and Appendix 9]

DaVita-Lynnwood’s Medicaid revenues are projected to be 4.5% of total revenues. Pro forma financial data provided in the application shows Medicaid revenues. [source: Application, p13 and Appendix 9]

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 to its DaVita-Lynnwood patients by including a ‘charity’ line item as a deduction from revenue within the pro forma income statement. [source: Application, Appendix 9]

As previously stated, in Washington State, most dialysis patients qualify for either Medicare or Medicaid services. Charity care is generally not used by dialysis providers. Typically, the department requires applicants to submit a copy of the charity care policy to demonstrate a willingness to provide charity care if necessary. The department concludes DaVita’s project **meets this sub-criterion.**

Department Superiority Review

In conclusion, both PSKC and DaVita **meet this sub-criterion.** Further, each application is equivalent to the other.

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

Department Evaluation

This sub-criterion is not applicable to either of the two applications.

(b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.

Department Evaluation

This sub-criterion is not applicable to either of the two applications.

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

Department Evaluation

This sub-criterion is not applicable to either of the two applications.

(4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:

(a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.

Department Evaluation

This sub-criterion is not applicable to either of the two applications.

(b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.

Department Evaluation

This sub-criterion is not applicable to either of the two applications.

(5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

Department Evaluation

This sub-criterion is not applicable to either of the two applications.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Puget Sound Kidney Centers **met** the applicable financial feasibility criteria in WAC 246-310-220.

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that DaVita HealthCare Partners, Inc. **met** the applicable financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant’s pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

Puget Sound Kidney Centers

PSKC anticipates the additional seven stations will be operational at PSKC-South by the end of December 2016. Based on this timeline, PSKC determined calendar year 2017 is the facility’s first full year of operation with 34 stations. [source: Application, p9]

PSKC provided the assumptions used to project in-center and home treatments and patients for calendar years 2017 through 2020 for PSKC-South with 34 stations, which is summarized below. [source: April 29, 2016, screening responses, Attachment 2]

- In-Center dialysis patient census was based on existing patient population at PSKC-South.
- Future growth increases 5-6 patients each year through 2020.
- Home dialysis patient census increases are based on current home dialysis growth at PSKC-South. Growth is 2.2% annual increase for peritoneal dialysis and 1.0% for hemodialysis.
- In-center dialysis treatments are based on PSKC-South’s experience and assumed at 154 treatments per patient per year for patient census. The number of new patient treatments was assumed to be slightly less than 154.

Using the assumptions stated above, PSKC’s projected number of in-center / home patients and dialyses for PSKC-South with 34 stations. [source: Application, p22 and Exhibit 8]

**Table 12
PSKC-South
Projected Patients and Dialyses for Years 2017-2020**

	Year 1 - 2017	Year 2 – 2018	Year 3 - 2019	Year 4 - 2020
# of Stations	34	34	34	34
Total Treatments	31,435	32,211	33,123	34,046
Total Patients	179	185	191	198

The assumptions PSKC used to project revenue, expenses, and net income for PSKC-South as a 34-station facility for years 2017 through 2020 are summarized below. [source: April 29, 2016, screening responses, Attachment 2]

- Payer mix is based on current actuals at PSKC-South and is not expected to change with the additional stations. Payer mix is shown below.

Source	Percentage
Medicare	69.0%
Medicaid	6.0%
Other	25.0%
Total	100.0%

- Charity care is assumed to be 1.6% of net revenue; bad debt is assumed at 1.2% of net revenue.
- Staffing expenses are based on current staffing model increased for growth as patient population increases.
- Medical director fees are based on medical director agreements applicable to PSKC-South at \$50,000 annual.
- Corporate medical director and chief medical officer fees are allocated to PSKC-South and are identified as a separate line item in the financial statements. The costs of \$12,000/annual are included in the overhead allocation section of the statement.
- Other expenses, such as medical supplies and pharmacy are based on current experience at PSKC-South.
- Office supplies and miscellaneous expenses are based on current experience at PSKC-South.
- Depreciation expenses are estimated based on the actual useful lives PSKC assigns to certain equipment classifications. The estimates for new equipment were combined with the remaining life of current PSKC-South equipment.
- Overhead allocation is in the financial statements and based on actual experience at PSKC-South. Overhead allocation is assumed at \$29 per treatment per year.

Using the projected assumptions above, PSKC projected the revenue, expenses, and net income for PSKC-South with 34 dialysis stations and its home dialysis treatment program. A summary of the projections is in Table 13 below. [source: Application, Exhibit 8]

Table 13
PSKC-South Revenue and Expense Statement
Projected Years 2017 through 2020

	CY 2017	CY 2018	CY 2019	CY 2020
Net Revenue	\$ 8,224,845	\$ 8,428,154	\$ 8,669,920	\$ 8,913,971
Total Expenses	\$ 6,896,308	\$ 7,096,721	\$ 7,333,370	\$ 7,572,562
Net Profit / (Loss)	\$ 1,328,537	\$ 1,331,433	\$ 1,336,550	\$ 1,341,409

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

The ‘Total Expenses’ line item includes all expenses related to the operation of PSKC-South, including allocated costs. The line item also includes direct and corporate medical director costs consistent with the executed medical director agreements provided in the application. [source: Application, Exhibit 2]

PSKC provided a copy of the Warranty Deed to demonstrate ownership of the PSKC-South site. Since the site is owned by PSKC, no lease or rent costs are included in the expenses above. [source: Application, Exhibit 6]

Public Comments

- *Unreliable financial statements.* PSKC provided incomplete historical financials. The pages PSKC has provided appear to be from audited financials, as they indicate in the footer that there are ‘accompanying notes’ in the auditor’s report that explain or clarify the financial

information provided. But PSKC has omitted the notes. It would be quite reasonable for the department to be concerned as to why PSKC chose to provide only selected pages from its financials, rather than the complete report which would contain the auditor's notes and other information. The Department could conclude that because the financial statements provided by PSKC are incomplete, they are unreliable as the basis for demonstrating financial feasibility.

- Unrealistic missed-treatment rate. In its pro forma, PSKC assumes a missed-treatment rate varying from 1.9% (in 2017) to 3.7% (in 2020). This is an unrealistically low assumption, which artificially inflates PSKC's projected revenue.
- Understatement of medical director fees. PSKC included a \$50,000 medical director fee, based on the medical director agreement, in its pro forma. But this does not fully reflect medical director costs, because Exhibit B of the medical director agreement indicates that PSKC also is obligated to pay \$40,000 per year in corporate medical director fees. Those fees, or at least a portion of them, should be expensed to PSKC-South. Calling it a corporate medical director overhead allocation, at \$12,000, is understating the expenses and is unexplained.
- Inaccurate data regarding charity care and bad debt. As an existing facility, PSKC has actual historical figures for charity care and bad debt. But although PSKC stated that its revenue projections are based on historical data, it chose not to use historical data for charity care and bad debt, and instead to use assumptions. It provided no explanation for which it did not wish to disclose or use the actual historical figures at PSKC-South.
[source: DaVita, July 15, 2016, public comments, pp3-4]

PSKC Rebuttal Comments [source: August 15, 2016, rebuttal comments, pp3-4]

- Missed Treatment Rate. PSKC's missed treatment rate was based on a three year average of actual utilization. In addition, PSKC assumed that new patients would have an average of approximately 80% utilization as patients begin dialysis at various times during the year. Therefore, the average number of treatments per year varied slightly (from 153 in 2017 to 150 by 2020 due to the difference in the number of new patients projected each year (consistent with the WAC projection methodology). Our estimates are accurate.
- Corporate Medical Director Fees Are Accurately Stated. The corporate medical director fees are correctly presented in the proforma. PSKC identified the expense as a "corporate medical director overhead allocation" because it is an allocated company-wide expense of which we have assigned a portion (30%) to PSKC-S. The allocation was based upon PSKC-S's share (34 stations) of all PSKC stations (113 total stations), including the seven requested stations. The math is $\$40,000 \times 30\% = \$12,000$.
- Charity Care and Bad Debt Are Accurately Estimated. PSKC's charity care and bad debt were assumed to be 1.6% and 1.2%, respectively as noted in Exhibit 7 of our screening response. These assumptions reflect PSKC's experience over the past three years and are consistent with the assumptions used and accepted in previous CN applications.

Department Evaluation of WAC 246-310-220(1) for PSKC

DaVita claims that PSKC’s financial statements are unreliable for the following reasons:

- medical director costs cannot be substantiated;
- missed treatment rate is too low; and
- charity care and bad debt is not based on historical data at PSKC-South.

In rebuttal, PSKC provided explanations of its approach to the financial projections and stated that the approach is similar to PSKC applications reviewed and approved by the department. The department reviewed the three most recently approved applications submitted by PSKC.⁹ The review substantiates that PSKC has used a similar approach to estimate its charity care and bad debt; consistently provided costs for both the facility and corporate medical directors; and its miss treatment rates are calculated similarly. The concerns raised by DaVita are not grounds for denial of PSKC’s application.

The assumptions used by PSKC to determine the number of patients and treatments at PSKC-South with an additional seven stations are reasonable. The assumptions used by PSKC to project revenues, expenses, and net income for PSKC-South are also reasonable.

The department concludes PSKC’s project **meets this sub-criterion**.

DaVita HealthCare Partners, Inc.

DaVita anticipates the proposed seven-station dialysis center will be operational by the end of December 2017. Based on this timeline, DaVita determined calendar year 2018 would be the facility’s first full year of operation and 2020 is year three. [source: Application, p4]

DaVita provided the assumptions used to project in-center and home treatments and patients for calendar years 2018 through 2020. Below is a summary of the assumptions. [source: Application, p18]

- Patient volume is based on a 4-year projection of the Snohomish County ESRD planning area #3 patients using a regression of five years historical data.
- In-Center treatments are based on an assumption of three treatments per week per patient for 52 weeks with a 5% allowance for missed treatments.

Using the assumptions stated above, DaVita’s projected the number of in-center and training dialyses and patients for DaVita-Lynnwood with seven stations. [source: Application, p18]

Table 14
DaVita-Lynnwood
Projected Patients and Dialyses for Years 2018-2020

	Year 2 – 2018	Year 3 - 2019	Year 4 - 2020
# of Stations	7	7	7
Total Treatments	2,134	4,001	5,661
Total Patients	12	25	34

⁹ Recently approved PSKC applications are: App #12-04A PSKC-Whidbey Island; App #12-21 PSKC-Anacortes; and App #13-31 PSKC-Monroe.

The assumptions DaVita used to project revenue, expenses, and net income for DaVita-Lynnwood for years 2018 through 2020 are restated below. [source: April 29, 2016, screening responses, p2]

“Because the DaVita Snohomish dialysis center will be a new facility, it does not have historical financial data. Therefore, DaVita based the revenue and expense projections on an average of the historical revenue per treatment and operating expenses at DaVita’s existing facilities in the area, known within DaVita as Region 4a. That region includes DaVita Westwood, Olympic View, Bellevue, Mill Creek, Whidbey Island, Everett, and Pilchuck.”

Using the projected assumptions above, DaVita projected the revenue, expenses, and net income for DaVita-Lynnwood with seven in-center dialysis stations and its home dialysis treatment program. A summary of the projections is in Table 15 below. [source: Application, Appendix 9]

**Table 15
DaVita-Lynnwood Revenue and Expense Statement
Projected Years 2017 through 2020**

	CY 2018	CY 2019	CY 2020
Net Revenue	\$ 1,191,841	\$ 2,234,702	\$ 3,161,690
Total Expenses	\$ 907,777	\$ 1,324,117	\$ 1,695,954
Net Profit / (Loss)	\$ 284,064	\$ 910,585	\$ 1,456,736

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

The ‘Total Expenses’ line item includes all expenses related to the operation of DaVita-Lynnwood, including allocated costs. The line item also includes medical director costs consistent with the draft Medical Director Agreement provided in the application. [source: Application, Appendix 3]

Also included in the expense category is the lease cost for the new facility. DaVita provided an executed lease agreement between Total Renal Care Inc. (DaVita) and B33 Mukilteo, LLC, the building owner. [source: Application, Appendix 15]

Public Comments

- ***Payer Mix.** Despite the fact that DV has operated in Snohomish 3 since 2009, its proposed Lynnwood payer mix is not based on market specific data. The accuracy of the assumed payer mix is extremely critical because it drives net revenue and net income and ultimately, the financial performance of the facility. Table 2 compares the proposed payer mix for DV Lynnwood to PSKC-S. As Table 2 indicates, DV Lynnwood’s proposed revenue from Insurance/HMO is 55% higher than PSKC’s; a facility that actually operates in the proposed service area.*

**Table 2 [of PSKC Public Comments]
Comparison of Payer Mix for DV Lynnwood and PSKC – S Applications**

<i>Payer</i>	<i>Percent of Revenue</i>			<i>Percent of Patients</i>		
	<i>PSKC-S²</i>	<i>DV Lynnwood³</i>	<i>% Difference</i>	<i>PSKCS⁴</i>	<i>DV Lynnwood⁵</i>	<i>% Difference</i>
<i>Medicare</i>	69%	56.7%	-12.3%	80%	78.9%	-1.1%
<i>Medicaid/State</i>	6%	4.5%	-1.5%	9%	7.7%	-1.3%
<i>Insurance/HMO</i>	25%	38.8%	13.8%	11%	13.4%	2.4%
Total	100%	100.0%		100.0%	100.0%	

Source: PSKC – S and DV Lynnwood CN Applications

Footnotes in Table:

2= PSKC –S CN Application, Table 5, p. 9.

3= DV Lynnwood CN Application, Table 4 a p. 13. Table 4 on page 13 of the application indicates that this payer mix is a “Company-wide’ payer mix

4= PSKC –S CN Application, Table 5, p. 9.

5= DV Lynnwood CN Application, Table 5 a p. 13. Table 5 on page 13 of the application indicates that this payer mix is a “Company-wide’ payer mix.

In its screening response when specifically asked about the underlying assumptions, DV stated:

*‘Because the DaVita Snohomish dialysis center will be a new facility, it does not have historical financial data. Therefore, DaVita based the **revenue and expense projections (emphasis added)** on an average of the historical revenue per treatment and operating expenses at DaVita’s existing facilities in the area, known within DaVita as Region 4a. That region includes DaVita Westwood, Olympic View, Bellevue, Mill Creek, Whidbey Island, Everett and Pilchuk.’*

However, DV did not provide any specific information from its ‘Region 4a’ that would allow the CN Program to validate its assumptions. And, in fact, the revenue payer mix (Table 4 of the application) indicates that it was based on a national, not local payer mix.

- **Lease Expense.** *As part of its evaluation of an applicant’s compliance with the financial feasibility criteria in WAC 246-310-220, the CN Program has a consistent and well known history of requiring that each applicant provide documentation of site control for the proposed facility. The site control documentation must, among other things, outline the proposed expenses associated with the selected site, including the expected lease expenses. The CN Program, in its review, substantiates the lease expenses in the applicant’s pro forma financial statements. Because the CN Program evaluates a project’s financial feasibility through the facility’s first three full years of operation, the lease expenses must be verifiable through at least that period. Without substantiated lease expenses, the CN Program lacks the necessary data to evaluate whether a project is financially feasible under WAC 246-310-220. In fact, the CN Program has previously denied applications when it could not verify and substantiate lease expenses through the applicable time period. The lease agreement (Appendix 15 of its application), for the proposed DV Lynnwood facility states the following:
Beginning on the Commencement Date, Tenant shall pay as initial annual base rent (“Base Rent”) the amount set forth in the Data Sheet...*

The ‘data sheet’ in the lease agreement lists the base rent for the first 10 years of the lease as well as three options. There are four different scenarios for the lease expenses and none of

them 'match' the lease expenses in the pro forma financials. Table 5 provides the specific detail:

**Table 5 [of PSKC Public Comments]
Comparison of Lease Assumptions for DV Lynnwood,
Lease Agreement and Pro Forma Financials**

Source of Lease Expense	Cost/SF (Base Rent/Year)
Data Sheet (Years 1-5)	\$15.00 (months 1-12)- \$16.24 (months 49-60)
Option 1: Months 1 through 60	\$19.72
Option 2: Months 1 through 60	\$21.69
Option 3: Months 1 through 60	\$23.86
Pro Forma Financials (excludes \$5/SF for other lease expenses as noted in Footnote 3)	\$15.23 (2018-Year 1) to \$17.11 (2022-Year 5)

Source: DV Lynnwood CN Application, Appendix 15,
Lease Agreement (Data Sheet)

Given the above, the CN Program does not have the information it needs to confirm that the lease expenses for the proposed facility are consistent with the lease agreement as required, and in fact, the CN application should be denied for this failure.

- **Medical Director Agreement.** In its application, DV has provided a medical director agreement that spells out the following in Schedule 1:

Name of Facility: Snohomish III Dialysis

Address: In or around the Snohomish, WA area

Compensation: the annual compensation, post Medicare certification, and presented on Schedule 1 of the Medical Director Agreement (Appendix 3 of the DV Lynnwood CN application) is detailed as follows:

**Table 6 [of PSKC Public Comments]
Medical Director Services and Compensation**

Service	Monthly Compensation	Annual Compensation
Hemodialysis	\$3,750.00	\$45,000.00
Peritoneal Dialysis	\$1,458.33	\$17,500.00
Home Hemo Dialysis	\$1,458.33	\$17,500.00
Nocturnal Dialysis	\$416.67	\$5,000.00
Total	\$7,083.33	\$85,000.00

Source: DV Lynnwood CN Application, Appendix 3

As Table 6 indicates, the medical director will be providing medical directorship and be compensated for four services. Within the DV Lynnwood application, there is only discussion of three of the four services. There is no mention in the application of a nocturnal program. There is no explanation regarding how this service ties to patient projections and the 80% utilization calculation. In addition, consistent with the requirement noted above (that the CN Program must be able to verify the information for the medical director agreement in the pro forma financials), if there is no nocturnal program, the CN Program cannot verify and substantiate medical director expenses through the applicable time period. In addition, the location of the facility and

name of the facility listed in Schedule 1 of the Medical Director Agreement do not match the application. The application names the facility as DV Lynnwood not Snohomish III. Again, this calls into question the ability of the CN Program to confirm DV Lynnwood's conformance with the financial feasibility criteria contained in WAC 246-310-220.

[source: PSKC, July 15 2016, public comments, pp2-6]

DaVita Rebuttal Comments [source: August 15, 2016, rebuttal comments, pp1-8]

- Payer Mix. PSKC appears to argue that DaVita's application should be denied because DaVita provided company-wide payor mix information in Section II(h) of the application form. This is another hollow argument. Because this is a new facility, there is no historical payor mix data for the facility at issue. DaVita accordingly provided its company-wide figures, as it does in every CN application for a new facility. PSKC's argument that DaVita's application should be denied because it provided company-wide payor mix information is an argument that has been rejected by the Department, repeatedly, during previous application cycles.
- Lease Expense. PSKC argues that there are inconsistencies between DaVita's lease and pro forma. PSKC is mistaken. It appears that PSKC overlooked the fact that the lease is expected to commence six months before the beginning of the first full year of facility operation, and therefore PSKC failed to take into account the annual increases in lease expenses that occur at the midpoint of each calendar year. As clearly stated in DaVita's application, for the first twelve months of the lease, rent is \$15 per square foot and estimated operating expenses, including CAM, insurance, and taxes, are \$5 per square foot.² Per the terms of the lease, rent increases by 2% annually. We have estimated that operating expenses will increase by 3% annually. The first full year of the facility's operation will begin on January 1, 2018. But the expected commencement date of the lease is June 29, 2017. Accordingly, the annual increases in rent and estimated operating expenses (by 2% and 3% respectively) occur at the midpoint of 2018 and each subsequent calendar year. The calculations of lease expenses are summarized in the following table:

Table Provided in DaVita Rebuttal Responses, p3

	<i>Lease Expenses for January-June</i>	<i>Lease Expenses for July – December</i>	<i>Annual Lease Expenses</i>	<i>Pro Forma Figure</i>	<i>Match?</i>
<i>Full Year 1 (2018)</i>	$((\$15+\$5)*6950)*6/12 = \$69,500$	$((\$15*1.02+\$5*1.03)*6950)*6/12 = \$71,064$	\$140,564	\$140,564	Yes
<i>Full Year 2 (2019)</i>	$((\$15*1.02'+\$5*1.03)*6950)*6/12 = \$71,064$	$((\$15*1.02+\$5*1.03)*6950)*6/12 = \$72,664$	\$143,728	\$143,728	Yes
<i>Full Year 3 (2020)</i>	$((\$15*1.02+\$5*1.03)*6950)*6/12 = \$72,664$	$((\$15*1.02+\$5*1.03)*6950)*6/12 = 74,302$	146,966	146,966	Yes
<i>Full Year 4 (2021)</i>	$((\$15*1.02+\$5*1.03)*6950)*6/12 = 74,302$	$((\$15*1.02+\$5*1.03)*6950)*6/12 = 75,977$	\$150,279	\$150,279	Yes
<i>Full Year 5 (2022)</i>	$((\$15*1.02+\$5*1.03)*6950)*6/12 = 75,977$	$((\$15*1.02+\$5*1.03)*6950)*6/12 = 77,693$	\$153,670	\$153,670	Yes

The lease expenses in the pro forma are calculated correctly in each year, consistent with the terms of the lease and the estimated operating expenses identified in the application. DaVita did not make an error in its application. PSKC made a mistake in its comments: it overlooked the fact that the annual increase in lease expenses occurs at the end of June, not at the end of December.

- Medical Director Agreement. PSKC argues that there are inconsistencies between DaVita's pro forma and medical director agreement. PSKC is again mistaken. The draft medical director agreement with Dr. Nakamoto clearly identifies the following compensation:

*Table Provided in DaVita Rebuttal Responses
Medical Director Expenses
(Post-Medicare Certification)*

<i>Service</i>	<i>Monthly Compensation</i>	<i>Annual Compensation</i>
<i>Hemodialysis</i>	<i>\$3,750.00</i>	<i>\$45,000</i>
<i>Peritoneal Dialysis</i>	<i>\$1,458.33</i>	<i>\$17,500</i>
<i>Home Hemodialysis</i>	<i>\$1,458.33</i>	<i>\$17,500</i>
<i>Nocturnal</i>	<i>\$416.67</i>	<i>\$5,000</i>
<i>Total</i>	<i>\$7,083.33</i>	<i>\$85,000</i>

This compensation, per the terms of the Medical Director Agreement, exactly matches the medical director expenses in the proforma: \$85,000 per year. PSKC also contends that if the medical director does not provide services relating to nocturnal dialysis, the medical director fee in the pro forma would be inaccurate (i. e., it should be \$80,000 instead of \$85,000, because \$5,000 of the compensation relates to nocturnal dialysis). But DaVita must include in the medical director agreement all compensation the medical director may receive, and so it appropriately included compensation for nocturnal dialysis in both the Medical Director Agreement and the pro forma. And even if, for the sake of argument, the medical director were not compensated for nocturnal dialysis, this would not affect the financial feasibility of DaVita's facility; indeed, the only effect would be to decrease operating costs by \$5,000 per year.

PSKC complains that the Medical Director Agreement refers to the facility "as Snohomish III" but "[t]he application names the facility as DV Lynnwood not Snohomish III." At this point, PSKC's comments cross the line from mistaken to frivolous. Obviously "Snohomish III" and "Lynnwood" refer to the same project, which is the only DaVita project under review: DaVita's application to establish a new dialysis facility called DaVita Lynnwood Dialysis Center, located at 13619 Mukilteo Speedway, Suite D-1, Lynnwood, Washington 98087, which is in the Snohomish III planning area.

Department Evaluation of WAC 246-310-220(1) for DaVita

PSKC claims that DaVita's financial statements are unreliable for the following reasons:

- payer mix is inaccurate and cannot be substantiated by the facility's historical payer mix;
- lease expenses cannot be verified in the lease agreement or the projected financial statements; and
- the costs associated with the medical director agreement include amounts for nocturnal dialysis. If there is no nocturnal program, the costs for the medical director cannot be verified; and
- medical director agreement does not include a reference to the new facility, therefore, it is not conclusive that medical director is for this project.

In rebuttal, DaVita provided explanations for its approach to the financial projections, including the medical director and lease expenses. DaVita's payer mix approach is similar to the approach

DaVita has used in past applications. The department reviewed the three most recently approved applications submitted by DaVita.¹⁰ The review substantiates that DaVita has used a similar approach to estimate its payer mix and its lease costs for the facility. DaVita provided a table showing all calculations used to determine the lease costs through full year five (2022). The lease agreement was executed on February 22, 2016, and outlines the roles and responsibilities for both parties. The agreement identifies all costs associated with the lease of space.

The department's review of the three most recently approved applications submitted by DaVita revealed that the reference to compensation for nocturnal dialysis is a recent addition to the medical director agreements submitted by DaVita. DaVita's application does not indicate that it would be offering a nocturnal dialysis program; however, DaVita's approach of including the payment to the medical director if a nocturnal program is established at the new center is acceptable. The approach is acceptable because DaVita has identified and accounted for all possible medical director costs in the financial statement. The medical director agreement provides adequate reference to the new dialysis center in Lynnwood. The concerns raised by PSKC are not grounds for denial of DaVita's application.

The assumptions used by DaVita to determine the number of patients and treatments at DaVita-Lynnwood as a seven-station center are reasonable. The assumptions used by DaVita to project revenues, expenses, and net income for DaVita-Lynnwood are also reasonable.

The department concludes DaVita's project **meets this sub-criterion**.

Department Superiority Review

The department concludes both PSKC and DaVita **meet this sub-criterion**. Further, each application is equivalent to the other.

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

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

Puget Sound Kidney Centers

The actual cost for the addition of seven stations to PSKC-South is \$377,823. The costs include minor remodel of the existing center, equipment, and associated fees and taxes. PSKC clarifies that no new construction is required to make the seven additional stations operational at PSKC-South. [source: Application, pp30-31]

PSKC also identified allocation of construction costs that were expended in year 1997 when PSKC-South was first established with 14 dialysis stations. With \$172,833 in allocated construction and equipment costs and associated fees and taxes, PSKC identified a total cost of

¹⁰ Recently approved DaVita applications are: App #15-04A2 DaVita Tacoma Dialysis Center; App #15-06A DaVita Centralia Dialysis Center; and App #15-30 DaVita Federal Way Dialysis Center.

\$550,656 for the project. The capital cost breakdown is shown in Table 16 below. [source: Application, p30 and April 29, 2016, screening responses, pp30-31]

**Table 16
PSKC-South Estimated Capital Costs**

Item	Actual	Allocated
Building Remodel	\$ 108,300	-----
Fixed Equipment	\$ 52,139	-----
Moveable Equipment	\$ 181,170	-----
Architect/Engineering Fees	\$ 15,000	-----
Taxes (building & equipment)	\$ 18,973	-----
Other Costs (taxes & insurance)	\$ 2,240	-----
Allocated Costs	-----	\$ 172,833
Total Estimated Capital Costs	\$ 377,823	\$ 172,833

PSKC also provided the following statements related to this sub-criterion. [source: Application, p31]

“No new construction is required to make the 34 stations operational. In 2015, PSKC-South relocated home training from the main area of the dialysis unit to a space that had previously been a meeting room in order to enhance the teaching environment for our growing home patient program. This allowed the space in the main unit to make all seven stations operational. Please note we are reporting 100% of the cost associated with the remodeling of the home training space as ‘new’ for purposes of this CN because the costs had previously not been reported in any prior PSKC-South CN application. These ‘new’ costs reflect the actual costs incurred for the remodel.

*PSKC is also aware that the Program expects applicants to put forward a reasonable methodology to estimate ‘construction costs’ including historical costs for the **sole purpose of CN tiebreakers**. [emphasis in original] PSKC review the actual historical cost associated with the 1997 project, and divided the cost by the number of 33 (total capacity of PSKC-South at that time.) The total construction cost in 1997 for PSKC-South was \$814,786, all of which was reported in the original CN application. The facility was originally approved to operate 14 stations, but had a total facility capacity of 33. In a January 27, 2016, conversation with CN Program staff, it was agreed that the total project costs would be allocated based on the facility capacity of 33 stations. The specific calculation is included below.*

*The calculation is \$184,786/33 stations = \$24,690 * 7 = \$172,833.*

Furthermore, PSKC understands that the total project cost (allocated plus new) will be used solely for determining the cost per station in the tiebreaker analysis in the event one of the applications is not deemed superior, and the CN Program reaches tiebreakers.”

PSKC also stated that no changes in costs or charges for dialysis services at PSKC-South are anticipated. Given the size of the existing facility (27 stations), PSKC states that the addition of seven stations is expected to reduce the average cost per treatment because of the savings realized by improved economies of scale. [source: Application, p32]

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-220(2) for PSKC

PSKC’s actual costs of \$377,823 appear to be reasonable for minor remodel of an existing dialysis center. Additionally, PSKC’s description of its cost allocation formula to be used under the tie-breaker criteria is also reasonable. No concerns with PSKC’s costs were identified.

The department concludes PSKC’s project **meets this sub-criterion.**

DaVita HealthCare Partners, Inc.

The capital expenditure associated with the establishment of a new seven-station dialysis center in Lynnwood is \$1,720,865. The capital cost breakdown is shown in Table 18 below. [source: Application, Appendix 7 and April 29, 2016, screening responses, p2]

**Table 17
DaVita-Lynnwood Estimated Capital Costs**

Item	Actual
Construction/Leasehold Improvements	\$ 1,073,675
Fixed / Moveable Equipment	\$ 460,105
Architect/Engineering /Professional Services Fees	\$ 104,750
Real Estate Commission	\$ 82,335
Total Estimated Capital Costs	\$ 1,720,865

DaVita also provided the following statements related to this sub-criterion. [source: Application, p23]

“This will be a new facility in an existing lease structure. As such, there are no acquisition or historical costs associated with the construction of the facility to report to the department.”

No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project. The proposed facility will operate at utilization levels consistent with required utilization levels. 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 increase in charges for services within the ESRD planning area.”

Public Comments

- Revenue Per Treatment. PSKC has a documented history of providing services at a significantly lower charge than other providers, particularly DV. As Table 2 above details, the difference in revenue between the applicants is dramatically different, truly significant to the cost to the health care system. As Table 3 details, the proposed payer mix significantly affects revenue, and results in net revenue per treatment for DV Lynnwood being more than double the actual of PSKC-S:

**Table 3 [of PSKC Public Comments]
Net Revenue/Treatment by Applicant, Years 1-3**

Applicant	PSKC - S	DV Lynnwood
Year 1	\$261.65	\$558.50
Year 2	\$261.65	\$558.54
Year 3	\$261.75	\$558.50

Source: PSKC - S CN Application, Exhibit 8, DV Lynnwood Appendix 9

*And, finally, as Table 4 indicates, these assumptions also significantly affect the 'bottom line' as net income per treatment is **three to six times higher** for DV Lynnwood than PSKC-S during the first three years of the project.*

**Table 4 [of PSKC Public Comments]
Net Income/Treatment by Applicant, Years 1-3**

Applicant	PSKC - S	DV Lynnwood
Year 1	\$42.26	\$133.11
Year 2	\$42.36	\$227.59
Year 3	\$42.52	\$258.92

Source: PSKC - S CN Application, Exhibit 8, DV Lynnwood Appendix 9

DV will argue that it negotiates contracts "better than" PSKC. We beg to differ; we negotiate contracts that provide a reasonable return on our investment without over-charging payers and ultimately patients and employers. WAC 246-310-220(2) states:

(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.

The data provided in the applications demonstrates irrefutably that the approval of additional stations to DV will have an unreasonable and unnecessary impact on the costs and charges for health services. Approval of additional stations at PSKC-S will ensure that patients and payers have improved access to dialysis services without an increase in costs and charges. [source: PSKC, July 15 2016, public comments, pp2-6]

DaVita Rebuttal Comments [source: August 15, 2016, rebuttal comments, pp1-8]

- Revenue per Treatment. *PSKC argues that DaVita's application should be denied because DaVita's revenue per treatment is too high. However, PSKC is well aware that the overwhelming majority of dialysis patients are beneficiaries of Medicare or other government-based programs. The reimbursement rates for those patients are set by the government, and there is no difference between what DaVita or PSKC would be reimbursed. For the small number of patients covered by commercial insurance prior to their enrollment in Medicare, reimbursement rates are set through arms-length contractual negotiations between commercial insurers and dialysis providers. Obviously, providers prefer to receive as much as possible and insurers prefer to pay as little as possible; the agreed reimbursement rates reflect a compromise that both find acceptable. PSKC presents no evidence that DaVita's reimbursement rates in the region would have any impact on the costs and charges of health services, much less an "unreasonable" one. Indeed, PSKC's argument depends on the illogical proposition that insurers, who possess enormous expertise, sophistication, and skill in pricing healthcare services, pay DaVita amounts that are unreasonable. We would expect the Department to recognize the absurdity of such an argument. [In footnote #12 of*

the rebuttal comments, DaVita provided the following statements: *Although it is irrelevant to this concurrent review, we must note that PSKC's suggestion that it voluntarily accepts lower reimbursement than commercial insurers are willing to pay is unbelievable.*]

Department Evaluation of WAC 246-310-220(2) for DaVita

DaVita's costs to establish a new seven-station center is \$1,720,865. PSKC claims that DaVita's revenue per treatment is high and could result in an unreasonable impact on the costs and charges for health services. In its rebuttal, DaVita asserts that "...the reimbursement rates for those patients are set by the government, and there is no difference between what DaVita or PSKC would be reimbursed." This statement is not completely accurate.

Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider.

The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by 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 department concludes DaVita's project **meets this sub-criterion**.

Department Superiority Review

When comparing two competing projects, the department does not automatically conclude that the establishment of a new facility in a planning area would cause an unreasonable impact on costs and charges for health services when compared to an expansion of an existing provider. A conclusion for this sub-criterion is reached, in part, by taking into consideration the costs of each project, the services to be provided, and the benefit to the community.

In summary, the department concludes both PSKC and DaVita **meet this sub-criterion**. Further, each application is equivalent to the other.

(3) The project can be appropriately financed.

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

Puget Sound Kidney Centers

PSKC intends to fund the project using PSKC corporate cash reserves. [source: Application, p10] Since PSKC is the applicant and intends to fund the project, PSKC did not provide a letter from itself (PSKC) to demonstrate a financial commitment to the project.

PSKC provided a copy of its audited financial statements for years 2012, 2013, and 2014 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 1]

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-220(3) for PSKC

Actual PSKC cost for the seven station addition is \$377,823. PSKC intends to finance the project with reserves and demonstrated costs can be financed. If this project is approved, the department would attach a condition requiring PSKC to finance the project consistent with the financing description in the application.

With a financing condition, the department concludes PSKC’s project **meets this sub-criterion.**

DaVita HealthCare Partners, Inc.

The capital expenditure for this project is \$1,720,865 and DaVita intends to fund the project using corporate reserves. DaVita provided a letter from its corporate chief operating officer for kidney care to demonstrate an operational and financial commitment to the project. [source: Application, p23 and Appendix 6]

DaVita provided a copy of its audited financial statements for years 2012, 2013, and 2014 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 10]

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-220(3) for DaVita

DaVita’s costs to establish a seven-station dialysis center is \$1,720,865. DaVita intends to finance the project with reserves and demonstrated the costs can be financed. If this project is approved, the department would attach a condition requiring DaVita to finance the project consistent with the financing description in the application.

With a financing condition, the department concludes DaVita’s **project meets this sub-criterion.**

Department Superiority Review

The department concludes both PSKC and DaVita **meet this sub-criterion with a financing condition.** Further, each application is equivalent to the other.

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Puget Sound Kidney Centers **met** the applicable structure and process of care criteria in WAC 246-310-230.

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that DaVita HealthCare Partners, Inc. **met** the applicable structure and process of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

Puget Sound Kidney Centers

PSKC-South is currently operating with 27 dialysis stations. If this project is approved, the center will have a total of 34 stations. Table 18 below provides a breakdown of current and projected FTEs [full time equivalents] for PSKC-South. Current year is 2016 and projected years are 2017 through 2020. [source: Application, p34]

**Table 18
PSKC-South Current and Proposed FTEs for Years 2016-2020**

FTE by Type	CY 2016 Current	CY 2017 Increase	CY 2018 Increase	CY 2019 Increase	CY 2020 Increase	Total FTEs
Direct Care Manager	1.00	0.00	0.00	0.00	0.00	1.00
RN	9.00	0.00	0.20	0.00	0.00	9.20
Dialysis Techs	21.50	0.60	0.40	0.50	1.00	24.00
Chief Tech	1.00	0.00	0.00	0.00	0.00	1.00
Biomed Tech	2.00	0.00	0.00	0.00	0.00	2.00
Stock Tech	1.00	0.00	0.00	0.00	0.00	1.00
Lab Tech	0.75	0.00	0.00	0.00	0.00	0.75
Medical Social Worker	1.50	0.00	0.00	0.00	0.00	1.70
Dietician	1.50	0.00	0.00	0.20	0.00	1.70
Admin Coordinator	1.00	0.00	0.00	0.20	0.00	1.00
Admin Assistant	1.69	0.00	0.00	0.00	0.00	1.69
Total FTEs	41.94	0.60	0.60	0.90	1.00	45.04

PSKC also clarified that all PSKC medical directors are under contract and not included in the table above. Physician contracts include:

- a nephrologist for medical director services for each PSKC facility. Specific to PSKC-South, the medical director is Win Kyaw, MD.
- a nephrologist who functions as the ‘corporate medical director’ that oversees all medical directors associated with PSKC facilities. PSKC’s corporate medical director is Mark Gunning, MD.

PSKC also has an employed nephrologist, Pamila Keech, MD who serves as chief medical officer. Since the chief medical officer is an employee of PSKC, costs associated with this role are allocated to each of the dialysis centers. [source: Application, p4]

PSKC states it does not expect difficulty recruiting the additional staff needed for the seven station addition at PSKC-South because it expects only modest increases in staff for years 2017 through 2020. PSKC would add 3.1 FTEs in all four years. PSKC states it offers a competitive wage package, a positive and supportive work environment, and a philosophy that encourages existing staff to receive training and additional education. [source: Application, p35]

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-230(1) for PSKC

PSKC has the majority of its dialysis staff in place at PSKC-South. Information provided in the application demonstrates that PSKC is a well-established provider of dialysis services in Skagit, Island, and Snohomish counties. Specific to PSKC-South, it has been operating in the planning area since approximately 1998. Based on the above information, the department concludes that PSKC has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project.

The department concludes PSKC’s project **meets this sub-criterion.**

DaVita HealthCare Partners, Inc.

DaVita-Lynnwood would be a new seven-station facility in the planning area. Table 19 below provides a breakdown of projected FTEs for calendar years 2018 through 2020. [source: Application, p25]

**Table 19
DaVita-Lynnwood Proposed FTEs for Years 2016-2020**

FTE by Type	CY 2018 Current	CY 2019 Increase	CY 2020 Increase	Total FTEs
Administrator	1.00	0.00	0.00	1.00
Administrative Assistant	0.13	0.12	0.10	0.35
Medical Social Worker	0.12	0.11	0.09	0.32
Dietician	0.12	0.11	0.09	0.32
RN/In-Center/PD/HHD	0.47	0.35	0.38	1.20
PCT	1.03	1.05	0.77	2.85
BioMed Tech	0.18	0.00	0.00	0.18
Total FTEs	3.05	1.74	1.43	6.22

Since DaVita’s medical directors are under contract, they are not included in the FTE table above. DaVita provided a copy of the draft medical director agreement among Total Renal Care, Inc. (DaVita), The PolyClinic (group), and Lisa Nakamoto, MD (physician). The PolyClinic is a Washington company that employs physicians, including nephrologists. Dr. Nakamoto is the

physician specifically named in the draft agreement that would be providing medical director services at DaVita-Lynnwood. [source: Application, Appendix 3]

DaVita provided the following statements related to recruitment and retention of staff for DaVita-Lynnwood. [source: Application, p26]

“DaVita anticipates no difficulty in recruiting the necessary personnel to staff the Lynnwood Dialysis Center. Based on our experience establishing a new facility within a planning area, DaVita anticipates that staff from the DaVita Mill Creek Dialysis Center and geographically adjacent facilities will serve patients at the Lynnwood Dialysis Center. Moreover, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer (davita.com.about/awards) and offers a competitive wage and benefit package to employees. DaVita posts openings nationally both internally and external to DaVita.”

Public Comments

None

Public Comments

None

Department Evaluation of WAC 246-310-230(1) for DaVita

DaVita is proposing to establish a new facility in the planning area. Information provided in the application demonstrates that DaVita is a well-established national provider of dialysis services. Specific to Washington State, DaVita has been providing services in Washington State since approximately 1996. For Snohomish County planning area #3, DaVita has one dialysis center located in Bothell [98021]. Based on the above information, the department concludes that DaVita has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project.

The department concludes DaVita’s project **meets this sub-criterion.**

Department Superiority Review

The department concludes both PSKC and DaVita **meet this sub-criterion.** Further, each application is equivalent to the other.

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

WAC 246-310 does not contain specific WAC 246-310-230(2) criteria as identified in WAC 246-310-200(2)(a)(i). There are 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 ability to establish and maintain appropriate relationships and ancillary/support services.

Puget Sound Kidney Centers

PSKC states it has been providing dialysis services in Skagit, Island, and Snohomish counties for many years. This project proposes the expansion of PSKC-South in Mountlake Terrace, within Snohomish County planning area #3. PSKC-South has been in operation since approximately

1997. This project proposes a seven station increase in dialysis stations that would result in a 34-station facility.

PSKC states it currently maintains the appropriate relationships with ancillary and support services PSKC-South. Medicare required ancillary and support services include the following:

- | | |
|------------------------------|---------------------|
| Social Services | Staff Education |
| Nursing Services | Information Systems |
| Nutrition Services | Plant Operations |
| Patient Education | Material Management |
| Patient Financial Counseling | Technical Services |
| Administration | |
- [source: Application, p35]

Specifically related to medical director services, PSKC has two physician contracts. A summary of the contracts is below. [source: Application, Exhibit 2]

- A nephrologist for medical director services for each PSKC facility. Specific to PSKC-South, the medical director is Win Kyaw, MD. This agreement was executed on July 1, 2014, and is initially for three years, with annual automatic renewals. The agreement identifies roles and responsibilities for both PSKC and Dr. Kyaw.
- A nephrologist who functions as the ‘corporate medical director’ that oversees all medical directors associated with PSKC facilities. PSKC’s corporate medical director is Mark Gunning, MD. This agreement was executed on January 1, 2015, and is initially for five years, with one annual automatic renewal. The agreement identifies roles and responsibilities for both PSKC and Dr. Gunning.

PSKC also has an employed nephrologist, Pamila Keech, MD who serves as chief medical officer. Since the chief medical officer is an employee of PSKC, there is no medical director contract for these services and costs associated with this role are allocated to each of the dialysis centers. [source: Application, p4]

Public Comments

None

Rebuttal Comments

None

Department Evaluation for WAC 246-310-230(2) for PSKC

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that PSKC will continue to maintain the necessary relationships with ancillary and support services to provide dialysis services at PSKC-South. The department concludes that approval of additional stations to PSKC-South would not negatively affect existing healthcare relationships.

The department concludes PSKC **meets this sub-criterion.**

DaVita HealthCare Partners, Inc.

DaVita provides dialysis services throughout Washington State and the Snohomish County planning area #3. For its Lynnwood facility, the following ancillary and support services would be provided on site: social services, nutrition, financial counseling, pharmacy access, patient and staff education, human resources, material management, administration and biomedical technical services.

Additional services are coordinated through DaVita’s corporate offices in Denver, Colorado and support offices in Federal Way and Tacoma, Washington; El Segundo, California; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: Application, p26]

The draft medical director agreement provided by DaVita for its DaVita-Lynnwood facility is with The PolyClinic (group) and Lisa Nakamoto, MD (physician). The draft agreement is initially for three years, with annual automatic renewals. The agreement identifies roles and responsibilities for DaVita, The PolyClinic, and Dr. Nakamoto. [source: Application, Appendix 3]

DaVita also provided a copy of an example patient transfer agreement that would be used at the new Lynnwood facility. [source: Application, Appendix 12]

Public Comments

None

Rebuttal Comments

None

Department Evaluation for WAC 246-310-230(2) for DaVita

While DaVita would not be a new provider in the service area, its Lynnwood Dialysis Center would be a new facility that would require its own ancillary and support agreements and relationships. If DaVita’s project is approved, the department would include two conditions. One requiring DaVita to provide a copy of the executed Medical Director agreement and a second condition requiring DaVita to provide a copy of the executed transfer agreement with a local hospital.

With the following two conditions, the department concludes DaVita’s project **meets this sub-criterion.**

1. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed medical director agreement. The executed agreement must be consistent with the draft agreement provided in the application.
2. Prior to providing services, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed transfer agreement with a local hospital. The executed agreement must be consistent with the draft agreement provided in the application.

Department Superiority Review

PSKC meets this sub-criterion with no specific conditions. The department also concludes that DaVita meets this sub-criterion with two specific conditions. Each application is equivalent to the other.

- (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 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.

Puget Sound Kidney Centers

PSKC states it does not have any history with respect to the actions noted in CN regulations WAC 248-19-390(5) (a), now codified at 246-310-230(5)(a), that states:

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

PSKC states it will operate all existing programs in conformance with applicable federal and state laws, rules and regulations. [source: Application, p6 & p37]

Public Comments

- *"PSKC-South for many years has operated 33 stations, even though it has only been CN approved for 14-27 stations. This application process has revealed that PSKC has, apparently for 19 years, operated 33 stations at PSKC-South. But PSKC has never had CN approval to operate more than 27 stations. To ensure the integrity of the CN process, and to avoid rewarding PSKC for this practice, we strongly encourage the Department to deny PSKC's application for this reason.*

While processing PSKC's application, the Program learned from the Department's Investigations and Inspections Office, that PSKC was operating a 33-station facility, even though it had CN approval for only 27 stations. In screening, the Program asked PSKC to explain this. In response, PSKC admitted that when it originally received CN approval in 1996 to build PSKC South, a 14-station approval, PSKC built a 33-station facility.

DaVita does not argue that it was improper for PSKC to construct built-out space for future expansion at PSKC-South, assuming this was consistent with what PSKC proposed in its application. To the contrary, DaVita believes that it is appropriate for dialysis providers to include some expansion space in new facilities. But PSKC further admitted that it did not simply build out space for 19 future expansion stations. It equipped and operated all 33 stations.

PSKC assures the Program that it has never had more than 27 patients dialyzing at any given time at PSKC-South, then goes on to admit that it ran the facility with 33 equipped and operational stations and did not stop doing so until 2016. PSKC's justification for this effectively is that "everybody does it." Specifically, PSKC asserts that "historically there was confusion between providers and the State surveyors about how many stations could be operational."

DaVita does not dispute that dialysis providers historically have maintained some additional operational stations in order to accommodate emergencies or non-isolation patients at facilities with isolation stations. For example, if a facility has an isolation station and no isolation patients, an extra non-isolation station allows the facility to use the number of stations for which it has CN approval without forcing patients not requiring isolation to use the isolation room, which many patients would be uncomfortable doing because they know it is designed to be used for patients with communicable diseases requiring isolation. As another example, if there is a problem with a station, having an extra station available allows a facility to continue treating all of its patients while that problem is resolved.

*What is unprecedented here is that PSKC has operated **six additional stations** beyond its CN approved capacity **at the time of the application-** and presumably more than six for a period of time, because the facility was previously approved for fewer than 27 stations. To DaVita's knowledge, no other dialysis provider in Washington is doing this as the Department and surveyors' interpretation of station utilization has been evidenced in other facility citations since at least early 2015. In practice, having multiple stations ready for operational use facilitates what is colloquially referred to as a "**hot-turn**". This means that, rather than fully disinfecting a station between patients, PSKC can take one patient off of a machine and immediately put the next patient on a clean, non-CN certified, machine in order to accept more patients with greater speed.*

PSKC actually tries to use to its advantage, in this concurrent review, its operation of six additional stations. Throughout its application, PSKC criticizes DaVita's Mill Creek facility for taking longer than expected to reach 80% utilization, and highlights that PSKC-South continues to have a higher utilization rate than DaVita's facility. But now that it has come to light that PSKC-South operated, until 2016, with the ability to operate 33 stations, this utilization data is not at all surprising. The Department should seriously question the impact that PSKC-South's operational practices have had on the utilization rate for its own facility as well as DaVita Mill Creek's. In an apparent reference to its operation of six more stations than its CN-approved capacity, PSKC praises itself for employing "strategies" to improve patient access. PSKC's definition of "strategy" in this context should be viewed with skepticism.

We urge the Department to deny PSKC's application on the ground that at the time PSKC applied, or until just before, PSKC was still operating PSKC-South with six more operational stations than its CN-approved capacity. Such a denial is necessary to protect the integrity of the CN process. Moreover, much of the data in PSKC's application - including its utilization figures and claims regarding its own efficiency - must be viewed as unreliable, because they are driven by PSKC's operation of PSKC-South with 33-stations in a "hot turn" environment. If, after PSKC has for a reasonable period of time operated PSKC-South with only 27 operational stations, as it has been instructed to do, there is need for additional stations in

Snohomish 3 and PSKC can satisfy all other CN requirements, PSKC can apply again at that time.” [source: DaVita July 15, 2016, public comments, pp1-3]

PSKC Rebuttal [source: August 15, 2016, rebuttal comments, pp3-4]

- *Among DV’s public comments, DV’s most egregious is its suggestion that PSKC violated rules regarding the number of stations PSKC–S is authorized to operate. For the record, PSKC has **never** dialyzed more than 27 patients at PSKC-S at a time. Further, PSKC’s original CN for the establishment of PSKC-S identified the design of, and construction costs for, a 33 station facility. While less than 33 stations were approved, the entire construction cost was approved, and the CN Program was aware of this fact. This was a common practice among reputable providers for many years.*

DV’s accusation regarding the number of patients treated at PSKC-S is without merit and is, quite frankly, little more than a desperate attempt to have PSKC’s application rejected.

Department Evaluation of WAC 246-310-230(3) for PSKC

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 two 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. Finally, the department focused on its own state survey data performed by the Department of Health’s Investigations and Inspections Office. Below is a summary of the three focused reviews for each applicant.

Centers for Medicare & Medicaid Services (CMS) Star Ratings

On January 22, 2015, the Centers for Medicare & Medicaid Services (CMS) released a media statement with the following information related to its dialysis facility compare website.

“Today, the Centers for Medicare & Medicaid Services (CMS) added star ratings to the Dialysis Facility Compare (DFC) website. These ratings summarize performance data, making it easier for consumers to use the information on the website. These ratings also spotlight excellence in health care quality. In addition to posting the star ratings, CMS updated data on individual DFC quality measures to reflect the most recent data for the existing measures.

“Star ratings are simple to understand and are an excellent resource for patients, their families, and caregivers to use when talking to doctors about health care choices,” said CMS Administrator Marilyn Tavenner. “CMS has taken another step in its continuous commitment to improve quality measures and transparency.”

DFC joined Nursing Home Compare and Physician Compare in expanding the use of star ratings on CMS websites. The DFC rating gives a one to five-star rating based on information about the quality of care and services that a dialysis facility provides. Currently, nine DFC quality measures are being used collectively to comprise the DFC star ratings. In the future, CMS will add more measures.

In related news, CMS plans to add the Standardized Readmission Ratio (SRR) for dialysis facilities to the publicly reported quality outcome measures available on the Compare website. SRR is a measure of care coordination. SRR is not included in DFC’s star rating at this time.

DFC quality measure data is either updated quarterly or annually. CMS plans to update the DFC's star rating on an annual basis beginning in October 2015."

CMS provided the following overview regarding its star rating for dialysis centers. [source: CMS website]

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

CMS assigns a one to five 'star rating' in two separate categories: best treatment practices and hospitalizations and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

- Best Treatment Practices

This is a measure of the facility's treatment practices in the areas of anemia management; dialysis adequacy, vascular access, and mineral & bone disorder. This category reviews both adult and child dialysis patients.

- Hospitalization and Deaths

This measure takes a facility's expected total number of hospital admissions and compares it to the actual total number of hospital admissions among its Medicare dialysis patients. It also takes a facility's expected patient death ratio and compares it to the actual patient death ratio taking into consideration the patient's age, race, sex, diabetes, years on dialysis, and any co-morbidities.

The Dialysis Facility Compare website currently reports on 9 measures of quality of care for facilities. These measures are used to develop the star rating. Based on the star rating in each of the two categories, CMS then compiles an 'overall rating' for the facility. As with the separate categories: the more stars, the better the rating. The star rating is based on data collected from January 1, 2011 through December 31, 2014.¹¹

The measures used in the star rating are grouped into three domains by using a statistical method known as Factor Analysis. Each domain contains measures that are most correlated. This allows CMS to weight the domains rather than individual measures in the final score, limiting the possibility of overweighting quality measures that assess similar qualities of facility care. The three domains are as follows:

¹¹ The information or data on Dialysis Facility Compare comes from two key sources: 1) CMS Statistical Analytical Files (Medicare Claims); and 2) Consolidated Renal Operations in a Web-enabled Network (CROWN). Some ratios are calculated annually based on the information that facilities send Medicare each month; other ratios are calculated quarterly.

- "Standardized Outcomes (SHR, SMR, and STrR)" – This first domain combines the three outcome measures for hospitalization, mortality and transfusions (SHR, SMR, and STrR).
- "Other Outcomes 1 (AV fistula, tunneled catheter)" – The arteriovenous fistula and catheter measures forms the second domain.
- "Other Outcomes 2 (Kt/V, hypercalcemia)" – The All Kt/V and hypercalcemia measures forms the third domain.

Facilities are rated as long as they have at least one measure in each of the three domains. Because the vascular access measures in the “Other Outcomes 1 (AV fistula, tunneled catheter)” domain do not apply to peritoneal dialysis patients, peritoneal dialysis-only facilities are rated based on the other two domains. They receive ratings as long as they have scores for at least one of the two domains not related to vascular access.

CMS Star Rating for Out-of-State Centers

PSKC does not own or operate any healthcare facilities outside of Washington State.

CMS Star Rating for Washington State Centers

The department reviewed the star rating for the following six dialysis centers owned and operated by PSKC (listed in alphabetical order).

- | | |
|------------------|-----------------------|
| PSKC – Anacortes | PSKC – Smokey Point |
| PSKC – Everett | PSKC – South |
| PSKC – Monroe | PSKC – Whidbey Island |

Of the six, two are new centers and do not yet have the necessary amount of data to compile a star rating.¹² The remaining four centers had a three or better star rating. PSKC-South’s star rating is a five.

Washington State Survey Data

The department reviewed the compliance history for all six centers above. In the most recent two years, the department has conducted and completed at least six surveys. All surveys resulted in no significant non-compliance issues. [source: DOH IIO survey data]

In addition to the facilities owned and operated by PSKC, the department also reviewed the compliance history for the medical directors identified for PSKC. All current PSKC medical directors are expected to continue employment if this project is approved. In this process, the Certificate of Need program used compliance data from the Medical Quality Assurance Commission (MQAC). This review found that all staff associated with the current unit are licensed and in good standing.

DaVita asserts that PSKC’s project should be denied because it has operated 33 stations at PSKC-South, instead of the approved 27 stations. DaVita states that approval of more stations at PSKC-South under these circumstances could be viewed as a reward to PSKC for operating out of compliance.

¹² The two centers are: PSKC-Anacortes and PSKC-Monroe.

In its rebuttal, PSKC took offense at the suggestion by DaVita that it has been operating more stations than approved. PSKC provided the following statement: “*PSKC has **never** dialyzed more than 27 patients at PSKC-S at a time.*” [emphasis added]

It is clear from the statement above and has been substantiated by IIO survey staff, PSKC has been certified for 33 stations, rather than the 27 approved. PSKC’s position is that it has never **operated** more than 27 stations at a time. This clarification between ‘certified’ stations and ‘operating’ stations is not new, but it is incorrect. Whether the providers have ‘as a common practice’ been doing this as stated by PSKC, it is not compliant with the Certificate of Need statute, rules, or approvals issued by the CN program. All dialysis providers have been informed that the practice of certifying more stations than CN approved is not compliant with statute and rules. The department has also modified its internal processes to ensure providers do not inadvertently certify more stations than the CN approval allows.

In review of this sub-criterion, the department considered the total compliance history of the health care facilities owned and operated by PSKC. The department also considered the compliance history of the medical directors associated with PSKC and PSKC-South. Further, taking into consideration that PSKC quickly responded to the non-compliance issues within the IIO survey for PSKC-South, there is reasonable assurance that PSKC-South would be operated and managed in conformance with applicable state and federal licensing and certification requirements.

The department concludes that PSKC’s project **meets this sub-criterion**.

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, pp8-9 and pp26-27, and Appendix 4]

“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 eight years ago (2007) and DaVita voluntarily temporarily shut down a facility in Texas seven years ago (2008). ...Although it is outside the scope of WAC 246-310-230(5)(a), DaVita also discloses that it entered into a settlement agreement that is described in the SEC Form 8K dated October 22, 2014, a copy of which is provided as Appendix 4 to this application.”

“The applicant has no adverse history of license revocation or decertification in Washington State. The Lynnwood Dialysis Center will provide comprehensive in-center dialysis services. As previously described, DaVita is committed to its highly-effective Continuous Quality Improvement program and seeks to assure the appropriate structure and process of care through uncompromising quality goals on an ongoing basis. DaVita has demonstrated industry leading performance in both of the CMS performance ranking systems, The Quality Incentive Program (QIP) and Dialysis Facility Compare or Five-Star ranking program (davita.com, news release January 11, 2016). Based on 2014 performance, DaVita had five times fewer facilities receive a revenue penalty for 2016 than its competitors as well as the highest number of centers to receive four or five stars in the Five-Star metric. Further, the Department of Health surveys dialysis centers to ensure compliance with federal and state laws.”

Public Comments

- *While both PSKC-S and DV provide high quality care, in this specific market, PSKC-S is superior. Furthermore, DV has several corporate integrity agreements that must be considered and raises concerns about DV's conformance with WAC 246-310-230. In an effort to make quality data for dialysis facilities available and accessible to consumers, CMS has established a star rating system for quality of care. The star rating is from 1 to 5 stars and it is based on 9 measures of quality. Facilities in the top 10% of the final scores receive a Star Rating of 5. Comparing the two existing facilities within Snohomish 3, PSKC-S received a 5-star rating and DV Mill Creek did not; they received a 4-star rating. In addition to the ratings on Medicare Dialysis Compare, during the dialysis rulemaking process, the CN Program reviewed various CMS data and scored each facility in the State. In that review, PSKC-S also scored above DV Mill Creek. As DV noted in its application, on October 22, 2014, it entered into a settlement agreement with the United States Department of Justice (USDOJ). The USDOJ issued the following press release about the settlement agreement which stated:*

DaVita Healthcare Partners, Inc., one of the leading providers of dialysis services in the United States, has agreed to pay \$350 million to resolve claims that it violated the False Claims Act by paying kickbacks to induce the referral of patients to its dialysis clinics, the Justice Department announced today. DaVita is headquartered in Denver, Colorado and has dialysis clinics in 46 states and the District of Columbia.

The settlement today resolves allegations that, between March 1, 2005 and February 1, 2014, DaVita identified physicians or physician groups that had significant patient populations suffering renal disease and offered them lucrative opportunities to partner with DaVita by acquiring and/or selling an interest in dialysis clinics to which their patients would be referred for dialysis treatment.

Footnote #7 of public comments: Source: <http://www.justice.gov/opa/pr/davita-pay-350-million-resolve-allegations-illegal-kickbacks>, October 22, 2014.

The DOJ press release further states:

“Health care providers should generate business by offering their patients superior quality services or more convenient options, not by entering into contractual agreements designed to induce physicians to provide referrals,” said Deputy Assistant Attorney General for the Justice Department’s Civil Division Jonathan F. Olin. “The Justice Department is committed to protecting the integrity of our healthcare system and ensuring that financial arrangements in the healthcare marketplace comply with the law.”

“This case involved a sophisticated scheme to compensate doctors illegally for referring patients to DaVita’s dialysis centers. Federal law protects patients by making buying and selling patient referrals illegal, so as to ensure that the interest of the patient is the exclusive factor in the referral decision,” said U.S. Attorney John Walsh. When a company pays doctors and/or their practice groups for patient referrals, the company’s focus is not on the patient, but on the profit to be extracted from providing services to the patient.”

“Companies seeking to boost profits by paying physician kickbacks for patient referrals – as the government contended in this case - undermine impartial medical judgment at the expense of patients and taxpayers,” said Daniel R. Levinson, Inspector General for the U.S. Department of Health and Human Services.

In its Lynnwood application, DV indicates that it believes that the settlement agreement is outside the scope of WAC 246-310-230(5)(a). PSKC respectfully disagrees. A Corporate Integrity Agreement (CIA) is a document that outlines the obligations an entity agrees to as part of a civil settlement. An entity agrees to the CIA obligations in exchange for the OIG’s agreement that it won’t seek to exclude an entity from participation in Medicare, Medicaid or other Federal health care programs. The CIAs have common elements, but each one is tailored to address the specific facts of the case and CIAs are often drafted to recognize the elements of a pre-existing compliance program. The DV CIA is the result of a four-year long investigation of ten years of DV operating history. The DV CIA will be in place for the next five years. This agreement cannot be ignored by the CN Program.

Despite DV’s suggestions to the contrary, its behavior raises an uncertainty concerning DV’s capability to meet the requirements of WAC 246-310-230(5). This section requires the CN Program to consider whether the patient services to be provided in a proposed project “will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules and regulations.” This issue should not be overlooked in assessing proposals which, in other respects, are close in quality, but not equal. The record should further note that unlike DV, neither PSKC-S nor any of the PSKC facilities are operating under a Corporate Integrity Agreement.

[source: PSKC July 15, 2016, public comments, pp7-8]

DaVita Rebuttal Comments [source: August 15, 2016, rebuttal comments, p7]

- PSKC's quality comparison. *PSKC argues that it provides higher-quality dialysis than DaVita. This claim is baseless—bordering on offensive.*

*First, PSKC points out that PSKC-South has a 5-star rating and DaVita Mill Creek has a 4-star rating. As a preliminary matter, these are both **very good** ratings. Moreover, what PSKC fails to acknowledge is that PSKC-South is its **only** 5-star facility, and Whidbey Island is PSKC's **only** 4- star facility. PSKC's other rated facilities, Everett and Arlington, are both 3-star facilities. [emphasis in original]*

*DaVita, by comparison, operates **seven** 5-star facilities, of only 15 such facilities in Washington. DaVita also operates **eleven** of the state's 24 facilities with 4-star ratings. In other words, nearly half of the highest-rated dialysis facilities in Washington (18 of 39 facilities rated 5-star or 4-star) are operated by DaVita. [emphasis in original]*

PSKC should be proud of its 5-star rating at PSKC-South. But PSKC grossly overreaches by trying to suggest that this means it provides higher quality dialysis than DaVita. It does not. In DaVita's view, the Department should conclude that both applicants are high quality providers. But if PSKC insists on a quality comparison, the Department should conclude that DaVita has a stronger record operating highly-rated facilities in the state of Washington than does PSKC.

Second, PSKC points out that DaVita entered into a settlement agreement with the government in 2014 relating to the structuring of certain joint venture agreements with physician groups. This settlement agreement is fully described in DaVita's application. PSKC's argument that this settlement agreement should be considered in a superiority analysis is frivolous. Indeed, PSKC's argument has been rejected by the Department, repeatedly, during previous application cycles. [emphasis in original]

Department Evaluation of WAC 246-310-230(3) for DaVita

CMS Star Rating for Out-of-State Centers

DaVita operates or provides administrative services in approximately 2,197 outpatient dialysis centers in 45 states and the District of Columbia.¹³ For Washington State, DaVita owns or operates 40 dialysis centers. The department obtained the star rating for all of the out-of-state centers.

Of 2,197 facilities operated by DaVita, 2,193 of them were listed in the CMS data set, and of those, 275 facilities had no star rating. For the remaining 1,918 facilities with a star rating, 87.5% had a rating of three or better.

CMS Star Rating for Washington State Centers

DaVita owns, operates, or manages 40 facilities in 18 separate counties. The department reviewed the star rating for all 40 centers. Of the 40, six are new centers and do not yet have the necessary amount of data to compile a star rating.¹⁴ Of the remaining 34 centers, 33 had a star rating of three or better. Only Olympic View Dialysis Center had a star rating of 2.

Washington State Survey Data

For Washington State, DaVita owns, operates, or manages 40 facilities in 18 separate counties. Four of the 40 are CN approved, but not yet state surveyed and operational. The department reviewed the compliance history for the 36 operational DaVita dialysis centers listed below and continuing on the following page (listed in alphabetical order).

Battle Ground Dialysis Center	North Spokane Renal Center
Belfair Dialysis Center	Olympia Dialysis Center
Bellevue Dialysis Center	Olympic View Dialysis Center (management only)
Cascade Dialysis Center	Parkland Dialysis Center
Chinook Dialysis Center	Pilchuck Dialysis Center
Downtown Spokane Renal Center	Puyallup Community Dialysis Center
East Wenatchee Dialysis Center	Rainier View Dialysis Center
Echo Valley Dialysis Center	Seaview Dialysis Center
Ellensburg Dialysis Center	Spokane Valley Renal Center
Everett Dialysis Center	Tacoma Dialysis Center
Federal Way Dialysis Center	Tumwater Dialysis Center

¹³ Forty-five states are: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin. DaVita also operates facilities in the District of Columbia.

¹⁴ The six centers are: Belfair Dialysis Center, Cascade Dialysis Center, Echo Valley Dialysis Center, Rainier View Dialysis Center, Pilchuck Dialysis Center, Tumwater Dialysis Center.

Graham Dialysis Center
Kennewick Dialysis Center
Kent Dialysis Center
Lakewood Dialysis Center
Mid-Columbia Kidney Center
Mill Creek Dialysis Center
Mt. Adams Dialysis Center

Union Gap Dialysis Center
Vancouver Dialysis Center
Wenatchee Valley Dialysis Center
Westwood Dialysis Center
Whidbey Island Dialysis Center
Yakima Dialysis Center
Zillah Dialysis Center

For the facilities above, the department has conducted and completed at least 36 surveys in the most recent three years. All surveys resulted in no significant non-compliance issues. [source: DOH IIO survey data]

In addition to the facilities owned and operated by DaVita, the department also reviewed the compliance history for the proposed medical director identified in this application. In this process, the Certificate of Need program used compliance data from the Medical Quality Assurance Commission (MQAC). This review found that the proposed medical director is licensed and in good standing.

PSKC asserts that DaVita's project should be denied because it is operating under a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the Department of Health and Human Services that was signed on October 22, 2014. [source: Application, Appendix 4]

DaVita provided a copy of the signed agreement. The department notes that the agreement focuses on DaVita's joint ventures with nephrologists to operate dialysis clinics; rather than patient care or billing practices.

DaVita's CIA has 16 specific sections under 'Term and Scope' that requires DaVita to:

- establish and maintain a Compliance Program that includes a Chief Compliance Officer and Management Compliance Committee;
- establish written standards for covered persons (as defined in the CIA);
- establish training and education for covered persons;
- ensuring compliance with anti-kickback statute;
- provide notice to joint venture partners and medical directors of specific information related to patient referrals and ownership information;
- unwind specific joint venture clinics;
- retain an independent monitor selected by OIG;
- establish compliance audits;
- establishment of a risk assessment and mitigation process;
- establish a financial recoupment process;
- cooperate with all OIG investigations;
- maintain its disclosure program;
- removal of 'ineligible persons' as defined in the CIA;
- notify the OIG of government investigation or legal proceedings;
- repayment of overpayments; and
- report all reportable events as defined in the CIA.

Appendix B of the CIA identifies the eleven separate joint ventures that must be unwound, which includes a total of 26 dialysis clinics in five different states.¹⁵ None of the joint ventures or dialysis clinics are located in Washington State.

For this specific CIA, DaVita would not be excluded from participation in Medicare, Medicaid or other Federal health care programs provided that DaVita complies with the obligations outlined in the CIA.

Given the compliance history of DaVita, which includes continued compliance with the CIA, the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the new seven-station Lynnwood dialysis center would operate in compliance with state and federal regulations.

The department concludes that DaVita’s project **meets this sub-criterion**.

Department Superiority Review

The department concludes that both PSKC **meets this sub-criterion** with no specific conditions. The department concludes that DaVita **meets this sub-criterion**. Each application is equivalent to the other.

- (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.

Puget Sound Kidney Centers

PSKC provided the following statements in response to this sub-criterion. [source: Application, p36]

“PSKC’s philosophy and culture is to operate with a collaborative, comprehensive, and patient centered approach to the provision of dialysis services in the community. This, coupled with our unrelenting focus on high-quality, compassionate care, respect for the patients, staff, and other providers has served the community well. With the expansion of this facility, we will continue to maintain all existing working relationships that support care in the Planning Area, including:

Hospitals

Providence Regional Medical Center, Everett

Physicians

Dr. Mark Gunning, M.D., PSKC – Corporate Medical Director

Dr. Win Kyaw, M.D., PSKC – South Medical Director

Transportation

DART bus service in Snohomish County – low cost, shared ride service

¹⁵ The five states are: California (9); Colorado (7); Florida (5); Kentucky (1); and Ohio (4).

*Hopelink Snohomish County – Medicaid/DSHS patients
ACCESS King County – low cost, shared ride service*

Residential: Long Term Care Facilities (may vary with patient census)

*Aldercrest Health & Rehab
Brookdale Care Center
Emerald Hills Rehab and Skilled Nursing
Manor Care
Parkridge Care Center
Richmond Beach Rehab
Various Adult Family Homes*

Colleges/Educational Institutions

*Bastyr University, Kenmore
University of Washington School of Public Health, Seattle*

PSKC provided a copy of the patient transfer agreement currently used at PSKC-South. The transfer agreement is between PSKC and Providence Regional Medical Center-Everett. The patient transfer agreement will continue to be used at the PSKC-South with the additional stations. [source: Application, p36 and Exhibit 9]

Public Comment

None

Rebuttal Comment

None

Department Evaluation of WAC 246-310-230(4) for PSKC

Given that PSKC-South has been providing dialysis services in Snohomish County planning area #3 since approximately 1998, the facility is already part of the health care infrastructure in the planning area. The addition of dialysis stations would continue to promote continuity in the provision of healthcare services in Snohomish County planning area #3.

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.

The department concludes PSKC's project **meets this sub-criterion**.

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, p26 and Appendices 12, 17, and 18]

“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 an example draft transfer agreement; without an operating facility an actual transfer agreement with specific terms cannot be executed. 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)."

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-230(4) for DaVita

DaVita has been providing dialysis services in the planning area since approximately 2012 with its Mill Creek Dialysis Center. The project proposes a new facility in the planning area. DaVita's project would also promote continuity in the provision of healthcare services in Snohomish County planning area #3 by operating seven additional stations. Given that its Lynnwood facility would be new to the planning area, DaVita provided a draft transfer agreement that would be used at the facility. If DaVita's project is approved, the department would attach a condition requiring DaVita to provide a copy of the executed transfer agreement with a local hospital.

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.

With the condition identified above, the department also concludes that DaVita's project **meets this sub-criterion**.

Department Superiority Review

The department concludes PSKC **meets this sub-criterion** with no conditions. The department also concludes that DaVita **meets this sub-criterion with one condition**. Each application is equivalent to the other.

- (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.*

Puget Sound Kidney Centers

This sub-criterion is addressed in sub-section (3) above and is **met**.

DaVita HealthCare Partners, Inc.

This sub-criterion is addressed in sub-section (3) above and is **met**.

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Puget Sound Kidney Centers **met** the applicable cost containment criteria in WAC 246-310-240.

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that DaVita HealthCare Partners, Inc. **met** the applicable cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.
To determine if a proposed project is the best alternative, the department takes a multi-step approach. First, the department determines if the application has met the other criteria of WAC 246-310-210 thru 230. If the project has failed to meet one or more of these criteria, then the project cannot be considered to be the best alternative in terms of cost, efficiency, or effectiveness. As a result, the application would fail this sub-criterion.

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

If there are multiple applications, the department’s assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type. The adopted superiority criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility type superiority criteria as directed by WAC 246-310-200(2) (a)(i), then the department would use WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Puget Sound Kidney Centers

Step One

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

Step Two

For this sub-criterion, PSKC provided discussion related to the following two options:

- Do nothing; and
- Establish a new seven-station center within the planning area.

Do Nothing - PSKC noted that PSKC-South has operated at or near 90% occupancy since before 2009, and there has been station need in Snohomish County planning area #3 for five of the past six years. For these reasons, the option of do nothing was rejected. [source: Application, p38]

Establish a new seven-station center within the planning area - Before submitting this application to add seven stations to PSKC-South, PSKC considered the option of establishing a new seven-station center within the planning area. PSKC rejected this option because of the relative proximity of stations in King County planning areas #1, #7, and Snohomish County planning area #2 for some of the residents of the service area. PSKC states that the existing patient population in Snohomish County planning area #3 is largely concentrated around our existing center in Mountlake Terrace. In fact, only a very small portion of Snohomish County planning area #3 is located outside of a three mile radius of PSKC-South and DaVita Mill Creek. [source: Application, p38]

PSKC states that expansion of PSKC-South was deemed to be the superior option due to access, timing, cost and operating efficiencies. PSKC provides the following history related to the utilization of PSKC-South. [source: Application, pp38-39]

“Quarterly, PSKC has evaluated opportunities to address the need and respond to requests from our patients and providers; however, our efforts have been stymied by DaVita’s inability to reach an 80% occupancy rate. As stop gap measures, and as noted earlier, we have recommended other providers to patients if we could not accommodate their scheduling needs, and promoted home training. Despite real success with these two strategies, the need for additional stations has continued to grow (from two stations in 2010 to seven stations today). At the same time, we evaluated how and where to expand when DaVita-Mill Creek finally reached the 80% threshold for utilization, or when the proposed new dialysis rules came into effect, whichever occurred first. Finally, PSKC believes that in terms of access, quality of care and cost, its proposal is superior. PSKC-South provides all of the access related services required by the Program (shift after 5:00PM, home training, a permanent bed station, and isolation capabilities). PSKC-South has received a five-star rating from CMS Dialysis Compare. This rating is just one reflection of our superior outcomes related to several different aspects of dialysis, including mortality, dialysis adequacy, catheter use, and calcium levels as PSKC-South consistently performs above the State and National averages. PSKC provides high quality, accessible services at very competitive rates. PSKC would encourage the Program to request the applicants’ average net revenue per commercial treatment in screening.”

Public Comments

None

Rebuttal Comments

None

Step Three

Step Three of the department evaluation of the PSKC project will be discussed below, concurrently with the DaVita Step Three evaluation.

DaVita HealthCare Partners, Inc.

Step One

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

Step Two

Before submitting this application to establish a new seven-station dialysis center in Lynwood, DaVita considered and rejected the following two alternatives. [source: Application, p28]

Do Nothing or Status Quo

Related to this alternative, DaVita stated:

“There are currently two dialysis facilities in the planning area, neither of which has reached 6.0 or 100% utilization. However, the existing need for seven stations, as well as demonstrated growth patterns in the planning area, provided convincing reason to establish a new DaVita center that will offer enhanced geographic choice and superior advantages to patients than our competitors. This alternative was not selected.”

Add 7 stations to Mill Creek Dialysis Center

Related to this alternative, DaVita stated:

“This option would have been favored from a cost standpoint, as it is typically less expensive to expand an existing center than it is to establish a new one. However, after consulting with our architect and construction partners, it was determined that the existing Mill Creek structure does not have sufficient square footage to adequately support such an expansion. Even had an expansion been possible, this option would have not have [sic] provided the advantage to patients of being able to dialyze in a new facility, located in a zip code that is rapidly growing relative to the planning area as a whole. This alternative was not selected.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation of Steps One and Two for PSKC and DaVita

Each applicant provided a comprehensive discussion of alternatives considered before submitting their respective applications. Both applicants rejected the ‘do nothing’ alternative because the numeric methodology shows need for stations in the planning area. Given that the numeric methodology is based on the historical number of patients dialyzing in the planning area, the methodology also demonstrates patient growth in the planning area. Both PSKC and DaVita appropriately rejected the ‘do nothing’ alternative.

PSKC states it rejected the alternative of establishing a new center in the planning area because the existing patient population in Snohomish County planning area #3 is largely concentrated around PSKC-South located in Mountlake Terrace. The department’s review of a Snohomish County map and information provided in Table 7 of this evaluation substantiates this claim.

DaVita states it rejected the alternative of adding stations to Mill Creek Dialysis Center located in the planning area zip code of 98021 for two reasons. First, the dialysis center does not have expansion capacity. A review of the facility’s single line drawings from its 2007 application [App #08-11], substantiates that Mill Creek Dialysis Center does not have the capacity to accommodate another seven stations.

Second, DaVita considered a new center in a zip code with patient growth to be advantageous for patient access. The department agrees that DaVita elected to establish a dialysis center in a zip code that has shown historical patient growth which allows for geographical access for some rural patients. The department also agrees that the consistent high utilization at PSKC-South also demonstrates need for additional stations in its zip code.

The department does not have the data to measure which is more valuable—increasing access to dialysis services in an existing facility vs creating a new facility to increase geographic access to dialysis services. The statements provided by each applicant in relation to this sub-criterion can be substantiated. The department did not identify any alternative for consideration that was superior in terms of cost, efficiency, or effectiveness that is available or practicable for PSKC or DaVita.

Step Three - Department's Superiority Review

Throughout this evaluation, the department evaluated the superiority of each application to the other and concluded that neither was superior over the other. Therefore, the department used the tiebreaker criteria in WAC 246-310-288.

WAC 246-310-288 identifies specific tie-breaker criteria that must be applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. Under tie-breaker criteria, the department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.

Below is an evaluation of the tie-breaker criteria under WAC 246-310-288(1) and (2).

WAC 246-310-288(1) - A total of five points is possible.

(1) The department will award one point per tie-breaker to any applicant that meets a tie-breaker criteria in this subsection.

(a) Training services (1 point):

(i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or

(ii) The applicant is an existing provider in the planning area that offers training services in any of its existing facilities within thirty-five miles of the proposed new facility and either intends to offer training services at the new facility or through those existing facilities; or

(iii) The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and

(iv) Northwest Renal Network's most recent year-end facility survey must document the provision of these training services by the applicant.

(b) Private room(s) for isolating patients needing dialysis (1 point).

(c) Permanent bed stations at the facility (1 point).

- (d) *Evening shift (1 point): The applicant currently offers, or as part of its application proposes to offer at the facility a dialysis shift that begins after 5:00 p.m.*
- (e) *Meeting the projected need (1 point): Each application that proposes the number of stations that most closely approximates the projected need.*

Puget Sound Kidney Centers

Table 20 below shows the distribution of tie-breaker points under this sub-criterion for PSKC.

Table 20
WAC 246-310-288(1)
PSKC Tie-Breaker Review

WAC 246-310-288(1)	Point	Source
(a)(i) & (ii) Training services	1	Application, p5, p26, and CMS data
(b) Private room(s) for isolating patients	1	April 29, 2016, screening response, p2
(c) Permanent bed stations at the facility	1	April 29, 2016, screening response, p2
(d) Evening shift	1	Application, p26 and CMS data
(e) Meeting the projected need	1	Application, pp19-21
Total Points	5	

DaVita HealthCare Partners

Table 21 below shows the distribution of tie-breaker points under this sub-criterion for DaVita.

Table 21
WAC 246-310-288(1)
DaVita Tie-Breaker Review

WAC 246-310-288(1)	Point	Source
(a)(i) & (ii) Training services	1	Application, p12, Appendix 16, and CMS data
(b) Private room(s) for isolating patients	1	Application, p12 and Appendix 16
(c) Permanent bed stations at the facility	1	Application, p12 and Appendix 16
(d) Evening shift	1	Application, p12
(e) Meeting the projected need	1	Application, pp18-20
Total Points	5	

Under WAC 246-310-288(1), each applicant could receive a maximum of 5 points, PSKC and DaVita each received 5 points.

WAC 246-310-288(2) – only once applicant may be awarded a point for each criteria

- (2) *Only one applicant may be awarded a point for each of the following four tie-breaker criteria:*
 - (a) *Economies of scale (1 point): Compared to the other applications, an applicant demonstrates its proposal has the lowest capital expenditure per new station.*
 - (b) *Historical provider (1 point)*
 - (i) *The applicant was the first to establish a facility within a planning area; and*
 - (ii) *The application to expand the existing facility is being submitted within five years of the opening of its facility; or*
 - (iii) *The application is to build an additional new facility within five years of the opening of its first facility.*
 - (c) *Patient geographical access (1 point): The application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of*

them. The department will award the point for the facility located farthest away from existing facilities within the planning area provided:

- (i) The facility is at least three miles away from the next closest existing facility in planning areas that qualify for 4.8 patients per station; or*
 - (ii) The facility is at least eight miles from the next closest existing facility in planning areas that qualify for 3.2 patients per station.*
- (d) Provider choice (1 point):*
- (i) The applicant does not currently have a facility located within the planning area;*
 - (ii) The department will consider a planning area as having one provider when a single provider has multiple facilities in the same planning area;*
 - (iii) If there are already two unrelated providers located in the same planning area, no point will be awarded.*

Only one applicant may receive a point for each of the four tie-breaker criteria under this section. Table 22 below shows the distribution of tie-breaker points under this sub-criterion for PSKC.

Table 22
WAC 246-310-288(2)
PSKC Tie-Breaker Review

WAC 246-310-288(2)	Point	Source
(a) Economies of Scale	1	Application, p30 and April 29, 2016, screening response, pp2-3 [\$78,665]
(b) Historical Provider	0	
(c) Patient Geographical Access	0	
(d) Provider Choice	0	
Total Points	1	

The economies of scale point under WAC 246-310-288(2)(a) is awarded to the applicant that demonstrates its project has the lower capital expenditure per new station. To ensure that competing projects are reviewed fairly, the department requires applicants adding stations to an existing facility to allocate construction costs already expended to the new stations. A description of the formula used by an applicant to determine the amount of costs to allocate is provided in the application.

For this project, PSKC identified the cost allocation and a description of the formula used to compute the costs in the financial feasibility sub-criterion within WAC 246-310-220(2). Within this evaluation, the department concluded that \$172,833 in allocated construction costs is reasonable. The capital expenditure used for this tie-breaker point is \$550,656, which includes \$172,833 in allocated costs and \$377,823 in actual costs to add seven stations to PSKC-South.

Table 23 on the following page shows the distribution of tie-breaker points under this sub-criterion for DaVita.

Table 23
WAC 246-310-288(2)
DaVita Tie-Breaker Review

WAC 246-310-288(2)	Point	Source
(a) Economies of Scale	0	Application, Appendix 7 [\$245,838]
(b) Historical Provider	0	
(c) Patient Geographical Access	1	Application, p5 and Map quest
(d) Provider Choice	0	
Total Points	1	

To receive the geographical access point under WAC 246-310-288(2)(c), the new facility be must be at least three miles away from the next closest existing facility in planning area. The department measured the statute miles for both existing facilities in the planning area. DaVita’s Lynnwood Dialysis center would be 4.8 statute miles from PSKC-South and 4.1 statute miles from its Mill Creek Dialysis Center. DaVita’s project qualifies for this tie breaker point under WAC 246-310-288(2)(c).

Table 24 below shows the total accumulation of tie-breaker points for both PSKC and DaVita.

Table 24
WAC 246-310-288 – Tie-Breaker Summary Table

	Tie-Breaker Point Distribution	
	PSKC	DaVita
1(a) – Training services	1	1
1(b) – Private Room	1	1
1(c) – Permanent Bed Station	1	1
1(d) – Evening Shift	1	1
1(e) – Meets Need	1	1
2(a) – Economies of Scale	1	0
2(b) – Historical Provider	0	0
2(c) – Geographical Access	0	1
2(d) – Provider Choice	0	0
Cumulative Total	6	6

At the completion of the tie-breaker point allocations, both PSKC and DaVita accumulated a total of six points. WAC 246-310-288 provides the following guidance if competing projects remain tied after applying tie breaker points.

“If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.”

Since the numeric need in the planning area is an odd number (7), the department must determine the breakdown of stations to award as equally as possible for both applicants.

PSKC proposes to add stations to an existing facility. Based on the financial information provided in the application, the department is confident that PSKC-South will operate near the 4.8 standard

and revenues will cover expenses regardless of the number of stations added. PSKC proposes the additional stations would be operational by the end of December 2016. As a result, PSKC could alleviate its overcrowding at PSKC-South within a short time after approval of its project.

DaVita proposes to establish a new dialysis facility in the planning area. The new center is expected to be operational by the end of December 2017. The department reviewed DaVita's the projected number of patients and pro forma financial statements for the first year of operation to determine the fair number of stations to be awarded to DaVita.¹⁶ Table 25 below summarized the review.

Table 25
DaVita Lynnwood Year One-2018 Projections-12 Patients

	Utilization	Revenues	Expenses	Net Income
3 Station Approval	4.00	\$ 1,191,841	\$ 907,777	\$ 284,064
4 Station Approval	3.00			
5 Station Approval	2.40			

Taking into account the high utilization at PSKC-South and that the additional stations would become operational by the end of year 2016, the department concludes that four stations should be awarded to PSKC and DaVita should be awarded the remaining three stations.

For both applicants, **this sub-criterion is met.**

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

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

Puget Sound Kidney Centers

PSKC states that no new construction is required for the addition of seven stations at PSKC-South. With minor remodel, and purchase of both fixed and moveable equipment, the facility could be operating with 34 dialysis stations. No planned modifications to the physical plant are required for this project. [source: Application, pp30-31] PSKC concludes that this sub-criterion is not applicable to this project.

Public Comments

None

Rebuttal Comments

None

¹⁶ In a previous review, the department concluded that an applicant could not feasibility serve 17 patients in a three-station facility and provide dialysis services in an isolation station without operating a fourth patient shift. [source: March 11, 2016, evaluation for King County Planning Area #5] DaVita projects to serve 12 patients in year one. If one station were used for isolation services, DaVita could still provide dialysis services to 11 or 12 patients in the remaining two available stations.

DaVita HealthCare Partners, Inc.

DaVita states that it experience with operating or managing over 2,197 Medicare-certified dialysis center throughout the country, including many in the Northwest, provides the background for designing facilities that satisfy all patient requirements and provide the greatest value for the investment dollar. [source: Application, p29]

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-240(2)(a) for PSKC and DaVita

This sub-criterion is not applicable to the PSKC project.

DaVita proposes to lease space in an existing building. These costs were evaluated in the financial feasibility section of this analysis. There is no information within the application that would cause the department to conclude that the costs of the project are unreasonable. The department concludes **this sub-criterion is met.**

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

Puget Sound Kidney Centers

PSKC did not provide a response to this sub-criterion.

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-240(2)(b) for PSKC

PSKC's project involves minor remodel of the existing center to accommodate the additional stations. There is no evidence in the application that the project would have an unreasonable impact on costs and charges to the public.

The department concludes PSKC **meets this sub-criterion.**

DaVita HealthCare Partners, Inc.

DaVita provided the following statements related to this sub-criterion. [source: Application, p23]

“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 increase in charges for services within the ESRD planning area.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-240(2)(b) for DaVita

DaVita’s project involves construction. With the need for additional stations in Snohomish County planning area #3 and the assumptions related to the costs and charges discussed under the Financial Feasibility section of this evaluation, the department does not anticipate an unreasonable impact on the costs and charges to the public as a result of establishing a new dialysis center in the planning area.

The department also concludes that DaVita **meets this sub-criterion**.

Department Superiority Review

The department concludes PSKC **meets this sub-criterion**. The department also concludes that DaVita **meets this sub-criterion**. Each application is equivalent to the other.

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

Puget Sound Kidney Centers

PSKC provided the following statements related to this project. [source: Application, p39]

“PSKC states that this project will improve both staff and system efficiencies. The expansion, as proposed, will offer improved economies of scale in addition to meeting the needs of patients in a superior way. For example, management and clinical and ancillary staff are already in place and can accommodate the additional volumes with no additional management FTEs and only a few additional clinical FTEs.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-240(3) for PSKC

PSKC’s project has the potential to improve delivery of dialysis services to the residents of Snohomish County planning area #3 with the addition of seven stations. The department is satisfied PSKC’s project is appropriate and needed.

The department concludes PSKC **meets this sub-criterion**.

DaVita HealthCare Partners, Inc.

DaVita provided the following statements related to this project. [source: Application, p29]

“The Lynnwood Dialysis Center will meet all current energy conservation standards. The Lynnwood Dialysis Center is designed to meet current energy code requirements; therefore, additional energy costs associated with unused space does not substantially add to energy consumption.”

Public Comments

None

Rebuttal Comments

None

Department Evaluation of WAC 246-310-240(3) for DaVita

DaVita's project has the potential to improve delivery of dialysis services to the residents of Snohomish County planning area #3 with the addition of a new provider in the planning area. The department is satisfied DaVita's project is appropriate and needed.

Department Superiority Review

The department concludes PSKC **meets this sub-criterion**. The department also concludes that DaVita **meets this sub-criterion**. Each application is equivalent to the other.

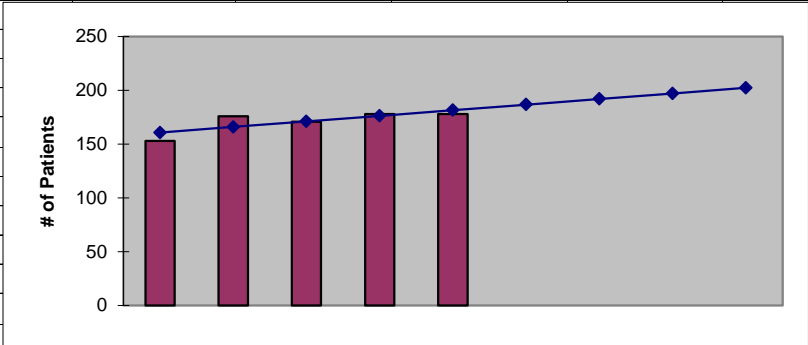
APPENDIX A



2015
Snohomish County 3
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Snohomish Three (3)		2009	2010	2011	2012	2013	2014
98012		16	20	23	19	20	19
98020		17	15	18	14	10	8
98021		7	9	10	13	17	14
98026		22	18	19	18	15	18
98036		21	20	30	29	41	39
98037		30	29	31	30	25	25
98043		11	19	14	19	16	17
98087		14	14	20	17	23	28
98296		11	9	11	12	11	10
TOTALS		149	153	176	171	178	178
246-310-284(4)(a)	Rate of Change		2.68%	15.03%	-2.84%	4.09%	0.00%
	6% Growth or Greater?		FALSE	TRUE	FALSE	FALSE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2015	Year 2 2016	Year 3 2017	Year 4 2018
Projected Resident Incenter Patients	from 246-310-284(4)(b)			186.80	192.00	197.20	202.40
Station Need for Patients	Divide Resident Incenter Patients by 4.8			38.9167	40.0000	41.0833	42.1667
	Rounded to next whole number			39	41	42	43
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				36	36	36	36
Results of (4)(c) above			-	39	41	42	43
Net Station Need				-3	-5	-6	-7
Negative number indicates need for stations							
Planning Area Facilities							
Name of Center	# of Stations						
PSKC- South	27						
DaVita Mill Creek	9						
Total	36						
Source: Northwest Renal Network data 2009-2014							
Most recent year-end data: 2014 posted 02/12/15							

x	y	Linear
2010	153	161
2011	176	166
2012	171	171
2013	178	176
2014	178	182
2015		186.80
2016		192.00
2017		197.20
2018		202.40



SUMMARY OUTPUT

<i>Regression Statistics</i>	
Multiple R	0.77794118
R Square	0.60519248
Adjusted R Square	0.473589973
Standard Error	7.668115805
Observations	5

ANOVA					
	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	270.4	270.4	4.598639456	0.12134259
Residual	3	176.4	58.8		
Total	4	446.8			

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>
Intercept	-10291.2	4878.84192	-2.109353033	0.125444195	-25817.85244	5235.452442	-25817.85244	5235.452442
X Variable 1	5.2	2.424871131	2.144443857	0.12134259	-2.51702217	12.91702217	-2.51702217	12.91702217

RESIDUAL OUTPUT

<i>Observation</i>	<i>Predicted Y</i>	<i>Residuals</i>
1	150.2	-1.2
2	157.8	-4.8
3	165.4	10.6
4	173	-2
5	180.6	-2.6

APPENDIX B

Snohomish County Planning Area #3

