

EXECUTIVE SUMMARY

EVALUATION OF THE FOLLOWING THREE CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN CLALLAM OR JEFFERSON COUNTIES:

- **DAVITA, INC. PROPOSING ESTABLISH AN EIGHT-STATION DIALYSIS CENTER IN THE CITY OF SEQUIM TO SERVE CLALLAM AND JEFFERSON COUNTIES**
- **NORTHWEST KIDNEY CENTERS PROPOSING TO ADD THREE STATIONS TO THE EXISTING EIGHT-STATION DIALYSIS CENTER LOCATED IN PORT ANGELES TO SERVE CLALLAM AND JEFFERSON COUNTIES**
- **OLYMPIC PENINSULA KIDNEY CENTER PROPOSING TO ESTABLISH A SIX-STATION DIALYSIS CENTER IN PORT TOWNSEND TO SERVE JEFFERSON COUNTY**

BRIEF PROJECT DESCRIPTIONS

DaVita Inc.

This project proposes to establish an 8-station facility in Sequim to be located at 190 Priest Road. The new dialysis center would serve the residents of both Clallam and Jefferson counties. [source: DaVita Application, pp 1 and 3; April 27, 2007, supplemental information, p1]

The capital expenditure associated with the establishment of the 8-station facility is \$1,315,865. [source: Application, p6] If this project is approved, DaVita anticipates all 8 stations would become operational by the end of July 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [source: DaVita Application, p10]

Northwest Kidney Centers

Northwest Kidney Centers currently operates an 8-station dialysis center, known as Port Angeles Kidney Center, located at 809 Georgiana Street in the city of Port Angeles within Clallam County. This project proposes to add 3 stations for a facility total of 11 stations at the dialysis center. Northwest Kidney Centers also proposes that the 11-station facility would serve the residents of both Clallam and Jefferson counties. [source: NKC Application, Executive Summary and Appendix 1]

The capital expenditure associated with the 3-station addition is \$116,030. [source: NKC Application, Appendix 7] If this project is approved, Northwest Kidney Centers anticipates commencement of the project immediately and all 11 stations would be available for patient use by the end of March 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation with 11 dialysis stations and 2011 would be year three. [source: NKC Application, Executive Summary]

Olympic Peninsula Kidney Center

This project proposes the establishment of a 6-station facility to be located on the ground floor of a building located at 2500 West Simms Way in the city of Port Townsend within Jefferson County. [source: OPKC April 30, 2007 supplemental information, p1 and Attachment 2] The new 6-station dialysis center would serve the residents of Jefferson County.

The capital expenditure associated with the establishment of the 6-station facility is \$518,700. [source: OPKC Application, p21] If this project is approved, Olympic Peninsula Kidney Center

anticipates commencement of the project immediately and all 6 stations would be available for patient use by the end of June 2008. Under this timeline, year 2009 would be the new facility's first full calendar year of operation and 2011 would be year three. [source: OPKC April 30, 2007, supplemental information, p2]

APPLICABILITY OF CERTIFICATE OF NEED LAW

All three projects are subject to Certificate of Need review. Two projects—DaVita, Inc. and Olympia Peninsula Kidney Center—as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a). The Northwest Kidney Centers project is subject to review as an increase of dialysis station capacity in an existing dialysis center under RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

CONCLUSIONS

DaVita Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish an eight-station dialysis center in the city of Sequim within Clallam County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Northwest Kidney Centers proposing to add three dialysis stations to the existing eight-station facility known as Port Angeles Kidney Center is not consistent with applicable criteria. However, the addition of two stations to Port Angeles Kidney Center is consistent with those criteria. With this reduction in the number of stations, the project meets the relevant criteria for the project. The approved capital expenditure associated with the addition of two stations is \$116,030.

Olympic Peninsula Kidney Center

For the reasons stated in this evaluation, the application submitted on behalf of Olympic Peninsula Kidney Center proposing to establish a six-station dialysis center in the city of Port Townsend within Jefferson County is consistent with applicable criteria provided Olympic Peninsula Kidney Center agrees to the following term and condition.

TERM

To ensure that appropriate ancillary and support agreements will be established at its Port Townsend facility, prior to providing services at the new Port Townsend dialysis center, Olympic Peninsula Kidney Center will provide an executed copy of the Patient Transfer Agreement, that includes the new facility in Port Townsend, for the department's review and approval.

Provided that Olympic Peninsula Kidney Center agrees to the term identified above, a Certificate of Need should be issued for the establishment of a six-station dialysis center to be located in the city of Port Townsend within Jefferson County, with the following condition:

CONDITION

Prior to commencement of the project, Olympic Peninsula Kidney Center will provide an executed copy of the lease agreement, consistent with the draft lease agreement provided in the application, for the department's review and approval.

The approved capital expenditure associated with the establishment of the six-station dialysis center is \$518,700.

EVALUATION OF THE FOLLOWING THREE CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN CLALLAM OR JEFFERSON COUNTIES:

- **DAVITA, INC. PROPOSING ESTABLISH AN EIGHT-STATION DIALYSIS CENTER IN THE CITY OF SEQUIM TO SERVE CLALLAM AND JEFFERSON COUNTIES**
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- **OLYMPIC PENINSULA KIDNEY CENTER PROPOSING TO ESTABLISH A SIX-STATION DIALYSIS CENTER IN PORT TOWNSEND TO SERVE JEFFERSON COUNTY**

PROJECT DESCRIPTIONS

DaVita Inc.

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,300 outpatient centers located in 42 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [source: DaVita Application, p4]

In Washington State, DaVita owns or operates a total of fourteen kidney dialysis facilities in six separate counties--Clark, Franklin, King, Kittitas, Pierce, and Yakima. Below is a listing of the fourteen DaVita facilities located in Washington. [source: CN historical files; & Application, p4]

Clark

Vancouver Dialysis Center

Franklin

Mid-Columbia Kidney Center

Pierce

Lakewood Community Dialysis Center

Puyallup Community Dialysis Center

Tacoma Dialysis Center

Kittitas

Ellensburg Dialysis Center

King

Bellevue Dialysis Center

Federal Way Community Dialysis Center

Kent Community Dialysis Center

Olympic View Dialysis Center (management only)

Westwood Dialysis Center

Yakima

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

This application proposes to establish a dialysis facility in Clallam County. The new facility, to be known as Sequim Dialysis Center, would have 8 stations and be located at 190 Priest Road and would serve the residents of both Clallam and Jefferson counties. [source: DaVita Application, pp 1 and 3; April 27, 2007, supplemental information, p1]

The capital expenditure associated with the establishment of the 8-station facility is \$1,315,865, of which approximately 55% is related to leasehold improvements at the site; 36% is related to both fixed and moveable equipment; and the remaining 9% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p6]

If this project is approved, DaVita anticipates all 8 stations would become operational by the end of July 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation and 2011 would be year three. [source: DaVita Application, p10]

Northwest Kidney Centers

Northwest Kidney Centers (NKC) is a private, not-for-profit entity incorporated in the state of Washington that provides dialysis services through its facilities. Established in 1962, NKC operates as a community-based dialysis program working to meet the needs of dialysis patients and their physicians. [source: NKC Application, p1]

NKC is governed by a volunteer Board of Trustees comprised of medical, civic, and business leaders from the community. An appointed Executive Committee of the Board oversees operating policies, performance benchmarks, and approves capital expenditures for all of its facilities. [source: NKC Application, p2]

In Washington State, NKC owns or operates a total of thirteen kidney dialysis facilities, twelve in King County and one in Clallam County. Below is a listing of the thirteen NKC facilities in Washington. [source: NKC Application, Appendix 1 and CN historical files]

Clallam

Port Angeles Kidney Center

King

Auburn Kidney Center
Elliot Bay Kidney Center
Haviland Kidney Center
Lake City Kidney Center
Lake Washington Kidney Center
Mount Rainier Kidney Center
Scribner Kidney Center
Seattle Kidney Center
SeaTac Kidney Center
Snoqualmie Kidney Center
Totem Lake Kidney Center
West Seattle Kidney Center

This application proposes to add 3 dialysis stations to the existing 8-station facility in Clallam County, known as Port Angeles Kidney Center located at 809 Georgiana Street in the city of Port Angeles. If approved, the 11-station facility would serve the residents of Clallam County and a portion of Jefferson County. [source: NKC Application, Executive Summary and Appendix 1]

The capital expenditure associated with the addition of 3 stations is \$116,030, of which 53% is related to construction costs and the remaining 47% is related to fixed and moveable equipment. [source: NKC Application, Appendix 7]

If this project is approved, NKC anticipates commencement of the project immediately and all 11 stations would be available for patient use by the end of March 2008. Under this timeline, year 2009 would be the facility's first full calendar year of operation for Port Angeles Kidney Center with 11 dialysis stations and 2011 would be year three. [source: NKC Application, Executive Summary]

Olympic Peninsula Kidney Center

Olympic Peninsula Kidney Center (OPKC) is a private, non-profit entity that provides dialysis services through three facilities located in Kitsap County. OPKC is governed by an 11-member Board of Directors comprised of medical, civic, and business leaders from the community. An appointed executive director and appointed administrator oversee day-to-day operations of OPKC. [source: OPKC Application, p1 and Appendix B]

Below is a listing of the three OPKC facilities in Kitsap County. [source: OPKC Application, p1]

Kitsap

OPKC-Bremerton
OPKC-Port Orchard
OPKC-Poulsbo

For this project, OPKC proposes the establishment of a 6-station facility to be located on the ground floor of a building located at 2500 West Simms Way in the city of Port Townsend within Jefferson County. [source: OPKC April 30, 2007 supplemental information, p1 and Attachment 2] The new 6-station dialysis center, referenced in this document at OPKC-Jefferson, would serve the residents of Jefferson County.

The capital expenditure associated with the establishment of the 6-station facility is \$518,700, of which 48% is related to construction, 44% is related to fixed and movable equipment, and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: OPKC Application, p21]

If this project is approved, OPKC anticipates commencement of the project immediately and all 6 stations would be available for patient use by the end of June 2008. Under this timeline, year 2009 would be the new facility's first full calendar year of operation and 2011 would be year three. [source: OPKC April 30, 2007, supplemental information, p2]

APPLICABILITY OF CERTIFICATE OF NEED LAW

All three projects are subject to Certificate of Need review. Two projects—DaVita, Inc. and Olympia Peninsula Kidney Center—as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a). The Northwest Kidney Centers project is subject to review as an increase of dialysis station capacity in an existing dialysis center under RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

CRITERIA EVALUATION

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); 246-310-240 (cost containment). Additionally, each applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 288.¹

APPLICATION CHRONOLOGY

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

¹ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-287.

Action	DaVita	NKC	OPKC
Letter of Intent Submitted	January 31, 2007	January 31, 2007	January 31, 2007
Application Submitted	February 28, 2007	February 27, 2007	February 28, 2007
Department's pre-review Activities including screenings and responses	March 1, 2007 through May 15, 2007		
Beginning of Review	May 16, 2007		
Public Hearing Conducted End of Public Comment	August 2, 2007 ²		
Rebuttal Comments Received	September 4, 2007		
Department's Anticipated Decision Date	October 19, 2007		
Department's Actual Decision Date	October 18, 2007		

CONCURRENT REVIEW AND AFFECTED PERSONS

The concurrent review process promotes the expressed public policy goal of RCW 70.38 that the development or expansion of health care facilities are accomplished in a planned, orderly fashion and without unnecessary duplication. For dialysis projects, concurrent review allows the department to review dialysis applications proposing the serve the same planning area [as defined in WAC 246-310-280(9)] simultaneously to reach a decision that serves the best interests of the planning area's residents.

In the case of these projects submitted by DaVita, NKC, and OPKC, the department will issue one single evaluation regarding whether all three, any, or none of the projects should be issued a Certificate of Need.

For each application, the other two applicants sought and received affected person status under WAC 246-310-010. No other entity sought or received affected person status related to these three projects.

SOURCE INFORMATION REVIEWED

- DaVita, Inc.'s Certificate of Need application submitted February 28, 2007
- Northwest Kidney Centers' Certificate of Need application submitted February 27, 2007
- Olympic Peninsula Kidney Center's Certificate of Need application submitted February 28, 2007
- DaVita, Inc.'s supplemental information dated April 27, 2007
- Northwest Kidney Centers' supplemental information dated April 27, 2007
- Olympic Peninsula Kidney Center's supplemental information dated April 30, 2007
- Public comment received during the course of the review or at the August 2, 2007, public hearing
- DaVita, Inc.'s rebuttal comments received September 4, 2007

² Under the concurrent review cycle 1 schedule, the 60-day public comment period begins May 16 and concludes on July 16. For these projects, the coordination of a hearing date resulted in an additional 21 days of public comment, which, in turn, added 21 days to the anticipated decision date.

SOURCE INFORMATION REVIEWED (continued)

- Northwest Kidney Centers' did not provide rebuttal comments
- Olympic Peninsula Kidney Center's rebuttal comments received September 4, 2007
- Years 2001 through 2006 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2006 Northwest Renal Network 4th Quarter Data
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from DaVita, Inc.'s webpage (davita.com)
- Data obtained from Northwest Kidney Centers' webpage (nwkidney.org)
- Olympic Peninsula Kidney Centers does not appear to have its own webpage.
- Certificate of Need historical files

CONCLUSIONS

DaVita Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish an eight-station dialysis center in the city of Sequim within Clallam County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

Northwest Kidney Centers

For the reasons stated in this evaluation, the application submitted on behalf of Northwest Kidney Centers proposing to add three dialysis stations to the existing eight-station facility known as Port Angeles Kidney Center is not consistent with applicable criteria. However, the addition of two stations to Port Angeles Kidney Center is consistent with those criteria. With this reduction in the number of stations, the project meets the relevant criteria for the project. The approved capital expenditure associated with the addition of two dialysis stations to Port Angeles Kidney Center is \$116,030.

Olympic Peninsula Kidney Center

For the reasons stated in this evaluation, the application submitted on behalf of Olympic Peninsula Kidney Center proposing to establish a six-station dialysis center in the city of Port Townsend within Jefferson County is consistent with applicable criteria provided Olympic Peninsula Kidney Center agrees to the following term and condition.

TERM

To ensure that appropriate ancillary and support agreements will be established at its Port Townsend facility, prior to providing services at the new Port Townsend dialysis center, Olympic Peninsula Kidney Center will provide an executed copy of the Patient Transfer Agreement, that includes the new facility in Port Townsend, for the department's review and approval.

Provided that Olympic Peninsula Kidney Center agrees to the term identified above, a Certificate of Need should be issued for the establishment of a six-station dialysis center to be located in the city of Port Townsend within Jefferson County, with the following condition:

CONDITION

Prior to commencement of the project, Olympic Peninsula Kidney Center will provide an executed copy of the Lease Agreement, consistent with the draft lease agreement provided in the application, for the department's review and approval.

The approved capital expenditure associated with the establishment of the six-station dialysis center is \$518,700.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that:

- DaVita, Inc.'s project has not met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280 through 286;
- Northwest Kidney Centers' project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280 through 286, with a reduction in the number of approved stations; and
- Olympic Peninsula Kidney Center's project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280 through 287.

(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 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology, adopted January 1, 2007, 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.³

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

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years 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.

³ 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]

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

DaVita’s Application of the Numeric Methodology

DaVita proposes to establish an 8-station dialysis center in Sequim (Clallam County) to serve patients in two separate planning areas—Clallam County and Jefferson County. Consistent with WAC 246-310-280(9), DaVita applied the numeric methodology separately for each planning area using linear regression for both counties. [source: Application, pp15-17]

NKC’s Application of the Numeric Methodology

NKC proposes to add 3 stations to its existing 8-station dialysis center located in Port Angeles (Clallam County), known as Port Angeles Kidney Center. The proposed 11-stations would serve patients in Clallam County and a portion of Jefferson County, specifically the northeastern portion of the county. Consistent with WAC 246-310-280(9), NKC also applied the numeric methodology separately for each planning area using linear regression for both counties. [source: Application, pp16-21 and Appendices 14 & 15]

OPKC’s Application of the Numeric Methodology

OPKC proposes to establish a 6-station dialysis center in Port Townsend (Jefferson County) to serve patients in Jefferson County. Consistent with WAC 246-310-280(9), OPKC applied the numeric methodology to Jefferson County using linear regression. [source: Application, pp10-11]

Department’s Application of the Numeric Methodology

For reader ease, the department will address the numeric methodology separately for each county.

Clallam County

Based on the calculation of the annual growth rate in the planning areas as described above, the department also used linear regression to project need for Clallam County and divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

Based on the numeric methodology, Table 1 below depicts a summary of the projected net need provided by DaVita and NKC and the department’s projected net need for Clallam County. The department’s numeric methodology for Clallam County is attached to this evaluation as Appendix A.

**Table 1
Clallam County Numeric Methodology Summary of Projected Net Station Need**

	4.8 in-center patients per station			
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
DaVita	9.13	8	1.13	2
NKC	9	8	1	1
DOH	9.13	8	1.13	2

When comparing the projection results shown in Table 1 above, it is noted that the results of DaVita’s projections match the department’s projections. A review of NKC’s projection results reveal that the difference in the projected number of stations could be attributed to the historical data used by NKC. NKC based its projections on seven consecutive years’ historical data (2000-2006), rather than five consecutive years as directed in WAC 246-310-284(4)(b). The additional two years of Clallam County historical data results in one fewer station.

Jefferson County

Based on the calculation of the annual growth rate in the planning areas as described above, the department used linear regression to project need for Jefferson County. As required in WAC 246-310-284(5), the department divided the projected number of patients by 3.2 to determine the number of stations in Jefferson County.

Based on the numeric methodology, Table 2 below depicts a summary of the projected net need provided by each applicant and the department’s projected net need for Jefferson County. The department’s numeric methodology for Jefferson County is attached to this evaluation as Appendix B.

**Table 2
Jefferson County Numeric Methodology Summary of Projected Net Station Need**

	3.2 in-center patients per station			
	2010 Projected # of stations	Minus Current # of stations	2010 Net Need	2010 Net Need (Rounded)
DaVita	5.5	0	5.5	6
NKC	4	0	4	4
OPKC	6	0	6	6
DOH	5.5	0	5.5	6

When comparing the applicants’ and department’s projection results shown in Table 2 above, it is noted that the results of both DaVita’s and OPKC’s projections match the department’s projections. A review of NKC’s projection results reveal that the difference in the projected number of stations could be attributed to the following two factors—historical data used and sub-area proposed to be served.

Historical Data Used to Project

NKC based its projections on seven consecutive years historical data (2000-2006), rather than five consecutive years as directed in WAC 246-310-284(4)(b). Again, the additional two years of historical data for Jefferson County results in two fewer stations.

Sub-Areas Proposed to be Served

For Jefferson County, NKC proposed to capture only a portion of the county, specifically the northeastern portion, which includes the cities of Brinnon, Chimacum, Gardiner, Port Hadlock, Nordland, Port Ludlow, Port Townsend, and Quilcene. NKC did not project to serve residents in the southwestern portion of the county which includes the cities of Clearwater, Kalaloch, and Queets. As a result, NKC under-projected by two stations the number of stations needed to serve Jefferson County.

In summary, the net station need for Clallam County is two-stations as shown in Table 1 above and the Jefferson County net need is six stations as shown in Table 2 above.

For Clallam County, WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. The county currently has eight stations operating within the planning area located at one facility—NKC’s Port Angeles Kidney Center located in Port Angeles. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period is February 1, 2007. [source: WAC 246-310-282] The quarterly modality report from NRN available at that time is December 31, 2006, which became available on January 20, 2007. Table 3 below shows the December 31, 2006, utilization of NKC’s Port Angeles Kidney Center and demonstrates that this capacity requirement is met.

**Table 3
December 31, 2006-Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
NKC’s Port Angeles Kidney Center	8	39	4.88

For Jefferson county, there is no dialysis facility located within the county, therefore, this requirement under WAC 246-310-284(5) does not apply.

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For Clallam County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] Both DaVita and NKC propose dialysis stations to be located within Clallam County, as a result, both applicants must demonstrate compliance with this criterion using the 4.8 in-center patient per station. Further, both DaVita’s and NKC’s third full year of operation is year 2011. A summary of both DaVita’s and NKC’s projected utilization for year 2011 is shown in Table 4 below.

**Table 4
Year 2011 Projected Facility Utilization**

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita Sequim Dialysis Center	2011	8	44	5.5
NKC Port Angeles Kidney Center	2011	11	54	4.9

As shown in Table 4 above, both DaVita’s and NKC’s projections meet this standard. [sources: DaVita application, p15 & Table 11; April 30, 2007, Appendix 4. NKC application, Appendix 10]

For Jefferson County, the requirement is 3.2 in-center patients per approved station [WAC 246-310-284(6)(b)]. OPKC proposes its dialysis facility would be located in Jefferson County, as a result, OPKC must demonstrate compliance with this criterion using the 3.2 in-center patient per stations. OPKC’s third full year of operation is 2011 and a summary of its projected utilization for year 2011 is shown in Table 5 on the following page. [source: OPKC application, p12]

Table 5
Year 2011 Projected Facility Utilization

Facility Name	# of Stations	# of Pts	Pts/Station
OPKC-Port Townsend	6	19	3.2

As shown in Table 5 above, OPKC’s projections meet this standard.

WAC 246-310-286 provides standards for planning areas without an existing facility. Given that one of the three applicants proposes to establish a facility in a planning area without an existing facility, this standard applies to the department’s review of these three projects. For those planning areas, this rule requires the department to award the first project proposing to establish a facility in planning areas without an existing facility, provided the project meets applicable review criteria and standards. Jefferson County is included in the list of planning areas without an existing provider.⁴ While both DaVita and NKC propose to serve Jefferson County, only OPKC proposes to locate a facility within the county.

Based on the above information and standards, the department’s conclusion regarding this sub-criterion follows.

OPKC

OPKC’s proposes to establish a 6-station dialysis center in a planning area without an existing facility. Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. This sub-criterion is met for OPKC’s application.

DaVita

DaVita proposes to establish an 8-station dialysis center in Sequim (Clallam County) to serve patients in two separate planning areas—Clallam and Jefferson counties. DaVita based its projections by applying the numeric methodology separately for each planning area, resulting in a combined numeric need for 8 stations. Approval of the OPKC’s project makes it unnecessary to include Jefferson County within DaVita’s need projections. Once 6 of DaVita’s projected 8 stations are subtracted from the need, DaVita is left with a projected numeric need of 2 stations in the Clallam County planning area, rather than the 8 stations requested by DaVita.

WAC 246-310-287 allows the department to approve more than the projected number of stations if the applicant meets the following criteria and standards.

- 1) *All other applicable review criteria and standards have been met; and*
- 2) *One or more of the following have been met:*
 - (a) *The department finds the additional stations are needed to be located reasonably close to the people they serve; or*
 - (b) *Existing dialysis stations in the dialysis facility are operating at six patients per station. 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; or*

⁴ Planning areas without an existing provider as of January 1, 2007, are: Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties

- (c) *The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and*
- 3) *The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing.*

Other than the numeric need methodology for the combined planning areas of Clallam and Jefferson County, no other documentation was provided by DaVita to demonstrate need for an 8-station facility in Clallam County. As a result, DaVita did not provide any documentation to demonstrate that the standard under WAC 246-310-287 should apply to this project.

NKC

NKC proposes to add 3 stations to its existing 8-station dialysis center located in Clallam County. NKC proposes the 3 additional stations would serve patients in Clallam County and a portion of Jefferson County. Approval of the OPKC’s project makes it unnecessary to include Jefferson County within NKC’s need projections. The numeric methodology projects a need for 2 additional stations in Clallam County. NKC also did not provide any documentation to demonstrate that the standard under WAC 246-310-287 should apply to this project.

As a result, NKC’s proposal to add 3 stations is not consistent with applicable criteria of the Certificate of Need Program, however, the addition of 2 stations would be consistent with this criterion, provided NKC could meet the facility operation standards under WAC 246-310-284(6) as a 10-station facility rather than the projected 11 stations. The result of the department’s second review of NKC’s projected utilization is shown in Table 6 below.

**Table 6
Year 2011 Projected Facility Utilization**

Facility Name	# of Stations	# of Pts	Pts/Station
NKC Port Angeles Kidney Center	10	54	5.4

As shown in Table 6 above, as a 10-station facility, NKC’s Port Angeles Kidney Center could provide dialysis services to the same number of patients it projects to serve with 11 stations. This assumption is reasonable when taking into consideration that NKC had projected to serve only a portion of Jefferson County from its Clallam County site, rather than the entire county.

Comments related to the need criterion were provided by DaVita, OPKC, Jefferson Healthcare, and four dialysis patients residing in Jefferson County. The comments focus on patient access to dialysis services and are summarized below. [sources where noted]

- DaVita asserts that its application is superior to the NKC application because NKC’s project “*offers a small expansion of an existing facility to serve only Clallam County patients.*” DaVita also asserts its project is superior to the OPKC application because OPKC’s project “*proposes to establish a 6-station facility in the northern tip of Jefferson County to address Jefferson County dialysis need.*” As a result, DaVita’s states its project is the only one that would meet the station need in both planning areas, improve access for patients in both planning areas, and provide choice for patients in both planning areas, by establishing a centrally located dialysis center in Sequim. DaVita also

states that its project will improve travel time access to residents of both Clallam and Jefferson counties, and “*travel time will be virtually eliminated for residents in the Sequim area, which currently includes 19 hemodialysis patients.*” Further, DaVita asserts that while establishment of a dialysis center in Sequim will improve travel time for the current 12 Jefferson County in-center hemodialysis patients, only the DaVita project will improve travel time to residents in the two planning areas under concurrent review. From the concurrent review standpoint, DaVita states its application is the superior alternative. [source: DaVita August 2, 2007, public hearing documents, p1; September 4, 2007, rebuttal documents, p2]

- OPKC asserts that its own project is superior because the majority of the station need is in Jefferson County, rather than Clallam County, and its project proposes to locate dialysis stations in the county where they are needed. Additionally, OPKC states that its own project improves access to dialysis services to patients within Jefferson County, rather than requiring those patients to travel to the nearest facility in either Clallam or Kitsap counties. OPKC also states that “*Jefferson County dialysis patients deserve improved access to dialysis care and should not have to continue traveling outside of the county to receive treatment if an outpatient unit can be located within the county and proposed by OPKC.*” [source: OPKC, August 2, 2007, public hearing documents, p1 and September 4, 2007, rebuttal documents, pp1-2]
- Jefferson Healthcare, the local hospital in Jefferson County, provided public comment at the August 2, 2007, hearing in Jefferson County. Jefferson Healthcare provides acute care services, as well as home health and hospice, outpatient diagnostic, rehabilitation services and community education. Jefferson Healthcare’s letter supports the establishment of dialysis stations in Jefferson County so that dialysis patients will not be required to travel to Kitsap or Clallam counties for services. [source: Jefferson Healthcare August 2, 2007, public hearing document]
- Community Members-the department also received letters of support from dialysis patients or families of dialysis patients residing in Jefferson County. All four letters support the establishment of a dialysis center in the county, rather than requiring the patients to travel three times per week for dialysis services. [source: August 2, 2007, community public comment]

Department’s Evaluation of the Comments Provided

WAC 246-310-284(1) states

“Applications for new stations may only address projected station need in the planning area in which the facility is to be located.”

The purpose of the requirement above is to have stations located within the planning area where the patients reside. The department and these rules recognize there are a number of planning areas, primarily rural, that currently do not have a dialysis facility located within them. One reason may be that the projected number of stations is too small to support a dialysis facility. However, when the number of projected stations in these planning areas is at least four, WAC 246-310-286 requires the department to award a Certificate of Need to the first approval project to be located in that planning area.

WAC 246-310-284(1)(a) states:

“If there is no existing facility in an adjacent planning area, the application may also address the projected station need in that planning area.” [emphasis added]

This rule permits, but does not require, an applicant to add enough stations to the number being requested to serve the needs of the residents in the adjacent planning area that is without a facility. This serves as a stopgap measure until a project to be located within the planning area is approved.

WAC 246-310-286 states:

“Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum planning areas do not have an existing kidney dialysis facility as of the effective date of these rules. The department will award the first project proposing to establish a facility in each of these planning areas a minimum of four stations provided the project meets applicable review criteria and standards. The facility must be projected to operate at 3.2 in-center patients per station by the third full year of operation. For purposes of this section, the applicant may supplement data obtained from the Northwest Renal Network with other documented demographic and utilization data to demonstrate station need.” [emphasis added]

When both rules are taken into consideration, it is clear that department preference is to allow the establishment of a dialysis center within a planning area that does not have an existing facility.

Additionally, the department must take into consideration the support of dialysis patients within Jefferson County. Within its rebuttal documents, DaVita acknowledged the four community letters of support for a dialysis provider to be located in Jefferson County; however, DaVita appeared to discount two of the letters because the patients were commuting to a dialysis facility only one or twice monthly, rather than the typical three times a week. DaVita continued to assert that a dialysis provider in Sequim would increase convenience and reduce travel time for patients in Clallam and Jefferson counties. A dialysis provider in Sequim may reduce travel time for some patients in Clallam and Jefferson counties, however, a dialysis center located in Jefferson County would certainly improve access to dialysis services for the 13 Jefferson County dialysis patients identified in year 2006, and the projected 18 dialysis patients in year 2010.

Further, 2002 to 2006 historical NRN data demonstrates that while the majority of the dialysis patients are located in the larger county of Clallam—37 patients in 2006 compared to 13 patients in 2006 for Jefferson County—without a dialysis center located in Jefferson County, the majority of the station need is in Jefferson County. Only the OPKC project proposes to locate a facility in Jefferson County to accommodate the majority of the station need for the two planning areas. If OPKC can meet the other applicable review criteria and standards, locating a dialysis center in Jefferson County, rather than Clallam County, would improve access and choice for patients within the planning area.

Based on the above information, the department makes the following conclusions regarding the three applications.

DaVita, Inc.

The application submitted on behalf of DaVita, Inc. proposing to establish an 8 station facility to serve the residents of Clallam and Jefferson counties is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need should be denied.

Northwest Kidney Centers

The application submitted on behalf of Northwest Kidney Centers proposing to add 3 stations to its existing 8-station facility located in Port Angeles within Clallam County is not consistent with applicable criteria of the Certificate of Need Program. However, the addition of 2-stations to the existing 8-station facility located in Port Angeles within Clallam County is consistent with those criteria.

Olympic Peninsula Kidney Center

The application submitted on behalf of Olympic Peninsula Kidney Centers proposing to establish a 6-station dialysis center in the city of Port Townsend within Jefferson County is consistent with the applicable review criteria and a Certificate of Need should be issued with any appropriate terms and conditions.

- (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.

As previously stated, all three applicants currently provide dialysis services to residents of specific service areas within Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the service area would continue to have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. 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 any assurances regarding access to treatment.

To determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current admission and indigent care policies that would also be used at the new Sequim facility. The Admission policy outlines the process/criteria that the new facility will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing

chronic hemodialysis will be accepted for treatment at the dialysis center without regard to race, color, national origin, sex, age, religion, or disability. [source: Application, Appendix 14]

DaVita currently provides services to Medicare and Medicaid eligible patients at its existing fourteen dialysis centers and intends to maintain this status. A review of the Charity Care Policy provided for the Sequim facility identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. [source: Application, Appendix 14]

Additionally, DaVita demonstrated its intent to provide charity care to residents by submitting its charity care policy that outlines the process a patient would use to access this service. Further, DaVita included a 'charity care' line item as a deduction from revenue within the pro forma financial documents. [source: Application, Appendix 14 and April 27, 2007, supplemental information, Attachment 4]

Based on the above information, the department concludes that all residents of the planning area would have reasonable access to the health services at the proposed DaVita Sequim Dialysis Center. This sub-criterion is met.

Northwest Kidney Centers

To demonstrate compliance with this sub-criterion, NKC provided a copy of its admission criteria, patient compliancy, and charity care policies that are currently used in the NKC facilities, including the Port Angeles Kidney Center. [source: Application, Appendices 20, 21, & 22]

The documents provided by NKC outline the process/criteria that the dialysis center uses to admit patients for treatment. It is intended to ensure that patients will receive appropriate care at the dialysis center. The Admission criteria states that any patient with end stage renal disease needing treatment will be accepted to NKC's facility without regard to race, color, religion, sex, national origin, or age. [source: Application, Appendix 20]

NKC currently provides services to Medicare and Medicaid eligible patients at its existing thirteen dialysis centers and intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive both Medicare and Medicaid reimbursements. Additionally, NKC demonstrated its intent to continue to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the pro forma financial documents. [source: Application, Appendix 9]

Based on the above information, the department concludes that all residents of Clallam County have reasonable access to the health services at NKC's Port Angeles Kidney Center, and the addition of two stations would not negatively affect this access to services. This sub-criterion is met.

Olympic Peninsula Kidney Center

To demonstrate compliance with this sub-criterion, OPKC provided a copy of its admission criteria, charity care policies, and mission statement that are currently used in the OPKC facilities located in Kitsap County. The admission criteria would also be used in the new dialysis facility in Port Townsend. [source: Application, Appendices K, L, & M]

The documents provided by OPKC outline the process/criteria that the dialysis center uses to admit patients for treatment. It is intended to ensure that patients will receive appropriate

care at the dialysis center. The Admission criteria states that any patient with end stage renal disease needing treatment will be accepted to OPKC's facility without regard to race, color, national origin, sex, age, religion, or disability. [source: Application, Appendix K]

OPKC currently provides services to Medicare and Medicaid eligible patients at its existing three dialysis centers and intends to maintain this status. A review of the anticipated revenue indicates that OPKC expects to continue to receive both Medicare and Medicaid reimbursements, and would receive both reimbursements at its proposed Jefferson County dialysis facility in Port Townsend. Additionally, OPKC demonstrated its intent to provide charity care to Jefferson County residents by including a 'charity care' line item as a deduction from revenue within the pro forma financial documents. [source: April 30, 2007, supplemental information, Attachment 5]

Based on the above information, the department concludes that all residents of Jefferson County would have reasonable access to the health services at OPKC's proposed Port Townsend facility. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.'s project has not met the financial feasibility criteria in WAC 246-310-220;
- Northwest Kidney Centers' project has met the financial feasibility criteria in WAC 246-310-220 with a reduction in the number of approved stations; and
- Olympic Peninsula Kidney Center's project has met the financial feasibility criteria in WAC 246-310-220.

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

DaVita Inc.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the 8-station facility would be operational by the end of July 2008. Based on this timeline, year 2009 would be Sequim Dialysis Center's first full calendar year of operation and 2011 would be year three. [source: Application, p10]

Using the financial information provided in the application, Table 7 on the following page illustrates the projected revenues, expenses, and net income for years 2008-2011 for Sequim Dialysis Center. [source: Application, Appendix 9]

Table 7
Sequim Dialysis Center
Projected Revenues and Expenses Calendar Years 2008 - 2011

	Partial Year 2008	Full Year 1 2009	Full Year 2 2010	Full Year 3 2011
# of Stations	8	8	8	8
# of Treatments ^[1]	2,778	4,429	6,379	7,130
# of Patients ^[2]	18	28	40	44
Utilization Rate ^[2]	2.3	3.5	5.0	5.5
Net Revenue ^[1]	\$ 782,442	\$ 1,415,845	\$ 2,125,799	\$ 2,653,834
Total Expense ^[1,3]	\$ 894,565	\$ 1,139,831	\$ 1,496,215	\$ 1,805,754
Net Profit or (Loss) ^[1]	(\$ 112,123)	\$ 276,014	\$ 629,584	\$ 848,080
Net Patient Revenue/Treatment ^[1]	\$ 290.22	\$ 337.67	\$ 354.89	\$ 402.77
Total Operating Exp./Treatment ^[1]	\$ 331.81	\$ 271.84	\$ 249.79	\$ 274.06
Net Profit (Loss) per Treatment ^[1]	(\$ 41.59)	\$ 65.83	\$ 105.11	\$ 128.71

[1] includes both in-center and home dialysis patients; [2] in-center patients only; [3] includes deductions for bad debt, charity care and allocated costs

As shown in Table 7 above, at the projected volumes identified in the application, DaVita anticipates that its Sequim Dialysis Center would be operating at a loss in partial year 2008, and a profit in years 2009 through 2011 as an 8-station facility.

When reviewing DaVita's application, it is noted that the lease agreement and the financial information provided in the pro forma revenue and expense statements are inconsistent. The lease agreement identifies a 6,000/sf facility with an annual lease amount of \$18/psf or \$108,000 annually. Further the lease indicates that the annual cost of \$108,000 will remain consistent through year 5, and beginning in year 6, the lease amount will increase to \$21/psf or \$126,000 annually. The pro forma revenue and expense statement provided show consistently different annual lease/rent amounts than those identified in the draft lease agreement. Table 8 provides a comparison of the amounts.

Table 8
Lease Costs and Pro Forma Comparison

	Lease Amounts	Pro Forma Amounts	Differences
2008-Year 1	\$ 108,000	\$ 162,400	\$ 54,400
2009-Year 2	\$ 108,000	\$ 125,454	\$ 17,454
2010-Year 3	\$ 108,000	\$ 129,218	\$ 21,218
2011 Year 4	\$ 108,000	\$ 133,094	\$ 25,094
2012-Year 5	\$ 108,000	\$ 137,087	\$ 29,087
5 yr Total	\$ 540,000	\$ 687,253	\$ 147,253

The overstatement of lease/rent amounts in the pro forma would result in an overstatement of expenses, resulting in an overstatement of net loss in year 2008, and an understatement of net profit in years 2009 through 2011. This overstatement/understatement issue could be viewed as "conservative pro forma projections," it is also indicative of inconsistencies within the application. While the inconsistencies in the pro formas and projected lease may not affect the viability of this project, the proposed Clallam County facility cannot be fully evaluated on its long-range capital and operating costs.

Both NKC and OPKC provided comments related to the financial feasibility of DaVita's project. The comments focus on DaVita's draft lease agreement, site for the project, and the pro forma information provided in the application. DaVita provided responses to the comments, which are also stated below. [sources where noted]

NKC Comments [source: August 2, 2007, public hearing documents, pp1-3]

- DaVita submitted an incomplete application from the onset. When the application was submitted on February 28, 2007, DaVita did not identify a site for the dialysis center or provide complete documentation that it has sufficient interest in a site.
- The lessor of the property identified in the draft lease is different than the current owner of the property based on the Clallam County Assessor website.
- The draft lease agreement does not include two exhibits referenced in the document. Exhibit A should be the legal description/building site plan, and Exhibit B should be the premises floor plan.
- The property is currently a two-lot subdivision and the lease does not clarify whether the proposed site is to be on lot 1 or lot 2.

OPKC Comments [source: August 2, 2007, public hearing documents, pp1-3]

OPKC echoed the concerns raised by NKC above and concludes:

- DaVita cannot demonstrate sufficient interest in a site;
- the owner identified in the lease agreement cannot demonstrate legal title of ownership; and
- DaVita cannot warrant its lease costs because of a lack of ownership and has failed to demonstrate site control as required in CN guidelines.

DaVita's Response to NKC and OPKC Comments [source: September 4, 2007, rebuttal documents, pp1-3]

- The lessor—Sequim Y3K LLC—is a developer with a long-term lease from the property owners [identified in the Clallam County Assessor's website]. County property records do not show the LLC's leasehold interest and properly show the title holders.
- The subdivision information is consistent with the LLC status as property developer and lessor.
- The lease description/building site plan and the floor plan were provided in responses to the department's screening questions and are part of the application.

After reviewing the comments provided by both NKC and OPKC and the responses provided by DaVita, the department concludes that the draft lease agreement provided by DaVita does not demonstrate appropriate control of the site as required under CN application guidelines. According to the Clallam County Assessor website, the property is jointly-owned by two individuals. However, the landlord identified in the lease agreement is a Washington State corporation established in May 2001 known as Sequim Y3K, LLC. DaVita did not provide any documentation to demonstrate that Sequim Y3K, LLC has the legal control of the property to enter into a lease agreement.

Additionally, as previously stated, the inconsistencies revealed when comparing the lease costs in the draft lease agreement and the costs identified in the pro forma also raise concerns by the department. During the screening process, the department requested any necessary

updates to DaVita’s pro forma “*that reflects all costs associated with the site for the project.*” [source: Department’s March 30, 2007, letter, screening question #7] DaVita responded that no changes were necessary in the pro forma other than the correct calendar year headings previously requested in screening. [source: April 27, 2007, supplemental information, p3] As a result, the proposed Clallam County facility cannot be fully evaluated on its long-range capital and operating costs.

Given that the department concluded in the need section of this evaluation that DaVita’s project is not consistent with applicable criteria of the Certificate of Need Program, the projected number of dialysis treatments proposed by DaVita is likely overstated, and because of the inability to evaluate the lease costs, this sub-criterion is not met.

Northwest Kidney Centers

As stated in the project description portion of this evaluation, if this project is approved, NKC anticipates the 3 additional stations would be added to Port Angeles Kidney Center immediately and all 11 stations would be operational by the end of March 2008. Based on this timeline, year 2009 would be Port Angeles Kidney Center’s first full calendar year of operation with 11 stations and 2011 would be year three. [source: Application, Executive Summary]

NKC provided documentation demonstrating it owns the site of the dialysis center, and no lease costs are necessary for the pro forma documentation.

In the need section of this evaluation, the department concluded that NKC’s project met the methodology and standards if two stations were added to the existing facility, rather than the requested three. The department also concluded that Port Angeles Kidney Center could treat the same number of patients with 10 stations as it projected with 11 stations. Using the financial information provided in the application, Table 9 below illustrates the projected revenues, expenses, and net income for years 2008-2011 for Port Angeles Kidney Center as a 10-station facility. [source: Application, Appendix 9]

Table 9
Port Angeles Kidney Center
Projected Revenues and Expenses Calendar Years 2008 - 2011

	Partial Year 2008	Full Year 1 2009	Full Year 2 2010	Full Year 3 2011
# of Stations	10	10	10	10
# of Treatments ^[1]	7,020	7,488	7,956	8,424
# of Patients ^[2]	45	48	51	54
Utilization Rate ^[2]	4.5	4.8	5.1	5.4
Net Revenue ^[1]	\$ 1,473,639	\$ 1,571,881	\$ 1,670,123	\$ 1,768,366
Total Expense ^[1,3]	\$ 1,441,744	\$ 1,535,881	\$ 1,622,761	\$ 1,709,640
Net Profit or (Loss) ^[1]	\$ 31,895	\$ 36,000	\$ 47,362	\$ 58,726
Net Patient Revenue/Treatment ^[1]	\$ 209.92	\$ 209.92	\$ 209.92	\$ 209.92
Total Operating Exp./Treatment ^[1]	\$ 205.38	\$ 205.11	\$ 203.97	\$ 202.95
Net Profit (Loss) per Treatment ^[1]	\$ 4.54	\$ 4.81	\$ 5.95	\$ 6.97

[1] includes in-center only; no home dialysis patients are projected; [2] in-center patients only; [3] includes deductions for bad debt, charity care and allocated costs

As shown in Table 9, at the projected volumes identified in the application, NKC anticipates that its Port Angeles Kidney Center would be operating at a profit in years 2008 through 2011 as an 11-station facility. Given that the facility could provide the same number of dialyses with 10 stations, the department also concludes that Port Angeles Kidney Center would also operate at a profit as a 10-station facility

During the concurrent review of this project, neither DaVita nor OPKC provided concerns regarding NKC's financial information provided in its application.

Based on the above evaluation, NKC's projections appear to be reasonable with 10 dialysis stations, and this sub-criterion is met.

Olympic Peninsula Kidney Center

As stated in the project description section of this evaluation, if approved, OPKC anticipates commencement of the project immediately and all 6 stations would be available for patient use by the end of June 2008. Under this timeline, year 2009 would be the new facility's first full calendar year of operation and 2011 would be year three. [source: OPKC April 30, 2007, supplemental information, p2]

OPKC also provided a copy of its draft lease agreement for the site. The draft agreement identifies the roles and responsibilities of both OPKC as the tenant and the individual owner of the site. The draft agreement identifies all costs associated with the lease, and those costs are substantiated in the pro forma financial documents provided in the application.

A review of the financial information provided in the application reveals that OPKC did not provide projections for partial year 2008, rather, OPKC provided its facility projections and revenue, expenses, and net income for years 2009-2011 for the Jefferson County facility. Table 10 below is a summary of the information provided by OPKC. [source: Application, p12; and OPKC April 30, 2007, supplemental information, p2 & Attachments 5 & 6]

**Table 10
Olympic Peninsula Kidney Center's Jefferson County Dialysis Facility
Projected Revenues and Expenses Calendar Years 2009 – 2011**

	Full Year 1 2009	Full Year 2 2010	Full Year 3 2011
# of Stations	6	6	6
# of Treatments ^[1]	2,712	3,092	3,314
# of Patients ^[2]	16	18	19
Utilization Rate ^[2]	2.7	3.0	3.2
Net Revenue ^[1]	\$ 652,061	\$ 743,983	\$ 800,252
Total Expense ^[1,3]	\$ 657,074	\$ 707,955	\$ 765,677
Net Profit or (Loss) ^[1]	(\$ 5,013)	\$ 36,028	\$ 34,575
Net Patient Revenue/Treatment ^[1]	\$ 269.67	\$ 282.24	\$ 278.54
Total Operating Exp./Treatment ^[1]	\$ 271.74	\$ 268.57	\$ 266.51
Net Profit (Loss) per Treatment ^[1]	(\$ 2.07)	\$13.67	\$12.03

[1] includes both in-center and home dialysis patients; [2] in-center patients only;
[3] includes deductions for bad debt, charity care and allocated costs

As shown in Table 10, at the projected volumes identified in the application, OPKC anticipates that its Jefferson County facility would be operating in a loss for the first full year of operation and a profit in years 2010 and 2011. Even though OPKC did not provide it, the department must assume that the facility would also be operating at a loss in year 2008, the facility's first partial year of operation.

DaVita provided comments related to the financial feasibility of OPKC's project. The comments focus on the pro forma information provided in the application. NKC did not provide comments related to OPKC's financial feasibility. OPKC provided responses to DaVita's comments, which are also stated below. [sources where noted]

DaVita Comments [source: August 2, 2007, public hearing documents, pp4-5]

- Financial feasibility of OPKC's Jefferson County dialysis facility rests upon a "razor's edge" for break even or profit. If OPKC's projections are even 10% less treatments than anticipated, the facility would barely break even in its 3rd full year of operation; a 20% reduction in treatments would result in a financial loss through at least year 2011. [10%, 20%, 30%, and 40% comparison table provided by DaVita] If only a few Jefferson County patients do not dialyze at the new Port Townsend facility, the 6-station center will be non-profitable.
- 2006 CHARS data shows a number of Jefferson County residents rely on health care resources in Kitsap County [Bremerton area] and likely would do the same for dialysis services.

OPKC's Response to DaVita's Comments [source: September 4, 2007, rebuttal documents, pp4-5]

- DaVita uses CHARS data as an indicator of dialysis patient travel patterns and preferences, which is speculative and unsubstantiated. The department has a long history of noting how travel patterns for acute care (episodic care) vary from patterns for chronic care (i.e., dialysis). Since dialysis patients would travel 3 times per week for 52 weeks for the rest of their life, this is not a valid indicator of travel patterns for dialysis patients.
- OPKC has been in brief contact with majority of the Jefferson County patients and all have expressed a strong interest in, and support of, a local unit in the county. DaVita's suggested market share of 55-60% is very low in an area as isolated as Jefferson County.
- In previous/recent DaVita applications for rural areas, DaVita has assumed approximately 100% market share of patients when it proposes to be the only provider in the planning area. [examples provided by OPKC]

After reviewing the comments provided by DaVita and the responses provided by OPKC, the department concludes that the concerns raised by DaVita regarding the market share of patients projected by OPKC and the financial viability of the new dialysis center if the projected market share percentages are not realized are of concern to the department. Loss of 10% of projected dialyses in year 2011 is merely a decrease of 2 patients—from 21 to 19. While projections are relied upon in this type of application, the projections are not absolute numbers and actual numbers can fluctuate from projected numbers. Further, the department recognizes that if the only dialysis facility operating in a planning area (Jefferson County) is forced to close, vulnerable patients must be relocated out of the planning area to another facility. This action, in turn, would force nearby facilities to accommodate the relocated

patients, while continuing to provide dialysis services to residents of their own planning areas. Dialysis facility closure and patient relocation has the potential to overcrowd dialysis centers and cause patients to travel even further for necessary services.

However, OPKC’s response regarding projected market shares of dialysis patients has merit, as well. OPKC also compared its own projections for Jefferson County with a project submitted by DaVita in an application for Kittitas County. A comparison chart showing similarities of the two projects is below.

DaVita Project	OPKC Project
DaVita Ellensburg, Kittitas County	OPKC Port Townsend, Jefferson County
No existing dialysis provider in county	No existing dialysis provider in county
Patients are driving out of county into Yakima County for dialysis services	Patients are driving out of county into Kitsap County for dialysis services
DaVita owns Yakima facilities where Kittitas County patients are dialyzing; no other provider operating in Yakima County	OPKC owns Kitsap facilities where Jefferson County patients are dialyzing; no other provider operating in Kitsap County
Methodology shows need for 2 dialysis stations in year 2010 (based on 2002-2006 data)	Methodology shows need for 6 dialysis stations in year 2010 (based on 2002-2006 data)
Methodology projects 9 patients in Kittitas County in year 2010 (based on 2002-2006 data)	Methodology projects 18 patients in Jefferson County in year 2010 (based on 2002-2006 data)
DaVita proposes to establish a 4 station center in Kittitas County	OPKC proposes to establish a 6-station center in Jefferson County
DaVita projects that a number of patients would transfer from its Yakima facility into the new Ellensburg facility	OPKC projects that a number of patients would transfer from its Kitsap facilities into the new Port Townsend facility
DaVita projects it will serve 12 patients in year 2010, equating to 33% (3) more patients than projected in the methodology.	OPKC projects it will serve 18 patients in year 2010, equating to 100% of the patients projected in the methodology.

As shown in the comparison chart, there are many similarities with the two projects. DaVita’s Kittitas County application requesting a 4-station center in Kittitas County was initially denied on March 30, 2007. DaVita submitted its request for an adjudicative proceeding related to the denial. As allowed under the adjudicative rules, both DaVita and the department participated in settlement discussions to determine whether settlement was feasible. On May 30, 2007, the department issued its settlement evaluation approving

DaVita to establish a 2-station dialysis center in Kittitas County.⁵ Even with two stations, DaVita's financial projections proposed it would dialyze 12 patients in year 2010. These projections, while ambitious, were considered reasonable given that DaVita owned the facilities where the Kittitas patients were already dialyzing. Further, seven Kittitas County residents submitted letters of support for DaVita's establishment of a dialysis center in Kittitas County so that they would not have to continue to travel to Yakima County for dialysis services.

Even though DaVita's financial projections relied on 133% market share of the Kittitas county patients, the department recognized the need for a dialysis center in a rural county with no current provider. DaVita proposed to meet that need, and when approved, accepts the financial responsibility to maintain services for the rural Kittitas County patients.

OPKC's Jefferson County project is not unlike DaVita's Kittitas County project. While the department recognizes that a slight decrease in patients or dialyses at OPKC's Jefferson County center could equate to a net loss through year 2011, rather than a net profit, by submission of this application, OPKC—like DaVita in its Kittitas County project—has ultimately accepted the financial responsibility to maintain dialysis services for the Jefferson County patients. Further, the department concluded in the numeric need section of this evaluation that need for 6-stations in Jefferson County has been demonstrated.

Based on the above information, the department concludes that OPKC's revenues and expenses are reasonable. Given that OPKC submitted a draft lease agreement for the site, this sub-criterion is met provided that OPKC agrees to a condition to provide the executed lease agreement before commencing the project.

- (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.

DaVita Inc.

The capital expenditure associated with the establishment of DaVita's 8-station facility is \$1,315,865, of which approximately 55% is related to leasehold improvements at the site; 36% is related to both fixed and moveable equipment; and the remaining 9% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p6]

To demonstrate compliance with this sub-criterion, DaVita provided the following statements:

"...Funding from previously allocated operations funds is the least costly approach. Debt financing for this project will not be required since there is sufficient cash on hand. Furthermore, the method of financing would have no impact on the amount charged for each unit of service." [source: Application, p21]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in the chart on the following page. [source: Application, p22]

⁵ The settlement evaluation also required DaVita to decertify two stations at its Yakima Dialysis Center so that the Yakima facility could meet the 80% utilization standard as required under the rules in place at the time that application was submitted.

Source of Revenue	Percentage of Revenue
Medicare	72%
State (Medicaid)	8%
Insurance/HMO	20%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 80% of the revenue at DaVita’s Sequim Dialysis Center. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. The costs and charges per dialysis for the proposed project cannot be compared to recent kidney dialysis proposals submitted to the department. The department is not able to calculate the average costs per dialysis with any certainty due to inconsistent pro-forma data, which includes the lease costs.

Based on the information above, the department cannot conclude that the costs of this project would not result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

Northwest Kidney Centers

The capital expenditure associated with the addition of 3 stations is \$116,030 of which 53% is related to construction costs and the remaining 47% is related to fixed and moveable equipment. [source: NKC Application, Appendix 7]

To demonstrate compliance with this sub-criterion, NKC provided the following statements related to its station addition project:

“Construction estimates are based on recent similar dialysis station development project costs. The capital costs indicated for dialysis machines and recliners reflect our contract purchase pricing. The majority of reimbursements for dialysis services flow from Medicare ESRD entitlements, which are not subject to, or affected by, capital improvements and expenditures by providers.” [source: Application, p15]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, NKC also provided the sources of patient revenue shown in the chart below. [source: Application, p8]

Source of Revenue	Percentage of Revenue
Medicare	74%
State (Medicaid)	7%
Insurance/HMO	19%
Total	100.0%

As shown above, the Medicare and State (Medicaid) entitlements are projected to 80% of the revenue at NKC’s Port Angeles Kidney Center in Clallam County. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. This sub-criterion is met.

Olympic Peninsula Kidney Center

The capital expenditure associated with the establishment of the 6-station facility is \$518,700, of which 48% is related to construction, 44% is related to fixed and movable equipment, and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: OPKC Application, p21]

To demonstrate compliance with this sub-criterion, OPKC provided the following statements related to its Port Townsend dialysis center project:

“The construction costs are based on OPKC’s recent experience in creating satellite facilities. The equipment costs are based on current contracts with national vendors. The projected capital and operating costs, as well as anticipated charges, will not have a material effect on the provision of health services other than a favorable impact on the access to and availability of outpatient dialysis services in Jefferson County.” [source: Application, p21]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, OPKC also provided the sources of patient revenue shown in the chart below. [source: Application, p23]

Source of Revenue	Percentage of Revenue
Medicare	40.8%
State (Medicaid)	6.3%
Insurance/HMO	52.9%
Total	100.0%

As shown above, for OPKC, the Medicare and State (Medicaid) entitlements are projected to be slightly above 55% of the revenue at the Port Townsend facility. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. This sub-criterion is met.

(3) The project can be appropriately financed.

DaVita Inc.

As previously stated, the capital expenditure associated with the establishment of DaVita’s 8-station facility is \$1,315,865, of which approximately 55% is related to leasehold improvements at the site; 36% is related to both fixed and moveable equipment; and the remaining 9% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p6] A review of DaVita’s historical financial statements shows the funds necessary to finance the project are available. [Application, Appendix 10]

Based on the information provided, the department concludes the establishment of an 8-station dialysis center in Clallam County would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met.

Northwest Kidney Centers

The capital expenditure associated with the addition of 3 stations is \$116,030, of which 53% is related to construction costs and the remaining 47% is related to fixed and moveable equipment. [source: NKC Application, Appendix 7] In the need section of this evaluation, the department concluded that NKC should add two stations, rather than the requested three, however, the department does not anticipate the reduction of one station would significantly affect the capital expenditure. A review of NKC's historical financial statements shows the funds necessary to finance the project are available. [source: Application, Appendix 25]

Based on the information provided, the department concludes the addition of two stations to NKC's Port Angeles Kidney Center would not adversely affect the financial stability of NKC as a whole. This sub-criterion is met.

Olympic Peninsula Kidney Center

As previously stated, the capital expenditure associated with the establishment of the 6-station facility is \$518,700, of which 48% is related to construction, 44% is related to fixed and movable equipment, and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: OPKC Application, p21] A review of OPKC's historical financial statements shows the funds necessary to finance the project are available. [source: Application, Appendix O]

Based on the information provided, the department concludes the establishment of a 6-station facility in Jefferson County would not adversely affect the financial stability of OPKC as a whole. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.'s project has not met the structure and process (quality) of care criteria in WAC 246-310-230;
- Northwest Kidney Centers' project has met the structure and process (quality) of care criteria in WAC 246-310-230 with a reduction in the number of approved stations; and
- Olympic Peninsula Kidney Center's project has met the structure and process (quality) 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.

DaVita Inc.

To staff its proposed 8-station facility in Sequim, DaVita intends to recruit 3.2 FTEs in partial year 2008, which would increase to a total of 8.5 FTEs by the end of full calendar year three (2011). A breakdown of the proposed FTEs is shown in Table 11 on the following page. [source: Application, p23]

Table 11
DaVita's Clallam County Dialysis Center 2008 – 2011 Projected FTEs

Staff/FTEs	2008 Partial Year	2009 Increase	2010 Increase	2011 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	0.20	0.40	0.20	0.20	1.00
RN	1.10	0.60	0.30	0.30	2.30
Patient Care Techs	1.20	0.80	0.80	0.70	3.50
Biomedical Techs	0.20	0.00	0.00	0.00	0.20
Re-Use Techs	0.10	0.10	0.10	0.00	0.30
Administrative Assistant	0.00	0.00	0.30	0.10	0.40
MSW	0.10	0.10	0.00	0.10	0.40
Dietitian	0.20	0.10	0.00	0.10	0.40
Total FTE's	3.20	2.10	1.70	1.50	8.50

As shown in Table 11 above, after the initial recruitment of FTEs, DaVita expects a steady increase in FTEs for its Clallam County dialysis facility through year 2011. DaVita states it expects no difficulty in recruiting staff for its Sequim facility because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. In addition, DaVita states that several employees have already expressed interest in working at its proposed Sequim facility. [source: Application, p24]

DaVita has identified Dimitri Vasin, MD as the proposed medical director for the facility. The applicant provided a copy of an executed contract with Dr. Vasin to demonstrate that he would provide services in this capacity. The agreement outlines the roles and responsibilities of both entities and includes a draft addendum to the contract that incorporates the new dialysis center in Sequim. The executed agreement identifies the annual compensation limits for the medical director responsibilities. [source: DaVita Application, Appendix 3] If this project is approved, DaVita would be required to submit an executed addendum to the medical director agreement for the department's review before DaVita could provide dialysis services.

Based on this information, the department concludes that adequate staffing for a new dialysis center in Clallam County is available or can be recruited. This sub criterion is met.

Northwest Kidney Centers

Currently, NKC's Port Angeles Kidney Center employs 9.90 FTEs to staff the 8-station facility. To implement this project, NKC proposes to add approximately .75 FTEs each year based on the projected number of patients in those years. In the need section of this evaluation, the department concluded that NKC should add two stations, rather than the requested three, however, the department does not anticipate the reduction of one station would significantly affect the FTEs proposed within the application.

The current FTEs at the Port Angeles facility and the proposed increases for years 2008 - 2010 are shown in Table 12 on the following page. [source: NKC's April 27, 2007, supplemental information, p1]

**Table 12
Port Angeles Kidney Center 2008 – 2010 Projected FTEs**

Staff/FTEs	2007 Current Year	2008 Increase	2009 Increase	2010 Increase	Total FTEs
Medical Director	Professional Services Contract				
RN	4.10	0.25	0.25	0.25	4.85
LPN	0.80	0.00	0.00	0.00	0.80
Patient Care Techs	3.50	0.50	0.50	0.50	5.00
Administrative Assistant	0.50	0.00	0.00	0.00	0.50
MSW	0.50	0.00	0.00	0.00	0.50
Dietitian	0.50	0.00	0.00	0.00	0.50
Total FTE's	9.90	0.75	0.75	0.75	12.15

As shown in Table 12 above, NKC expects a minimal increase in FTEs for the additional three stations at Port Angeles Kidney Center. The staffing at NKC facilities is sufficient, as NKC states that they have not had to refuse admission to new patients due to staffing shortages, nor do they anticipate difficulties in availability or recruitment of qualified staff. [source: Application, p17]

NKC has identified Robert Wilburn, MD as the current medical director for the facility. The applicant supplied a current contract that indicates Dr. Wilburn's continued service in this capacity. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation limits for the medical director responsibilities. [source: NKC Application, Appendix 1]

Based on this information, the department concludes that adequate staffing for the two additional stations at NKC's Port Angeles facility is either available or can be recruited, and this sub-criterion is met.

Olympic Peninsula Kidney Center

To staff its proposed 6-station facility in Port Townsend, OPKC intends to recruit all FTEs in partial year 2008, and does not anticipate any further FTE increases through the end of full calendar year three (2011). A breakdown of the proposed FTEs is shown in Table 13 below. [source: OPKC April 30, 2007, supplemental information, Attachment 6]

**Table 13
OPKC's Port Townsend Kidney Center 2008 – 2010 Projected FTEs**

Staff/FTEs	2008 Partial Year	2009 Increase	2010 Increase	2011 Increase	Total FTEs
Medical Director	Professional Services Contract				
Administrator	1.08	0.00	0.00	0.00	1.08
RN	1.50	0.00	0.00	0.00	1.50
LPN/Techs	1.10	0.00	0.00	0.00	1.10
Administrative Assistant	0.0	0.00	0.00	0.00	0.0
MSW	0.80	0.00	0.00	0.00	0.80
Dietitian	0.08	0.00	0.00	0.00	0.08
Total FTE's	3.84	0.00	0.00	0.00	3.84

As noted in Table 13, OPKC does not propose any clerical staffing at its Jefferson County center, rather, OPKC anticipates administrative duties will be performed through its dialysis center in Bremerton, within Kitsap County. Further, the administrative staffing for the clinic chief tech, social worker, and dietitian will also be allocated from the Bremerton facility. [source: OPKC April 30, 2007, supplemental information, p1]

OPKC states it has actively recruited new staff to accommodate the growth at all of its facilities and does not anticipate problems recurring new staff for a new facility in Jefferson County. [source: Application, p24]

OPKC has identified Kenneth Cogan, MD as the proposed medical director for the new facility. The applicant provided a copy of its current contract demonstrating Dr. Cogan's continued service in this capacity at OPKC's three Kitsap County facilities which incorporates the proposed Jefferson County facility. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation limits for the medical director responsibilities. [source: OPKC Application, Appendix C; April 30, 2007, supplemental information, Attachment 4]

Based on this information, the department concludes that adequate staffing for the 6-station dialysis center in Jefferson County is either available or can be recruited, and this sub-criterion is met.

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

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing fourteen dialysis centers. For a new facility in Clallam County, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site. Additional services would be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: Application, p24]

DaVita acknowledges that since this would be a new facility in Clallam County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [source: Application, p24 and Appendix 12]

Based on this information, the department concludes that DaVita currently has appropriate relationships with ancillary and support services. If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed transfer agreement with a local hospital in Clallam County. Provided that DaVita would agree to the term, this sub-criterion would be met.

Northwest Kidney Centers

Documentation provided in the application confirms that NKC maintains appropriate relationships with ancillary and support services for its existing thirteen dialysis centers. For this project, NKC provided documentation to confirm that its Port Angeles Kidney Center

currently has appropriate relationships with ancillary and support services. Ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, plant operations, and administration and technical services are provided either through NKC's Haviland facility in the central Seattle area or its Lake City facility located in north Seattle area. [source: Application, p18] Further, NKC has an umbrella hospitalization transfer agreement with Swedish Medical Center in Seattle that incorporates all NKC patients and programs by specific reference. [source: April 30, 2007, supplemental information, Exhibit 3]

Based on this information, the department concludes that both NKC, and specifically its Port Angeles facility, currently have appropriate relationships with ancillary and support services and approval of two additional stations would not negatively affect those relationships. This sub-criterion is met.

Olympic Peninsula Kidney Centers

Documentation provided in the application confirms that OPKC maintains appropriate relationships with ancillary and support services for its existing three dialysis centers located in Kitsap County. For this project, OPKC states that typical ancillary and support services, such as social and dietary ancillary services would be established with the existing Jefferson County providers. Further, some existing agreements in place for the Kitsap County facilities, such as pharmacy, laboratory, and radiology, would be extended to include Jefferson County. [source: Application, p24, Appendix R] OPKC has an existing transfer agreement with Harrison Medical Center in Bremerton for its Kitsap County facilities. OPKC anticipates the Jefferson County facility would be incorporated into this agreement. [source: April 30, 2007, supplemental information, p2]

OPKC did not provide a copy of the existing transfer agreement with Harrison Medical Center. To receive approval the department will include a term requiring OPKC to provide a copy of the executed transfer agreement with a Harrison Medical Center that includes its new Jefferson County facility. Provided that OPKC would agree to the term, this sub-criterion would be met.

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

DaVita, Inc.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,300 outpatient centers located in 42 states (including Washington State) and the District of Columbia. [source: DaVita Webpage] Prior to the October 1, 2005, acquisition of the dialysis operations of Gambro Healthcare US, DaVita operated 665 centers in 37 states and the District of Columbia. Currently within Washington State, DaVita owns and operates fourteen kidney dialysis treatment centers. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public⁶. To accomplish this task, in January 2007 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the 42 states and the District of Columbia where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Of the 43 entities, the department received responses

⁶ WAC 246-310-230(5).

from 28 states or 66% of the 42 states.⁷ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁸

Ten of the 28 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Delaware, one in New York and one in Texas, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2006 due to several condition-level citations, but was operating in compliance at the time of survey. The New York facility was cited with condition-level deficiencies. This facility was voluntarily de-certified and closed by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005. No further fines were identified for this facility.

As stated earlier, DaVita owns or manages 1,300 facilities. While the department did not receive responses from all states where DaVita operates, it did have a 66% return rate. The noted non-responsive locations equate to 0.23% of DaVita's total facilities. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 32 compliance surveys for the operational facilities that DaVita either owns or manages.⁹ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Office of Health Care Survey]

Dimitri Vasin, MD has agreed to provide medical director services at the proposed dialysis center. DaVita provided a copy of the executed medical director agreement between itself and Dr. Vasin, with a draft addendum that incorporates the new dialysis center in Sequim. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation for the medical director responsibilities. A review of the compliance history of Dr. Vasin has shown that his credentials are current and reveal no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Based on DaVita's compliance history and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the new dialysis center would be operated in conformance with state and federal regulations. This sub-criterion is met.

⁷ Alabama, Arizona, Connecticut, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New York, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

⁸ Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

⁹ DaVita's Ellensburg Dialysis Center and Tacoma Dialysis Center are not yet operational. Olympic View Dialysis Center is owned by Group Health and managed by DaVita.

Northwest Kidney Centers

As stated earlier, NKC is currently a provider of dialysis services in Washington State. NKC will continue to provide Medicare and Medicaid services to the residents of its planning areas throughout the current kidney dialysis treatment centers in operation.

For Washington State, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 45 compliance surveys for the NKC facilities in operation.¹⁰ The compliance surveys revealed minor non-compliance issues related to the care and management at the NKC facilities. These non-compliance issues were typical of a dialysis facility and NKC submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Office of Health Care Survey]

Robert Wilburn, MD is the current medical director and will continue to provide services at Port Angeles Kidney Center. A review of the compliance history of Dr. Wilburn has shown that his credentials are current and reveal no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Given the compliance history of NKC and the existing medical director, the department concludes that there is reasonable assurance that Port Angeles Kidney Center would continue to operate in conformance with state and federal regulations with two additional stations. This sub-criterion is met.

Olympic Peninsula Kidney Center

OPKC is also a current provider of dialysis services in Washington State. OPKC will continue to provide Medicare and Medicaid services to the residents of its planning areas throughout the current kidney dialysis treatment centers in operation.

For Washington State, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 11 compliance surveys for the OPKC facilities in operation. The compliance surveys revealed minor non-compliance issues related to the care and management at the OPKC facilities. These non-compliance issues were typical of a dialysis facility and OPKC submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Office of Health Care Survey]

For its three dialysis centers located in Kitsap County, OPKC has a medical director contract with Kenneth Cogan, MD to provide medical director services. Dr. Cogan has agreed to provide services at the new facility in Port Townsend within Jefferson County once it is established. To comply with this criterion, OPKC provided a copy of the executed medical director agreement with Dr. Cogan for the Kitsap County facilities, as well as an executed agreement which incorporates the Jefferson County facility. [source: Application, Appendix C; April 30, 2007, supplemental information, Attachment 4] A review of the compliance history of Dr. Cogan has shown that his credentials are current and reveal no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Given the compliance history of OPKC and the existing medical director, the department concludes that there is reasonable assurance that the new dialysis center would be operated in conformance with state and federal regulations. This sub-criterion is met.

¹⁰ NKC's Seattle Kidney Center is not yet operational.

- (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.*

DaVita, Inc

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [source: Application, p24, Appendices 18 & 19]

The department also considered DaVita's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

Additionally, the department must consider the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 2 additional dialysis stations in the Clallam County service area and need for 6 stations in the Jefferson County service area. Within its application, DaVita proposed to serve both service areas by establishing an 8-station center in Sequim within Clallam County. However, as stated in the need portion of this evaluation, approval of OPKC's 6-station facility in Jefferson County makes it unnecessary for DaVita to establish an 8-station facility in Clallam County. Therefore, the department concludes that approval of an additional dialysis center in Clallam County would have the potential of fragmentation of dialysis services within the service area, and this sub-criterion is not met.

Northwest Kidney Centers

In response to this criterion, NKC states that, "*the NKC-Port Angeles Kidney Center has been providing outpatient dialysis services to the communities of Clallam and Jefferson counties since 1986. The additional capacity will allow that commitment to the community to continue and will help prevent the situation in which served persons must leave their community to seek care elsewhere.*" [source: Application, p18]

The department also considered NKC's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for many years and has been appropriately participating in relationships with community facilities, such as the Swedish Medical Center, to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Office of Health Care Survey Historical Record]

Additionally, the department must consider the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 2 additional dialysis stations in the Clallam County

planning area and need for 6 stations in the Jefferson County planning area. Within its application, NKC proposed to serve Clallam County and a portion of Jefferson County by adding 3 additional stations to its existing facility in Clallam County. However, as stated in the need portion of this evaluation, approval of OPKC's 6-station facility in Jefferson County makes it unnecessary for NKC to add 3 stations in Clallam County. Therefore, the department concludes that approval of 2 additional dialysis stations in Clallam County is consistent with the need methodology and would not have the potential of fragmentation of dialysis services within the planning area. Provided NKC agreed to reduce its approved stations from three to two, this sub-criterion would be met.

Olympic Peninsula Kidney Center

In response to this criterion, OPKC states that, "*the project will make kidney dialysis services more accessible to patients living in Jefferson County, while continuing to be a part of the OPKC system. It will also allow for maximum efficiency, coordination, and continuity of care through shared staff, administrative, and other functions.*" [source: Application, p25]

The department also considered OPKC's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for many years and has been appropriately participating in relationships with community facilities, such as Harrison Medical Center, to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Office of Health Care Survey Historical Record]

Additionally, the department must consider the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a need for 6 stations in the Jefferson County planning area. Within its application, OPKC proposed to serve Jefferson County by establishing a 6-station facility within the county. Further, WAC 246-310-286 provides standards for planning areas without an existing facility, such as Jefferson County. Under the standard, the department is required to approve the first project proposing to establish a facility in a planning area without an existing facility, provided the applicant can meet the other applicable criteria. Only OPKC's project proposes to locate stations in Jefferson County. Establishment of dialysis stations in Jefferson County is consistent with the need methodology and would not have the potential of fragmentation of dialysis services within the planning area. This sub-criterion would be met.

- (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.*

For all three projects, this sub-criterion is addressed in sub-section (3) above and is considered met.

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

Based on the source information reviewed, the department determines that:

- DaVita, Inc.'s project has not met the cost containment criteria in WAC 246-310-240;
- Northwest Kidney Centers' project has met the cost containment criteria in WAC 246-310-240 with a reduction in the number of approved stations; and
- Olympic Peninsula Kidney Center's project has met the cost containment criteria in WAC 246-310-240.

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

DaVita, Inc.

Within the application, DaVita provided discussion regarding the following two alternatives to this project. [source: Application, p26]

- Do nothing or status quo

DaVita states that doing nothing would not address the existing need or provide a choice of providers in Clallam County. DaVita acknowledges a net need of 2 stations is calculated for Clallam County, however, a facility in Sequim located within Clallam County would be a convenient location for Jefferson County patients. Based on this rationale, DaVita rejected this option.

- Establish a 6-station center in Jefferson County

DaVita rejected this option because it has located more suitable site in Sequim (Clallam County) than in areas within Jefferson County that would enhance both choice of facilities and access while minimizing development costs for a facility.

Based on DaVita's discussion of the two options above, both options were rejected before submitting this project.

Northwest Kidney Centers

Before submitting its application to add three stations to Port Angeles Kidney Center in Clallam County, NKC considered and rejected the following six alternatives to this project. [source: Application, pp19-20]

- Postponement

NKC states that this option would require patients to travel outside their community to access care, which would not be in alignment with NKC's goals to continuously see opportunities to improve convenience and access to care. This option was rejected.

- Nighttime Services

Since outpatient dialysis involves 3-5 hours of treatment, 3 times weekly, industry standard is typically 3 patient shifts in a dialysis center. Adding a 4th shift would require patients to dialyze between the hours of 11:00pm to 7:00 am. These hours have little appeal to patients, nephrologists, and facility staff. This option was rejected.

- Shortened Treatment Times

It is NKC's intent to continue to provide quality, patient care with favorable outcomes. There is a body of medical evidence suggesting that longer dialysis times, not shorter, result in better overall care and outcomes. This option was rejected.

- Home Dialysis

NKC offers this dialysis modality, however, this has not yet appealed to a larger number of patients. This option was rejected.

- Kidney Transplantation
NKC advocates for kidney transplants for ESRD patients for whom it is not contraindicated and who demonstrate interest. Currently, over 40% of NKC patients are on the waiting list at one or more of the three transplant centers in Seattle. However, the supply of available donor organs has not kept pace with demand.
- Shared/Contract Services Arrangements
NKC states that there are no other dialysis facilities in Clallam County, and no facility at all in Jefferson County. Therefore, this option was rejected by the applicant.

Based on NKC's discussion of the six options, all were rejected before submitting this project.

Olympic Peninsula Kidney Centers

Before submitting its application to establish a 6-station center in Port Townsend within Jefferson County, OPKC considered and rejected the following two alternatives to this project. [source: Application, p26]

- Do nothing or status quo
OPKC states it rejected this alternative because of the inconvenience and hardship patients would incur if they had to travel to Everett, Port Angeles, Seattle, or Tacoma for their dialysis services.
- Expand the existing dialysis centers in Bremerton and/or Poulsbo
OPKC rejected this option for Bremerton because it is currently built to capacity at 16 stations. Adding a second floor is not feasible due the inadequate parking at the site. Expanding the 8-station Poulsbo facility is a consideration because the site could accommodate up to 15 stations. However OPKC does not believe that adding station capacity in Poulsbo would address the access problems being experienced by patients traveling from Jefferson County.

Based on OPKC's discussion of the two options above, both options were rejected before submitting this project.

The department recognizes that all three projects would increase the dialysis station access for Clallam and Jefferson County patients. Additionally, the numeric portion of the need methodology supports the addition of 2 stations in Clallam County and 6 stations in Jefferson County. Further, WAC 246-310-284(1)(a) allows an applicant to include an adjacent planning area if there is no provider in that planning area. For this project, Clallam County has an existing facility and Jefferson County does not, which makes it a good example of when a provider may elect to serve an adjacent county. However, the option for a provider to serve a county with no provider from an adjacent county is not preferable when compared to establishing a facility in the county with no provider. In the case of Jefferson County, since 6 stations have been projected to be needed, establishing a 6-station facility in Jefferson County is the preferred alternative. [WAC 246-310-286]

One alternative considered by DaVita was to establish a 6-station facility in Jefferson County, however DaVita rejected the alternative because it could not find a suitable site. NKC did not consider establishing a facility in Jefferson County. Only OPKC submitted an application to establish a facility in Jefferson County. Given that WAC 246-310-286 requires approval of dialysis centers in this instance (provided OPKC can meet all other

applicable criteria and standards), OPKC's project is considered the best available alternative.

As stated in the need portion of this evaluation, once Jefferson County is not being considered in conjunction with Clallam County, need for two additional dialysis stations in Clallam County is still demonstrated. NKC's project fulfills that need provided NKC agrees to add only two stations rather than three.

In summary, OPKC's project is the best available alternative for Jefferson County, and this sub-criterion is met. NKC's project is the best available alternative for Clallam County, and this sub-criterion is met. DaVita's project is not the best available alternative for either Clallam or Jefferson counties, and this sub-criterion is not met.

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

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

This project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met.

Northwest Kidney Centers

This project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.

Olympic Peninsula Kidney Center

This project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that 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.

DaVita, Inc.

As stated in the project description portion of this evaluation, this project involve construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met.

Northwest Kidney Centers

This project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.

Olympic Peninsula Kidney Center

This project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is met.

E. Kidney Disease Treatment Centers—Tie-breakers (WAC 246-310-288)

This criterion is 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. Once the department evaluates the applications for compliance with the other applicable review criterion, only then can it determine if this criterion is to be applied.

To determine if this criterion applies to the three applications under review, the department considered its findings on the other review criteria. The department previously concluded that the DaVita application did not meet all the applicable review criteria, the NKC application met the applicable review criteria with a reduction in the number of approved stations, and the OPKC application met all of the review criteria as presented in the application. Because approval of OPKC's application removes the need for dialysis stations in Jefferson County, only DaVita's and NKC's applications address the need in Clallam County. Given that DaVita's application failed to meet three of the four required universal review criteria, this tie-breaker criterion is not applicable.