

**RECONSIDERATION EVALUATION OF THE CERTIFICATE OF NEED APPLICATION  
SUBMITTED ON BEHALF OF DAVITA INC PROPOSING TO ESTABLISH A NINE-STATION  
DIALYSIS CENTER IN THE CITY OF PORT ORCHARD WITHIN KITSAP COUNTY**

**PROJECT DESCRIPTION**

Currently, 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]

When this application was submitted in February 2006, DaVita owned or operated eleven kidney dialysis facilities in four separate Washington State counties--Franklin, King, Pierce, and Yakima. [source: CN historical files; & Application, p4] As of the writing of this reconsideration evaluation, DaVita owns or operates fourteen kidney dialysis facilities in six separate Washington State counties. Below is a listing of the fourteen DaVita facilities located in Washington. [source: CN historical files]

**Clark**

Vancouver Dialysis Center

**Pierce**

Lakewood Community Dialysis Center

Puyallup Community Dialysis Center

Tacoma Dialysis Center

**Yakima**

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

**Franklin**

Mid-Columbia Kidney 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

This application proposes to establish a nine-station dialysis facility in Kitsap County, to be known as DaVita Port Orchard Dialysis Center (hereinafter referred to as "PODC"). The new dialysis facility would be located within a newly constructed building. As of the writing of this reconsideration evaluation, the United States Post Office had not assigned the property a physical address. The property is located east of the northeast corner of Bethel Road and Sedgwick Road in Port Orchard. The Kitsap County Assessor parcel number is 0123 013 122 2006.<sup>1</sup> DaVita provided a copy of the draft lease agreement for the site. The draft agreement identifies all costs associated with the lease. If this project is approved, the department would include a term requiring DaVita to provide a copy of executed lease agreement between itself and NS Northwest #3, LLC (the lessor) consistent with the draft lease. [source: April 24, 2006, supplemental information, p1 and Attachment 3]

The capital expenditure associated with the establishment of the nine-station facility is \$1,042,746, of which 54% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p7]

---

<sup>1</sup> There is an existing structure on the land with the address of 1901 SE Sedgwick Road; however the address may change with the new development planned for the site.

When this application was submitted in February 2006, DaVita anticipated that, if approved, the project would commence immediately and all nine stations would become operational in December 2007. Under this timeline, year 2008 would have been the facility's first full year of operation. [source: Application, p8; April 24, 2006, supplemental information, p2] Under this reconsideration timeline, if the project is approved, year 2009 would be the facility's first full year of operation.

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

This project is subject to Certificate of Need review 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).

### **BACKGROUND INFORMATION AND APPLICATION CHRONOLOGY**

As previously stated, DaVita submitted this application on February 22, 2006. On September 5, 2006, the department determined that the project was not consistent with the applicable review criteria and a Certificate of Need was denied. The table below summarizes the timeline for the initial application.

#### **Initial Application Timeline**

January 1, 2006	Letter of Intent Submitted
February 22, 2006	Application Submitted
February 23, 2006	Department's Pre-Review Activities
through May 2, 2006	<ul style="list-style-type: none"><li>• 1<sup>st</sup> screening activities and responses</li></ul>
May 3, 2006	Department Begins Review of the Application
	<ul style="list-style-type: none"><li>• public comments accepted throughout review</li></ul>
June 9, 2006	Public Hearing Conducted/End of Public Comment
June 26, 2006	Rebuttal Documents Received at Department
August 10, 2006	Department's Anticipated Decision Date
September 5, 2006	Department's Actual Decision Date

On October 3, 2006, DaVita submitted a "Request for Reconsideration" related to the department's September 5, 2006, denial of DaVita's project. Within DaVita's reconsideration request, DaVita asked the Program to hold its decision to grant or deny reconsideration until the health law judge issued "Findings of Fact, Conclusions of Law, and Final Order" in a similar DaVita project that was undergoing an adjudicative proceeding. [DaVita-Federal Way, Docket #06-01-C-2003CN] On March 14, 2007, the Adjudicative Service Unit Issued the "**Amended** Findings of Fact, Conclusions of Law, and Final Order" [hereinafter referenced as the "Amended Final Order"]

The Amended Final Order remanded the DaVita-Federal Way project back to the Certificate of Need Program for further analysis and decision to be released by April 30, 2007. The Amended Final Order also directed the Program to "*identify a 12-month period from which it will determine an annual utilization rate using more than one quarterly data point to recalculate its market share analysis under WAC [Washington Administrative Code] 246-310-280(4) in a manner that is consistent with this Order.*" Given that the issues in the DaVita Federal Way project that resulted in the Amended Final Order, and the issues in this DaVita Port Orchard project are similar, the Program granted DaVita's request for reconsideration for this Port Orchard project. The timeline on the following page summarizes the reconsideration process used for this DaVita Port Orchard reconsideration.

## **Reconsideration Timeline**

April 17, 2007	Program Grants Reconsideration/Reconsideration Public Hearing Scheduled
June 5, 2007	Program Conducts Reconsideration Public Hearing
July 5, 2007,	Rebuttal Documents Received at Department <sup>2</sup>
August 20, 2007	Department's Anticipated Decision Date
August 20, 2007	Department's Actual Decision Date

## **CRITERIA EVALUATION**

To obtain Certificate of Need approval, DaVita, Inc. must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).<sup>3</sup> On January 1, 2007, the Program adopted new rules that apply to the expansion or the establishment of dialysis centers. However, this project was submitted 11 months prior to the adoption of the new rules. With the contested decision being released 3 months prior to the adoption of the new rules, the Program will continue to apply the rules that were in effect at the time this application was submitted. Those rules are referenced as WAC 246-310-280 (the dialysis station projection methodology and standards).

## **AFFECTED PERSONS**

Throughout the initial review of this project, two entities sought and received affected person status under WAC 246-310-010. Both entities are providers of dialysis services within Kitsap County.

- Harrison Medical Center Hospital, an inpatient dialysis provider located in the city of Bremerton;<sup>4</sup> and
- Olympic Peninsula Kidney Center (OPKC), an outpatient dialysis provider located in the cities of Bremerton, Port Orchard, and Poulsbo.

During the reconsideration review of this project, only one entity—OPKC—continued to participate in the reconsideration process.

## **SOURCE INFORMATION REVIEWED**

- DaVita's Certificate of Need Application submitted February 22, 2006
- DaVita's supplemental information dated April 24, 2006 (initial review)
- Public comment received throughout the review of the application (initial review)
- Public hearing documents received at the June 9, 2006, public hearing (initial review)
- Rebuttal comments provided by DaVita, Inc. received June 26, 2006 (initial review)
- Historical kidney dialysis data obtained from the Northwest Renal Network
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey (initial review)

---

<sup>2</sup> Based on DaVita's June 5, 2007, extension request, the program granted a 15-day extension for DaVita and Affected Persons to submit rebuttal documents.

<sup>3</sup> 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).

<sup>4</sup> While Harrison Medical Center sought and received affected person status, it did not provide public comment, attend the public hearing, or provide rebuttal comments during the initial or reconsideration processes.

### **SOURCE INFORMATION REVIEWED (continued)**

- Licensing and/or survey data provided by out of state health care survey programs (initial review)
- Data obtained from Center for Medicare and Medicaid (CMS) “Dialysis Facility Compare” website (<http://www.medicare.gov/Dialysis/home.asp>).
- Data obtained from the Internet regarding health care providers
- Data obtained from DaVita, Inc.’s webpage (<http://www.davita.com>)
- Data obtained from Gambro AB’s webpage (<http://www.gambro.com>)
- Certificate of Need historical files
- DaVita’s reconsideration request submitted October 3, 2006
- OPKC’s December 20, 2006 response to DaVita’s reconsideration request
- Public hearing documents received at the June 5, 2007, reconsideration public hearing
- DaVita’s rebuttal comments received July 5, 2007
- OPKC’s rebuttal comments received July 5, 2007

### **CONCLUSION**

For the reasons stated in this reconsideration evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a nine-station dialysis center in Port Orchard within Kitsap County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

## RECONSIDERATION EVALUATION

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

Based on the source information reviewed, the department determines that the applicant 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.

(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.*

Within its October 3, 2006, reconsideration request and its June 5, 2007, public hearing documents, DaVita identified four issues for reconsideration. The four issues are:

1. The program should determine utilization at existing facilities by reference to four quarters of data;
2. The program should obtain from OPKC the training data needed to project training station need;
3. The program should round up the 2010 station need determination from 2.43 to 3.0, as it has consistently done in past evaluation; and
4. The program should determine whether the project is financially feasible operating at the determined station need level of three stations plus training station need.

The program will address each issue separately.

### RECONSIDERATION ISSUE #1:

#### THE PROGRAM SHOULD DETERMINE UTILIZATION AT EXISTING FACILITIES BY REFERENCE TO FOUR QUARTERS OF DATA

As previously stated, the Amended Final Order issued on March 14, 2007, related to a DaVita Federal Way project denied based on similar issues as the denial of this Port Orchard project. For this reconsideration project, the Program will identify the factors listed in the Amended Final Order and address them as they pertain to this Port Orchard project. The factors are listed below and where necessary include a summary of the decisions reached in the Amended Final Order.

#### Service Area

The first step in performing the regression analysis outlined in WAC 246-310-280 is to determine the service area of the project. WAC 246-310-010 provides the following definition of the ESRD service area:

*“End-stage renal dialysis (ESRD) service areas means each individual county, designated by the department as the smallest geographic area for which kidney dialysis station need projections are calculated, or other service area documented by patient origin.”*

In the initial evaluation, both DaVita and the Program agreed that the service area for this project was Kitsap County as a whole. [source: Application, p3 & p11; September 5, 2006, initial evaluation p, 4] During the reconsideration process, there was no data submitted to change this conclusion.

Within the initial evaluation, the Program concluded that DaVita’s dialysis station need projections were inaccurate for the following two reasons. [source: Program’s September 5, 2006, initial evaluation pp 5-6]

- 1) DaVita used years 2000-2004 historical patient data, rather than the most recent data (2001-2005) available; and

- 2) The methodology requires the count of all dialysis stations at facilities within the ESRD service area. All stations include in-center stations, training stations, and stations that are CN approved, but not yet operational. Within its projection methodology, DaVita did not include all 38 stations when determining ‘existing capacity’ of the service area. Rather, DaVita counted 35 stations, thereby subtracting 3 training stations operating at an existing facility in Bremerton.

Using the rules in place at the time of the submission and review of this application, the Program’s projections for Kitsap County are shown in Table 1 below. [source: Program’s September 5, 2006, initial evaluation p5 and Appendix A.]

**Table 1**  
**Department’s Dialysis Station Projections**  
**for Kitsap County Based on 2001-2005 Historical Data**

Year	Stations	Existing Capacity	Net Need (Surplus)
2007	35	(subtract) 38 <sup>5</sup>	(3)
2008	37		(1)
2009	39		1
2010	40		2

As shown in Table I above, the Program projected a surplus of dialysis stations in Kitsap County for years 2007 and 2008, net need for an additional station in year 2009, and two stations by the end of year 2010.

Impermissible Market Impact and Market Share Analysis

WAC 246-310-280(4) states,

*“All kidney disease treatment centers that would stand to lose market share by approval of the applicant’s facility, must be operating at 748.8 dialyses per nontraining station per year before additional nontraining stations are approved.”*

The phrase “748.8 dialyses per non training station per year” is typically referenced as “the 80% rule” and is calculated as follows:

- 936 is the annual number of dialyses one station will accommodate at 100% utilization of a three-patient shift.
- 748.8 is the annual number of dialyses one station will accommodate during three-patient shift at 80% utilization. [748.8 divided by 936 is 0.8 or 80%]

When applied to this project, WAC 246-310-280(4) requires all three dialysis centers in Kitsap County be operating at 80% utilization before additional stations could be added to the service area. The Amended Final Order confirmed that the Program should use the most recent facility data obtained from Northwest Renal Network<sup>6</sup> to calculate the 80% rule and in its initial

<sup>5</sup>OPKC-Bremerton-19 stations; OPKC-South in Port Orchard-11 stations; and OPKC-Poulsbo-8 stations.

<sup>6</sup> Northwest Renal Network is a private, not-for-profit corporation independent of any dialysis company, individual unit, or transplant center. Funded by the Centers for Medicare and Medicaid Services, Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD program, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. Northwest Renal Network collects data from facilities located in the states of Washington, Alaska, Idaho, Montana, and Oregon.

evaluation. The Program used June 2006 quarterly data.<sup>7</sup> Application of the 80% rule for OPKC-Bremerton facility revealed that it was operating at 76% utilization with its 16 in-center stations; OPKC-Port Orchard showed to be operating at 72.7% utilization with 11 in-center stations; and OPKC-Poulsbo was operating at 83.3% utilization with 8 in-center stations. The Program concluded that neither Bremerton nor Port Orchard met this standard.

The Amended Final Order concluded that the Program erred when calculating the market share impact—or the 80% rule—required under WAC 246-310-280(4) by using only one data point in its calculation. In the DaVita Port Orchard project, the Program used the June 2006 quarterly data. The Amended Final Order required the Program to include all stations either operational or CN approved; and identify a twelve month period for calculating the 80% rule.

Using the Amended Final Order as guidance, the Program’s recalculation of the market share impact—or the 80% rule—is below.

Program’s Recalculation of the Market Share Impact

As previously stated, WAC 246-310-80(4) requires existing dialysis centers that would stand to lose market share by approval of a project be operating at 80% capacity of a 3-patient shift, per non-training station, per year, before additional stations may be added. This standard applies to facilities regardless of whether they are located within or outside an applicant’s proposed service area. Further, it is critical to review the most current data available, which would reflect the most recent utilization of the dialysis centers. For this project, this standard will be applied to the three facilities located within the Kitsap County planning area.

The initial decision date for this project was September 2006, and the most current available data was the June 2006 quarterly data obtained from the Northwest Renal Network. Therefore, the twelve-month period to be used to calculate the “per year” requirement is June 2006, March 2006, December 2005, and September 2005.

The tables below summarize the utilization for the three facilities using the four data points identified above [source: Northwest Renal Network, Quarterly Utilization Data] Additionally, as required in the Amended Final Order, the Program will count all in-center dialysis stations at each facility regardless of when the facility became operational.

**Table 2**  
**OPKC-Bremerton Facility**  
**Facility Utilization Based on Four Quarters NRN Data**  
**NUMBER OF NON-TRAINING STATIONS = 16**

	<b>July/Aug/Sept 2005</b>	<b>Oct/Nov/Dec 2005</b>	<b>Jan/Feb/Mar 2006</b>	<b>Apr/May/June 2006</b>	<b>Annual Average</b>
<b># of Patients</b>	90	92	93	73	86
<b>% Utilization</b>	93.8%	95.8%	96.9%	76.0%	89.6%

<sup>7</sup> Data is reported quarterly from the dialysis facilities to Northwest Renal Network. Quarterly data is a snapshot of a facility’s patient enrollment as of the end of the respective quarter.

**Table 3**  
**OPKC-Port Orchard Facility**  
**Facility Utilization Based on Four Quarters NRN Data**  
**NUMBER OF NON-TRAINING STATIONS = 11**

	<b>July/Aug/Sept 2005</b>	<b>Oct/Nov/Dec 2005</b>	<b>Jan/Feb/Mar 2006</b>	<b>Apr/May/June 2006</b>	<b>Annual Average</b>
<b># of Patients</b>	58	64	60	48	57.3
<b>% Utilization</b>	87.9%	97.0%	90.9%	72.7%	86.9%

**Table 4**  
**OPKC-Poulsbo Facility**  
**Facility Utilization Based on Four Quarters NRN Data**  
**NUMBER OF NON-TRAINING STATIONS = 8**

	<b>July/Aug/Sept 2005</b>	<b>Oct/Nov/Dec 2005</b>	<b>Jan/Feb/Mar 2006</b>	<b>Apr/May/June 2006</b>	<b>Annual Average</b>
<b># of Patients</b>	0	0	0	40	13.3
<b>% Utilization</b>	0.0%	0.0%	0.0%	83.3%	27.8%

Tables 2 and 3 show that OPKC’s Bremerton and Port Orchard facilities did not operate at or above 80% utilization for the three months covering April through June 2006. When the four data points are averaged for a 12-month average, both dialysis centers’ utilization is above 80%.

As shown in Table 4 above, OPKC’s Poulsbo did not operate at or above 80% utilization for the previous 12 months. When averaged, the Poulsbo facility’s average utilization is well below 80%.

As a result, none of the three facilities have operated at or above 80% capacity of a 3-patient shift, per non-training station in all of the four quarters reviewed by the Program. While two of the three facilities 12-month average utilization is above 80%, OPKC Poulsbo’s average 12-month average utilization was below 80%. This standard is not met.

**RECONSIDERATION ISSUE #2:**

**OBTAIN FROM OPKC THE TRAINING DATA NEEDED TO PROJECT TRAINING STATION NEED**

There is no logical reason to obtain training station data from OPKC to project training station need because throughout DaVita’s application for the nine-station center, DaVita asserts that all nine stations would be used for in center chronic dialysis patients. Given that no training stations were requested by DaVita, calculations for numeric need for training stations would be irrelevant to this project.

**RECONSIDERATION ISSUE #3:**

**ROUND UP THE 2010 STATION NEED DETERMINATION FROM 2.43 TO 3.0, AS IT HAS CONSISTENTLY DONE IN PAST EVALUATIONS**

In past evaluations, the Program has rounded up the number of stations, when numeric need for additional stations has been demonstrated AND all other standards have been met. In the initial evaluation and this reconsideration evaluation, the Program concluded that the standard under WAC 246-310-280(4) has not been met, therefore, this issue is moot.

**RECONSIDERATION ISSUE #4:**

**DETERMINE WHETHER THE PROJECT IS FINANCIALLY FEASIBLE OPERATING AT THE DETERMINED STATION NEED LEVEL OF THREE STATIONS PLUS TRAINING STATION NEED.**

Throughout its initial application, DaVita requested a nine-station dialysis center and did not request any training stations. DaVita provided financial documents to support nine in-center stations. DaVita's reconsideration request now reduces the number of stations by two-thirds by suggesting the Program review a three in-center, plus one training station facility. This substantial reduction in the number of stations is not consistent with the grounds for reconsideration outlined in WAC 246-310-560. In addition, it includes a request to add a service not previously requested. Both require an amendment to the application under WAC 246-310-100. The timeline to amend the application is after the initial submission and before the end of public comment [WAC 246-310-100(5)]. For this project, the amendment period was between February 22, 2006, and June 9, 2006. As a result, DaVita's request to review the project for four stations (three in-center plus one training) rather than the requested nine stations is inappropriate for reconsideration.

For the reasons stated in this reconsideration evaluation, this sub-criterion continues to remain un-met.

- (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.

In its September 5, 2006, initial evaluation, the Program recognized that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently have access to services at all DaVita dialysis facilities. The Program further noted that the establishment of a new dialysis center in Port Orchard is not expected to change this access. There was no additional information provided during the reconsideration review that would change this conclusion by the Program, therefore, this sub-criterion remains met.

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

Based on the source information reviewed, the department determines that the applicant has not 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.  
(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.  
(3) The project can be appropriately financed.

In its September 5, 2006, initial evaluation, the Program concluded that the project did not meet the financial feasibility criteria outlined in WAC 246-310-220 because the project failed under the dialysis facility standards evaluated within the need criteria.

Within the need portion of this reconsideration evaluation, the Program continues to conclude that the dialysis facility standards have not been met. Given this conclusion, the Program's conclusions regarding the financial feasibility criteria remains unchanged, and this criterion is not met.

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

Based on the source information reviewed, the Program determines that the applicant has not 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.
- (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.
- (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.
- (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.
- (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.

In its September 5, 2006, initial evaluation, the Program concluded that the project did not meet the structure and process of care criteria outlined in WAC 246-310-230 because the project failed under the dialysis facility standards evaluated within the need criteria.

Within the need portion of this reconsideration evaluation, the Program continues to conclude that the dialysis facility standards have not been met. Given this conclusion, the Program's conclusions regarding the structure and process of care criteria remains unchanged, and this criterion is not met.

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

Based on the source information reviewed, the department determines that the applicant has not 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.

In its September 5, 2006, initial evaluation, the Program concluded that the project did not meet the cost containment criteria outlined in WAC 246-310-240 because the project failed under the dialysis facility standards evaluated within the need criteria.

Within the need portion of this reconsideration evaluation, the Program continues to conclude that the dialysis facility standards have not been met. Given this conclusion, the Program's conclusions regarding the cost containment criteria remains unchanged, and this criterion is not met.