

**REMAND EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED
ON BEHALF OF DAVITA INC PROPOSING TO ADD TEN DIALYSIS STATIONS TO THE
EXISTING FIFTEEN-STATION DIALYSIS CENTER KNOWN AS FEDERAL WAY
COMMUNITY DIALYSIS CENTER LOCATED IN KING COUNTY**

PROJECT DESCRIPTION

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,200 outpatient centers located in 41 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 twelve kidney dialysis facilities in five separate counties--Clark, Franklin, King, Pierce, and Yakima. Below is a listing of the twelve DaVita facilities in Washington. [source: CN historical files]

Clark

Vancouver Dialysis Center

Franklin

Mid-Columbia Kidney Center

Yakima

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

Pierce

Lakewood Community Dialysis Center
Puyallup Community Dialysis Center

King

Bellevue Dialysis Center
Federal Way Community Dialysis Center
Kent Community Dialysis Center
Olympic View Dialysis Center
Westwood Dialysis Center

This application proposes to add 10 stations to the existing 15-station facility known as Federal Way Community Dialysis Center (FWCDC) located at 1015 South 348th Street in the city of Federal Way. If this project is approved, FWCDC would be operating 25 dialysis stations—24 incenter and one training station [source: AR 00010]

The capital expenditure associated with the 10-station addition is \$442,630, of which approximately 51% is related to leasehold improvements at the site; 42% is related to fixed, moveable, and clinical equipment; and the remaining 7% is related to architect and engineering fees. [source: AR 00010]

DaVita has already constructed the building that would house the proposed facility. As a result, if this project is approved, DaVita anticipated all 21 stations would become operational within six months of approval. Under this timeline, year 2006 would be the facility's first full calendar year of operation. [source: AR 00015]

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

BACKGROUND INFORMATION ON THE PROJECT

On November 17, 2004, DaVita Inc. submitted two Certificate of Need applications for review—this FWCDC project and a separate application proposing to establish a new 11-station facility in the city of Auburn, within King County—to be known as White River Dialysis Center. The two applications were reviewed simultaneously and, on September 27, 2005, the Program released its evaluation denying both projects. [source: Department’s September 25, 2005, evaluation]

On October 26, 2005, DaVita requested a reconsideration hearing related to the department’s September 25, 2005, denial of the two projects. On December 12, 2005, the department denied DaVita’s request for reconsideration. On January 6, 2006, the Adjudicative Service Unit within the Department of Health received DaVita “Request(s) for Adjudicative Proceeding” related to the department’s denial of the Federal Way Dialysis Center station addition project.¹ The table below summarizes the actions from September 25, 2005, to March 14, 2007, related to the Federal Way Dialysis Center adjudicative appeal.²

Date	Action
January 6, 2006	DaVita submits “Request for Adjudicative Appeal”
February 2, 2006	Adjudicative Service Unit issues scheduling order identifying the adjudicative hearing date of July 17, 2006
July 11, 2006	Adjudicative Service Unit issues revised scheduling order identifying the adjudicative hearing date of July 20, 2006
July 20, 2006	Adjudicative hearing conducted in Kent Washington
July 21, 2006 to August 4, 2006	Post Hearing Briefs and Reply Briefs filed by DaVita, Inc and the Certificate of Need Program
November 17, 2006	Adjudicative Service Unit issues “Findings of Fact, Conclusions of Law, and Final Order”
November 27, 2006	Certificate of Need Program files “Motion for Reconsideration” related to the November 17, 2006, “Findings of Fact, Conclusions of Law, and Final Order”
November 28, 2006 to January 16, 2007	DaVita, Inc and the Certificate of Need Program file briefs in accordance with the schedule set forth in the December 27, 2006, “Order Extending Briefing Schedule” issued by the Adjudicative Service Unit
March 14, 2007	Adjudicative Service Unit Issues “ Amended Findings of Fact, Conclusions of Law, and Final Order”

The “**Amended** Findings of Fact, Conclusions of Law, and Final Order” issued on March 14, 2007, remanded the FWCDC project back to the Certificate of Need Program for further analysis and decision. The remand order directs 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.*” Further, the **Amended** Findings of Fact, Conclusions of Law, and Final Order directed the Program to issue its analysis and decision no later than April 30, 2007. This document serves as the Program’s Remand Analysis and Decision.

¹ DaVita, Inc. did not submit an adjudicative appeal related to the establishment of the White River Dialysis Center.

² Docket #06-01-C-2003CN.

CRITERIA EVALUATION

To obtain Certificate of Need approval, DaVita, Inc. 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, DaVita, Inc must demonstrate compliance with WAC 246-310-280, the dialysis station projection methodology and standards that were in effect prior to January 1, 2007.³

AFFECTED PERSONS

No entities sought or received affected person status under WAC 246-310-010 for the Federal Way Dialysis Center project.⁴

SOURCE INFORMATION REVIEWED (initial evaluation)

- Federal Way Community Dialysis Center's supplemental information, received February 25, 2005; March 17, 2005
- 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
- Licensing and/or survey data provided by out of state health care survey programs
- 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>)
- Population data obtained from the Office of Financial Management
- Data obtained from the Internet regarding mileage and distance
- Data obtained from Office of Financial Recovery
- Data obtained from the Division of Information Resource Management's Geographic Information Systems.
- Certificate of Need historical files

For this remand evaluation, no additional information was requested or received from DaVita, Inc.

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to add ten dialysis stations to the existing fifteen station dialysis center known as Federal Way Community Dialysis Center does not meet the applicable review criteria, and Certificate of Need #1343 issued on November 30, 2006, should be vacated.

³ 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).

⁴ Northwest Kidney Centers sought and received affected person status for the project reviewed simultaneously with this project.

REMAND ANALYSIS

As previously stated, the “**Amended** Findings of Fact, Conclusions of Law, and Final Order” (hereinafter referenced in this document as “Amended Final Order”) issued on March 14, 2007, directs 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.*”

The Amended Final Order addresses several factors regarding DaVita’s FWCDC project. Those factors are listed below, along with a summary of the decisions reached in the Amended Final Order.

Service Area

- The service area for FWCDC is south King County.
- There are currently three dialysis providers in south King County—FWCDC, DaVita’s Kent Community Dialysis Center; and Northwest Kidney Center’s Auburn Kidney Center.
- The three dialysis centers equate to a total of 51 stations in the south King County service area. The table below identifies each facility, number of stations at each, and the distance in miles from FWCDC.

Name	# of Stations	Miles/Minutes from FWCDC
DaVita’s Federal Way Community Dialysis Center	15	N/A
DaVita’s Kent Community Dialysis Center	12	11 miles / 13 minutes
Northwest Kidney Center’s Auburn Kidney Center	24	5 miles / 7 minutes

- On May 17, 2005, a Certificate of Need was issued to Northwest Kidney Center approving the addition of 7 stations to Auburn Kidney Center, resulting in a 24-station facility. As of the writing of the initial FWCDC decision on September 27, 2005, the 7 stations were approved, but not-yet-operational.
- When applied to the south King County service area, the numeric methodology outlined in WAC 246-310-280(3) projects a net need for 6 stations in year 2006; 10 stations in 2007; and 15 stations in 2008, when subtracting all 51 stations located in the service area.

Impermissible Market Impact

- 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 both Kent Community Dialysis Center and Auburn Kidney Center to be operating at 80% utilization before additional stations could be approved at FWCDC.

- Most recent facility data obtained from Northwest Renal Network⁵ is used to calculate the 80% rule.
- In its initial evaluation, the Program used June 2005 quarterly data to calculate the 80% rule under WAC 246-310-280(4).⁶
- Application of the 80% rule to Kent Community Dialysis Center revealed that it was operating at 93% utilization; Auburn Kidney Center showed to be operating at 94% utilization, with 17 dialysis stations, rather than the 24 stations it was approved to operate. When counting all 24 stations, Auburn Kidney Center's utilization dropped to 65.3% utilization for the quarter ending June 2005.

Market Share Analysis

- The Amended Final Order concludes that the Program made an error when calculating the market share impact required under WAC 246-310-280(4) by using one data point (June 2005 quarterly data) in its calculation.
- Additionally, the Amended Final Order concludes that DaVita's health care analyst also made an error when calculating the market share impact under WAC 2456-310-280(4) for Northwest Kidney Center's Auburn Kidney Center facility. DaVita's analyst used four data points, but counted 17 stations for three data points and 24 stations for one data point. The four data points used by DaVita's analyst are June 2005, March 2005, December 2004, and September 2004.
- The Amended Final Order requires the Program to recalculate the annual utilization rate and determine whether Auburn Kidney Center's utilization would be below the 80% utilization threshold.
- In recalculating Auburn Kidney Center's annual utilization rate, the Amended Final Order requires the Program to:
 - include 24 stations at Auburn Kidney Center; and
 - identify a twelve month time period for calculating the 80% rule.

Program's Recalculation of the Market Share Impact

As previously stated, WAC 246-310-80(4) requires that the existing dialysis centers that would stand to lose market share by approval of a project, must 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. For this standard, it is critical to review the most current data available, which would reflect the most recent utilization of the dialysis centers. For this project where the decision date was September 2005, the most current data is the June 2005 quarterly data obtained from the Northwest Renal Network. Therefore, the twelve-month period to be used to calculate the "per year" requirement is June 2005, March 2005, December 2004, and September 2004.

⁵ 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.

⁶ 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.

There are three dialysis facilities located in south King County, including FWCDC—DaVita’s Kent Community Dialysis Center and Northwest Kidney Center’s Auburn Kidney Center. The Tables below summarize the utilization for both 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 24 dialysis stations at Northwest Kidney Center’s Auburn Kidney Center and 12 dialysis stations at DaVita’s Kent Community Dialysis Center.

Table 1
Northwest Kidney Centers-Auburn Kidney Center
Facility Utilization Based on Four Quarters NRN Data
NUMBER OF STATIONS = 24

	July/Aug/Sept 2004	Oct/Nov/Dec 2004	Jan/Feb/Mar 2005	Apr/May/June 2005	Annual Average
# of Patients	99	94	96	96	96.25
% Utilization	68.8%	65.3%	66.7%	66.7%	66.8%

Table 2
DaVita-Kent Community Dialysis Center
Facility Utilization Based on Four Quarters NRN Data
NUMBER OF STATIONS = 12

	July/Aug/Sept 2004	Oct/Nov/Dec 2004	Jan/Feb/Mar 2005	Apr/May/June 2005	Annual Average
# of Patients	52	55	64	67	59.5
% Utilization	72.2%	76.4%	88.9%	93.1%	82.6%

As shown in Tables 1 above, using the four data points covering the twelve-month period from July 2004 through June 2005, Northwest Kidney Center’s Auburn Kidney Center did not operate above 80% utilization. Additionally, when the four data points are averaged resulting in a 12-month average, Auburn Kidney Center’s average utilization fell below 80%.

Table 2 also demonstrates that DaVita’s Kent Community Dialysis Center did not operate above 80% utilization for the six months covering July 2004 through December 2004. However, when averaged, this dialysis center’s utilization was slightly above 80%.

As a result, neither facility has 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. Further, Auburn Kidney Center’s average annual utilization was below 80%. This standard is not met.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to add ten dialysis stations to the existing fifteen station dialysis center known as Federal Way Community Dialysis Center does not meet the applicable review criteria, and Certificate of Need #1343 issued on November 30, 2006, should be vacated.