STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICES UNIT

In Re: Certificate of Need Decision by Department of Health re: DaVita Inc's. Certificate of Need application for a 19 Station Kidney Dialysis Center In Tacoma, Washington, DaVita, Inc., Petitioner.	)	Docket No. 06-01-C-2004CN FINDINGS OF FACT. CONCLUSIONS OF LAW AND FINAL ORDER

APPEARANCES:

Petitioner, DaVita, Inc. (DaVita), by
Law Office of James M. Beaulaurier, per
James M. Beaulaurier, Attorney at Law

Intervener, Franciscan Health Systems (Franciscan), by
Ogden Murphy Wallace, P.L.L.C., per
Donald W. Black, Attorneys at Law

Department of Health Certificate of Need Program (Program), by
Office of the Attorney General, per
Richard A. McCartan, Assistant Attorney General

PRESIDING OFFICER: Zimmie Caner, Health Law Judge

This is an appeal of the Department of Health Certificate of Need Program (Program) analysis and denial of DaVita's certificate of need application for a new kidney dialysis treatment facility in Tacoma. Sustained.

ISSUE

Did the Program err when it denied DaVita's dialysis center certificate of need application for a failure to meet the need criteria set forth in WAC 246-310-210 and WAC 246-310-280?

SUMMARY OF PROCEEDINGS

In May 2004, Program approved DaVita's certificate of need (CN) application for a new kidney dialysis facility in Tacoma, Washington.[1] Program's decision was appealed by Franciscan. In November 2004, the Presiding Officer remanded the Program's decision for additional review, analysis, and decision pursuant to agreement of the parties.

In September 2005, after additional review and analysis, Program issued a reconsideration evaluation and decision that denied DaVita's CN application. DaVita appealed this denial and Franciscan appeared as an intervener. During the June 6, 2006 hearing, and pursuant to an agreement of the parties, the Presiding Officer ordered the second remand and continued the hearing to September 11, 2006. The Presiding Officer remanded Program's decision for additional analysis and decision regarding specific issues. In July 2006, Program issued its Amended Reconsideration

[1] The initial review was a comparative review of DaVita's proposed Tacoma facility and Franciscan's proposed Spanaway facility. After Program completed its comparative review, it rejected Franciscan's Spanaway CN application and granted a CN for DaVita's proposed Tacoma facility. Franciscan appealed Program's comparative review decisions. After the first remand and Program's reconsideration, Program affirmed the denial of the Franciscan application and reversed its decision on the DaVita application. DaVita appealed the denial of its application. Franciscan withdrew its appeal regarding the rejection of its application for a new facility in Spanaway. Franciscan participated as an intervening party in DaVita's appeal of Program's denial of its application. Franciscan supports Program's amended analysis and decision that found insufficient need for DaVita's proposed facility.

Evaluation and Decision that affirmed its denial of DaVita's application and amended its reasons for the denial.

During the hearing held on June 6, 2006 and September 11, 12, and 13, 2006, Karen Nidermayer; Randy Huyck; Monica Demitor; Catherine Richarson, M.D.; Keith Leffler, Ph.D.; Nancy Gallagher; Robert McGuirk; Jay Cushman; and Jody Corona testified.

The followings exhibits were admitted:[2]

Exhibit 1: Program administrative record (AR). (1,994 pages).[3]

Exhibit 2: Number of Hemodialysis Patients (Chart).

Exhibit 3: DaVita Tacoma Service Area Best Fit (Chart).

Exhibit 4: DaVita Tacoma Expanded service Area Best Fit (Chart).

Exhibit 5: Map of Tacoma Area Kidney Dialysis Centers.

Exhibit 6: 10/4/05 email from Ms. Sigman with Remand Reconsideration Evaluation Data.

Exhibit 8: NW Renal Network data as of 9/30/04 using data available 11/29/04.

Exhibit 9: NW Renal Network data as of 12/31/04 using data available 1/21/05.

Exhibit 10: NW Renal Network data as of 3/31/05 using data available 5/05/05.

Exhibit 11: NW Renal Network data as of 6/30/05 using data available 8/8/05.

Exhibit 16: Program's July 2006 Amended Reconsideration Evaluation.

[2] There is no Exhibit 7. Exhibits 21 through 34 were marked as demonstrative exhibits and not offered or admitted as substantive exhibits. The remaining exhibits were rejected.

[3] This record includes documents related to Program's comparative review of DaVita's application for a Tacoma facility and Franciscan's application for a Spanaway facility, and documents related to Program's September 2005 reconsideration evaluation/decision that affirmed the denial of Franciscan's CN application and reversing its decision to grant DaVita a CN.

Exhibit 17: April 5, 2006 deposition transcript of Janice Sigman.

Exhibit 18: Updated Historical Data regarding DaVita Tacoma Service Area.

Exhibit 19: Updated "Best Fit" Need Methodology Analysis for DaVita Tacoma Service Area.

Exhibit 20: Updated "Best Fit" Need Methodology Analysis for DaVita Tacoma Expanded Service Area.

Exhibit 34: Program's 1991 Analysis and Decision regarding St. Joseph's Tacoma Kidney Dialysis Center 18-station addition.

Exhibit 36 Jay Cushman's Resume.

Exhibit 37 DaVita Tacoma Index (chronology).

Exhibit 39 Program's 2003 Analysis and Decision regarding DaVita's application for additional stations at its Lakewood facility.

Closing arguments were presented through briefs.

I. FINDINGS OF FACT

1.1 On August 4, 2004, DaVita filed a CN application for a new 19-station kidney dialysis facility in Tacoma. Program, through its Amended Reconsideration Evaluation, denied DaVita's CN application to establish a new dialysis facility in Tacoma. Program found an insufficient need for a new dialysis facility. Program concluded that the existing facilities, which stand to loose market share, are not all operating at the minimum level required by the need criteria.

1.2 DaVita's proposed Tacoma facility is less than 2 miles from the St. Joseph Hospital dialysis center in downtown Tacoma. Tacoma is located in east Pierce County, on the county's northeastern shore of Puget Sound. The portion of Pierce County east of Puget Sound contains four dialysis facilities. These facilities include Franciscan's

50-station facility at St. Joseph's Hospital (St. Joseph), DaVita's Lakewood 21-station facility (Lakewood), Franciscan's Puyallup 12-station facility (Franciscan Puyallup), and DaVita's Puyallup 16-station facility (DaVita Puyallup). The Lakewood facility is located south of Tacoma and the two Puyallup facilities are southeast of Tacoma.[4] The portion of Pierce County located west of Puget Sound (Gig Harbor area) has one dialysis center with 6 stations.

1.3 The St. Joseph facility was the sole kidney dialysis center in Pierce County until DaVita opened its Lakewood 14-station facility in 1997. This was the beginning of a new trend, the opening of smaller facilities in suburban areas outside of Tacoma. This resulted in an out-migration of patients from the St. Joseph 50-station facility seeking their dialysis treatment in facilities that are closer to their home or work. In 2000, Franciscan opened its Puyallup 7-station facility. In 2001, DaVita opened its Puyallup 11-station facility. In 2002, Franciscan added 5 stations to its Puyallup facility. In 2003, DaVita added 7 stations to its Lakewood facility and in 2004 added 5 stations to its Puyallup facility. In 2004, Franciscan opened a new 6-station facility in Gig Harbor. A total of 80 new "suburban" kidney dialysis stations were opened. As a result, St. Joseph lost a number of patients who sought treatment from more convenient locations.

1.4 In 2000, St. Joseph provided 43,122 dialyses. In 2004, this number decreased to 38,610.[5] In 2003, St. Joseph was operating at 103 percent capacity, at

[4] Exhibit 5 (map of the Tacoma vicinity's kidney dialysis centers)
[5] Exhibit 16 at 43.

83 percent in 2004, and at 78 percent in 2005.[6] This percentage measures the utilization of the three of the four daily kidney dialysis shifts available at kidney dialysis facilities. (The last shift ends at approximate midnight.) The St. Joseph's facility has seen a decline in its utilization rate despite an increase in patients who live in a 21-zip code service area that includes Tacoma and the surrounding area. This change in utilization rate indicates that more patients are seeking dialysis treatment outside the 21 zip code area than those migrating into the service area for dialysis treatment from the St. Joseph facility. This shift is probably the result of patients obtaining dialysis treatment from more convenient suburban facilities rather than traveling to downtown Tacoma for dialysis from the St. Joseph facility.[7]

Service Area

1.5 Before need is assessed under the CN regulations, the appropriate service area must be designated. Program and DaVita disagree as to what is the appropriate service area[8] for DaVita's proposed Tacoma facility. Program concluded that a service area containing 21 zip codes[9] was the appropriate service area. DaVita proposed that a 26 zip code area is more appropriate.[10]

[6] These 2003 and 2004 percentage figures reflect the end of year utilization rate. The 2005 percentage reflects the utilization rate at the end of the first two quarters.
[7] Transcript, Day 4, 514.
[8] Service area for end stage renal dialysis treatment 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 document by patient origin." WAC 246-310-010.
[9] 98401-9, 98411, 98415-6, 98418, 98421-22, 98424, 98443-4, 98465-7.
[10] DaVita added the five additional zip codes because 25 percent of the patients residing in those 5 additional zip code areas dialyzed at the St. Joseph facility that is located within two miles from the proposed DaVita facility.

1.6 Since there is no need for DaVita's proposed facility in either the 21 zip code or 26 zip code service areas, it not necessary in this decision to determine which service area is the more appropriate service area. As stated below in the need analysis, there is no need for a new dialysis facility in Tacoma as proposed by DaVita because no need is indicated by the methodology set forth in the CN regulations.

Need Analysis

1.7 Need is determined by a methodology set forth in the rules under WAC 246-310-280. Under this methodology one must obtain historical data from the Northwest Renal Network[11] and review five years of kidney dialyses data for 2000–2004. Using this historical data, station need for the three years from 2007 through 2009 is projected.[12] The need methodology applied to the 21 zip code service area indicates a need for less than one dialysis station in 2007, a surplus of one station in 2008, and a surplus of two stations by 2009.[13] Applying this historical data to the 26 zip code service area to project need, one finds zero need in 2007, and a surplus of one station in 2008 and 2009.[14] The similar projection results from the 21 and 26 zip code service areas are understandable because the 21 zip code area has only 50 stations from one facility (St. Joseph) and the 26 zip code area has 70 stations from two facilities (St. Joseph and Lakewood).

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[11] The number of dialysis stations needed in a service area is determined using the data from the Northwest Renal Network. WAC 246-310-280(2). The Northwest Renal Network is a federally funded organization charged with keeping and collecting kidney dialysis utilization data.

[12] "Projection period" means the three-year time interval following the projection year. "Projection year" means the base year plus three years for kidney dialysis station projection purposes. "Base year" means the last full calendar year preceding the first year of dialysis station need projections. WAC 246-310-010.

[13] Exhibit 16 at 42.

[14] Exhibit 20 and Transcript, Day 4, 519-520.

1.8 DaVita found different projection results with the 26 zip code service area, indicating need for its proposed facility because DaVita modified the need methodology set forth in WAC 246-310-180(2)(a) and (3)(a). DaVita's approach utilizes different data than WAC 246-310-180 requires in subsections (2)(a) and (3)(a). DaVita used resident-based data (the number of patients residing in the proposed service area) rather than facility-based data (the number of dialysis treatments provided by existing facilities in the proposed service area). DaVita asserts that the facility-based data is unreliable due to factors such as temporary closures, and therefore, argues that the methodology set forth in WAC 246-310-180 should be modified. DaVita's modified version of WAC 246-310-180, in effect, eliminates a later step in the methodology, subsection (g)(ii), that requires that the results of WAC 246-310-280(3)(e) be subtracted out in determining the need for stations in a service area.[15] Therefore, the calculation that is directed in subsection (g)(ii) cannot be done under DaVita's approach.

1.9 The mathematical need methodology steps in question require two basic calculations. First, one must calculate the number of dialyses performed within the proposed service area using facility-based data. Second, one must calculate the number of dialysis patients who live within the service area (resident-based calculation).[16] These numbers are then projected out three years using a regression analysis.[17]

[15] Exhibit 16, page 41, line 8 of the worksheet. DaVita's expert Jay Cushman agrees that the methodology requires this subtraction and that DaVita's approach (using patient-based data rather than facility-based data) eliminates this mathematical step required in WAC 246-310-280(3)(g)(ii). .
[16] WAC 246-310-280(2).
[17] WAC 246-310-280(3)(a), (3)(b).

DaVita did not use facility-based data[18] in its mathematical need calculations regarding the number of dialysis treatments provided at the dialysis facilities within the proposed service areas.[19]

Market Share Impact

1.10 Before additional stations are approved for a service area, the existing facilities that may be affected by the proposed facility must be operating at an 80 percent utilization rate.[20] The parties dispute whether the application satisfies this 80 percent market share criteria.[21] Because DaVita's proposed facility is not needed in either the 21 or 26 zip code service areas, it is not necessary to address the market share criteria for existing facilities that may be affected by DaVita's proposed facility.[22]

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[18] DaVita itself has defended the facility-based approach it is now criticizing. During the comparative review of DaVita's and Franciscan's applications, DaVita defended the facility-based approach: "The Department historically has not assumed that all patients within a service area would choose only facilities within the service area. To do so would ignore the often significant number of patients who travel outside the service area for treatment. The assumption also fails to take into account the reality of overlapping service area, such as the service area the Program determined for FHS Spanaway. (Footnote omitted) How would patients residing in overlapping service areas be counted; to which facility would they be allocated? The Department has *avoided these inaccuracies and counting problems by measuring the number of dialysis provide by facilities in the service area, which more accurately reflects service area demand than counting patients* (who reside) in service area zip codes." (Emphasis added). Exhibit 1 at 1879-1880.

[19] DaVita suggests an approach Program is only used when there is no facility-based data because no facilities exist in the service area under consideration. Therefore, resident-based data must be used since no facility based data exists.

[20] Program's market impact determination is based upon the evaluation of one data point from June 2005 that indicates two of the four facilities were under the 80 percent market threshold: St. Joseph was at 78 percent and Franciscan Puyallup at 71 percent. DaVita argues that you must look at more than one data point to determine the "per year" utilization rate pursuant to WAC 246-310-280(4). Under this approach, DaVita found that the St. Joseph facility fell within the permissible market threshold, but the Franciscan Puyallup facility fell below the 80 percent threshold.

[21] Kidney disease treatment centers must operate at 748.8 dialyses per non-training stations per year before additional stations are approved. WAC 246-310-280(4). This equates to a facility operating at 80 percent of capacity. The 80 percent threshold measures the utilization of three of four daily kidney dialysis shifts available at kidney dialysis facilities. The last shift ends at approximate midnight.

[22] St. Joseph, Lakewood Franciscan Puyallup, and DaVita Puyallup.

II. CONCLUSIONS OF LAW

2.1 The development of health services and resources should be accomplished in a planned, orderly fashion, consistent with identified priorities, and without unnecessary duplication or fragmentation. RCW 70.38.015(2). The legislature adopted the certificate of need program to control costs by ensuring better utilization of existing health care facilities and services. RCW 70.38.105(3). Program implements the certificate of need program pursuant to chapters 70.38 RCW and 246-310 WAC. RCW 70.38.105(1).

2.2 The certificate of need applicant bears the burden to establish that the application meets all applicable criteria. WAC 246-10-606. Program then renders a decision whether to grant the requested CN in a written analysis that contains sufficient information to support Program's decision. WAC 246-310-200(2). The party challenging the decision bears the burden of showing that Program's decision is incorrect. The burden of proof is a preponderance of the evidence. WAC 246-10-606. Evidence is the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. RCW 34.05.452(1).

2.3 The establishment or expansion of a kidney dialysis center (facility) is subject to the certificate of need review. RCW 70.38.105(4). An applicant for the establishment or expansion of a center must meet the specific criteria set forth in WAC 246-310-280, in addition to the general review criteria set forth in WAC 246-310-210 (need), WAC 246-310- 220 (financial feasibility), WAC 246-310-230 (quality of care), and WAC 246-310-240 (cost containment). DaVita's application for a

new facility does not meet the need criteria under WAC 246-310-280, and therefore, fails to meet the general criteria set forth in WAC 246-310-210 through 246-310-240.

Service Area

2.4 Unlike other certificate of need programs, a kidney dialysis treatment applicant may identify a service area that Program may adopt; or Program may designate a different service area as the more appropriate smallest geographic area for which dialysis station need projections are to be calculated.[23]

> End-stage renal dialysis (ESRD) service areas means an 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.

WAC 246-310-010. An applicant may document patient origin using zip code information, which is provided by the Northwest Renal Network. Zip code information provided by the Northwest Renal Network reveals where a kidney dialysis patient resides, but does not reveal where that patient receives dialysis treatment.

2.5 There is no need to determine whether DaVita's proposed 26 zip code service area or Program's 21 zip code service area is the more appropriate service area because no need is projected under WAC 246-310-280 for either proposed service area.

[23] For example, ambulatory surgical facility applications are restricted to specified areas, defined as "secondary health services planning areas." WAC 246-310-270(3). The planning area for which nursing home bed need projections are developed means each individual county, except for the Clark-Skamania and Chelan-Douglas planning areas. WAC 246-310-010.

2.6 WAC 246-310-280 states, in relevant part:

(2) The number of dialysis stations needed in an ESRD [end stage renal disease] service area shall be determined using the following data of the Northwest Renal Network:

(a) The ESRD service area's total number of in-center dialyses provided for the previous five years.

(b) The number of end of year in-center patients for the ESRD service area for the previous five years.

(c) The number of patients trained for home hemo and peritoneal dialysis for the ESRD service area for the previous five years.

(3) The number of dialysis stations projected as needed in an ESRD service area shall be determined using the following methodology:

(a) Project the number of in-center dialyses needed in the ESRD service area through a three-year future regression analysis of the previous five years' data.

(b) Project the number of in-center dialyses needed to serve the residents of the ESRD service area by projecting the number of end of year in-center patients through a three-year future regression analysis of patient origin adjusted data for the previous five years. Multiply this result by one hundred fifty-six dialyses per year.

(c) Project the number of patients to be trained for home hemo and peritoneal dialysis in the service area through a three-year regression analysis of the previous five years' data.

(d) Determine the number of dialysis stations needed for in-center dialysis by dividing the result of (a) of this subsection by 748.8 (equivalent to eighty percent of a three-patient shift schedule).

(e) Determine the number of dialysis stations needed for in-center dialysis to serve residents of the service area by dividing the result of (b) of this subsection by 748.8 (equivalent to eighty percent of a three-patient shift schedule).

(f) Determine the number of stations needed for home hemo and peritoneal training in the service area by dividing the projected number of home hemo patients to be trained by six and peritoneal patients to be trained by twenty.

(g) Determine the number of dialysis stations needed in a service area by the projection year as the total of:

(i) The result of (e) of this subsection, designated as the number of resident stations;

(ii) The result of (d) of this subsection, minus the result of (e) of this subsection, designated as the number of visitor stations;

(iii) The result of (f) of this subsection, designated as the number of training stations.

(h) To determine the net station need for an ESRD service area, subtract the number calculated in (g) of this subsection from the total number of certificate of need approved stations.

WAC 246-310-280.

2.7 WAC 246-310-280(2) and (3) state the number of dialysis stations needed are based on the number of in-center dialyses provided for the past five years, and the projected number of in-center dialyses need through a three-year future regression analysis. Those sections require the use of in-center dialysis numbers derived from the service area, and therefore, the plain language of the subsection restricts what data may be utilized in the analysis steps. Subsection (2)(a) clearly requires the use of in-center dialysis rather than resident-based data in calculating the need for additional stations in a service area. This subsection does not provide a choice to the applicant or Program to use resident or dialysis data.[24]

2.8 Where the plain meaning of a statute is unambiguous, lends itself to only one meaning, the legislative intent is apparent and no statutory interpretations is necessary. *State v. Cromwell*, 147 Wn.2d 529 (2006). If the statutory language is not

[24] An exception to this rules requirement only arises when no in-center dialysis data exists for the service area in question. That is not the case at hand since two facilities are included in the 26 zip code service area and one facility in the 21 zip code service area.

clear, the language should be interpreted in a manner that avoids unlikely, absurd, or strained consequences, so the purpose of the statute (regulation) should prevail. *Glaubach v. Regence Blue Shield*, 246 Wn 2d 827 (2003). The language in question in WAC 246-310-280(2) is clear, and there is no need to interpret "service area's total number of in-center dialysis provided for the previous five years." "In-center dialysis provided" clearly means what is says. One may not substitute resident data to calculate in-center dialysis utilization data when the data is available. One is to use the actual number of in-center dialysis provided in the area from the existing facilities. DaVita's interpretation of WAC 246-310-280 requires an amendment to the regulation that is not appropriate here.

2.9 DaVita failed to prove with a preponderance of evidence that there is a need for additional dialysis stations under WAC 246-310-280, or that an exception applies under WAC 246-310-210(6).

Approval of More than the Number of Stations Identified as being Needed.

2.10 WAC 246-310-280(6) contains three exceptions that allow Program to approve more than the number of stations shown as needed by the need methodology. These exceptions are limited to special circumstances that permit Program, in effect, to "override" the need methodology as outlined in WAC 246-310-280(2)(3). None of the exceptions outlined in WAC 246-310-280(6) apply to the facts at hand. The rule's language is clear:

> The department shall not issue certificates of need approving more than the number of stations identified as being needed in a given ESRD service area unless:

(a) The department finds such additional stations are needed to be located reasonably close to the people they serve; or
(b) Existing nontraining dialysis stations in the treatment facility are operating at nine hundred thirty-six dialyses per year (three patient shifts); or
(c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis stations utilization in the service area; and

The department finds that an exceptional need exists and explains such approval in writing.

WAC 246-310-280(6). Subsection (a) applies when "additional stations are needed to be reasonable close to the people they serve." This exception does not apply to the facts at hand because the proposed facility would be located within two miles from St. Joseph, a facility that has the capacity to provide additional dialysis services. Subsection (b) permits an exception only when existing facilities are operating at 100 percent for three of the four patient shifts. This exception does not apply because St. Joseph is operating well below 100 percent. Subsection (c) applies when a significant change in ESRD treatment practice affects station utilization in the service area. No evidence was presented to support this exception.

III. ORDER

Program's denial of DaVita's application for a kidney dialysis facility is SUSTAINED.

Dated this _2___ day of February, 2007.

/s/
ZIMMIE CANER, Health Law Judge
Presiding Officer

NOTICE TO PARTIES

This order is subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any other applicable interstate/national reporting requirements. If adverse action is taken, it must be reported to the Healthcare Integrity Protection Data Bank.

Either party may file a **petition for reconsideration**. RCW 34.05.461(3); RCW 34.05.470. The petition must be filed within 10 days of service of this Order with:

The Adjudicative Service Unit
P.O. Box 47879
Olympia, Washington 98504-7879

and a copy must be sent to:

Certificate of Need Program
P.O. Box 47852
Olympia, Washington 98504-7852

The request must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Service Unit has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A petition for judicial review must be filed and served within 30 days after service of this Order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V., Judicial Review and Civil Enforcement. If a petition for reconsideration is filed, however, the 30-day period will begin to run upon the resolution of that petition. RCW 34.05.470(3).

The Order remains in effect even if a petition for reconsideration or petition for review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).