STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In Re: Certificate of Need Application of DaVita, Inc., to establish Kidney Dialysis Facility in Bellevue, King County	)))	Docket No. 03-09-C-2000CN
KIRKLAND DIALYSIS AND MILLIE TUNG, M.D.,	))))	FINDINGS OF FACT, CONCLUSIONS OF LAW, AND FINAL ORDER UPON RECONSIDERATION
Applicants.	))	

APPEARANCES:

Petitioners, Kirkland Dialysis L.L.C and Millie Tung, MD, by
Bennett Bigelow & Leedom, P.S., per
Stephen I. Pentz, Attorney at Law

Intervenor, DaVita, Inc., by
Law Offices of James M. Beaulaurier, per
James M. Beaulaurier, Attorney at Law

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

PRESIDING OFFICER: John F. Kuntz, Health Law Judge

Kirkland Dialysis L.L.C. and Millie Tung, M.D. filed a joint petition contesting the Certificate of Need Program's decision granting Certificate of Need No. 1269 to DaVita, Inc. to establish a ten station kidney dialysis facility in Bellevue, Washington. Certificate of Need Program decision is **affirmed**.

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ISSUES

When computing the kidney dialysis need methodology calculations under WAC 246-310-280(2) and (3), was DaVita restricted to considering only kidney dialysis station information from facilities located within its identified service area?

Does the Certificate of Need Program have the authority to designate a different end stage renal dialysis service area than the one proposed by DaVita in its application?

Were all kidney dialysis treatment centers that would stand to lose market share by the approval of DaVita's application operating at the required 80% utilization requirement set forth in WAC 246-310-280(4)?

Does DaVita's application meet the structure and process of care criteria set forth in WAC 246-310-230(5) that requires a facility to provide safe and adequate care to the public to be served in accordance with federal and state law?

SUMMARY OF EVIDENCE

Randall Huyck testified for the **Certificate of Need** Program (the Program).

Janis Sigman, Karen Nidermayer and Jody Carona (by affidavit) testified for Kirkland Dialysis. Monica Demitor testified for DaVita. **All but Exhibits 10 and 13 were admitted**:

Exhibit 1: DaVita Inc. Certificate of Need Application Record.

Exhibit 2: September 30, 2002, Patient Distribution by Zip Code Bellevue Dialysis Center Service Area (Map 1) (In color).

Exhibit 3: Existing Dialysis Facility Locations (Map 2) (In color).

Exhibit 4: May 12, 2003, DaVita rebuttal responses to public comments of Northwest Kidney Center.[1]

Exhibit 5: November 4, 2003, Program decision denying the Kirkland Dialysis certificate of need application (Docket No. 03-11-C-2005CN).

[1] This material was inadvertently left out of the application record.

Exhibit 6: Findings of Fact, Conclusions of Law and Final Order affirming the Program's decision to deny the Kirkland Dialysis application dated November 19, 2004.[2]

Exhibit 7: June 12, 1998, Program decision denying the Qualicenters application to establish a kidney dialysis center in North Spokane.

Exhibit 8: April 30, 1999, Program reconsideration review decision denying the Qualicenters application to establish a kidney dialysis center in North Spokane.

Exhibit 9: Notice of Proposed Settlement, In re Certificate of Need Application of Qualicenters, Inc., Docket No. 99-05-C-1076CN.

Exhibit 10: Denied.

Exhibit 11: July 3, 2003, Program decision denying DaVita certificate of need application to establish a kidney dialysis center in Seattle, King County.

Exhibit 12: Declaration of Jody Carona dated April 20, 2005 (with attachments).

Exhibit 13: Denied.[3]

Exhibit 14: September 5, 2003, Evaluation of the Certificate of Need Application Submitted on Behalf of Northwest Kidney Centers Proposing to Add Six Dialysis Stations to the Existing Eighteen Stations at Northwest Kidney Center-Lake Washington Kidney Center, for a Total of 24 Stations.

Exhibit 15: July 13, 2004, Evaluation of the Certificate of Need Application Submitted on Behalf of Northwest Kidney Centers Proposing to Add Five Dialysis Stations to the Existing Fifteen Station Facility Known as Totem Lake Kidney Center.

Exhibit 16: May 28, 2004, Department of Health Certificate of Need Program Evaluations for Davita, Inc., and Franciscan Health System.

[2] This decision is currently under appeal.

[3] Exhibits 13 – 16 are DaVita's proposed Exhibits 10 – 13. DaVita's proposed Exhibit 10 (renumbered as Exhibit 13) is a duplicate of Exhibit 5.

PROCEDURAL HISTORY

On February 21, 2003, DaVita, Inc. dba Bellevue Dialysis Center (DaVita) applied for a certificate of need to establish a twelve station kidney dialysis facility in Bellevue, Washington. On March 26, 2003, the Program began reviewing the application using the regular review process, and accepting written public comment regarding the application. The Program completed its review on August 7, 2003, and approved DaVita's application on a conditional basis. DaVita met the Program's conditions, and the Program issued Certificate of Need No. 1269 on August 11, 2003. DaVita began facility construction on October 27, 2003, and started treating patients on March 15, 2004

On September 2, 2003, Kirkland Dialysis, L.L.C. and Millie Tung M.D. (Kirkland Dialysis) filed a joint appeal of the Program's decision granting Certificate of Need No. 1269.[4] The Presiding Officer granted DaVita intervenor status on October 6, 2003. The prehearing conference and hearing dates were continued pending a final order in a related certificate of need matter (*In re: Kirkland Dialysis*, Docket No. 03-11-C-2005CN). Following resolution of the related matter, DaVita moved to dismiss the Kirkland Dialysis appeal as moot.[5] The Presiding Officer denied this motion. Prehearing Order No. 6. An administrative hearing was scheduled for April 12 – 13, 2005.

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[4] Kirkland Dialysis also filed a superior court action pursuant to chapter 34.05 RCW seeking an order staying the effectiveness of the Program's decision and ordering DaVita not to proceed with implementation of the project.
[5] Docket No. 03-11-C-2005CN is currently under appeal in superior court. No order staying the effectiveness of the administrative order was issued.

The Presiding Officer convened the hearing as scheduled on April 12 – 13, 2005. The Presiding Officer authorized the parties to file briefs in lieu of closing arguments pursuant to RCW 34.05.461(7). This authorization included filing additional post hearing exhibits and the affidavit of Jody Carona. Posthearing Orders No. 1 and 2.

On July 15, 2005, the Presiding Officer issued his Findings of Fact, Conclusions of Law and Final Order (the Final Order). In pertinent part the Presiding Officer held in the Final Order that:

1. **DaVita could establish six kidney dialysis stations rather than the ten authorized under the Program's analysis. The reduction in stations resulted in the Program's acceptance of DaVita's defined service area, which would exclude the Totem Lake stations in the need methodology calculations.**

2. **The "all kidney disease treatment centers" language contained in WAC 246-310-280(4) required that only kidney disease treatment centers within the defined service area should be examined for purposes of the 80% utilization requirement.**

On July 25, 2005, both Kirkland Dialysis and the Program filed petitions requesting the Presiding Officer reconsider the Final Order. Both parties disagreed with the Presiding Officer's interpretation of WAC 246-310-280(4), contending that kidney disease treatment centers outside the service area should be examined for purposes of the 80% requirement rule. Additionally, both parties contended that even if the Presiding Officer could reduce the number of stations authorized, such a reduction required a reexamination of the other certificate of need criteria. The two parties did not agree on what was the appropriate remedy. Kirkland Dialysis argued the Presiding Officer should reverse the Program's

analysis. The Program argued the Presiding Officer could remand the analysis to allow it to address any needed changes.

I. FINDINGS OF FACT

<u>DaVita Application</u>

1.1 DaVita applied for a certificate of need to establish a twelve station kidney dialysis facility in Bellevue, Washington in February 2003. DaVita defined the end stage renal dialysis service area (the service area) as a sub area of King County, and identified the sub area in question using zip code information.[6] DaVita chose zip code areas within a twenty minute drive time from the chosen Bellevue facility location.[7] While **DaVita identified** the facility **site** as being located in the city of Bellevue, the actual location is southwest of the intersection of Interstate 405 and Interstate 90.[8] The service area runs in a north – south direction along Interstate 405. The southern most borders reaches to Renton, Washington, and the northern most borders reaches Interstate 405 to East 124th Street. (See copy of map attached).

1.2 There are four Northwest Kidney Center facilities in or near the service area defined by DaVita.[9] Of the four facilities, DaVita identified the Lake Washington dialysis facility as the only other dialysis facility within its defined service area. DaVita anticipated serving some patients from the Mount Rainer Kidney Center in Tukwila. It excluded the Totem Lake Kidney Center from its identified service area.

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[6] "End stage renal dialysis (ESRD) service area" 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. WAC 246-310-010.
[7] Zip codes 98004, 98005, 98006, 98007, 98008, 98009, 98015, 98039, 98040, 98052, 98056 and 98059.
[8] Testimony of Randall Huyck, April 12, 2005 Report of Proceedings, page 16.
[9] Totem Lake, Lake Washington, Snoqualmie Ridge and Mount Rainier. For the sake of clarity the facilities will be referred to by these names.

1.3 DaVita calculated need existed for additional kidney dialysis stations in the service area.[10] Using historical data from the Northwest Renal Network, DaVita obtained in-center dialyses data for the five years immediately preceding its application (1997 – 2001). Using the historical data, DaVita then projected need for the three year projection period (2005 – 2007) following the 2004 base year.[11] DaVita calculated a net need existed for 12 additional kidney dialysis stations in its identified service area by year 2007.

1.4 Having established need existed in the service area, DaVita considered whether establishing its new facility would meet the 80% utilization rate (market share) criteria for Lake Washington and Mount Rainer, the two facilities it identified might be affected by its application.[12] DaVita found the Lake Washington dialysis facility's 2001 year-end utilization rate was 86%, and estimated the utilization rate would reach 95% at the end of the third quarter of 2002. Given those percentage figures DaVita concluded Lake Washington's utilization rate would not drop below 80%. DaVita found Mount Rainer reported a 79% utilization level, on a patient basis, based on the September 30, 2002 Northwest Renal Network data base.[13] DaVita anticipated Mount Rainer would

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[10] WAC 246-310-280(2) and (3).

[11] "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.

[12] 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% of capacity, commonly referred to as the 80% utilization rule.

[13] The number of dialysis stations needed in an [end stage renal dialysis) 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.

achieve the 80% utilization rate on a patient basis by the end of 2003 (the application year), thereby, meeting the market share regulatory requirement.

1.5 Prior to November 2001, DaVita operated centralized laboratories dedicated solely to providing lab tests required for end stage renal dialysis patients. DaVita included information regarding federal investigations related to historical billing practices at three (Florida, Minnesota and Pennsylvania) laboratories as part of its application. DaVita's information revealed:

- The Florida laboratory was undergoing an adjudicative review of its January 1995 – December 2002 Medicare reimbursement claims.
- The Minnesota laboratory was undergoing a post-payment review of Medicare reimbursement claims for January 1996 – December 1999.
- In February 2001, the Civil Division of the U.S. Attorney's Office requested DaVita cooperate in a review of some of DaVita's historical billing and operating practices.

Based on the information available to it at the time of its application, DaVita advised the Program it was unable to determine when or how the relevant federal organizations would resolve the investigations.

Program Analysis

1.6 In addition to reviewing other criteria, the Program reviewed DaVita's application under the following factors: (1) whether need existed in the identified service area; (2) **whether all kidney dialysis treatment centers that would stand to lose market share by approval of DaVita's application were operating at the** required 80% utilization rate; (3) whether DaVita could operate at the 80% level by its

third year of operation; and (4) whether DaVita provided reasonable assurance that its services would be provided in a manner to ensure safe and adequate care to the public.

A. Need

1.7 In reviewing whether another kidney dialysis facility was needed, the Program used 1998 – 2002 historical data in performing the need methodology calculations rather than 1997 – 2001 data used by DaVita. This was consistent with the Program's past practice of using the most recent available data to calculate the most accurate picture of area need. The 1998 – 2002 information was unavailable to DaVita at the time of its application. The Program also considered information received from Northwest Kidney Center during the public comment period. Northwest Kidney Center contended several of its other kidney dialysis facilities, beyond those identified by DaVita in its application, might affect the need methodology calculations. The Program considered the facilities identified by the Northwest Kidney Center (Totem Lake and Snoqualmie Ridge) when calculating the need methodology figures.

1.8 The Program also considered information DaVita submitted in response to Northwest Kidney Center's public comment. DaVita concluded the Snoqualmie Ridge facility would not affect the need calculations, as Snoqualmie Ridge served a population distinct from both Totem Lake and Lake Washington facilities. This conclusion was based on Northwest Kidney Center's own rationale in an earlier application, where Northwest Kidney Center argued the Snoqualmie Ridge facility served a distinct population. DaVita further argued the geographic location of Northwest's Lake Washington facility (located just north of Bellevue) would shield the DaVita facility from

having any substantial effect on the operation of the Totem Lake facility (a facility located even further north on Interstate 405).

1.9 The Program adopted DaVita's reasoning regarding the Snoqualmie Ridge facility and did not consider information from that facility in calculating need. The Program did include the Totem Lake kidney dialysis station figures when performing its need methodology calculations, reasoning the Totem Lake facility was geographically close enough to DaVita's identified service area to make an impact on the need methodology calculations. The Program calculated need existed for eleven additional kidney dialysis stations in DaVita's identified service area when it included the Totem Lake facility information.

B. Utilization Rate

1.10 Having concluded need existed, the Program examined whether the approval of DaVita's application affected the utilization rates for other kidney disease treatment centers.[14] The Program examined the Northwest Kidney Center's argument that approval of the DaVita application would affect the Totem Lake and Snoqualmie Ridge facilities. Northwest Kidney Center argued both of those facilities were operating under the 80% utilization (market share) at the end of the year 2002 (the year immediately preceding the DaVita application). The Program adopted DaVita's position that Snoqualmie Ridge served a patient population distinct from Lake Washington or Totem Lake. The Program determined approval of DaVita's application would not significantly affect the Snoqualmie Ridge facility utilization rate.

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[14] WAC 246-310-280(4).

1.11 The Program considered whether approving DaVita's application would affect the Totem Lake facility. In arguing it would not, the Program reasoned:

- Its facility was not expecting to draw patients from the zip codes served by Totem Lake.
- DaVita proposed to locate its facility southeast of the intersection of Interstate 5 and Interstate 405.[15] The Lake Washington facility, being located between the Totem Lake facility and DaVita's proposed Bellevue facility, would absorb any adverse impact.[16]

The Program concluded that any adverse impact on Totem Lake would be negligible, and would not prevent the Program approving the DaVita facility application.

1.12 While the Program calculated need existed for eleven new kidney dialysis stations, it authorized DaVita to establish ten. The Program reduced the station number by one to ensure that DaVita's kidney dialysis facility complied with the requirement that a facility operate at the required utilization capacity by its third (projection) year of operation.[17] The Program determined DaVita could not meet the required utilization capacity if it established eleven stations, but could do so by establishing less than that number.

C. Safe and Adequate Care

1.13 An applicant must show it will provide safe and adequate care to the public under federal and state laws and regulations.[18] The Program reviewed the

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[15] April 12, 2005 Report of Proceedings, at 16, lines 17 – 24 (Huyck testimony).
[16] See Exhibit 3, showing the then existing dialysis facility locations.
[17] WAC 246-310-280(5). The "projection" year means the base year (the last full calendar year preceding the first year of dialysis station need projections) plus three years. WAC 246-320-010. DaVita applied in 2003, so the base year is 2004. The projection year is 2007.

[18] WAC 246-310-230(5).

information DaVita included in its application regarding three laboratories being operated in Florida and Pennsylvania.[19] The Program's research found DaVita:

- Did not have a criminal history in the United States;
- Had no license denial or revocation of any health care facility by a licensing authority;
- Was not decertified by Medicare/Medicaid;
- Had no patient care issues;
- All the investigations relating to historical billing practices were unresolved; and
- Fully disclosed information relevant to the ongoing investigations.

As the DaVita investigations were not resolved at the time of the application, the Program determined DaVita was not in violation of the regulatory criteria and met the safe and adequate care to the public requirement.

Additional Findings

1.14 Need exists when calculating the need methodology for the service area identified by DaVita. Calculating the need methodology using only those facilities located in DaVita's identified service area, the number of new dialysis stations calculated using the need methodology is 6.157, or 6 stations when that figure is rounded down to the next nearest whole number.[20]

1.15 The Program's written analysis of DaVita's application was not consistent with the Program's need methodology calculations. In the text of the analysis the Program states it applies the 1998 – 2002 utilization data to DaVita's

[19] When the Program wrote its analysis only the Florida and Pennsylvania laboratories were operating.

[20] See Declaration of Jody Carona, item 11, page 3.

defined service area.[21] The only existing kidney dialysis facility in that service area is Lake Washington. However, this statement is not consistent with the actual need calculations performed by the Program, which included existing station capacity at the Lake Washington and Totem Lake kidney centers.[22] By performing the need methodology calculations in this manner, the Program expanded the service area to include Totem Lake.

1.16 The Existing Dialysis Facilitation Locations (Exhibit 3) provides information regarding how many patients reside in each identified zip code, but does not reveal where those patients receive their dialysis treatments.

1.17 The Program followed its past practice **by considering the service area definition provided by the applicant, but making its own determination of what constituted the appropriate service area.**

1.18 By including the Totem Lake kidney dialysis stations into its calculations, the Program modified **the service area defined by DaVita in its application**. Modifying the service area for purpose of the calculations was not consistent with the Program's **written analysis** that it **had** accepted DaVita's service area, and granted DaVita's application based on that service area. **However, this action was consistent with the Program's own past practice of defining the appropriate service area for purposes of determining need.**

1.19 In its written analysis of DaVita's application for compliance or noncompliance with the WAC 246-310-280(4) requirement (the 80% utilization

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[21] AR 425.
[22] AR 425, Table III.

requirement), the Program specifically addressed three of the four facilities (Lake Washington, Totem Lake and Snoqualmie Ridge) identified by Northwest Kidney Center during the public comment period. The fourth facility (Mount Rainier) was not specifically addressed in the text of the Program's analysis. A review of the application record submitted by the Program shows that Mount Rainier Kidney Center was operating at 79.9% utilization rate at the time of DaVita's application. The 79.9% utilization rate, when rounded up to the nearest whole number, is 80%.[23]

II. CONCLUSIONS OF LAW

2.1 The Program implements the certificate of need program under requirements set forth in chapter 70.38 RCW and chapter 246-310 WAC. RCW 70.38.105(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).

2.2 In all cases involving an application for license, the burden shall be on the applicant to establish that the application meets all applicable criteria. WAC 246-10-606.[24] The Program then renders a decision whether to grant a certificate of need in a written analysis that must contain sufficient information to support that decision. In so doing, the Program must rely on information contained in the application record or reach conclusions from information contained in the application record.

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[23] AR at 486.

[24] Chapter 246-10 WAC procedural rules supplement the hearing process statutes and rules in chapters 70.38 RCW and 246-310 WAC.

WAC 246-310-090(1)(a); WAC 246-310-090(1)(a); WAC 246-310-200(2)(a); see also *In re Auburn Regional Medical Center*, Docket No. 01-05-C-1052CN (February 20, 2003). The person challenging the decision bears the burden of showing that the Program's decision is incorrect. The burden of proof is by a preponderance of the evidence. WAC 246-10-606.

2.3 Certificate of need administrative proceedings do not supplant the certificate of review process. Rather the administrative proceeding assures that the procedural and substantive rights of the parties have been observed and that the factual record supports the Program's analysis and decision. *Ear, Nose, Throat & Plastic Surgery Assoc.*, Docket No. 00-09-C-1037CN, Order No. 6 at page 8 (April 2001).

2.4 While certificate of need administrative proceedings do not supplant the review process, certificate of need appeals are intra-agency appeals. RCW 34.05.464(4). A reviewing officer shall exercise all the decision-making power that the reviewing officer would have had to decide and enter the final order had the reviewing officer presided over the hearing. RCW 34.05.464(4); see *Tapper v. Employment Security Dept.*, 122 Wn.2d 397, 404 (1993); see also Andersen, *The 1988 Washington Administrative Procedure Act – An Introduction*, 64 Wash. L. Rev. 781, 816 (1989). Substantial weight should be given to the initial decision. **Id.** Where the Presiding Officer does substitute facts and/or conclusions, those facts and/or conclusions must be based on evidence contained in the record.

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Kidney Dialysis Treatment Center Requirements

2.5 A “kidney disease treatment center” means any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis and/or kidney transplantation, to person who have end-stage renal disease (ESRD). WAC 246-310-010. For Program approval of a kidney disease treatment center application, the applicant must meet the WAC 246-310-280 standards set forth in WAC 246-310-280. The applicant must also meet the applicable review criteria set forth in WAC 246-310-210 (determination of need), WAC 246-310-220 (determination of financial feasibility), WAC 246-310-230 (criteria for structure and process of care) and WAC 246-310-240 (determination of cost containment). WAC 246-310-280(1).

Issues on Appeal

2.6 Kirkland Dialysis raised three issues on appeal:

- The Program incorrectly applied the station need methodology under WAC 246-310-280(2) and (3), and if correctly applied, the Program’s decision does not support the ten approved dialysis stations.
- DaVita’s certificate of need application does not satisfy the 80% utilization standard under WAC 246-310-280(4).
- The Program failed to properly evaluate whether DaVita’s application satisfied the structure and process of care criteria under WAC 246-310-230(5).

Kirkand Dialysis did not raise any other issues in its post-hearing brief. The Presiding Officer, therefore, concludes DaVita’s application meets all uncontested certificate of need criteria. See *State v. Aten*, 130 Wn.2d 640 (1996).

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The Kidney Dialysis Station Need Methodology is Restricted to Facilities Located Within the Identified Service Area under WAC 246-310-280(2) and (3).

2.7 An "end stage renal disease service area" (service area) means an individual county *or other service area documented by patient origin*.

WAC 246-310-010 (emphasis added).[25] Unlike other certificate of need programs, a kidney dialysis treatment applicant can identify a service area smaller than an individual county.[26] **The Program may adopt the proposed service area or identify a different service area pursuant to WAC 246-310-010**. **While not specifically provided for in chapter 246-310 WAC,** 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.

2.8 DaVita defined its service area using zip code information, based on the zip codes located within a twenty minute driving time relative to its Bellevue, Washington location.[27] **In its written analysis** the Program **indicated it** accepted DaVita's identified service area. **In its need calculations the Program adopted a different service area that included the Totem Lake facility kidney dialysis station numbers**. Whether future need exists in the 2007 projection year is not contested. Need methodology calculations show a future need exists for 6 stations (if the

[25] The term "patient origin" is not defined.

[26] 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.

[27] There is nothing in chapter 70.38 RCW or chapter 246-310 WAC which establishes the 20 minute drive time as a requirement or standard, but parties have relied on drive time in past applications.

calculations rely on information for only those facilities within the service area) or 10 stations (if not so restricted), assuming the application meets all of the other required criteria. In its appeal Kirkland Dialysis contests the Program's decision to calculate need using information from kidney dialysis facilities located outside the applicant's identified service area.

2.9 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 (emphasis added).

WAC 246-310-280(2) and (3) state the number of dialysis stations needed are based on: (1) the number of in-center dialyses provided for the past five years; and (2) the projected number of in-center dialyses need through a three-year future regression analysis. Those sections require using numbers derived from the service area, and therefore, the plain language of the subsections restrict consideration to only those facilities located within the defined service area. When the plain language is unambiguous – that is, when the statutory language admits of only one meaning – the

legislative intent is apparent, and we will not construe the statute otherwise. *State v. J.P.*, 149 Wn.2d 444, 450 (2003). Words or phrases cannot be added to an unambiguous statute. *State v. J.P.*, id. Under the statutory language only those facilities within the service area should be considered in calculating need.[28]

2.10 Kirkland Dialysis contends, and the Program agrees with the contention, that only kidney disease treatment centers that are physically located within a specific service area may be counted for calculating the need methodology.[29] However, the Program argues the narrative portion of its analysis should not control the determination of what is the appropriate service area in this application. Rather, the Program argues the methodology calculations contained in the analysis indicate a different service area consistent with the Program's past practice. Under past practice the Program, not the applicant, determines what constitutes the correct service area when performing the need methodology calculations.[30] Having conceded the existence of this inconsistency, the Program argues the Presiding Officer should rely on the need calculations, rather than the text of the analysis, to understand how the Program defines the relevant service area for calculating need.

2.11 WAC 246-310-010 defines an "[e]nd stage renal dialysis (ESRD) service area" to mean:

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[28] Given his reading of the WAC 246-310-280(2) and (3) language, the Presiding Officer declines to address the issue of including whether it is necessary to include the Olympic View facility stations (a facility exempt from the certificate of need requirements) when calculating need.
[29] Certificate of Need Program Reply in Support of its Motion for Reconsideration, page 1, dated August 29, 2005.
[30] Id, page 2.

> **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 (emphasis added).**

The phrase "documented by patient origin" is not defined, but past applicants and the Program have used zip code information to identify the area documented by patient origin. No matter how one documents patient origin, it is clear that the Program designates the service area pursuant to WAC 246-310-010. Here the Program identified a service area that included the Totem Lake facility stations through the calculations set forth in its analysis. So even though DaVita defined an ESRD service area that excluded the Totem Lake facility, and the Program's text apparently agreed with that service area, the Program's definition (as shown by its calculations) should control. See *In Re: Kirkland Dialysis*, Docket No. 03-11-C-2005CN (November 19, 2004) at 9 – 10. [31]

2.12 The Program's determination of a service area is controlling. It is within the Program's authority to include the Totem Lake facility stations within its defined service area when calculating the need methodology. The Program's calculation shows that need exists for ten additional kidney dialysis stations for the projection year in question. DaVita's application can be granted, so long as all other requirements are met.

The DaVita Application Meets the 80% Utilization (Market Share) Requirement under WAC 246-310-280(4).

2.13 WAC 246-310-280(4) states:

[31] Exhibit 6.

> 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 (emphasis added).

Breaking the definition down into its component parts, the regulation requires: (1) all kidney disease treatment centers; (2) that would stand to lose market share[32] by approval of the applicant's facility; (3) must be operating at an 80% utilization rate.[33] The phrase "all kidney disease treatment centers" cannot be read in isolation. This phrase must be read in conjunction with the phrase "that would stand to lose market share by approval of the applicant's facility" and the 80% utilization requirement. Interpreted in this manner, WAC 246-310-280(4) anticipates the consideration of facilities which are outside of the defined service area when determining whether an application complies with the 80% utilization requirement. Statutes must be interpreted and construed so that all the language used is given effect, with no portion rendered meaningless or superfluous. *State v. J.P.,* 149 Wn.2d at 450.

2.14 The Program reasonably identified four kidney dialysis facilities in the service area which could stand to lose market share in its analysis of DaVita's application. Those facilities are Lake Washington, Totem Lake, Snoqualmie Ridge and Mount Rainier. The Lake Washington market share is 90.2%, which exceeds the 80% utilization rate requirement**.**[34] **Mount Rainier also meets the 80%**

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[32] The term "market share" is not defined.
[33] The 80% utilization rate is 748.8 dialyses per nontraining stations per year before additional nontraining stations are approved.
[34] Application Record (AR) at 486.

requirement. The Snoqualmie Ridge facility exists in a different service area, and its market share would not be affected by granting DaVita's application. The Lake Washington facility is geographically located between the Totem Lake facility and the DaVita facility, which effectively protects the Totem Lake market share from DaVita's facility. It is reasonable to conclude that DaVita's application met the 80% utilization requirement.

<u>DaVita's Application Complies with the Structure and Process of Care Criteria under WAC 246-310-230(5)</u>

2.15 WAC 246-310-230 states:

> A determination that a project fosters an acceptable or improved quality of health care shall be based on the following criteria.
> …
> (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 accordance with applicable federal and state laws, rules, and regulations. The assessment of the conformance of a project to this criterion shall include, but not be limited to, consideration as to whether:
>
> (a) The applicant or licensee has no history, in this state or elsewhere, of a criminal conviction which is reasonably related to the applicant's competency to exercise responsibility for the ownership or operation of a health care facility, a denial or revocation of a license to operate a health care facility, a revocation of a license to practice a health care profession, or a decertification as a provider of services in the Medicare or Medicaid program because of failure to comply with the applicable federal conditions of participation; or
>
> (b) If the applicant or licensee has such a history, whether the applicant has affirmatively established to the department's satisfaction by clear, cogent and convincing evidence that the applicant can and will operate the proposed project for which the certificate of need is sought in a manner that ensures safe and adequate care to the public to be served and conforms to applicable federal and state requirements.

DaVita provided information in its application showing that certain of its laboratory facilities were undergoing adjudicative review of some of its reimbursement claims, and that the U.S. Attorney's Office requested DaVita cooperate in a review of some of DaVita's billing practices. The Program reviewed the material and determined at the time of the application the information represented allegations, and not proof of federal violations of Medicare statutes or regulations. The Program balanced the information regarding the on-going adjudicative review and/or reimbursement claim review against information showing DaVita had no: (1) criminal history; (2) denial or revocation of any health care facility license; (3) decertification by Medicare or Medicaid; (4) patient care issues.

2.16 Given there was no final action limiting or revoking any DaVita health care facility license, the Presiding Officer concludes Kirkland Dialysis failed to submit sufficient evidence to contradict the Program's analysis of the information before it at the time of the application. DaVita's application met the safe and adequate criteria, and the Program's analysis of that information reasonably shows the criteria being met here.[35]

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[35] Kirkland Dialysis argues the Program reached the opposite position in an earlier Qualicenters application. Exhibit 7, pages 15 – 20. A review of the application reveals Qualicenters was subject to factors far in excess (False Claims Act action in U.S. District Court, a lawsuit and a table of deficiencies in response to the licensing surveys) of the ones to which DaVita is subject to here.

III. ORDER

Based on the foregoing Procedural History, Findings of Fact and Conclusions of Law, the Program's decision granting DaVita's certificate of need application to establish a ten station kidney dialysis facility is **AFFIRMED**.

Dated this __15th _ day of September, 2005.

/s/

JOHN F. KUNTZ, 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); 34.05.470. The petition must be filed within 10 days of service of this Order with:

The Adjudicative Service Unit
PO Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Department of Health Certificate of Need Program
PO Box 47852
Olympia, WA 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. A petition for reconsideration is not required before seeking judicial review. 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).